

## **Summary report regarding**

**Risk management of nickel in relation to chronic toxicity to freshwater sediment organisms.**

**Danish EPA, December 2012**

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**Letter from NiPERA reporting the outcome of the conclusion of the sediment testing program, Now 18<sup>th</sup> referring to research and reports commissioned by NiPERA. An Executive Summary drafted by the Chairman of the Technical Conclusion i) Group (C. Janssen, U. Ghent, Belgium) :**

- An Integrated Sediment Effects Assessment of Nickel<sup>1</sup> (M. Vangheluwe, ARCHE, Belgium)
- Appendix I: Draft Final Report: Toxicity of nickel-spiked freshwater sediments to benthic invertebrates: Spiking methodology, species sensitivity, and nickel bioavailability (USGS, Columbia, MO, USA)
- Appendix II: Final Report of the Field Validation Study of Nickel Contaminated Sediments (University of Michigan, USA)
- Appendix III: Final Report for Determining Nickel Speciation in Contaminated Sediments Using a Direct Method: X-Ray Absorption Spectroscopy (Northwestern University, USA)
- Appendix IV: Geochemical characterization of pore water and sediment in Lake Petit-Pas, Québec (CANMET MMSL and University of Quebec, Canada).
- Appendix V: Nickel Phase Partitioning and Toxicity in Field-Deployed Sediments (Costello et. al., 2011)
- Appendix VI: Inter-laboratory comparison of measurements of acid-volatile sulfide and simultaneously extracted nickel in spiked sediments (Brumbaugh et. al., 2011)

All reports above received by DK EPA Nov 16<sup>th</sup> Nov 2011 with the exception of the Appendix I received by DK EPA Dec. 23<sup>th</sup> 2012.

#### **Supplementary analysis and reports generated in 2012:**

Weight of Evidence Analysis of the Sediment Bioavailability Normalization Approach using the SEM-AVS Model for Nickel in Sediments, (for NiPERA, M. Vangheleuwe, ARCHE, Belgium, June 2012)

Risk Characterization of nickel in sediments (for DK EPA. J. Tørsløv DHI & P. Kortegaard; Contributors M. Vangheleuwe, ARCHE & K. Hicks Nickel Inst. Belgium; Final Report July 2012)

#### **Further attached information:**

Vandegheuchte M.B Environ. International 33 (2007), 736-42  
Ongoing further research:

- Advanced research on Ni toxicity in sediments: species, bioavailability and diet borne toxicity, NiPERA Oct. 15, 2012

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<sup>1</sup> Note that the Nov 16 version was discussed at a meeting between NiPERA and DK EPA In Dec. 2011 and based on this slightly revised and re-issued in a new version (April 6<sup>th</sup> 2012). The revision concerned removing bioavailability models based on TOC and CEC from the report.

- Experiments Measuring Bioavailability in Oxic and Spiked Sediments (EMBOSS), NiPERA Oct. 15, 2012

## 1. Summary and recommendations

Refined effects assessment of nickel has been performed according to Reg. 466/2008 and based on new test data regarding chronic nickel toxicity towards nine freshwater sediment dwelling species. A species sensitivity distribution curve for the chronic EC<sub>10</sub>-values for the four sensitive freshwater sediment species in the lab tests, a "realistic worst-case" freshwater sediment (10P AVS) a generic HC5 - value of 94 mg Ni / kg sediment d.w. was calculated. Based on this and Weight of Evidence which included several long-term field studies and that four of the species in the lab tests were insensitive to nickel an AF of 2 was selected and a robust PNEC<sub>freshwater sediment</sub> of 47 mg Ni / kg sediment d.w. for freshwater sediment organisms regarding chronic toxicity of nickel derived. It is noted that the HC5-value and the default PNEC<sub>freshwater sediment</sub> -value are valid for freshwater sediments with an AVS concentration equal to the 10 percentile of known AVS concentrations for European freshwater sediment systems.

In addition development and validation of a quantitative bioavailability AVS normalization approach has taken place. Use of this bioavailability normalization approach is valid for freshwater sediments within the 10 and 90 percentile of AVS concentrations found in European freshwater sediments.

Furthermore an indicative risk characterization ( $PEC_{\text{freshwater sediment}}/PNEC_{\text{freshwater sediment}} = RCR_{\text{freshwater sediment}}$ -calculation) has been performed on selected nickel industry sectors where new emission or exposure data were available. It is estimated that the analysis covered approximately 75 % of all industrial nickel emission to EU surface freshwater/sediment systems. Based on this indicative risk characterization it can be concluded that the number of sites with potential risk for freshwater sediment organisms seems to be at least as high as the number of sites with potential risk for pelagic organisms. Therefore, introduction of additional risk management measures and/or refinement of risk assessment relating to both emission and exposure assessment and to bioavailability normalization may be warranted in a relatively high number of cases.

Based on the above and on the duty for the registrant(s) to update his registration without undue delay with relevant new information according to Article 22 of REACH, update of REACH registration dossiers without such undue delay is expected taking into account

- the newly generated information available on hazard data on freshwater sediment organisms,
- the recommendation on using an AF of 2 to derive  $PNEC_{\text{freshwater sediment}} = 47 \text{ mg Ni/kg sed. dw}$ ,
- using the established bioavailability approach ( i.e. the prescribed use of AVS normalisation models) and/ or reducing nickel emission/ exposure and/ or refining the nickel emission/exposure assessment with appropriate exposure scenarios with recommendations for safe use.

Based on a systematic review of risk management options both under REACH and under other relevant Union legislation and the above mentioned findings for sediment organisms it is recommended that:

- 1) The Commission proposes an EQS for freshwater sediment organisms under the Water Framework Directive (WFD) in addition to that currently proposed for pelagic freshwater organisms.
- 2) For sites with potential risk for freshwater sediment organisms REACH registrants, downstream users and MSCAs involved in compliance monitoring of  $EQS_{\text{freshwater sediment}}$  under the Water Framework Directive, it is recommended to ensure compliance with REACH and the Water Framework Directive by reducing exposure, refining the emission/exposure assessment and/or employing or further developing and implementing the above described bioavailability normalization approach according to the AVS concentration in sediment of the receiving freshwater system at the local site
- 3) Member State Competent Authorities for the Industrial Emission Directive should require implementation of BAT in relevant industrial sectors and monitor compliance of local emissions and EQS for relevant environmental media, which should also specifically include freshwater sediments.
- 4) it is recommended that ECHA without undue delay, when the REACH registration dossiers of nickel substances have been updated by IND with the new information from the sediment research program, considers the need to perform a targeted compliance check concerning the hazard and risk assessment for the sediment compartment. (For consistency ECHA could also consider extending the targeted compliance check to include the risk assessment of both the pelagic and sediment compartment).

## 2. Background.

Risk assessment concerning 5 nickel high production volume substances (nickel (metal) and four water soluble nickel salts: nickel dinitrate, nickel chloride, nickel sulphate & nickel (hydroxy)carbonate were concluded under the former ESR programme (Council Reg. 793/EEC), with the exception of the risk assessment of nickel for freshwater sediment dwelling organisms<sup>2</sup>. Hence further information (sediment toxicity testing to establish a PNEC for sediment organisms) was requested in COM Reg. 466/2008 ("Sediment toxicity testing").

In response to the requirements of COM Reg. 466/2008, NiPERA, on behalf of the Nickel industry, established a targeted research program working group ("Technical conclusion i) Group") and invited the Danish EPA (Rapporteur) and experts from any other EU CAs to participate. In response experts from DK and NL participated in all meetings, telephone conferences etc. throughout the implementation of this research program, whereas an expert from DE participated in most meetings and experts sponsored by the CAs of ES, F, and UK participated in the initial meetings of the program whereas also an expert from ECHA participated in the last meetings. During the different phases of the research program the results of the earlier phases were thoroughly discussed and plans for the next phases agreed. Various experts involved in the further research program and representatives from NiPERA participated in the working group besides the experts from the above mentioned member states (cf. executive chairman report: "111107-D-UGent – Technical Conclusion i) Group Summary. docx" (attached)).

The present summary report contains the main findings of NiPERA's research program regarding generation of new test data for PNEC<sub>freshwater sediment</sub>-derivation. Industry is recommended to use those data and the generic PNEC<sub>freshwater sediment</sub> of 47 mg Ni / kg sediment dw in its updates of the REACH nickel dossiers. The current report also includes a summary of the results of various research activities undertaken that were beyond that requested in COM Reg. 466/2008. These latter activities were initiated to make it possible to refine the effects and risk assessment of nickel for freshwater sediment organisms. One main activity focused on the development and validation of a bioavailability normalization approach

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<sup>2</sup> The outcome of initial previous research program for establishment of PNEC<sub>freshwater sediment</sub>, including a bioavailability approach was agreed not be successful by the participants at TCNES when a draft report was discussed and based on this COM Reg. 466/2008 was later concluded (c .f. also e.g. Vandegehuchte M.B Environ. International 33 (2007), 736-42 – attached as annex)

for chronic nickel toxicity towards sediment organisms. Another main activity took place to make it possible for the Danish EPA to make an indicative risk based analysis and based on that to make recommendations on risk management options for nickel in relation to its chronic toxicity towards freshwater sediment organisms. Hence this summary report includes four sections besides this introduction. They address:

*Bioavailability normalization* of chronic nickel toxicity towards sediment dwelling organisms (including a WoE analysis of the freshwater sediment bioavailability normalization approach using the SEM-AVS model for nickel in freshwater sediments)

*Indicative risk characterization* for sediment organisms (including emission and exposure assessment for freshwater sediment),

Review of risk management options and *recommendations for risk management measures*, including a proposal for establishment of an EQS for freshwater sediments to supplement the established EQS for surface water under the Water Framework Directive (WFD). It is recommended the relevant regulatory bodies under the WFD to use the current report (incl. annexes & appendices) as the starting point for development of such a generic EQS, bioavailability normalization approaches and risk assessment refinement strategy, as well as any additional relevant sediment data generated prior to the development of the proposed EQS<sub>freshwater sediment</sub>. Industry is recommended to use these approaches in relation to refinements of its generic risk assessment of nickel to sediment organisms. This section includes furthermore a suggestion to the relevant MS and COM experts to consider the relevance and need for revision of the current BREF notes for the plating industry<sup>3</sup>, under the Industry Emission Directive (Dir. 2010/75/EC). Finally it is recommended in this section that ECHA, when the REACH registration dossiers of the nickel substances have been updated by IND with the new information from the sediment research program, considers the need to perform a targeted compliance check concerning the hazard and risk assessment for the sediment compartment (For consistency ECHA could also consider extending the targeted compliance check to include the risk assessment of both the pelagic and sediment compartment).

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<sup>3</sup> Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Surface Treatment of Metals and Plastics /August 2006) This Reference Document (BREF) entitled 'Surface Treatment of Metals and Plastics (STM)' reflects an information exchange carried out under Article 16(2) of Council Directive 96/61/EC (IPPC Directive).



Overview of *possible refinement options* for the freshwater sediment risk assessment in relation to exceeding the EQS for nickel for freshwater sediments and risk characterization ratio of 1 for freshwater sediments (i.e. when  $PEC_{\text{freshwater sediment}}/PNEC_{\text{freshwater sediment}} > 1$ ). The refinement approach is flexible and includes refining the exposure assessment and/ or bioavailability normalization.

The following chapters of this summary report address each of the above mentioned issues. More details can be found in the attached reports (Annex 8) to which reference is made in each chapter. Note that representatives of DK EPA and NiPERA have comprehensively discussed and agreed on each of the attached background reports (Annex 8).

Finally, two short reports are included in an Appendix providing a brief overview of current uncertainties concerning the present database relating to chronic effects of nickel towards sediment organisms and the established bioavailability normalization approach. They also present ongoing research activities initiated by NiPERA to be able in future (after 2014) to address and potentially reduce these uncertainties.

### **3. Derivation of PNEC for sediment organisms<sup>4</sup>.**

As described in Vangheleuwe & Verdonck F (Nov 2011) section 2 & 4 and its references to background reports (see Annex 8), a generic PNEC for fresh water sediment organisms was derived after an initial extensive research to optimize freshwater sediment spiking methods for nickel.

First chronic toxicity tests were performed on 9 freshwater sediment dwelling species. They included two amphipods, three insects (mayfly and two midges), two oligochaetes, a mussel species, and a nematode. This was done using standard freshwater sediment test methods employing sediments representing approximately the 10 percentile of EU freshwater sediments as regards AVS, TOC, Fe and CEC. The goal of these tests was to establish relevant and reliable chronic toxicity test data (NOEC or EC10).

However, four of these species did not display toxicity within the test ranges i.e. no effects were observed, and in addition tests on one of the selected organisms (the nematode species) were generally not successful. Hence for these species no NOEC or EC10 could be derived. The current

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<sup>4</sup> as required by COM Reg. 466/2008.

guidance for employing a Species Sensitivity Distribution (SSD) for sediment organisms refers to guidance developed for pelagic organisms, and specific guidance for performing an SSD for sediment organisms is not available. The endpoint specific REACH guidance for aquatic toxicity describes that application of SSD for pelagic species is appropriate for derivation of a  $HC_{5(50\%)}$ , if chronic data are available for at least 8 species and if further specific conditions are met including availability of data for a wide range of taxonomic groups, ecological functions and feeding strategies. Nevertheless, the application of a SSD based on the 4 chronic toxicity data for sediment organisms for nickel was judged to be acceptable, even if not optimal. First it is noted that the availability of standardized long-term ecotoxicity tests on freshwater sediment species is considerably lower than that for freshwater pelagic species. In addition the justification for employing an SSD on only four chronic data points was that even though only four data points were used in the actual SSD, the full data-set included 8 high-quality, relevant and reliable chronic NOEC (although 4 unbound) or EC10-values on a wide diversity of sediment organisms, covering different taxonomic groups, feeding strategies and ecological niches. Lack of effects (unbounded NOECs) on the additional four species assured the cautiousness of the approach, because the SSD indeed is based on the sediment species that are known to be the most sensitive ones.<sup>5</sup>

Lack of data on benthic decomposers (e.g. bacteria) and photosynthetic organisms (periphyton) and hence lack of use of such data to establish the SSD is due to lack of available standardized test methods for these types of organisms. In addition, such organisms have traditionally not been employed for regulatory establishment of setting PNEC<sub>sed</sub>.

A range of potentially other options to derive  $HC_{5(50\%)}$  was considered. These options included using aquatic (pelagic) chronic toxicity data from one of the benthic species with unbounded NOECs, by estimating the toxicity in porewater using the EqP method<sup>6</sup> and thereby increasing the

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<sup>5</sup> The SSD and resulting  $HC_{5(50\%)}$ -value of 94 mg Ni /kg sediment dw was established based on a statistically accepted curve fit by the conventional employed log-normal fit function. It is however also noted that when an SSD is based on only 4 data point only extreme deviations from the distribution of the selected fit function (here the conventional log-normal) will be identified with the goodness of fit functions employed. Hence acceptance of fit function to the measured SSD cannot really be used as an argument for high reliability of the data, SSD and HC5.

<sup>6</sup> EqP: Equilibrium partitioning method where the toxicity to sediment organisms is estimated from the distribution coefficient ( $K_d$ ) to sediment and the toxicity to pelagic organisms assuming pelagic and sediment organisms to be equally sensitive.

number of data points behind the SSD to five chronic data. It also included the use of various alternative fit functions to the dataset on the four or five data points. However, it was concluded that using these approaches causes higher uncertainty than using the conventional  $HC_{5(50\%)}$  on the four measured chronic data points as described above.

The REACH endpoint specific Guidance stipulates that an appropriate Assessment Factor (AF) should be employed upon the  $HC_{5(50\%)}$  in order to derive the PNEC by taking the residual uncertainty into account. For nickel these uncertainties mainly relate to those mentioned above regarding employment of the SSD approach. However as described in Vangheleuwe & Verdonck F (Nov 2011) section 4 for nickel, there are supporting evidence from field studies that the uncertainty may not be extensive. The field studies on freshwater sediment organisms include several long-term (2 months and up to 9 months) studies conducted in US and EU (i) with varying water and sediment characteristics, (ii) in different seasons, and (iii) in both lotic and lentic systems. These studies investigated colonization over time to *in situ* deployed spiked sediments. The most recent field study was conducted on the same sediments used in the chronic laboratory tests. All field studies supported that no effects were observed at the concentration of 94 mg Ni/kg sediment dw, i.e. at the  $HC_{5(50\%)}$ -value. Furthermore, the lowest effect in any of the performed field studies occurred at 500 mg Ni /kg sediment dw (more than five times the  $HC_{5(50\%)}$ -value).

Based on these considerations use of an AF of 2 may be considered for derivation of a generic  $PNEC_{\text{freshwater sediment}}$  of 47 mg Ni/kg sediment dw based on the derived  $HC_{5(50\%)}$ -value of 94 mg Ni/kg sediment dw. This  $PNEC_{\text{freshwater sediment}}$ -value can be compared with (i) 46 mg Ni/kg sediment dw for the 90 percentile of, and (ii) 18 mg Ni/kg sediment dw for the 50 percentile of ambient Ni-concentrations in the FOREGS database for EU<sup>7</sup>.

Which AF to employ to derive the  $PNEC_{\text{freshwater sediment}}$  has neither been agreed between EU MS nor between the Danish EPA and NiPERA. Because of this and the view of NiPERA that the AF should be lower than 2, it was agreed that this indicative risk characterization analysis could also include tentative PNEC values by use of AFs of 1 and 1.5. Finally,  $PNEC_{\text{freshwater sediment}}$  derivation by use of an AF of 3 was also included, mainly because of the uncertainty of the  $HC_{5(50\%)}$  and SSD based on only four data points.

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<sup>7</sup> The FOREGS database contains natural and ambient (natural + anthropogenic) nickel concentrations

#### **4 Bioavailability normalization of chronic nickel toxicity towards sediment organisms<sup>8</sup>.**

Considerable new research has been conducted to develop predictive bioavailability models, and its implication for chronic nickel toxicity to sediment organisms has been described in Vangheleuwe & Verdonck F (Nov 2011) section 3 and references therein (cf. Annex 8).

Bioavailability models based on chronic toxicity related to sediment Ni-AVS and Fe were established and validated for three sediment species. This resulted in two rather similar models for the two crustacean species (*Hyallorella* & *Gammarus*) and a deviating one for the insect *Hexagenia* sp. The latter model indicated less impact of AVS and Fe on the chronic toxicity. This latter model is recommended for use on the fourth nickel sensitive species *Lumbriculus* sp., on which no bioavailability normalization model was established. This will assure a cautious employment of bioavailability models across species used for the data points of the SSD curve. Employment of these models to the SSD curve in order to derive a bioavailability normalized  $HC_{5(50\%)}$  and a  $PNEC_{\text{freshwater sediment}}$  may (as described in section 7) be considered if (i) a first tier sediment risk assessment on nickel indicates a potential risk, and if (ii) data on sediment AVS or Fe can be obtained or generated.

Note in relation to the above discussion of AF for  $PNEC_{\text{freshwater sediment}}$ , that there are currently uncertainties due (i) to the lack of a bioavailability model for *Lumbriculus* sp., and (ii) to the employment of the *Hexagenia* model for that species; even though some sensitivity analysis conducted indicate that the impact may not be highly influential on the derivation of the  $HC_{5(50\%)}$  –value. There is furthermore uncertainty in relation to the reason for why the *Hexagenia* bioavailability model is so different from the two crustacean models. One hypothesis is that *Hexagenia* is also exposed to dietary Ni and exhibits chronic toxicity to also the dietary nickel sources; another is that this species creates a microhabitat by actively circulating oxygenated overlying water through its U-shaped burrow. The presence of oxygen within the burrow may oxidize AVS, thereby releasing Ni and creating the opportunity for exposure to the organisms. Alternatively, residual soluble Ni in pore water could be drawn to the burrow via pore water flow. These issues are amongst topics that are currently addressed in a voluntary further research program recently initiated by NiPERA (cf. the Appendix). Regardless of the cause, the occurrence of such a

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<sup>8</sup> provided beyond that required according to COM Reg. 466/2008

difference in bioavailability amongst benthic species indicates that there may be further significant differences between different taxonomic groups and feeding habits, and species of different ecological niches. It also raises the issue on whether such "deviating" bioavailability models are indeed applicable for other sediment species for which bioavailability models have not yet been developed and validated.

Finally as described in "The WoE analysis of the sediment bioavailability normalization approach using the SEM-AVS model for Nickel in Sediments" (Vangleuwe, 2012), it seems that the AVS concept does in general hold true for nickel bioavailability and chronic toxicity to freshwater sediment organisms, although it may not always hold true for bioaccumulation, i.e. freshwater sediment biota concentration which may also have been exposed to nickel via the dietary route. It is currently unknown whether dietary nickel exposure may be a significant cause of chronic toxicity for some sediment species. Even though information about this is scarce one hypothesis is that this may not be the case, because nickel via this administration route predominantly seems to be detoxified and stored in the cells of certain sediment organisms as probably bio-unavailable granules. NiPERA has after the conclusion of the further research programme for establishment of a  $PNEC_{\text{freshwater sediment}}$  for nickel initiated new targeted research addressing these residual uncertainties.

## **5. Indicative Risk Characterization for sediment organisms<sup>8</sup>.**

The Danish CA should based on the information to be provided by nickel IND according EU COM Reg. 466/2008 make recommendations to the Commission, ECHA and the EU MS on appropriate regulatory measures, if any. However the information to be provided only addressed the  $PNEC_{\text{freshwater sediment}}$ . In addition, the additionally provided information by NiPERA exclusively addressed establishment of appropriate bioavailability models for modifying a generic  $PNEC_{\text{freshwater sediment}}$  according to relevant abiotic conditions (AVS).

Thus, in order to make appropriate recommendations in this context, the Danish CA decided to consider indicatively the risk and not only the hazard for sediment organisms. Therefore an indicative risk characterization of nickel towards sediment organisms was conducted based on new environmental emission / exposure data provided by NiPERA (Cf. Annex 8, "Risk characterization of nickel in sediments", July 2012). It is thus noted that the risk characterization can only be considered as indicative, and that it does not challenge the obligation of industry to document safe use in the registration dossier and for that purpose to

conduct a proper risk assessment according to the provisions of REACH. Furthermore, the current indicative risk characterization of nickel does not contain such an assessment for several industry sectors such as multiple steel production manufacturers, nickel alloy production, recycling, steel production and foundry & metal product manufacturers. Furthermore the coverage of the industry sectors that are included in the assessment was variable (e.g. for the metal plating sector very poor as it only includes exposure data from 18 out of a total number of more than 800 sites). However, because it is estimated that this indicative risk characterization does account for industrial sectors representing approximately 75 % of the total industrial nickel release to the aquatic system in the EU it was considered that this was sufficient to allow for proper recommendations to be drawn as regards the need for and nature of further risk management measures to be made.

The current indicative risk characterization was developed and agreed in close collaboration between the Danish EPA and its consultant and NiPERA, on behalf of the Nickel industry, and its consultant, but it should be noted that the Danish EPA had no access to the detailed site specific nickel emission or exposure related data, but only to the industry sector specific information.

Like for the earlier performed aquatic (i.e. pelagic) risk characterization of nickel (Commission 2008), the coverage of emission / exposure information varied between the industry sectors included in this indicative nickel risk characterization for freshwater sediment organisms, i.e. from full coverage concerning the nickel production sector to very low coverage of the nickel plating sector. The following industry sectors were included in the assessment. (Note in parenthesis for each sector: number of sites out of the total number and approx. percentage of nickel release out of the estimated total release for all of the included industry sectors):

Nickel production	(7/7; 2.1%)
Stainless steel production	(19/23; 51%)
Ferro-Nickel producers	(1/1; 22%)
Nickel chemical production	(11/>18; 3.2%)
Nickel plating	(8/>800; 21%)
Catalyst production	(13/13; 0.3 %)
Battery production	(3/7; 0.1%)
Ceramics production	(2/>10; 0.0%)

Note that for industrial sectors not fully covered in the analysis the average release/exposure for the covered sites was applied to the sites with no site specific release/exposure information<sup>9</sup>.

For each industry site on which information was available the  $RCR = \frac{PEC_{\text{freshwater sediment, total}}}{PNEC_{\text{freshwater sediment}}}$  was calculated under a number of assumptions, i.e. in relation to the choice of AF (use of the recommended AFs of 2 but also for AFs = 1, 1.5 and 3) and for EU freshwater sediment with 10, 50 and 90 percentiles of the EU freshwater sediment AVS concentrations

Note that the  $PEC_{\text{freshwater sediment, total}}$  was calculated based on  $PEC_{\text{freshwater sediment, regional}} + PEC_{\text{freshwater sediment, local}}$  and that  $PEC_{\text{freshwater sediment, regional}}$  was based on the generic regional value for EU freshwater sediment (33.5 mg Ni /kg dw) or marine sediment (16.1 mg Ni /kg dw) if no country specific information was available.

It should also be noted that local nickel sediment concentrations have been estimated from estimated surface water concentrations in most cases derived from local site specific emission and dilution data and use of a default  $K_d$ -value.

Overall the analysis indicated that:

1) the freshwater sediment compartment may have a higher sensitivity to chronic nickel toxicity than the pelagic compartment at high RCRs for sediment (high  $PEC_{\text{freshwater sediment}}/PNEC_{\text{freshwater sediment}}$ ) but that the sensitivity may be equal at lower RCRs for sediment

2) the choice of AF significantly influences the number of sites at potential risk, i.e. an AF of 3 indicates potential risk at 64 sites, an AF of 2 indicates this for 24 sites, an AF of 1.5 indicates 22, whereas an AF of 1 indicates 17, all being number of sites out of 68 sites with potential risk to sediment organisms. It may tentatively be concluded that selection of an AF of 3 could result in  $RCR > 1$  in many cases even if the exposure assessment has been refined (see section 7), while this may not be the case, if an RCR of 2 is chosen.

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<sup>9</sup> Hence it was assumed that the sites that did provide new release / exposure data were representative for the whole industrial sector in question. For the industrial sectors where the total number of sites is not known for sure, the total number of sites was assumed to be the following: for nickel plating 800, for nickel chemicals production 18 and for ceramics production 10.

3) it is likely that employment of the proposed bioavailability normalization of the SSD curve for derivation of  $PNEC_{\text{freshwater sediment}}$  may significantly reduce the number of sites with potential risk.

4) further refinement of the emission or exposure assessment is warranted for a number of sites because even at high AVS-sediment concentrations and employment of an AF of 2, RCR remains over 1 (e.g. for nickel metal producers in 1 out of 7 sites, for stainless steel in 6 out of 23 sites, for nickel plating in 3 out of 12 and for catalyst production in 2 out of 10 sites with exposure information). Alternatively risk management measures / revised operational conditions decreasing the environmental nickel emission may be considered for (some of) these sites.

5) No firm conclusion can be drawn for the nickel plating sector because of the very poor coverage of this industrial sector as regards updated information about the environmental nickel emission of individual sites.

6) No conclusion can be drawn for the nickel industry sectors not covered by the indicative sediment risk characterization, i.e. for the multiple steel production manufacturers, nickel alloy production, recycling, steel production and foundry & metal product manufacturers.

Note that further information and analysis is available relative to these conclusions in the background report for this indicative freshwater sediment risk assessment: "Risk Characterization of nickel in sediments", July 2012 (attached amongst the background reports).

In conclusion it seems based on this indicative risk characterization for nickel to freshwater sediment organisms that both refinements relating to emission and exposure assessment and to bioavailability normalization may be warranted in a relatively high number of cases (cf. further in section 7). Alternatively risk management measures / revised operational conditions decreasing the environmental nickel emission may be considered for (some of) these sites.

Finally also further future refinement of the  $PNEC_{\text{freshwater sediment}}$  derivation and further information about factors influencing nickel bioavailability and chronic toxicity towards freshwater sediment organisms may have an impact on the bioavailability normalization approach to apply (cf. further in the Annex), i.e. on the way a refined site specific sediment risk characterization for nickel could be performed.



## 6. Review of risk management options and recommendations for risk management measures.

According to REACH registrants of the five nickel substances should update the REACH dossiers with relevant new data on sediment organisms and use this data in an update CSR for sediment organisms in relation to all use scenarios with emission/loss/ discharge to surface water. The Danish EPA has received information from NiPERA that such an update is planned for 2014.

In relation to the update of the CSR on nickel for sediment organisms the Danish EPA recommends, if the registrants use the currently available data reported here, to employ the generic  $PNEC_{\text{freshwater sediment}}$  on 47 mg Ni /kg sediment dw (i.e. an  $HC_{5(50\%)}$  –value of 94 mg Ni/kg freshwater sediment dw, and AF of 2) and the risk characterization refinement approach (regarding bioavailability and refined exposure assessment) included in this report.

According to articles 136(2) and 48 the rapporteur member state should evaluate whether the information provided on transitional substances indicates that:

- no follow up action or
  - further REACH specific measures :
    - (harmonized classification and labeling, and/or
    - restrictions, and/or
    - SVHC-identification (Candidate Listing) & authorization) and/or
  - other EU level measures and/or
  - national level measures and/or
  - voluntary action by industry
- are needed.

It is obvious that the option that no follow up is needed does not apply because potential for risk to sediment organisms has been indicated.

**Harmonized classification and labelling.**

It is similar obvious that the provided information does not affect the already adopted *harmonized classification and labelling* of nickel substances because the sediment data and provisional risk analysis are not relevant in relation to classification and labelling criteria.

**Restrictions under REACH (Annex XVII)**

In relation to consideration of whether further *restrictions on nickel concerning marketing and use* would be relevant, the information provided on freshwater sediment organisms seems to indicate that the general level of potential risk across nickel using industrial sectors may be similar to that for pelagic organisms even though a firm conclusion for each site evaluated cannot be drawn at this point in time due to the provisional nature of the conducted risk characterization for the local freshwater sediment sites. It is recalled that the Danish EPA did not have access to the detailed emission/exposure information from the nickel using industrial sites where new information were available, that the assessment does not include several nickel using industrial sectors and finally that the site specific information even for the covered industrial sectors was incomplete (c.f. section 5).

Article 68(1) of REACH stipulates that a restriction proposal should be made if an unacceptable risk of a substance is identified and the risk needs to be addressed on a Community wide basis. Such a restriction may concern limitations or conditions of the manufacture, use or placing of the substance in question – or mixtures containing the substance - on the market. One of the conditions related to registration under REACH and hence use of a registered substance is how the risk of the substance is assessed in the registration dossier. The new information on the chronic toxicity towards freshwater sediment organisms of nickel and the tentative freshwater sediment risk characterization indicating frequent occurrence of risk at local sites may suggest that further use of the restriction instrument at the EU level could potentially in future be a justifiable mean for controlling the risk. One option could be by setting a uniform and transparent basis for how the risk to freshwater sediment organisms at local sites should be assessed (i.e. by setting a generic PNEC for freshwater sediments organisms as modified by local bioavailability factors by the use of a prescribed normalisation model in relation to the emission at each of the local freshwater sediment sites, see also below).

In this context it is however noted that IND will update the nickel registration dossiers in 2014 in relation to the new effect data on freshwater sediment organisms (including information about bioavailability normalisation) and relevant local industrial emission data for the nickel

using industrial sectors. It is assumed that nickel IND in these registration dossier updates will demonstrate safe use of the substances (i.e. an  $RCR_{\text{freshwater sediment}} < 1$  for all sites with emissions to the freshwater (pelagic and sediment) environment (cf. also section 7)). In this context it is recommended that the current summary report and attached annexes & appendices are used by the registrants.

No compliance check under REACH has yet been performed on the chemicals safety assessment for registered nickel substances in relation to the freshwater sediment compartment. Hence a subsequent (targeted) compliance check by ECHA in relation to the hazard and risk assessment for nickel towards sediment species may be warranted to assure that the  $PNEC_{\text{freshwater sediment}}$  has been derived robustly as implied by COM Reg. 466/2008. If it turns out in such a subsequent compliance check that nickel registrants recommendations to down-stream industrial nickel users on the safe use of nickel for the sediment compartment has not been demonstrated or if the performed risk assessments contains obvious flaws, further actions may be triggered such as requests for further information, enforcement or proposals for and implementation of appropriate restrictions.

One possible option not yet employed under REACH would as mentioned above be to consider making a specific restriction under REACH for safe use of nickel in relation to sediment organisms by setting a generic  $PNEC_{\text{freshwater sediment}}$ -value (and possibly bioavailability normalization approach) which must not be exceeded. This is an option which would have the advantage of being relatively easy to implement, provide clarity on how registrants should perform the freshwater specific nickel risk characterization and which may be an efficient tool in controlling how site specific nickel emissions are reported across industrial sectors in a consistent way. The latter so, because establishment of a generic EU wide  $PNEC$ -value for freshwater sediment, which may be modified based on the prescribed bioavailability normalisation model, will probably have the effect that local industrial nickel using sites will comply with this basic  $PNEC$ -value as potentially modified in accordance with the site specific freshwater AVS-concentration. Hence a generic but bioavailability modifiable  $PNEC$  -value for freshwater sediment organisms employed for all industrial sites with nickel emissions to freshwater and freshwater sediments set under REACH as a restriction may provide a consistent regulatory basis for enforcement of the equivalent EQS under the Water Framework Directive.

It is namely noted that a compliance check of REACH dossiers and or even a potential future REACH restriction as described above may only

assist in the actual control of site specific nickel emissions. It will not address whether downstream nickel users of the various industry sectors actually do comply with the site specific risk assessment as reported in the updated REACH registrations including the recommendations concerning safe use of nickel in relation to the freshwater and sediment compartment. Such type of control is rather performed by relevant local/regional/national authorities in charge of regulating industrial emissions / discharge / loss to surface water by various national and EU regulations (in particular in relation to the Water Framework Directive). The emission control includes relevant monitoring activities and the enforcement typically includes assurance of the implementation of measures to revise local operational conditions and / or improve risk management measures reducing the emissions to the aquatic (i.e. pelagic and sediment) environment for those sites where RCR > 1 (c.f. section below).

In conclusion and based on the current level of information and considering also other regulatory instruments (see below), a proposal for restricting under REACH (Annex XVII) on the use of nickel due to concerns for sediment organisms does not seem to be the most obvious regulatory instrument to propose at this stage.

#### **Inclusion on Candidate list/Authorization List.**

The last type of REACH regulatory measures is to consider whether the new information on sediment organisms indicates the nickel substances to be substances of very high concern and hence of relevance to consider in relation to *Candidate Listing and inclusion on the Authorization list*. **This does however also not seem obvious**, because the **PBT/vPvB criteria do not refer to use of sediment toxicity data**. It is also noted that even though nickel has a high toxicity towards aquatic (including freshwater sediment) organisms, and may be considered persistent its bioaccumulative potential is below the trigger value if a PBT assessment was conducted (vPvB/PBT assessment is generally targeted organic substances). It is furthermore noted that the nickel substances here do have a harmonized classification in relation to their **CMR-properties** based on which a Candidate Listing potentially could be proposed. However this **does not concern the newly generated toxicity data** on sediment organisms. Hence it is concluded that the newly provided chronic toxicity data on freshwater sediment organisms do not indicate that a proposal for Candidate / Authorisation listing is relevant.

### **Other Community wide measures:**

#### **Water Framework Directive (Dir. 2000/60/EC)**

In relation to *other Community wide measures* it is obvious that the new data on chronic toxicity of nickel to sediment organisms are relevant in relation to nickel emissions to surface water. **Nickel has furthermore already been included as a priority substance under the Water Framework Directive.** Currently an EQS and a bioavailability normalization approach for pelagic organisms have been proposed and a similar approach based on the new data and provisional risk characterization for nickel in relation to freshwater sediment organisms seems obvious to consider. The main reason for proposing using this regulatory measure is that relevant local/regional/national authorities will monitor that the EQS for pelagic organisms, as well as EQS for freshwater sediment organisms if that will be set, will not be exceeded for any major industrial site emitting nickel to the aquatic environment (cf. also the above section on restrictions under REACH).

Hence it is **proposed that an appropriate EQS for freshwater sediment organisms is being established for nickel under the WFD.** It is furthermore proposed that it is considered how a refined local risk assessment (evaluation of whether local nickel sediment concentrations are exceeding the EQS) based on a site specific bioavailability normalization and/ or refinement of emission / exposure assessment can be performed. In this context it is recommended that the data and analysis of this report and its annexes are used as starting points for further development and implementation of such an approach by the relevant expert committee under the Water Framework Directive (WFD).

It is due to the ongoing further research initiative by NiPERA furthermore likely that further refinement of the  $PNEC_{\text{freshwater sediment}}$  may take place under the development of an  $EQS_{\text{freshwater sediment}}$  for nickel. The same applies to **development of further guidance and tools for a stepwise refinement of both the emission/exposure as well as bioavailability normalization.**

Denmark also being Rapporteur of EQS for nickel under the WFD intends therefore to raise this issue in the relevant WFD forum with the purpose to recommend the Commission to make a proposal for an EQS for freshwater sediment at the EU level and to consider the inclusion of options to use an AVS based bioavailability approach.

#### **Industrial Emission Directive (Dir. 2010/75/EC).**

Even though the current indicative nickel risk characterization for freshwater sediment organisms only contains information about a very

limited number of sites with potential risk for the nickel plating industry sector, the assessment does actually suggest concern. This is supported by the general finding that the sensitivity of the freshwater sediment compartment is more sensitive (at high RCRs for sediment) or equally sensitive (at lower RCRs for sediment) than the pelagic freshwater compartment. It is furthermore supported by the fact that the EU risk assessment report under the Existing Substance Regulation (ECHA 2008) concluded that potential risk was observed for a high number of sites within the nickel industry plating sector. Therefore it seems obvious to emphasize that the **existing recommendations made earlier for implementation of BAT in certain nickel using industries are already covering all environmental media, but will be extended as regards its local emission control provisions, if an EQS is being established for freshwater sediment species besides the EQS now being proposed for pelagic species:**

- that competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2010/75/EC<sup>10</sup>, conditions, emission limit values or equivalent parameters or technical measures regarding nickel and the four nickel compounds in order for the installations concerned to operate according to the best available techniques (BAT) taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions including site specific data concerning the local receiving environments which may include site specific and refined nickel emission or local concentration data and relevant bioavailability normalisation information;
- that Member States should carefully monitor the implementation of BAT regarding nickel and the four nickel compounds and report any important developments to the Commission in the framework of the exchange of information on BAT.
- to facilitate permitting and monitoring under Directive 2010/75/EC<sup>11</sup> nickel and the four nickel compounds should be included in on-going work to develop the guidance on 'Best Available Techniques' (BAT);
- local emissions to the environment (air, surface water & sediment, soil) should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected; (i.e. that the EQS is complied with for each site, c.f. article 18 of the directive)

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<sup>10</sup> Directive 2010/75/EC of 1 November 24 2010 concerning integrated pollution prevention and control, OJ L 334, 17.12.2012 p. 17-119

Earlier a recommendation relating to concerns including concerns for chronic nickel toxicity to pelagic organisms has been made to relevant **MS and COM experts to consider the relevance and need for revision of the current BREF notes for the plating industry**<sup>11</sup>, under the Industry Emission Directive (Dir. 2010/75/EC). The current tentative risk characterization for the nickel plating industry sector and sediment organisms is very tentative due to the very limited information about sediment exposure. This limited information is however supplemented with a general indication of equal or even higher sensitivity to chronic nickel toxicity of sediment organisms compared with that of pelagic organisms. Taken together this seems to suggest that the recommendation for revision of the BREF notes for the plating industry is relevant for both aquatic compartments, i.e. both the pelagic and the sediment compartment.

#### **Voluntary action by IND.**

Finally the option *voluntary action by IND* does not seem necessary to consider besides to follow the above mentioned recommendation because the proposed other measures are considered appropriate in relation to the new information on toxicity towards chronic toxicity towards sediment organisms provided for nickel.

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<sup>11</sup> Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Surface Treatment of Metals and Plastics /August 2006). This Reference Document (BREF) entitled 'Surface Treatment of Metals and Plastics (STM)' reflects an information exchange carried out under Article 16(2) of Council Directive 96/61/EC (IPPC Directive).

## **7. Overview of possible refinement options to be used in relation to exceeding EQS for nickel in freshwater sediments and risk characterization for sediments.**

In general a risk characterization is conducted using a realistic worst case (RWC) scenario with a default PNEC and an estimated PEC based on measured or estimated (modelled) emissions to the water compartment. Several options, however, are available to refine the risk characterization and to get to a more realistic risk estimate, which may be warranted especially when potential risk ( $PEC_{\text{freshwater sediment}} > PNEC_{\text{freshwater sediment}}$ ) is indicated. Such a refinement may include:

- collecting more detailed and comprehensive emission data,
- site specific total nickel sediment data and/ or
- when needed to include a full-blown bioavailability assessment for sediments by use of AVS modelling.

The sequence of approach to take when refining the assessment should however not be fixed. Rather the actual choice of the refinement method will most likely be driven by factors such as cost-efficiency to reach the envisaged goal (demonstrating no risk for the sediment compartment, i.e. safe use of nickel for the particular site or exposure scenario).

The Table below provides several options that when necessary could be used to calculate more realistically the risk at the local site. The table is not intended to suggest a hierarchical tiered approach but merely outlines the possible refinement options that can be applied in a flexible way.



**Table: Overview of possible refinement options with associated benefits and limitations.**

<b>Refinement of Predicted Environmental Concentration (PEC)</b>		
<b>Refinement:</b>	<b>Benefits :</b>	<b>Limitations:</b>
Provide additional exposure data for the local aquatic compartment	Reduces the uncertainty in deriving the PEC aquatic	EP method still needed to derive the sediment PEC Some data (e.g.) flowrate river and local Kd values may not exist and may need to be measured <sup>12</sup>
Provide additional exposure data for the local sediment compartment	Reduces the uncertainty in deriving the PEC sediment	Measured sediment data are scarce and hence new measurements may need to be made
<b>Refinement Predicted No Effect Concentration (PNEC)</b>		
Collect historical or generate new local SEM-AVS data	Allows to normalize the PNEC for bioavailability	Availability of historical SEM-AVS data is limited <sup>13</sup>  SEM-AVS measurements are not a routine measurement <sup>12</sup>
Provide local SEM-AVS data	SEM-AVS < 0 can be used as supporting evidence for absence of toxicity	SEM-AVS measurements are not routine measurements <sup>12</sup>

<sup>12</sup> Spatial and temporal variability should be taken into account when conducting new measurements so that these are representative in accordance with "the realistic worst case concept". Special attention to good sampling and measuring practice for the different types of measurements should be applied.

<sup>13</sup> The issues in footnote 12 should be considered when using historical data. Caution should generally be applied when historical data are considered or used.

The several refinement options are more detailed below

**Refinement option 1: Collect or measure more sophisticated exposure/emission data for the aquatic compartment** (surface water and sediment) at the local site.

Typically a fixed dilution factor is applied to the effluent concentration of an emission site or STP as appropriate in order to obtain the PEC surface water (by default assumed to be 10) (ECHA, 2010). Since this PEC local water subsequently can be used in the derivation of the sediment PEC value by applying the Equilibrium Partitioning approach, it may be worthwhile to conduct a more specific assessment. Data on effluent discharge rates and flow rate of the receiving surface water can for example be used to calculate the actual dilution factor after complete mixing. When considering the available dilution, account should be taken of the fluctuating flow-rates of typical receiving waters. The low-flow rate (or 10th percentile) of the receiving surface water system should always be used. Where only average flows are available, the flow for dilution purposes should be estimated as one third of this average. It must be noted that with the assumption of complete mixing of the effluent in the surface water no account is taken of the fact that in reality in the mixing zone higher concentrations will occur. For situations with relatively low dilution factors this mixing-zone effect can be accepted. For situations with very high dilution factors, however, the mixing zones may be very long and the overall area that is impacted by the effluent before it is completely mixed can be very substantial. Therefore, in case of site-specific assessments the dilution factor that is applied for calculation of the local concentration in surface water should never be greater than 1,000 (ECHA, 2010).

Next to the local conditions from the surface water around the point source, information on the partitioning to suspended solids can be used to refine the assessment. In absence of a local  $K_d$  value, a default  $K_d$  value is typically extrapolated from a distribution of measured  $K_d$  values over all EU countries from where data are available or from the country or surface water basin at which the site is located. In the latter cases typically a median value is being used (ECHA, 2008). To avoid the use of such a default  $K_d$  value, which implies uncertainty, a possible refinement is to measure  $K_d$  in experiments conducted under local site conditions. The measurements should be representative for the local site conditions of the receiving surface water system.

**Refinement option 2: Provide measured data for the sediment compartment.**

Instead of refining the  $PEC_{\text{fresh surfacewater}}$  for use in an estimation of  $PEC_{\text{freshwater sediment}}$  a more direct refinement is to use actual measured nickel concentration data in the freshwater sediment compartment. Since sediment organisms inhabit the top layer of a sediment, the top 5 cm should be sampled using a dredge or core sampler.

Due to spatial heterogeneity it is recommended to make a composite sample from several samples taken from depositional zones.

**Refinement option 3: Collect or measure bioavailability parameters for the sediment compartment and normalize data for bioavailability.**

Nickel bioavailability in sediments is governed by several freshwater sediment characteristics with AVS and iron as the predominant significant parameters mitigating nickel toxicity. ARCHE (2011) developed for the AVS parameter predictive bioavailability models that can be used to assess toxicity of nickel in freshwater sediments. If local sediment AVS data are not available alternatively use of iron concentrations in the sediment may be considered for use in a predictive bioavailability model for the assessment of chronic nickel toxicity in freshwater sediments (ARCHE 2011)

The generic  $PNEC_{\text{freshwater sediment}}$  reflects already conditions in which bioavailability of nickel in sediments can be considered relatively high (i.e. low AVS and organic carbon) and may be used to screen out those case where chronic nickel toxicity to sediment organisms is unlikely to occur. It is noted that the AVS content in the tests on sediment organisms used for the generic  $PNEC_{\text{freshwater sediment}}$  derivation did contain some AVS (approximately 10<sup>th</sup> percentile of the AVS encountered in the available AVS database for EU). Therefore very sensitive areas with AVS concentrations in the sediment of less than the 10 percentile of that in EU sediments are not covered by this approach. Hence further considerations should be made on the need for refinement of the risk assessment even when a potential risk is not indicated, if it is likely or known that there is a very low AVS level in local sediments at the local site. However, it may be noted for such typical aerobic sediments that binding to iron/manganese oxide may play a role in reducing the bioavailability of nickel even though no account presently can be taken, because of lack of bioavailability models for the impact of iron and manganese oxides on the bioavailability of nickel for sediment organisms

When this type of refinement (i.e. bioavailability normalization) has been chosen, representative local AVS measurements should be made for normalizing the generic  $PNEC_{\text{freshwater sediment}}$  towards the AVS conditions prevailing at the site. If available data from past monitoring campaigns for the surface water system or basin of interest may be considered and used instead if done in a cautious way in this context. Proper justification should, however, be given (e.g. sediment type, iron content, organic carbon content) in order to assess the cautious nature of the value chosen to represent the local sediment conditions.

Once a representative realistic worst case AVS concentration has been selected from the available or measured data, the nickel bioavailability models should be used to derive the site specific AVS normalized  $PNEC_{\text{freshwater sediment}}$  (cf. ARCHE 2011). Note that these models were developed with natural test sediments containing background values of other metals (Cu, Cd, Pb, Zn, Hg) that have a higher affinity to bind with AVS than Ni. Therefore these bioavailability models inherently take the multi metallic nature of the SEM-AVS concept into account. The background values of the different metals in the sediments used to derive the bioavailability models were < 2mg/kg dry wt for Cd, < 10 mg/kg dry wt for Cu, < 50 mg/kg dry wt for Pb and between 38-64 mg/kg for zinc. Note that if substantially lower or higher background values are known or can be expected for these metals, this should be taken into account in the assessment by subtracting the molar difference (background local site – background test sediment) from the selected AVS concentration.

The potential risks for the local site can subsequently be calculated from the  $PEC_{\text{freshwater sediment, Total}}$  and the  $PNEC_{\text{freshwater sediment, AVS normalized, site specific}}$  (Eq-1)

$$RCR = \frac{PEC_{\text{Total}}}{PNEC_{\text{AVS normalized, site specific}}} \quad (\text{Eq-1})$$

In case RCR indicates a potential risk, the assessment can be further refined by using actual measured SEM-AVS concentrations (upstream and downstream of the site) for the site under investigations.

Care should be taken to collect sediment samples in the season where AVS concentrations are expected to be the lowest, i.e. spring season in order to preserve the cautious nature of the assessment. In this regard, SEM and AVS concentrations needs also to be collected in the top 5 cm of a sediment core sample since AVS exhibits a pronounced vertical concentration profile. (i.e. lowest concentrations in the top layer)

As a third and supplementary option to confirm absence of risk at the local site, it may be considered to take the SEM and AVS concentrations into account because the difference between these parameters can be used as a general indicator for the absence of potential risks to sediment organisms (cf. ARCHE 2011):

$SEM_{\text{site specific}} - AVS_{\text{site specific}} < 0$ , no risk

$SEM_{\text{site specific}} - AVS_{\text{site specific}} > 0$ , potential risk

In case of  $SEM-AVS < 0$  no risk is indicated confirming a RCR of  $< 1$ .

In case of  $SEM-AVS > 0$  potential risk is indicated and further refinement of the assessment or consideration of implementation of appropriate revised operational conditions and/ or risk management measures decreasing  $PEC_{\text{freshwater sediment}}$  below  $PNEC_{\text{freshwater sediment}}$  is warranted.

**ATTACHMENT**

Conclusion of Environmental Risk Assessment of nickel and the four high production nickel substances (2008) regarding implementation of BAT.

It is recommended that:

that competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC<sup>14</sup>, conditions, emission limit values or equivalent parameters or technical measures regarding nickel and the four nickel compounds in order for the installations concerned to operate according to the best available techniques (BAT) taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions;

that Member States should carefully monitor the implementation of BAT regarding nickel and the four nickel compounds and report any important developments to the Commission in the framework of the exchange of information on BAT.

to facilitate permitting and monitoring under Directive 2008/1/EC<sup>15</sup>, nickel and the four nickel compounds should be included in on-going work to develop the guidance on 'Best Available Techniques' (BAT);

local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected;

it is recommended that for the river basins where emissions of nickel and nickel compounds may cause a risk, the relevant Member State(s) establish environmental quality standards (EQS) and the national pollution reduction measures to achieve those EQS in 2015 shall be included in the river basin management plans in line with the provisions of Directive 2000/60/EC. In particular, monitoring of the abiotic parameters (DOC, pH and hardness) and the use of these in estimating the available nickel fraction by use of an agreed ligand model should be mandatory;

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<sup>14</sup> Directive 2008/1/EC of 15 January 2008 concerning integrated pollution prevention and control, OJ L 24, 29/1/2008, p. 8–29

<sup>15</sup> Directive 2008/1/EC of 15 January 2008 concerning integrated pollution prevention and control, OJ L 24, 29/1/2008, p. 8–29

the latest information in the risk assessment for nickel and nickel compounds is taken into account in future policy proposals relating to soil, in particular, the intended revision of Council Directive 86/278/EEC on Sewage Sludge; and

the risk assessment process has identified other sources of nickel and nickel compounds emissions (e.g. from sewage treatment plants and unintended releases from inorganic fertilisers) than those from the produced or imported chemical. The need to consider if additional risk management is needed can best be considered under Directive 2008/1/EC and Directive 2000/60/EC using the information in the comprehensive risk assessment report.