DATA COMPILATION, SELECTION, AND DERIVATION OF PNEC VALUES FOR THE SEDIMENT COMPARTMENT

The Existing Substances Risk Assessment of Nickel was completed in 2008. The straightforward explanation of the goals of this exercise was to determine if the ongoing production and use of nickel in the EU caused risks to humans or the environment. The European Union launched the Existing Substances regulation in 2001 to comply with Council Regulation (EEC) 793/93. "Existing" substances were defined as chemical substances in use within the European Community before September 1981 and listed in the European Inventory of Existing Commercial Chemical Substances. Council Regulation (EEC) 793/931 provides a systematic framework for the evaluation of the risks of existing substances to human health and the environment.

The conceptual approach to conducting the environment section of the EU risk assessment of nickel included the following steps (Figure 1):

Researcher demonstrates the new method for spiking nickel into sediments

- Emissions of nickel and nickel compounds to the environment were quantified for the whole life cycle, i.e. from production,use, and disposal;
- Concentrations of nickel resulting from these emissions were determined in relevant environmental media (water, sediment, soil, tissue) at local and regional scales (PECs);
- Critical effects concentrations (PNECs) were determined for each of the relevant environmental media;
- Exposure concentrations were compared to critical effects concentrations for each of the relevant environmental media (risk characterization); and
- Appropriate corrective actions (also described as risk management) were identified for situations where exposure concentrations were greater than critical effects concentrations. Where exposure concentrations were below critical effects concentrations, there was no need for concern or action.

The initial EU Risk Assessments for Nickel and Nickel Compounds were developed over the period from 2002 to 2008 but the European Commission identified some remaining data gaps in particular with respect to the sediment compartment (Official Journal of the European Union 2008). Therefore, a multilaboratory, multiphase research project was conducted to provide a scientific basis for a bioavailability based approach for assessing risks of nickel in sediments. The laboratory testing initiative was conducted in three phases to satisfy the following objectives: 1) evaluate various methods for spiking sediments with nickel to optimize the relevance of sediment nickel exposures; 2) generate reliable ecotoxicity data by conducting standardized chronic ecotoxicity tests using 10 benthic species in sediments with low and high nickel binding capacity; and 3) examine sediment bioavailability relationships by conducting chronic ecotoxicity testing in sediments that showed broad ranges of acid volatile sulfides, organic carbon, and iron. A subset of 6 nickel-spiked sediments was deployed in the field to examine benthic colonization and community effects. The sediment testing program yielded a broad, high quality data set that was used to develop a Species Sensitivity Distribution for benthic organisms in various sediment types, a reasonable worst case predicted no-effect concentration for nickel in sediment ($PNEC_{sediment}$), and predictive models for bioavailability and toxicity of nickel in freshwater sediments (Schlekat et al., 2016).

1 INTRODUCTION

Environmental risks are typically characterized in the risk assessment framework by considering the ratio between exposure concentrations and critical effect concentrations. In the Organisation for Economic Co-operation and Development (OECD) countries, critical effect concentrations are based on Predicted No Effect Concentrations (PNEC), which are typically derived from long-term laboratory-based ecotoxicity tests using well-defined protocols on a limited number of species. Such information is usually retrieved from relevant literature and/or internationally recognized databases or direct ecotoxicity testing. Because the quality of the extracted data may vary considerably among individual source documents, it is important to evaluate all ecotoxicity data with regard to their reliability and relevance for PNEC derivation and risk assessment. This fact sheet provides clear guidance on how to perform such evaluation for the freshwater sediment compartment including criteria for acceptance (or rejection) of a study in accordance with the purpose of the assessment and examples how these data can be applied in the European Union Environmental Risk Assessment for Nickel and Nickel Compounds.

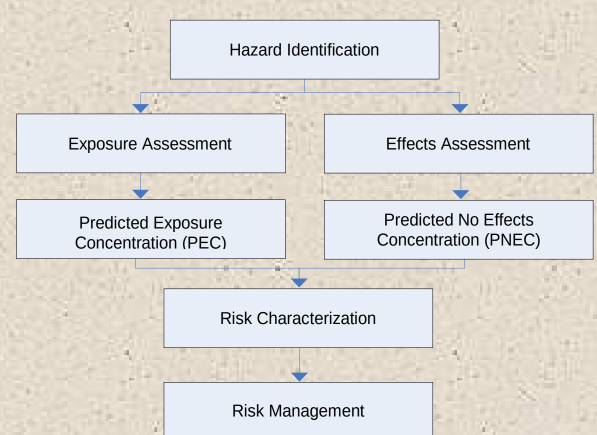

Figure 1: Schematic overview of the steps in the EU Environmental Risk Assessment

Earlier attempts to develop sediment toxicity data for nickel using laboratory toxicity tests were unsuccessful, largely because nickel spiked into natural sediments diffused from the sediment into overlying water, resulting in overlying water concentrations sufficiently high to cause toxicity (Vandegehuchte et al., 2007). A workshop sponsored by the European Chemicals Agency (ECHA) identified new scientific developments within sediment risk assessment and made recommendations on incorporating these advances into sediment risk assessment guidance (ECHA, 2014). The nickel sediment research program addressed many of the developments that were discussed at the ECHA workshop and represents an example for how research findings can be implemented into sediment risk assessment. The conceptual model of the integrated bioavailability based approach that was developed within the nickel sediment research program for assessing the risks of nickel to freshwater sediment ecosystems is given in Figure 2.

2 GUIDANCE

2.1 DATA GENERATION AND COMPILATION

Traditional sediment spiking methods, whereby soluble metal salts are added to sediments without further amendment, causes hydrolysis that results in a decrease in pore water pH and fosters significant metal release from the sediment compartment to the water compartment. To resolve this issue, new spiking procedures needed to be developed in order to generate scientifically sound toxicity data for the sediment compartment. Researchers at the United States Geological Survey (USGS) developed a two-step method for spiking nickel into freshwater sediments to create spiked sediments that were more representative of natural sediments gradually contaminated with nickel (Brumbaugh et al., 2013). The two-step approach required adding high concentrations of soluble $NiCl_2$ to sediments followed by an immediate pH adjustment with NaOH to mitigate the effects of hydrolysis. The product of the first step, referred to as a "super-spike," was equilibrated for four weeks. After this equilibration period, the super-spike sediment was diluted with clean sediment and equilibrated for six additional weeks to create gradients of sediment nickel concentrations that were used in sediment toxicity tests.

For sediment risk assessment, standardized sediment toxicity test protocols are available for only a small number of taxonomic groups. Also, no sediment-specific guidance is available on the number of species and taxonomic groups that are needed to represent an adequate database of benthic species for the determination of reliable sediment effects thresholds. The approach taken for the nickel sediment toxicity research project was to use as many species as possible considering a reliable test methodology was available. The REACH regulation risk assessment approaches are based on chronic ecotoxicity data, so only chronic toxicity tests were conducted. The chronic sediment effects data were generated by conducting toxicity tests with 10 benthic species with 8 nickel-spiked natural sediments representing sediments with a range of low to high nickel binding capacity. The ultimate nickel ecotoxicity database included amphipods (*H. azteca*, *G. pseudolimnaeus*), mayflies (*Hexagenia sp.*, *Epheron virgo*), oligochaetes (*T. tubifex*, *L. variegatus*), mussels (*L. siliquoidea*, *S. corneum*), and midges (*C. dilutus*, *C. riparius*) and is representative of different sediment exposure pathways, as well as a variety of feeding strategies and taxonomic groups representative of benthic ecosystems.

Full details on spiking procedures and the nickel sediment toxicity database can be found in Brumbaugh et al. (2013), Besser et al. (2013), Vangheluwe et al. (2013), Schlekat et al. (2016), and Vangheluwe and Nguyen (2015). Field studies using the same spiking procedures were also performed. Results of these studies showed that results from laboratory tests are protective of ecological-level effects in complex natural systems (Costello et al., 2011).

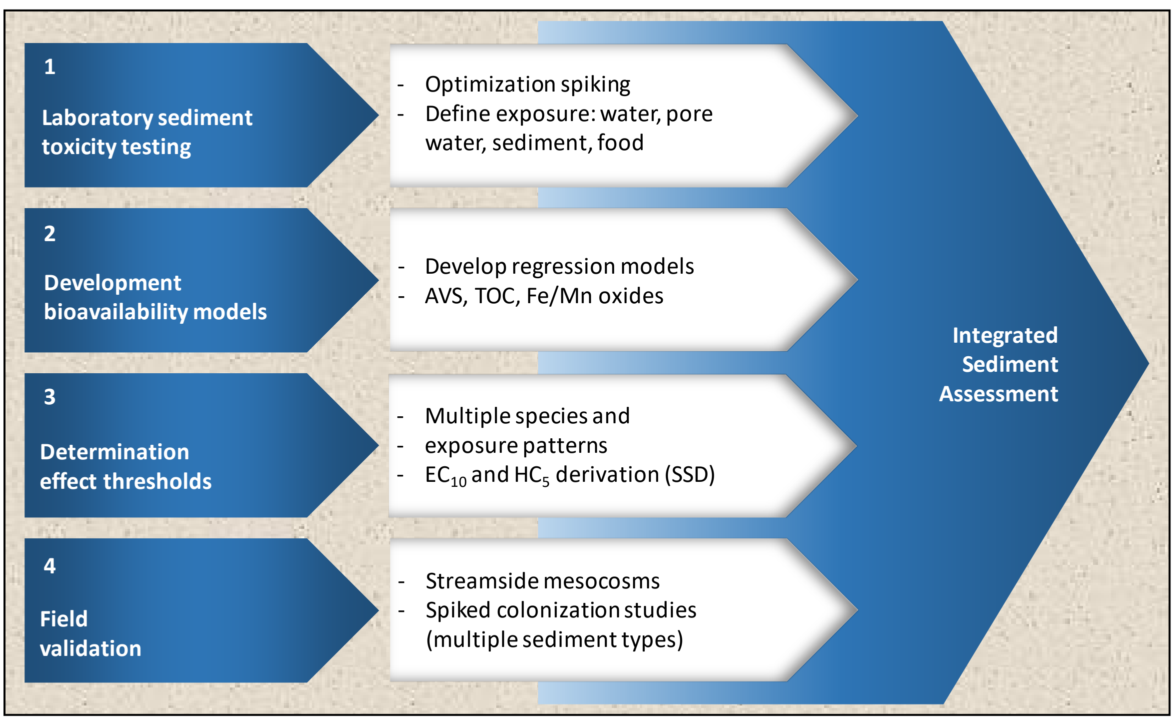

Figure 2: Conceptual model of the integrated bioavailability based approach for assessing the risks of nickel to freshwater sediment ecosystems (Schlekat et al., 2016)

2.2 DATA QUALITY SCREENING

Each individual ecotoxicity data point was screened for quality before incorporation in the nickel ecotoxicity database based on the criteria listed below, taking into account some recommendations of the ECHA sediment workshop (ECHA, 2014)[1].

- Data were retained for the following groups of organisms: crustaceans (amphipods), insects, oligochaetes, and molluscs.
- Data covered the following relevant endpoints: survival, growth (biomass), reproduction (abundance), and emergence.
- Data covered relevant feeding habits and ecological niches: burrowers, subsurface feeders, surface deposit feeders, and swimmers/sprawlers.
- Toxicity tests were conducted in natural (field collected) sediments spiked with nickel only.
- The results reported measured Acid Volatile Sulphides (AVS), Total Organic Carbon (TOC), iron (Fe), Cation Exchange Capacity (CEC), nickel, and metals.
- The range of the physico-chemistry of the test media (AVS, iron) were within the range of the concentrations found in natural sediments.
- The data were from studies conducted according to approved international standard test guidelines with a detailed description of the methods employed during toxicity testing, however, data following non-standardized tests protocols were also generated.
- Only long-term or chronic toxicity data were used, involving endpoints that are realized over periods of several weeks (typically 28 days) depending on the organism.
- Preference was clearly given to the use of measured nickel concentrations in the test concentrations.
- A clear concentration-response was observed.
- Toxicity threshold values calculated as $L(E)C_{10}$ and $L(E)C_{20}$ (the concentration that causes 10 or 20% effect during a specified time interval) values were calculated.
- The toxicity tests were performed with soluble nickel salts (e.g., $NiCl_2$).
- The toxicity data were related to the total concentration of nickel in sediments and the test results were expressed as mg Ni/kg dry weight.
- Ecotoxicity threshold values were derived using the proper statistical methods.

Ecotoxicity data had to fulfill these criteria to be used for the freshwater sediment PNEC derivation.

2.3 INCORPORATION OF BIOAVAILABILTIY (DATA NORMALIZATION)

The assessment of risks from metals in the sediment compartment is often hampered by the fact that no clear relationship has been established between measured total concentrations of metals in sediments and their potential to cause toxic effects on aquatic life (Di Toro et al., 1992). As a result, comparing total concentrations expressed on a dry or wet weight basis without taking bioavailability into account with an established threshold concentration has the potential to result in an under or overestimation of the associated risk. Normalization to similar conditions are necessary to make meaningful comparisons.

The chronic toxicity of nickel in sediments within the nickel sediment research program was influenced by several physicochemical characteristics of the tested sediments, with the highest toxicity found in sediments with low AVS concentrations, low TOC, low total recoverable Fe, and low CEC. For all species tested, the sediment parameter showing the strongest linear relationship was AVS. AVS has already been demonstrated as being one of the predominant factors controlling toxicity of divalent metals (Di Toro et al., 1992; Ankley et al., 1991, 1996). Within the nickel research program, chronic toxicity tests were conducted with several nickel-spiked sediments with a wide range of AVS concentrations in order to characterize the bioavailability relationships between nickel toxicity and AVS concentration for seven test species (i.e. linear regression models) (Vangheluwe et al., 2013; Vangheluwe and Nguyen, 2015). These empirical relationships between sediment toxicity endpoints and AVS concentration allow nickel ecotoxicity data to be normalized to different sediment scenarios (see example Section 3) and Figure 3.

Depending on the assessment (generic or local) the ecotoxicity data can be normalized to the targeted AVS concentration using the linear regression models developed for nickel (Vangheluwe et al., 2013; Vangheluwe and Nguyen, 2015). In order to derive a RWC PNEC the process of bioavailability normalization begins with the normalization of ecotoxicity values (e.g., EC_{10} values would be used for REACH) from each test to the target AVS concentrations [e.g., 0.8 mmol/kg dry weight for the RWC scenario (Vangheluwe et al., 2008)]. If a local assessment is conducted the typical AVS concentrations (median value) prevailing at a site can be used as normalization target. For further guidance on the available regression models for nickel see Fact Sheet 9, *Incorporation of Bioavailability in the Sediment Compartment*.

For species that were tested in multiple sediments, the geometric mean of normalized ecotoxicity values should be calculated (see Section 2.4).

2.4 DATA AGGREGATION

Normalized high quality ecotoxicity data are grouped/aggregated in order to avoid over-representation of ecotoxicological data from one particular species. The following major rules were used to aggregate data:

- If several chronic $L(E)C_{10}$ values based on the same toxicological endpoint were available for a given species, the values were averaged by calculating the geometric mean resulting in the "species mean" $/L(E)C_{10}$.
- If several (geometric mean) chronic $/L(E)C_{10}$ values based on different toxicological endpoints were available for a given species, the lowest (geometric value) value was selected.

After the data aggregation step, only one ecotoxicity value (i.e. the geometric mean for the most sensitive endpoint) was assigned to a particular species.

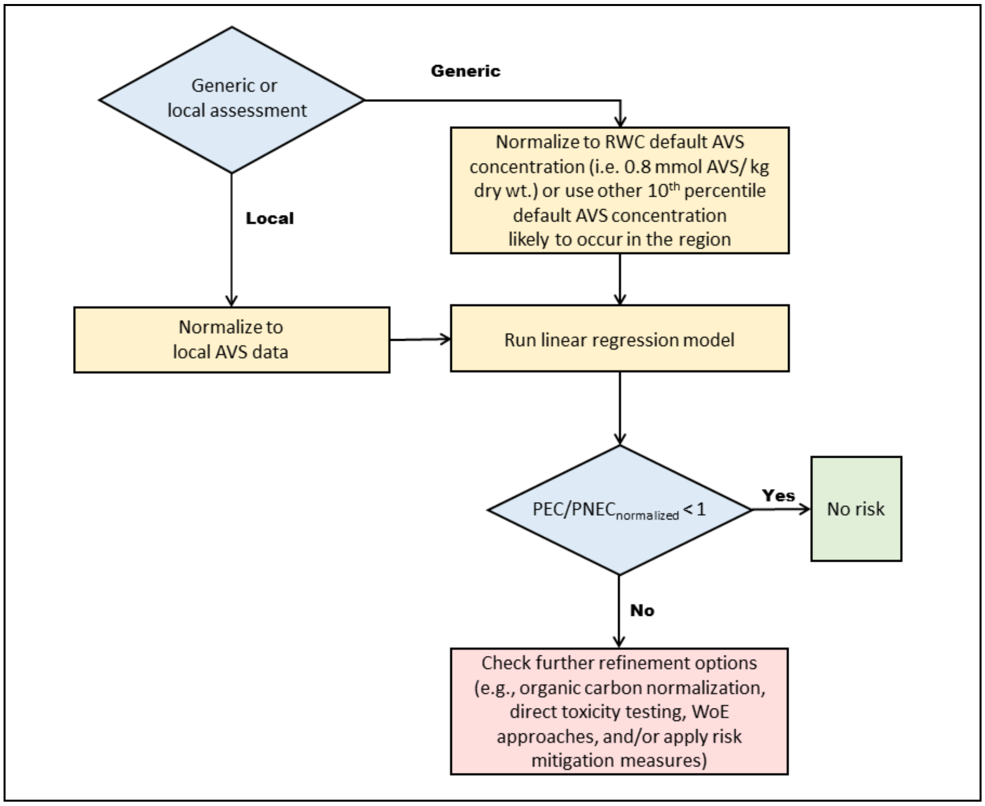

Figure 3: Flow chart of the sediment normalization process

2.5 CALCULATION OF PNEC USING STATISTICAL EXTRAPOLATION METHODS

Estimation of the HC_5 from the species sensitivity distribution

When a large data set for different taxonomic groups is available, the PNEC can be calculated using a statistical extrapolation method. Recommendations for the minimum number of species to use with a species sensitivity distribution range considerably. No guidance, however, is available for what species would represent an adequate database of benthic invertebrates for the determination of a PNEC for sediment. Applying a species sensitivity distribution (SSD) for the sediment compartment should definitely take into account:

1) the expected differences in species richness between sediment and water ecosystems;
2) the different exposure conditions and feeding behaviors of the organisms in the sediment (ingestion of sediment, body wall contact, exposure through pore water and overlying water); and
3) the limitation that very few standardized sediment toxicity test methods have been established for benthic species overall.

For nickel, a benthic database has been generated for 10 benthic species that are representative of different sediment exposure pathways, as well as a variety of feeding strategies and taxonomic groups. In short, this data set is representative of benthic ecosystems, thus fulfilling one of the characteristics that should be considered when evaluating whether or not the use of the species sensitivity distribution approach is appropriate.

In the SSD approach, the ecotoxicity data are ranked from low (most sensitive species) to high (least sensitive species) and a SSD is constructed by applying an appropriate distribution (usually a log-normal distribution) to the normalized chronic toxicity data (Aldenberg & Jaworska, 2000). From the SSD, a 5th percentile value (at the median confidence interval) is calculated (i.e. median HC_5) using the software program ETx as described by Van Vlaardingen et al. (2004).

Selection of appropriate assessment factor and derivation of the PNEC

To account for uncertainty, REACH guidance allows for the application of an assessment factor (AF) to the median HC_5. AFs vary between 1 and 5 and are determined on a case-by-case basis. The freshwater sediment PNEC is therefore calculated as follows:

$$\text{Freshwater sediment PNEC} = \text{median } HC_5/AF$$

Based on the available chronic $L(E)C_{10}$ data, the following factors were considered when determining the AF:

- the overall quality of the database and the end-points covered (e.g., are all the compiled data representative of "true" chronic exposure?);
- the diversity and representativeness of the taxonomic groups covered by the database [e.g., do the databases contain species representative of different sediment exposure pathways, as well as a variety of feeding strategies and taxonomic groups: a crustacean (e.g., amphipods) an insect (e.g., midge, mayfly), an olgochaete (e.g., tubificidae, lumbriculidae) and a family in any order of insect or any phylum not already presented (e.g., molluscs)];

- use of bioavailability models and approach for bioavailability correction [e.g., do the bioavailability models (see Fact Sheet 9, *Incorporation of Bioavailability in the Sediment Compartment*) allow the toxicity data for all species to be normalized?];
- statistical extrapolation and uncertainties (e.g., how well does the SSD fit the toxicity data?); and
- comparisons between field studies and the PNEC (e.g., is the PNEC value protective for the effects observed in field studies?).

Given the robust database that includes nickel ecotoxicity data from both laboratory (Besser et al., 2013) and field (Costello et al., 2011) studies, and our increased knowledge on nickel geochemical behavior in sediments (Brumbaugh et al., 2013), an AF of 1 is justified.

3 EXAMPLE PNEC DERIVATION FOR A REALISTIC WORST CASE SEDIMENT

3.1 DATA COMPILATION AND DATA SCREENING

The quality screening criteria as defined in Section 2.2 were applied to select the high quality chronic ecotoxicity data of nickel to freshwater sediment organisms. In total ecotoxicity data were available for 10 species. Two of the species produced unbounded values. An overview of all accepted individual high quality chronic ecotoxicity data is presented in Vangheluwe & Nguyen (2015) and Besser et al. (2013) and Table 1. In this example, the data were normalized towards the RWC physico-chemical conditions prevailing in sediments using the bioavailability models described in the Fact Sheet 9, *Incorporation of Bioavailability in the Sediment Compartment.* The RWC bioavailability is characterized by a low AVS content (i.e. 0.8 µmol AVS/g dry wt.).

3.2 DATA AGGREGATION AND OVERVIEW NICKEL SEDIMENT ECOTOXICITY DATABASE

The normalized chronic data from each test on a given sediment species were aggregated according to the criteria mentioned in Section 2.4. An overview of the normalized species mean L(E)C_{10} value for the most sensitive endpoint is provided in Table 1.

3.3 SSD CONSTRUCTION AND MEDIAN HC_5 DERIVATION

The normalized species mean NOEC/L(E)C_{10} values in Table 2 were ranked from low to high. Subsequently, a log-normal distribution was fitted through the ranked species means . The median HC_5 value calculated for the for RWC ecotoxicity data was 109 mg Ni/kg dry wt. (Figure 4).

3.4 PNEC DERIVATION

When an AF of 1 is used, the PNEC value is equivalent to the HC_5. Therefore, the RWC PNEC is 109 mg Ni/kg dry wt.

The example of the SSD construction and PNEC derivation for nickel presented here applies for RWC sediment chemistry (i.e., low in AVS). However, a range of AVS concentrations can be encountered in the EU, which results in different PNEC values. Several bioavailability scenarios encompassing the range of AVS typically encountered in sediments (1-40 µmol/g dry wt.) are shown in Table 2. The AVS concentrations and HC_{5-50}/PNEC values (AF = 1) calculated for the different selected freshwater sediments are summarized in Table 2.

When the range of AVS values observed in natural sediments is taken into account, PNEC values range from 109 mg Ni/kg dry wt. for the RWC scenario to 305 mg Ni/kg dry wt. for the high end of the AVS distribution (Table 2).

Taxonomic Group	Species	Life History/ Feeding Strategy	Most Sensitive Endpoint	Normalized Species Mean (NOEC/L(E)C_{10} Value (mg Ni/kg dry wt.)
Crustaceans	*Hyalella azteca*	Swimmer, sprawler,	Biomass	203.5
	Gammarus pseudolimnaeus	surface deposit feeder	Biomass	348.4
Insects	*Ephoron virgo*		Biomass	141.1
	Hexagenia sp.	Burrower, surface and sub-	Biomass	188.7
	Chironomus riparius	surface feeder	Development	673.5
	Chironomus dilutus		—	*
Oligochaetes	*Lumbriculus variegatus*	Burrower, subsurface	Abundance	529.8
	Tubifex	feeder	Biomass	1000.3
Molluscs	*Sphaerium corneum*	Burrower, surface	Biomass	322.1
	Lampsilis siliquoidea	deposit feeder	—	*

* Unbounded value >762 mg Ni/kg dry wt.

Table 1: Selected freshwater sediment normalized species mean ecotoxicity data to nickel for the most sensitive endpoint (Vangheluwe & Nguyen, 2015)

Eco-Region	Sediment Chemistry (µmol AVS/g dry wt.)	Median HC_5 (mg nickel kg dry wt.)	PNEC (mg nickel kg dry wt.)[2]
Generic Reasonable Worst Case Sediment	0.8	109 (40-182)	109
Spring River, Missouri, USA	0.9	115 (43-191)	115
Dow Creek, Michigan, USA	1.0	121 (46-201)	121
Brakel 1, Belgium	2.6	165 (66-264)	165
St. Joseph River, Michigan, USA	3.8	185 (75-296)	185
Raisin River (site 2), Michigan, USA	6.1	210 (85-337)	210
Brakel 2, Belgium	6.2	212 (86-339)	212
Raisin River (site 3), Michigan, USA	8.0	225 (91-336)	225
USGS Survey Pond 30, Missouri, USA	12.4	249 (99-403)	249
Lampernisse, Belgium	24.5	284 (108-469)	284
South Tributary Mill Creek, Michigan, USA	24.7	284 (108-470)	284
West Bearskin Lake, Minnesota, USA	38.4	305 (111-515)	305

Table 2: Overview of the water chemistry and median HC_5/PNEC values for the different selected EU eco-regions (values between brackets are 90% confidence intervals)

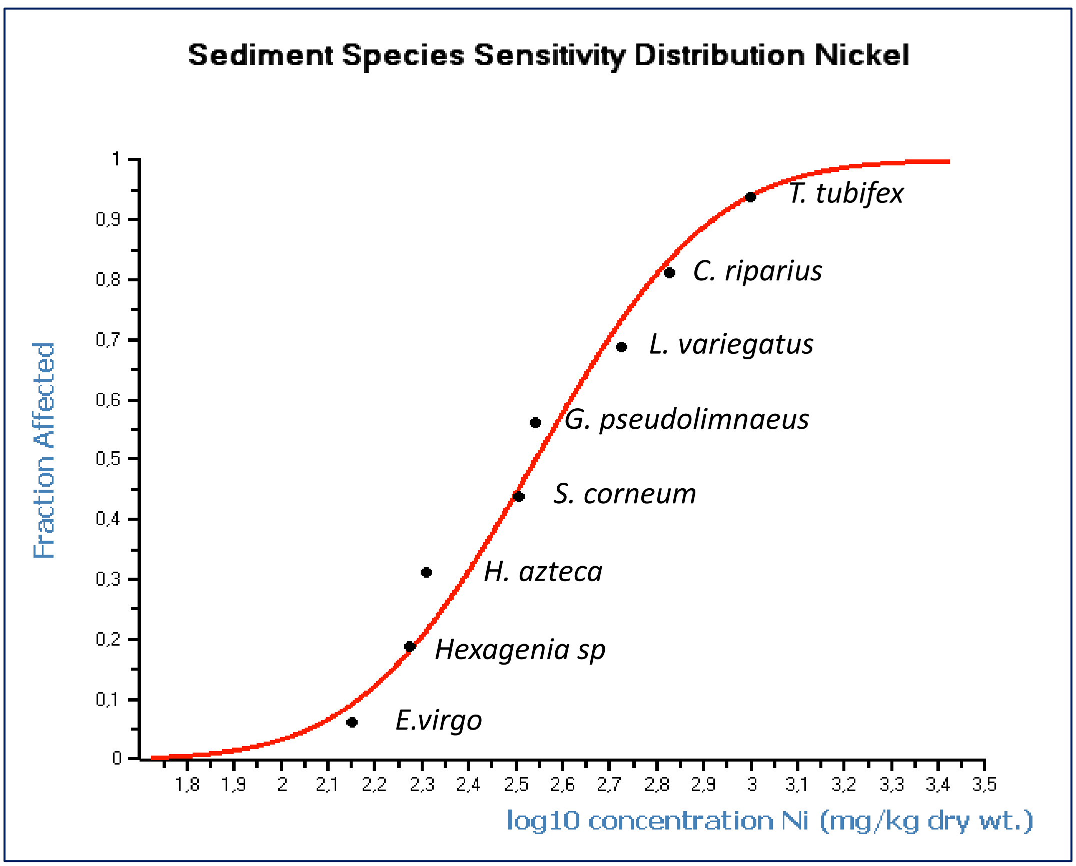

Figure 4: SSD and median HC_5 derivation for nickel using normalized ecotoxicity data for a RWC sediment containing 0.8 µmol AVS/g dry wt.

4 CONCLUSIONS AND NEXT STEPS IN RISK ASSESSMENT

This fact sheet presents the approach for data gathering, data selection, and data aggregation to be used for the derivation of the PNEC value for the freshwater sediment compartment based on the statistical extrapolation method using the SSD approach. Because the ecotoxicity of nickel is mitigated by the physico-chemistry of the sediment (AVS) it is highly recommended to normalize the ecotoxicity data for PNEC derivation using the available bioavailability models as described in the Fact Sheet 9, *Incorporation of Bioavailability in the Sediment Compartment.*

5 LINKS TO NICKEL EU RISK ASSESSMENT DOCUMENTS

The final report on the environmental risk assessment of nickel and nickel compounds can be retrieved from the following website:

http://echa.europa.eu/documents/10162/cefda8bc-2952-4c11-885f-342aacf769b3 (last accessed January 2017)

The opinion of the SCHER can be found at the following address:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_112.pdf (last accessed January 2017)

6 REFERENCES

Aldenberg T, Jaworska JS. 2000. Estimation of the hazardous concentration and fraction affected for normally distributed species sensitivity distributions. Ecotoxicology and Environmental Safety 46: 1-18.

Ankley GT, Phipps GL, Leonard EN, Benoit DA, Mattson VR, Kosian PA, Cotter AM, Dierkes JR, Hansen DJ, Mahony DJ. 1991. Acid Volatile sulfide as a factor mediating cadmium and nickel bioavailability in contaminated sediments. Environmental Toxicology and Chemistry 10: 1299-1307.

Ankley GT, Di Toro DM, Hansen DJ, Berry WJ. 1996. Technical basis and proposal for deriving sediment quality criteria for metals. Environmental Toxicology and Chemistry 15(2): 2056-2066.

Besser JM, Brumbaugh WG, Ingersoll CG, Ivey CD, Kunz JL, Kemble NE, Schlekat CE, Garman ER. 2013. Chronic toxicity of nickel-spiked freshwater sediments: Variation in toxicity among eight invertebrate taxa and eight sediments. Environmental Toxicology and Chemistry 32: 2495-2506.

Brumbaugh WG, Besser JM, Ingersoll CG, May TW, Ivey CD, Schlekat CE, Rogevich-Garman E. 2013. Nickel partitioning during chronic laboratory toxicity tests with eight different spiked freshwater sediments: Toward more environmentally realistic testing conditions. Environmental Toxicology and Chemistry 32: 2482-2494.

Costello DM, Burton GA, Hammerschmidt CR, Rogevich EC, Schlekat CE. 2011. Nickel phase partitioning and toxicity in field-deployed sediments. Environmental Science and Technology 45: 5798-5805

Di Toro DM, Mahony JD, Hansen DJ, Scott KJ, Carlson AR, Ankley GT. 1992. Acid volatile sulfide predicts the acute toxicity of cadmium and nickel in sediments. Environmental Science and Technology 26: 96-101.

ECHA (European Chemicals Agency). 2014. Principles for environmental risk assessment of the sediment compartment. In: Proceedings of the Topical Scientific Workshop; 2013 7-8 May; Helsinki, Finland. Helsinki (FI): European Chemicals Bureau. ECHA-14-R-13-EN.

Schlekat CE, Garman ER, Vangheluwe ML, Burton GA. 2016. Development of a bioavailability-based risk assessment approach for nickel in freshwater sediments. Integrated Environmental Assessment and Management 12(4): 735-746.

Van Vlaardingen PL, Traas TP, Wintersen AM, Aldenberg T. 2004. ETX 2.0. A program to calculate risk limits and fraction affected, based on normal species sensitivity distributions. Report no. 601501028/2004, National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands.

Vandegehuchte MB, Roman YE, Nguyen LT, Janssen CR, De Schamphelaere KA. 2007. Toxicological availability of nickel to the benthic oligochaete Lumbriculus variegatus. Environment International 33: 736-742.

Vangheluwe M, Verdonck F, Heijerick D, Shtiza A, Burton A, Taulbee K, Boucard T, Mäkinen J, Gonzales E. 2008. Acid volatile sulphide survey of large river and/or lake sediments in the United Kingdom (England and Wales) Spain and Finland in 2007. Final Report. September 2008. Gent, Belgium (BE): ARCHE (formerly EURAS).

Vangheluwe MLU, Verdonck FAM, Besser JM, Brumbaugh WG, Ingersoll CG, Schlekat CE, Garman ER. 2013. Improving sediment quality guidelines for nickel: Development and application of predictive bioavailability models to assess chronic toxicity of nickel in freshwater sediments. Environmental Toxicology and Chemistry 32: 2507-2519.

Vangheluwe M, Nguyen L. 2015. Advanced research on nickel toxicity in sediments: results additional species and modelling. Final Report. Durham (NC): Nickel Producers Environmental Research Association.

1 The application of the quality screening criteria would also apply in case additional or new ecotoxicity data would be generated

2 PNEC is calculated using an AF of 1

Fact Sheets on the European Union Environmental Risk Assessment of Nickel

This is the eight in a series of fact sheets addressing issues specific to the environment section of the European Union's Existing Substances Risk Assessment of Nickel (EU RA). The fact sheets are intended to assist the reader in understanding the complex environmental issues and concepts presented in the EU RA by summarizing key technical information and providing guidance for implementation.

NiPERA welcomes questions about the concepts and approaches implemented in the EU RA. For inquiries, please contact:

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