INCORPORATING DATA ON PARTICLE SIZE AND CHEMICAL COMPOSITION OF AEROSOLS INTO SITE-SPECIFIC EXPOSURE SCENARIOS (WORKERS)

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D6.1. Introduction

The Nickel REACH Consortia Secretariat is responsible for drafting the Generic Exposure Scenarios (GES). GES are broad exposure scenarios that describe a set of operational conditions and risk management measures to control exposure to nickel substances at a safe level, and thus demonstrating safe use of the substance. GES are included in the joint submission of the dossiers for each of the nickel substances. Individual companies are responsible for checking if they fit within the boundaries of those GES and proving the safe control of the substance. The site specific parameters (incorporating available data on environmental release and occupational exposure to nickel) and specific information on conditions of use, operational controls and risk management measures, from company sites in the EU have to be checked against the boundaries of the sites, as described in the GES.

The GES allow the individual industrial sites to modify the conditions described in the scenarios so they fit those of the actual conditions on site. The modifications need, however, to be in agreement with the guidance provided together with the GES. Therefore, the goal of this Guidance document is to help the companies assess their compliance with the GES for workers and provide them with tools to demonstrate that no risks are present in the company-specific operations. This Guidance document will help those companies that wish to incorporate site-specific data on particle size distribution and/or chemical composition of the workplace nickel exposures into the description of their own site-specific exposures.

Please note that the individual companies are responsible for data collection and reporting, including possible refinements to the risk characterization. Therefore, this guidance provides suggestions for possible refinements to GES descriptions but it does not intend to provide prescriptive protocols. This guidance is equally applicable to downstream users of nickel but it is not the registrants', nor the Nickel REACH Consortia legal responsibility to ensure that the individual downstream users comply with the GES. Finally, this Guidance document relates to the refinement of the Worker exposure part of the GES and does not relate to environmental release of nickel and nickel substances.

D6.2. Workplace Nickel DNELs

The Nickel REACH Consortia is using a Derived No Effect Level (DNEL) of 0.05 mg Ni/m^3 measured as the inhalable aerosol fraction for long term, repeated exposure of workers to nickel metal and all nickel compounds via inhalation. This value is based on the SCOEL (2011) approach for deriving nickel Occupational Exposure Limit (OEL) values, with some additional refinements. This DNEL is protective of respiratory toxicity (nickel metal and compounds) and carcinogenicity effects (nickel compounds) as well as possible reproductive effects (water soluble nickel compounds). Please see Appendix C2 of the nickel substances Chemical Safety Reports for more details on the derivation of the inhalable DNEL of 0.05 mg Ni/m^3.

In 2011, the SCOEL recommended the setting of two OELs for nickel substances: an inhalable OEL of 0.01 mg Ni/m^3 for all nickel compounds based on respiratory cancer (one human cohort) and a respirable OEL of 0.005 mg Ni/m^3 for nickel metal and all nickel compounds based on respiratory toxicity effects observed in animal studies and recognition that humans and animals are exposed to different particle size aerosols. A respirable DNEL for long-term exposure of workers was not derived by the Nickel REACH Consortia as there is a paucity of available respirable fraction exposure data for the nickel workplaces. Without solid respirable exposure data, the derivation of a meaningful Risk Characterisation Ratio (RCR) cannot be achieved.

Therefore, although a respirable DNEL for nickel has not been derived, in Section D6.2 of this appendix we describe the derivation of a site-specific respirable fraction guidance value of 0.01 mg Ni/m^3 applicable to all nickel substances to protect against possible adverse effects in the pulmonary region of the respiratory tract.

In the site-specific exposure scenarios, when inhalable exposures are higher than 0.01 mg Ni/m^3, it would be useful if each company could collect information on respirable exposure levels or particle size distribution for their site to justify the use of the inhalable 0.05 mg Ni/m^3 DNEL. This information would not be needed if the workplace exposures are below 0.01 mg Ni/m^3. The reason is that in the generic exposure scenarios, the assumption, based on published information for the nickel producing and using sectors, is that the particle size distribution (PSD) of the workplace aerosol is in the inhalable range, with respirable size particles comprising less than 10% of the aerosol (Oller and Oberdörster, 2010; Vincent et al., 1995; Vincent, 1996; Werner et al., 1996; 1999; Ramachandran et al., 1996; Tsai et al., 1995; 1996a, b).

When respirable exposure data are not available but information on particle size indicates or predicts the presence of very fine workplace aerosols in the respirable size fraction (respirable fraction = aerodynamic equivalent particle diameter ≤ 10 µm; 50% penetration at 4.25 µm), the use of the DNEL of 0.05 mg Ni/m^3 may not be justified. It is recommended that in these cases, the site specific exposure scenarios recognize that additional risk management measures may be needed to protect the workers and keep any respirable nickel exposures below 0.01 mg Ni/m^3.

It should also be recognized that neither the inhalable DNEL of 0.05 mg Ni/m^3 nor the site-specific guidance value of respirable 0.01 mg Ni/m^3 are derived based on effects of nanoparticles. Therefore, these values are not necessarily protective for exposure to nickel-containing nanoparticles, which are not covered in the registration dossiers of the Nickel REACH Consortia.

As mentioned above, the nickel REACH Consortia are using (for all the nickel substances) an inhalable DNEL of 0.05 mg Ni/m^3 to protect workers from repeated inhalation exposure. As described in Appendix C2, it may be possible to derive slightly different DNEL values for each of the main groups of nickel substances: water soluble nickel compounds, nickel oxides, sulphidic nickel compounds and metallic nickel. However, most workplaces do not have knowledge on the precise speciation of air exposures and in most cases it is likely that more than one form of nickel may be present. For these practical reasons, it is preferred to apply a conservative single DNEL to all nickel substance GES. This is why in the exposure scenarios included in the joint submission we compare the long-term, measured/estimated, total nickel exposures to the inhalable DNEL of 0.05 mg Ni/m^3.

D6.3. Derivation of a Site-Specific Guidance Value for Long-Term Exposure to Respirable Size Aerosols

The SCOEL (2011) recommended the setting of a respirable OEL of 0.005 mg Ni/m^3 for all nickel substances based on toxicity effects observed in the pulmonary region of rats exposed to nickel aerosols for a lifetime. In the absence of robust human data this approach is valid. Here, we derive a site-specific respirable guidance value of 0.01 mg Ni/m^3 based on the animal toxicity effects but taking into account: 1) the Human Concentrations (EHC) equivalent to the observed or calculated No Observed Adverse Exposure Concentration

(NOAEC) in the animal studies, 2) comparisons made at the deposited and retained dose levels, and 3) the limited human respiratory toxicity data in a weight of evidence approach.

Table D6.1 summarizes the respirable EHC values that can be derived based on the data from the chronic rat inhalation studies with 4 nickel substances. The derivation of respirable EHC based on retained doses takes into account differences in clearance rates between rats and humans, reduces uncertainty, and provides conservative estimates of safe exposure values. Please see Appendix C2, Section C2.4, and Tables C2.10 and C2.11 for detailed description of these calculations.

Table D6.1. Respirable EHC (mg Ni/m^3) at daily deposited and retained dose level[1]

	Animal aerosols		Human aerosols	
Substance	Particle Size	Respirable Exposure level (mg Ni/m^3)1	Respirable EHC to the NOAEC, based on daily deposited dose	Respirable EHC to the NOAEC, based on long-term retained dose
Nickel Sulfate				
Highest Observed NOAEC	MMAD=2.5 GSD=2.38	0.03	0.02	0.02
Nickel Subsulfide				
Calculated NOAEC	MMAD=2.17 GSD=2.34	0.04 (LOAEC 0.11/ 3)	0.02	0.02
Nickel Oxide				
Calculated NOAEC	MMAD=2.21GSD=1.97	0.17 (LOAEC 0.5/ 3)	0.08	0.01-0.06
Nickel Metal				
Calculated NOAEC	MMAD=1.8 GSD=2.4	0.03 (LOAEC 0.1/ 3)	0.02	0.01

1. MMAD = Masss Median Aerodynamic Diameter; GSD= Geometric Standard Deviation; Calculated NOAEC corresponds to the LOAEC divided by a factor of 3.

For respiratory toxicity effects after inhalation of particles of nickel (or most metal)-containing substances in the respirable range (i.e., 1-5 µm diameter), rats seem to be more susceptible to toxicity effects than primates or humans (Oberdörster, 1995; Mauderly, 1997; ILSI, 2000; Nikula et al., 2001; Greim and Ziegler-Skylakakis, 2007). For nickel substances, this is also true as rats have been consistently more sensitive to the inhalation toxicity effects than mice (NTP, 1996 reports).

Studies of respiratory disease in nickel-exposed workers are limited (Muir et al., 1993; Berge and Skyberg, 2003), but have not indicated that workers exposed to nickel aerosols at levels several-fold higher than the EHC values based on animal data experience pneumoconiosis to any significant extent. The overall incidence of irregular opacities (ILO ≥ 1/0) in X-rays taken at a nickel refinery (4.5%) was not significantly different from the incidence among "normal" X-rays from a hospital (4.2%), and was lower than for quarry workers (13.6%) (Berge and Skyberg, 2003). In this study the median and mean total nickel exposures were reported as 1.66 and 5.59 mg Ni/m^3 x years, respectively. Since the cases with ILO ≥ 1/0 had on average 25 years of exposure, the median and mean total nickel exposure of workers associated with ILO ≥ 1/0 can be calculated as 0.07 and 0.22 mg Ni/m^3, equivalent to~0.14 and 0.44 mg Ni/m^3 as inhalable and 0.014-0.044 mg Ni/m^3 as respirable fraction exposures. These estimates are conservative for fibrosis since an X-ray with an ILO of ≥ 1/0, by itself, does not constitute a "pneumoconiosis case" unless respiratory symptoms exist and respiratory function tests indicate a loss of respiratory function.

More information on respiratory disease can be obtained from mortality studies. Studies of tens of thousands of workers (many of whom would have experienced exposure to nickel well above the EHC corresponding to NOAECs for various nickel substances in rat studies) have not indicated increased mortality from non-cancer respiratory disease (Arena et al., 1998, Sorahan, 2004; Sorahan and Williams, 2005; Moulin et al., 2000; Cragle et al., 1984). These results are consistent with pneumoconiosis not being a significant problem for nickel workers and with humans not being more sensitive to respiratory toxicity effects than rats.

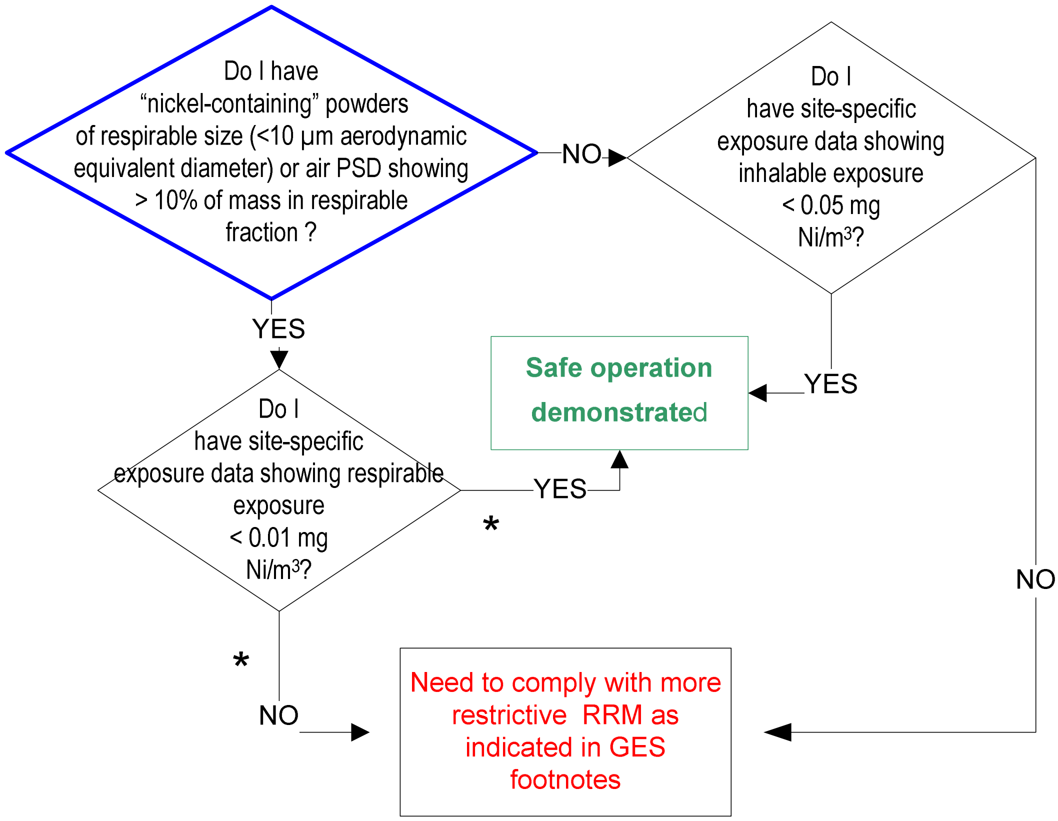
The respirable EHC values based on comparisons between rats and humans at the retained dose level (0.012-0.018 mg Ni/m^3), can be used as the starting point to derive a site-specific guidance value for respirable aerosols (Table D7.1). Assessment factors for toxicokinetics and toxicodynamic differences between rats and humans have already been considered in the calculations or are not needed (humans are not more sensitive to the toxicity effects of nickel than rats). To account for differences in response among workers, a default factor up to 3 could be applied (Appendix C2, ECETOC, 2010). However, since the derivation of the EHC based on retained doses already include very conservative assumptions, and a reality check using the available human data indicates that exposure levels in this range will be safe, an assessment factor lower than 3 was applied. ***Therefore, based on the animal data and a reality check against the limited human data a conservative site-specific long-term respirable guidance value of 0.01 mg Ni/m^3 can be derived for all nickel metal and nickel compounds.***

D6.4. Overall Strategy for Site-Specific Refinement of Exposure Scenarios for Workers

Currently, in section 4 of the nickel GES (Guidance to DU to evaluate whether he works inside the boundaries set by the GES) the following text is included:

> Collect process monitoring data with an inhalable sampler. The simultaneous use of a respirable sampler is encouraged. Use aerosol particle size information, when available, to confirm the appropriate use of the inhalable DNEL of 0.05 mg Ni/m^3 . Respirable fraction exposure levels should be kept below 0.01 mg Ni/m^3. See Appendix D6 for site-specific guidance on exposure data collection and Appendix C2 for further details on DNEL derivation.

Figure D6.1 describes a framework for assessing at the site-specific level whether compliance with the long-term inhalable DNEL of 0.05 mg Ni/m^3, or the long-term site-specific guidance value of respirable 0.01 mg Ni/m^3 is warranted.



* Document in site-specific ES.

Figure D6.1. Overall Strategy for Site-Specific Refinement of Exposure Scenarios for Workers

When to comply with inhalable DNEL of 0.05 mg Ni/m^3?

When measurements of workplace nickel particle size distribution indicate that ≤ 10% of the aerosol nickel mass is in the respirable fraction, compliance with 0.05 mg Ni/m^3 would be warranted.

When to comply with respirable Guidance Value of 0.01 mg Ni/m^3?

Independent of the forms of nickel present at the site, if the exposures to respirable size powders (particles ≤ 10 μm aerodynamic equivalent diameter; 50% penetration at 4.25 μm) of nickel substances are measured or measurements of workplace nickel particle size distribution indicate that > 10% of the measured total aerosol nickel mass is in the respirable fraction, compliance with 0.01 mg Ni/m^3 would be warranted.

D6.5. Guidance to Collection of Workplace Inhalable and Respirable Exposure Measurements

Information on personal respirable and inhalable samplers and sampling process has been summarized by IOM (IOM Report 1).

D6.6. Tiered approach to Collection of Workplace Aerosol Particle Size Distribution for Site-Specific Exposure Scenarios

If a combination of personal inhalable and respirable samplers is not routinely used to assess exposure at your site, information on workplace air particle size could be measured directly using a personal cascade impactor as recommended by IOM (IOM Report 2). Alternatively, other methods can be used to predict the particle size distribution of the workplace air with different degrees of confidence (IOM Report 3). A tiered approach to collecting site-specific particle size information (going from more precise to less precise data) is described below and in Table D6.2.

Tier 1 Particle Size Distribution of Workplace Aerosols Using Cascade Impactors.
If possible, collect particle size distribution information of workplace aerosol using a personal cascade impactor as described in IOM Report 2. Calculate Mass Median Aerodynamic Diameter (MMAD) and geometric Standard Deviation (GSD), and the fraction of the aerosol mass that is present in the inhalable, thoracic and respirable fractions. The presence of a respirable size fraction ≤10% of total aerosol mass can provide strong support for the use of the inhalable DNEL of 0.05 mg Ni/m^3. IOM Report 2 provides information on cascade impactors, data collection and analysis, cost and suppliers of cascade impactors. Information on a few laboratories that conduct these kinds of measurements is also included.

Tier 2 Particle Size Distribution of Materials/Products Using Dustiness Tests.
Conduct dustiness tests of the materials handled at the plant following guidance provided in IOM Report 3. These tests allow calculation of the fraction of the aerosol mass expected to be present in the inhalable and respirable fractions and in some cases (where a cascade impactor is attached) it allows estimation of the MMAD and GSD of the suspended dust. As indicated in Tier 1, the presence of a respirable size fraction with ≤10% of total aerosol mass can provide additional support for the use of the inhalable DNEL of 0.05 mg Ni/m^3.

Tier 3 Particle Size Distribution of Materials/Products Using Granulometry or SEM.
Suitable granulometry methods that can also be applied to materials handled at the plants are described in IOM Report 3. Methods such as sedimentation and electrozone sensing do not allow determination of MMAD but allow the assessment of respirable and inhalable fractions of dry powders and granules. The presence of a respirable size fraction <10% of total aerosol mass can provide additional support for the use of the inhalable DNEL of 0.05 mg Ni/m^3.

Sometimes information from Scanning Electron Microscopy (SEM) analysis of particles of plant materials exist. SEM analyses provide information on the number size distribution and may report the mean particle diameter of the sample. For example, if the data indicate an average particle diameter of 5 µm, this could be equivalent to 15 µm aerodynamic equivalent diameter, if particles are spherical and the density of the particles is 9 g/cm3. This kind of results would strongly suggest that most of the mass of the airborne particles will be associated with the non respirable fraction and this could justify the use of the inhalable DNEL of 0.05 mg Ni/m^3. SEM will yield a very conservative estimate of the respirable fraction mass.

Table D6.2. Summary of methods available under each tiered approach, as described in IOM Reports 2 and 3.

	Method allows determination of mass in various fractions or estimation of MMAD				Method can be applied to:	
	Respirable Fraction	Thoracic Fraction	Inhalable Fraction	MMAD, GSD	Workplace exposure	Materials/ products

Tier 1						
Cascade Impactors	√	√	√	√	√	√1
Tier 2						
Dustiness tests	√		√			√
- Rotating drum	√		√	√1		
- Single Drop						
- Continuous drop	√		√	√1		
- Fluidization						
Tier 3						
Granulometry	√		√			√
- Sedimentation	√		√			
- Coulter, Electrozone sensing	√		√			
- Phase Doppler Analyzer	√		√			

1. The cascade impactor can be coupled to the outlet of these methods allowing data on the MMAD and GSD of the suspended dust to be collected.

In the occasional instances where the particle size measurements indicate or predict the presence of very fine workplace aerosols in the respirable size fraction (aerodynamic equivalent particle diameter ≤ 10 µm), or workplace measurement indicate that the >10% of the total nickel mass is in the respirable fraction, the use of the inhalable DNEL of 0.05 mg Ni/m^3 may not be justified. It is recommended that in these cases, the site specific exposure scenarios recognize that additional risk management measures may be needed to protect the workers and keep their respirable size nickel exposures below 0.01 mg Ni/m^3.

D6.7. Workplace Aerosol Nickel Speciation Data for Site-Specific Exposure Scenarios

As indicated in Appendix C2 and in section D6.3 of this appendix, the different physicochemical and toxicological properties of the main groups of nickel substances can lead to some differences in the DNELs that could be derived from these substances. However, because information on speciation of workplace exposure is sparse and most workplace have exposures to more than one chemical form of nickel, a single inhalable long-term DNEL value of 0.05 mg Ni/m^3 is used in the nickel CSRs. In Section D6.3 we also suggest the use of single respirable guidance value of 0.01 mg Ni/m^3 for all nickel substances.

If companies are interested in assessing the speciation of their workplace exposures, there are many physical and chemical methods that can be applied (Zatka et al.1992; Andersen et al., 1998; Hoflich et al., 2000; Füchtjohan et al., 2001; Weinbruch et al., 2002; Conard et al., 2008; Oller et al., 2009). A description of these methods is beyond the scope of this Guidance document. Because physical and chemical methods have strengths and weaknesses, a combination of both types of methods is highly recommended.

D6.8. References and Additional Guidance Reports

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