SECONDARY POISONING RISK ASSESSMENT OF BIRDS AND MAMMALS EXPOSED TO NICKEL IN THEIR DIETS

The Existing Substances Risk Assessment of Nickel was completed in 2008. The straightforward explanation of the goal of this exercise was to determine if the ongoing production and use of nickel in the European Union (EU) causes 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):

The oystercatcher feeds on a bivalve.

- 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 EU Risk Assessments for Nickel and Nickel Compounds were developed over the period from 2002 to 2008. The Danish Environmental Protection Agency (DEPA) acted as the Rapporteur in this process, in close collaboration with the international nickel industry. EU Risk Assessment Reports (RARs) for the environment for nickel substances (metallic nickel, nickel carbonate, nickel chloride, nickel nitrate, and nickel sulfate) were submitted in the spring of 2008 after thorough review by the Technical Committee on New and Existing Substances (TCNES), which was comprised of technical representatives from the EU Member States. A final peer review was provided by the Scientific Committee on Health and Environmental Risks (SCHER) (see Section 9). The European Commission's Institute for Health and Consumer Protection published the final Risk Assessment Reports for nickel and nickel compounds in November 2009.

After the EU RARs received approval within Europe, the data sets were discussed at the international level within the Organization of Economic Cooperation and Development (OECD). The nickel ecotoxicity data sets used in the EU RARs were accepted at the OECD's SIDS (Screening Level Information Data Set) Initial Assessment Meeting (SIAM 28, October 2008), as was the use of nickel bioavailability models to normalize the nickel ecotoxicity data.

1 INTRODUCTION

Secondary poisoning refers to the toxicity of a chemical to an organism via its food. In other words, the concentration of a chemical in a particular organism may not be toxic to the organism itself, but it may be toxic to another organism that feeds upon it. According to the Technical Guidance Document (TGD) (ECB 2003), the assessment of secondary poisoning is performed to address this potential concern associated with "toxic effects in the higher members of the food chain which result from ingestion of organisms from lower trophic levels that contain accumulated substances." The focus on "higher members of the food chain" seems to imply that higher trophic level organisms are more sensitive than lower trophic levels, or that the tissue concentrations of the accumulated substance may increase progressively with trophic status (*i.e.*, that the accumulated substance biomagnifies).

In the case of nickel (Ni), an earlier assessment completed by DEPA (2004) concluded that Ni bioaccumulation (*i.e.*, uptake into the organism) in algae, crustaceans, and fish is sufficiently negligible that the secondary poisoning potential of Ni via these dietary pathways is not of concern. However, the relatively high bioaccumulation potential of Ni in some marine mollusks (including bivalves, such as clams) resulted in the development of a secondary poisoning assessment for Ni in mollusk-based marine food chains. In addition, a secondary poisoning assessment of Ni from earthworms and other invertebrates to predators in terrestrial (*i.e.*, soil-

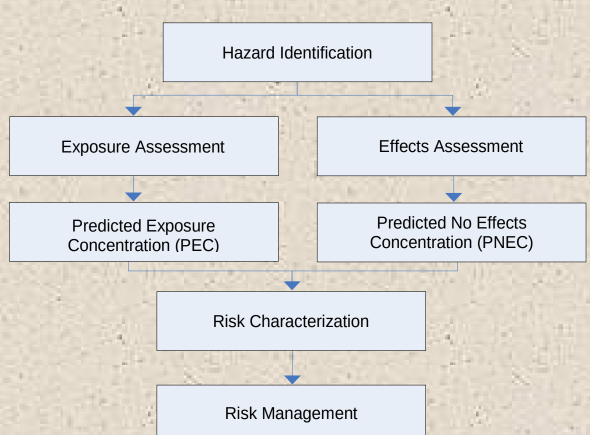

Figure 1: Schematic overview of the steps in the EU Environmental Risk Assessment

based) food chains was evaluated. This fact sheet summarizes the methods and results of these secondary poisoning assessments.

2 A BASICS OF THE RISK ASSESSMENT APPROACH

The basic structure of this risk assessment followed the TGD (ECB 2003) and included the development of dietary predicted exposure concentrations (PEC_{oral}) and dietary predicted no effect concentrations ($PNEC_{oral}$). Because only PEC_{oral} and $PNEC_{oral}$ values are discussed in this fact sheet, for simplicity these will hereafter be simply referred to as PECs and PNECs. Marine, freshwater, and terrestrial habitats were evaluated, and both mammalian and bird food chains were addressed for each of these habitats. The PEC in this assessment was the estimated Ni concentration in the diet of the representative predatory birds or mammals in each of the food chains evaluated, while the PNEC was the Ni concentration in bird and mammal diets at which no adverse effects are expected. The ratios of the PECs to corresponding PNECs were then calculated, which were termed Risk Characterization Ratios, or RCRs. Assuming that the data used to derive the PEC and PNEC are adequately conservative, an RCR <1 indicates that there is a negligible potential risk, while an RCR >1 indicates that there is a potential risk and a more refined assessment is necessary.

This refinement is based on a tiered approach, where conservative assumptions (*i.e.*, assumptions that are likely to overestimate potential risk) were used in the first tier and increasingly more realistic assumptions were used in successive tiers (Figure 2). If the secondary poisoning risk estimates from the lower tiers indicate a low potential risk then it can be confidently concluded that the risk is negligible. However, the assumptions used in the lower tiers also tend to be unrealistically conservative and it is necessary to refine the approach with each increasing tier.

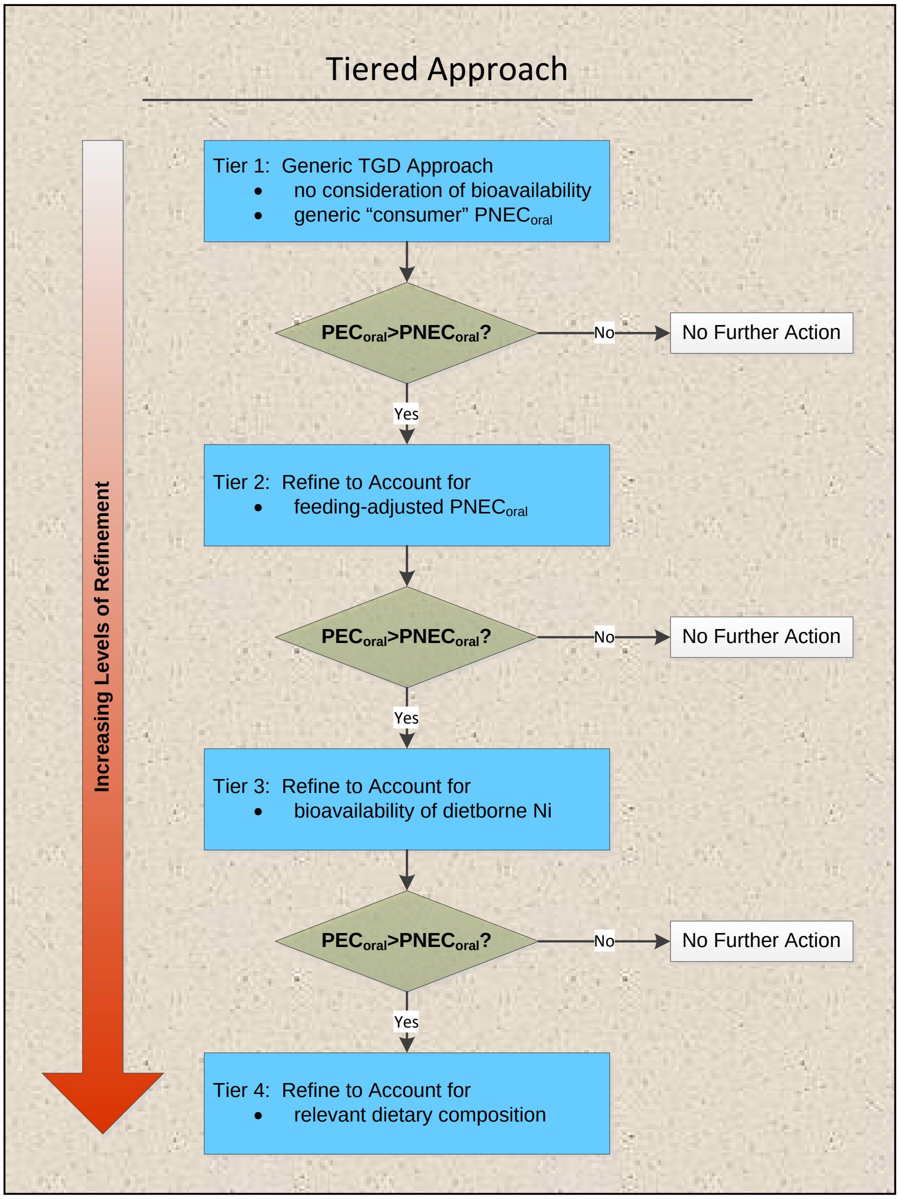

Figure 2: Flow chart for tiered risk characterization approach

3 FOOD CHAINS EVALUATED

Marine, freshwater, and terrestrial food chains determined to have the highest propensity for Ni bioaccumulation were identified. For example, the oystercatcher (*Haematopus ostralegus*) is the main predator of *C. edule*, which has a much higher propensity to bioaccumulate Ni than other marine organisms (Text Box 1).

Accordingly, an oystercatcher food chain was evaluated for marine birds. In terrestrial systems, earthworm-based food chains were identified because earthworms have a high exposure potential to chemicals in soil and are a common food item for a variety of bird and mammal species. The aquatic and terrestrial food chains identified for birds and mammals are provided in Table 1.

Text Box 1:
Overview of Nickel Bioaccumulation and Biomagnification Potential

The bioaccumulation potential of Ni from water into an aquatic organism or from soil into a terrestrial organism is generally low. One notable exception is the marine bivalve *Cerastoderma edule*, which may have Ni concentrations in its soft tissue that are >25,000 times the Ni concentration in the seawater that it lives in. Interestingly, the bioaccumulation potential of Ni in other marine bivalves is much lower. Accordingly, marine food chains that include *C. edule* are of particular interest in the secondary poisoning assessment. In terrestrial systems, Ni concentrations in soil-dwelling organisms rarely exceed the Ni concentration in the soil. On average, Ni concentrations in earthworms, for example, are approximately 1/3 of the Ni concentration in soil.

There is no evidence that Ni biomagnifies in aquatic or terrestrial food chains (*i.e.*, Ni concentrations do not increase with increasing trophic level). This contrasts with other chemicals, such as methyl mercury, which tends to biomagnify across multiple trophic levels, thereby resulting in higher trophic level organisms being potentially more susceptible to mercury poisoning. For Ni, the opposite is often the case, where "biodilution" of Ni may occur over increasing steps in the food chain (*e.g.*, Campbell *et al.* 2005; Lapointe and Couture 2006).

4 EXPOSURE ASSESSMENT

Ni PECs, or dietary Ni concentrations, were identified for each of the food chains in Table 1. As noted in Figure 2, the assumed dietary compositions for birds and mammals were sometimes refined from a diet based on conservative assumptions to a diet based on more realistic assumptions, such as a variable diet rather than feeding exclusively on an organism that tends to bioaccumulate the highest Ni concentrations. In addition, the basis of the data used to derive the PEC varied for some food chains. In most cases the Ni PEC was estimated from water or soil Ni concentrations using a bioaccumulation factor (BAF; see Text Box 2), while in some cases measured Ni concentrations in prey were used. For the marine food chain, it was assumed that *C. edule*, which accumulates Ni more than other marine organisms, would be a potential food item for the oystercatcher. For the harbor seal, and for the oystercatcher at other locations, it was assumed that *C. edule* would not be a relevant food item and that they would feed on prey items (*e.g.*, fish and mollusks other than *C. edule*) that do not bioaccumulate Ni to the same level. Where Ni concentrations in prey items were estimated from seawater, a BAF of 1,631 L/kg was used for scenarios including *C. edule* and a BAF of 270 L/kg was used for scenarios excluding *C. edule* (a realistic BAF for fish and other bivalves). For the freshwater food chains, a BAF of 270 L/kg was likewise used to estimate Ni concentrations in freshwater prey. For the terrestrial food chains, PECs were estimated for an earthworm diet, as well as diets that included a mixture of earthworms and isopods (DeForest, 2012). A BAF of 0.30 was used to estimate the Ni concentration in the tissue of the earthworm, while a BAF of 0.06 was used to estimate Ni in the tissue of isopods. In addition, the Ni concentration of the soil in the earthworm's digestive tract was estimated using recommendations from the TGD. The Ni PECs used to evaluate the marine, freshwater, and terrestrial food chains are summarized in Table 2.

5 EFFECTS ASSESSMENT

The PNECs represent dietary Ni concentrations below which adverse effects are not expected for birds or mammals. PNECs were identified in two tiers. In Tier 1, derivation of PNECs followed the standard guidance in the TGD and did not account for any species-specific differences in food ingestion rates and body weight. In Tier 2, PNECs were derived on the basis of species-specific food ingestion rate-to-body weight ratios for the birds and mammals considered in this evaluation.

The PNECs were based on the most sensitive (*i.e.*, lowest) dietary no-observed-effect concentrations (NOECs). For birds, six subchronic and chronic feeding studies in which bird diets were spiked with Ni were identified in the literature. The lowest

System	Consumer Organism	Food Chain	Conservative Dietary Assumption[1]	More Realistic Dietary Assumption[2]
Marine	Bird (oystercatcher)	seawater → bivalve mollusk → oystercatcher	100% *C. edule*	50% *C. edule*, 50% other mollusks
	Mammal (harbor seal)	seawater → fish/octopus/squid → harbor seal	100% mollusks or 100% fish	not applicable
Freshwater	Bird (mollusk-eating)	freshwater → mollusk → bird	100% mollusks	not applicable
	Mammal (otter)	freshwater → fish → otter	100% fish	not applicable
Terrestrial	Bird (worm-eating)	soil → earthworm → worm-eating bird	100% earthworms	50% earthworms, 50% isopods
	Mammal (shrew)	soil → earthworm → shrew	100% earthworms	30% earthworms, 70% isopods

1 In lower tiers it was assumed that the bird or mammals would feed exclusively on one prey organism.
2 In the highest tier, where justified, a more realistic mixed diet was assumed.

Table 1: Food chains evaluated in the nickel secondary poisoning risk assessment

Text Box 2:
Bioaccumulation Factors

Bioaccumulation factors, or BAFs, are ratios of the chemical concentration in an organism ($Conc_{org}$) to its concentration in its abiotic environment ($Conc_{env}$, *i.e.*, surface water for aquatic organisms and soil for terrestrial organisms):

$$BAF = Conc_{org}/Conc_{env}$$

For example, if it is assumed that Ni concentrations of 50 mg kg^{-1} and 0.1 mg/L are measured in an aquatic organism and its exposure water, respectively, the resulting BAF would be 500. A water or soil BAF for Ni can then be multiplied by Ni concentrations in water or soil, respectively, to estimate what the Ni concentration would be in an organism at another site or under another exposure scenario. It should be noted that BAFs for Ni and other metals, even within a species, will vary depending on multiple factors, including differences in Ni bioavailability between sites and the magnitude of the Ni exposure concentration (the BAF tends to be inversely related to the exposure concentrations). Accordingly, application of BAFs to estimate Ni concentrations in prey only provides an approximation of the potential Ni concentration at a given site or under a given scenario.

The following basic equation was used to derive PECs from water or soil Ni concentrations ($Conc_{env}$) using BAFs:

$$PEC = Conc_{env} \times BAF$$

Habitat	Dietary Assumption	Range in Ni Concentrations[1]	$PEC_{regional}$ (mg kg^{-1})
Marine	100% *C. edule*	---	5.3
	50% *C. edule*, 50% other bivalves	---	2.8
	100% bivalves	---	0.25
	100% fish	---	0.27
Freshwater	100% bivalves or 100% fish	0.7-7.9	0.19-2.1
Terrestrial	100% earthworms	1-81	0.15-12
	30% earthworms, 70% isopods	---	0.06-4.9

1 Concentrations for freshwater (µg Ni L^{-1}) and soil (mg Ni kg^{-1}) eco-regions. See Fact Sheet Nos. 4 and 5 for additional information on the freshwater and soil eco-regions, respectively.

Table 2: PECs for nickel in different exposure scenarios in marine, freshwater, and terrestrial food chains

NOECs, focusing on endpoints related to survival, growth, and the occurrence of tremors, were >150 mg Ni kg^{-1} based on a 42-day chicken study and 200 mg Ni kg^{-1} based on a 90-day study with mallard ducklings. For mammals, the lowest NOEC of 22 mg Ni kg^{-1} was derived from the no-observed-adverse-effect level (NOAEL) taken from the previously completed human health Ni risk assessment, which was identified as 1.1 mg Ni kg^{-1} bw d^{-1}. Following the TGD, these NOECs were divided by an assessment factor (AF) of 30 to account for interspecies variation in sensitivity and laboratory-to-field extrapolation, thereby resulting in Tier 1 bird PNECs of 5.0-6.7 mg Ni kg^{-1} and a mammal PNEC of 0.73 mg Ni kg^{-1} (Table 3). For Tiers 2 and 3, the NOECs were adjusted based on the food ingestion rate-to-body weight ratios of the specific species being evaluated relative to the species used in the toxicity tests. These ingestion rate-adjusted NOECs were divided by an AF of 10 in order to derive Tiers 2 and 3 PNECs (Table 3).

6 NICKEL BIOAVAILABILITY IN FOOD

The toxicity values used to derive the avian and mammalian PNECs were based on test organism exposures to highly soluble and, hence, bioavailable forms of Ni. Thus, both the avian and mammalian PNECs are expected to overestimate the bioavailability of biologically incorporated Ni in natural diets. In addition, in the terrestrial pathway, soil-adsorbed Ni in the earthworm gut is expected to have reduced bioavailability. Differences in the bioavailability of a substance between exposure media can be described using a relative absorption factor (RAF), which is the ratio of the absorbed fraction of the substance from one exposure medium versus the absorbed fraction from another exposure medium. The RAF can then be incorporated into the risk characterization, as shown in Section 7. RAF values of 3.6% and 2.5% were derived for mammals consuming earthworms and other prey (*e.g.*, isopods), respectively. For birds, no studies were identified on the relative bioavailability of Ni sulfate (the basis for the avian NOEC) added to laboratory diets versus biologically incorporated Ni, and no data on the bioavailability of Ni in soil are available for birds. Consequently, avian dietary and soil RAFs were not derived for birds (*i.e.*, 100% absorption was assumed, which is a conservative approach).

7 RISK CHARACTERIZATION

The risk characterization combines the results of the PEC, PNEC, and relative bioavailability (*i.e.*, RAF) evaluations. As discussed, the risk characterization was conducted in tiers, with the first tier being the most simplified and subsequent tiers being based on increasing levels of complexity. For each tier, a PEC-to-PNEC ratio, or RCR, was calculated as follows:

$$RCR = PEC \times RAF/PNEC$$

The RAF was 1 (*i.e.*, 100%) for birds in all tiers and in Tiers 1 and 2 for mammals.

7.1 MARINE

Birds

In Tier 1, the oystercatcher PECs based on a 100% *C. edule* diet were compared to the generic PNECs of 5.0 and 6.7 mg kg^{-1}. The RCRs suggest a secondary poisoning risk based on the PNEC of 5.0 mg kg^{-1} but not based on the PNEC of 6.7 mg kg^{-1}. In subsequent tiers, the RCR is reduced to 0.4 when the PNEC is adjusted for the ingestion rate of oystercatcher species and when the PEC is reduced to 0.2 assuming a mixed bivalve diet, as the oystercatcher will not feed exclusively on *C. edule*. Under this latter more realistic tier, no secondary Ni poisoning risk is estimated (Table 4).

Mammals

In Tier 1, the harbor seal PECs based on either a 100% bivalve diet or a 100% fish diet were compared to the generic PNEC of 0.73 mg kg^{-1} assuming an RAF of 1. The RCRs are 0.3 and 0.4 for bivalve and fish diets, suggesting no secondary poisoning risk. In subsequent tiers, the RCRs are further reduced when the PNEC is adjusted for the harbor seal food ingestion rate and body weight, and again reduced further to well below 1 if the RAF of 2.5% is incorporated (Table 5).

Predator Class	System	Species	NOEC (mg Ni kg^{-1})	Ingested Rate-Adjusted NOEC (mg Ni kg^{-1})	Assessment Factor Applied	PNEC (mg Ni kg^{-1})
Birds	All	Generic	150 200	---	30 30	5.0 6.7
	Marine	Oystercatcher	200	123	10	12.3
	Freshwater	Mollusk-eating bird	200	123	10	12.3
	Terrestrial	Worm-eating bird	200	85	10	8.5
Mammals	All	Generic	22	---	30	0.73
	Marine	Harbor seal	22	46	10	4.6
	Freshwater	Otter	22	23	10	2.3
	Terrestrial	Shrew	22	1.2	10	0.12

Table 3: Predicted no effect concentrations for nickel in wildlife diets

Tier	Species		PNEC (mg kg^{-1})	RAF	Diet Assumption	PEC (mg kg^{-1})	RCR
1	Generic	7	5.0/6.7	1	100% *C. edule*	5.3	0.8-1.1
2	Oystercatcher[1]	3	12.3	1	100% *C. edule*	5.3	0.4
3	Oystercatcher[1]		12.3	1	50% *C. edule*, 50% other bivalves	2.8	0.2

1 PNEC adjusted for the food ingestion rate-to-body weight ratio of the oystercatcher.

Table 4: RCRs for the mollusk (cockle)-eating bird like the oystercatcher

Tier	Species	PNEC (mg kg^{-1})	RAF	Diet Assumption	PEC (mg kg^{-1})	RCR
1	Generic	0.73	1	100% mollusks 100% fish	0.25 0.27	0.3 0.4
2	Harbor seal[1]	4.6	1	100% mollusks 100% fish	0.25 0.27	0.05 0.06
3	Harbor seal[1]	4.6	0.025	100% mollusks 100% fish	0.25 0.27	0.001 0.001

1 PNEC adjusted for the food ingestion rate-to-body weight ratio of the harbor seal.

Table 5: RCRs for fish/octopus/squid-eating mammal such as the harbor seal

7.2 FRESHWATER

Birds

In Tier 1, the PECs for a mollusk-eating bird that are representative of the different freshwater eco-regions were compared to the generic PNECs of 5.0 and 6.7 mg kg^{-1}. Regardless of the PNEC used, the RCRs are all less than 0.5 (Table 6), suggesting no secondary poisoning risk in the regional freshwater exposure scenarios. In Tier 2, the PNEC of 12.3 mg kg^{-1}, adjusted for the food ingestion rate and body weight of mollusk-eating birds was used, which resulted in RCRs well below 0.2. This result supports the conclusion of no secondary poisoning risk in the freshwater eco-regions for the bird freshwater food chain.

Mammals

In Tier 1, the European otter PECs that are representative of the different freshwater eco-regions were compared to the generic PNEC of 0.73 mg kg^{-1} assuming an RAF of 1. The RCRs range from 1.4 to 2.9 in three of the freshwater eco-regions and are <1 in the remaining three eco-region scenarios (Table 7). In Tier 2, which uses a PNEC adjusted for the food ingestion rate of the European otter, all RCRs are <1, and all RCRs are less than ≤0.02 when the RAF of 2.5% is also incorporated (Table 7).

Tier	Species	PNEC (mg kg^{-1})	RAF	Diet Assumption	PEC (mg kg^{-1})	RCR
1	Generic	5.0/6.7	1	freshwater eco-regions[1]	0.19-2.1	0.02-0.43
2	Mollusk-eating bird[2]	12.3	1	freshwater eco-regions[1]	0.19–2.1	0.02–0.17

1 See Fact Sheet No. 4 for a description of the freshwater eco-regions.

2 PNEC adjusted for the food ingestion rate-to-body weight ratio of a mollusk-eating bird.

Table 6: RCRs for a mollusk-eating bird

Tier	Species	PNEC (mg kg^{-1})	RAF	Diet Assumption	PEC (mg kg^{-1})	RCR
1	Generic	0.73	1	freshwater eco-regions[1]	0.19–2.1	0.26–2.9
2	European otter[2]	2.3	1	freshwater eco-regions[1]	0.19–2.1	0.08–0.93
3	European otter[2]	2.3	0.025	freshwater eco-regions[1]	0.19–2.1	0.001–0.02

1 See Fact Sheet No. 4 for a description of the freshwater eco-regions.

2 PNEC adjusted for the food ingestion rate-to-body weight ratio of a European otter.

Table 7: RCRs for fish-eating mammal like the European otter

7.3 SOIL

Birds

In Tier 1, regional PECs for a predominantly worm-eating bird were compared to the generic PNECs of 5.0 and 6.7 mg kg^{-1}. All regional RCRs were <1, except for an RCR of 2.4 in the clay soil (see Fact Sheet No. 5 for additional information on the representative eco-region soils) based on the PNEC of 5.0 mg kg^{-1} (Table 8). In Tier 2, using the PNEC adjusted for the food ingestion rate of the worm-eating bird slightly lowers the regional RCRs to ≤1.4 assuming a 100% earthworm diet, and to ≤0.8 assuming a 50% earthworm/50% isopod diet.

Mammals

In Tier 1, regional PECs for the shrew were compared to the generic PNEC of 0.73 mg kg^{-1} assuming an RAF of 1. Several soil eco-region RCRs were >1 (Table 9). In Tier 2, the PNEC of 0.12 mg kg^{-1}, adjusted for the food ingestion rate of the shrew was used, which resulted in higher RCRs because the shrew-adjusted PNEC was lower than the generic PNEC (Table 9). Tier 3 included incorporation of the RAF to account for difference in Ni bioavailability between the PECs and PNECs. For Tier 3, in which a 100% earthworm diet was assumed, two of the soil eco-regions resulted in RCRs >1. The Ni concentrations in these soils were 26 mg kg^{-1} (peaty soil) and 81 mg kg^{-1} (clay soil). In Tier 4, it was assumed that the shrew diet contains 30% earthworms and 70% isopods. The RCRs were ≤1.4 when the RAFs of 0.036 and 0.025 for the earthworm and isopod, respectively, were included (Table 9). In just a single regional scenario, the clay soil with a Ni concentration of 81 mg kg^{-1} resulted in a RCR >1.

Tier	Species	PNEC (mg kg^{-1})	RAF	Soil Type	Diet Assumption	PEC (mg kg^{-1})	RCR
1	Generic	5.0/6.7	1	eco-region soils[1]	100% earthworm	0.30–12.0	0.02–2.4
2	Worm-eating bird[2]	8.5	1	eco-region soils[1]	100% earthworm	0.30–12.0	0.02–1.4
3	Worm-eating bird[2]	8.5	1	eco-region soils[1]	50% earthworm, 50% isopod	0.087–7.0	0.01–0.8

1 See Fact Sheet No. 5 for a description of the eco-region soils. The background nickel concentrations in the eco-region soils ranged from 1 to 81 mg kg^{-1} dry weight.

2 PNEC adjusted for the food ingestion rate-to-body weight ratio of a worm-eating bird.

Table 8: RCRs for a worm-eating bird such as the European starling

Tier	Species	PNEC (mg kg^{-1})	RAF	Soil Type	Diet Assumption	PEC (mg kg^{-1})	RCR
1	Generic	0.73	1	eco-region soils[1]	100% earthworm	0.15–12.0	0.2–16.0
2	Shrew[2]	0.12	1	eco-region soils[1]	100% earthworm	0.15–12.0	1.3–100.0
3	Shrew[2]	0.12	0.036[3]	eco-region soils[1]	100% earthworm	0.15–12.0	0.09–3.6
4	Shrew[2]	0.12	0.036[3], 0.025[4]	eco-region soils[1]	30% earthworm, 70% isopod	0.061–4.9	0.02–1.4

1 See Fact Sheet No. 5 for a description of the eco-region soils. The background nickel concentrations in the eco-region soils ranged from 1 to 81 mg kg-1 dry weight.

2 PNEC adjusted for the food ingestion rate-to-body weight ratio of the shrew.

3 Earthworm RAF.

4 Isopod RAF.

Table 9: RCRs for a worm-eating mammals like the common shrew

8 CONCLUSIONS

Based on the outcome of the tiered secondary poisoning risk assessment for Ni, it is observed that none of the aquatic (marine or freshwater) food chains resulted in RCRs >1. For the terrestrial compartment, based on the refined approach of the upper tiers of the assessment, all RCRs were <1, except for one soil eco-region with an RCR of 1.4. This one soil with an RCR of 1.4 was a clay soil with naturally high Ni concentrations, indicating that the approach used to evaluate secondary Ni poisoning erred toward conservatism, even when considering the higher tiers of the assessment. The secondary poisoning evaluation described in this fact sheet focuses on the regional-level analyses, but application of the tiered approach succeeded in reducing the number of sites at risk for secondary poisoning under local scenarios that tended to have higher environmental Ni concentrations. This secondary poisoning evaluation highlighted key risk assessment components that should be considered in future localized, or site-specific, secondary poisoning assessments of Ni and other metals, including:

- consideration of ingestion rate-to-body weight ratios for the test organisms used to derive PNECs versus the representative wildlife species evaluated;
- the appropriateness of high assessment factors for deriving PNECs for naturally occurring essential elements;
- the use of relevant dietary assumptions;
- an evaluation of relative metal bioavailability between the dietary toxicity study and natural diets; and
- verifying the risk predictions versus background concentrations.

9 LINK 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 July 2015)

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 July 2015)

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Fact Sheets on the European Union Environmental Risk Assessment of Nickel

This is the sixth 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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