Comments from the Nickel Institute and NiPERA on the

Survey of Nickel Metal Report.

Part of the LOUS review
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Summary and Conclusions

- Page 8: In the first paragraph, it would be good to clarify in summary that target organ is respiratory tract via inhalation
- Page 8: The Danish OEL value of 0.05 mg/m3 applies to insoluble Ni compounds and Ni metal. Is the OEL value in Denmark defined regarding aerosol fraction (inhalable, total, or respirable)? Is it safe to assume that it was not meant to be respirable? This is important as it is directly compared to the SCOEL values, one of which is inhalable and the other one is respirable.
- Page 8: The following addition is suggested for clarification after the sentence referring to the SCOEL value of 0.01mg/m3 for protection against cancer: "However, this does not include metallic nickel *which is not considered by SCOEL as a human carcinogen. The recommendation is subject to further evaluation at European level.*"
- Page 8, use of nickel metal. It mentions that there is an increased use mainly driven by the construction sector in the developing countries. It's not just the construction sector, but across many sectors, e.g. transport, energy, food & beverage and process industries such as oil & gas, petrochemicals and pharmaceuticals, & not just in Asia.
- Page 9: The text states: "In waste a content of more than 1 % nickel will lead to a classification as hazardous. Pure non-contaminated alloys will not be regarded as hazardous waste according to the EU regulation from 2015." It is unclear what this means in terms of alloys containing nickel metal. It is better explained in section 4.1 (last paragraph) where it states: "Pure uncontaminated metal alloys will not be regarded as hazardous waste when the new classification criteria for waste (aligning waste classification with the principles in the CLP Regulation) will enter into force from June 1st 2015. E.g. uncontaminated stainless steel with more than 1 % nickel will not become hazardous waste based on the nickel content alone."
- Page 9: it is mentioned that measured nickel levels are in general below the EQS but the concentration often exceed the value. Isn't this a contradiction?
- Page 9: It is mentioned that "it is not possible to separate the exposure to nickel metal from the exposure to other nickel species as nearly all monitoring data are measured as total

nickel". However, this is only true when Ni metal + Ni compounds are present in the same site. We would propose rewording: *"Nevertheless it is not possible to separate the exposure to Ni metal from the exposure to other Ni species, when they are present (used or produced) in the same workplace, as nearly all monitoring data are measured as total nickel."*

- Page 10: there is mention of "observed lung damage". It is important to clarify that the lung damages were not observed in humans but in animals hence we would suggest to add "*in animal studies*". There has been minimal evidence of lung toxicity among Ni workers.

Introduction to the substance

- Section 1.1 – Scope of the Survey. Page 14: It is mentioned that "there is no clear evidence for carcinogenic effects of nickel metal in humans". It may be helpful to clarify that there is also no clear evidence of carcinogenicity in animals via inhalation. The inhalation study in rats with Ni metal powder did not increase incidence of lung tumors. Adrenal tumors were increased, by a secondary mechanism independent of Ni ion.

Regulatory Framework

- Section 2.1.1 – Existing legislation. Page 21, reference is made to the 20 ng Ni/m3 for the ambient air standard. We suggest to add "*as PM10*"
- Same section, page 21: The description of the SCOEL values is reported correctly in some sections and incorrectly in others. SCOEL respirable value of 0.005 mg Ni/m^3 is reported as applying to poorly soluble Ni compounds and nickel metal, but it leaves out that this value also applies to water soluble Ni compounds. This value protects from respiratory toxicity effects observed in animal studies. The inhalable value of 0.01 mg Ni/m^3 that applies to all nickel compounds but not metallic Ni is based on human lung cancer data with soluble Ni compounds. This is correctly reflected on page 8.
- Section 2.1.2 – Risk Assessment according to Regulation 793/93, page 21: the title refers to Regulation 793/931 – replace by 793/93 (delete the "1" after the 93)
- Same section, page 21: "the risk assessment conclusions have shown that it is the nickel ion …" We would suggest to add "have shown that, *in most instances,* it is the nickel ion …" There are some instances where Ni ion alone does not explain the hazard profile.
- Section 2.1.3.1 – Harmonised classification. Page 23, reference to classification of NiO having a harmonized classification of Carc 1A & how this can affect the resulting classification for Ni metal when NiO is present as an impurity. It may be better to clarify this further by changing to "...higher than 0.1% (W/W), the nickel metal *with this impurity* is classified as Carc 1A."
- Section 2.2 – summary & conclusions. Page 24. Cfr comment page 21 regarding SCOEL values. We would suggest to replace this text with the wording on page 8.

Manufacture and Uses

- Section 3.1 – the nickel life cycle. Page 25 first paragraph. The contributions mentioned, whilst important, are not the only significant ones. In stainless steel nickel stabilizes the austenitic structure, the largest group within the stainless steel family. These grades have excellent mechanical properties through a wide temperature range (from cryogenic to high temperatures), are weldable, very formable and therefore straightforward to fabricate with. Also they are non-magnetic (steels are normally magnetic) and this can be an important attribute in applications where there is a need to avoid interference with electrical and electronic systems. One use for instance which requires both cryogenic and non-magnetic properties is body scanners.
- Same section, page 25, first paragraph. Nickel metal (mainly in stainless steel) is used in a much wider variety of sectors than is listed here.
- Same section, Page 26: the wording "This is by volume far the largest pool or standing stock of …." reads a bit strange. How about changing this to "*by volume, this is by far the largest pool or* …"
- Section 3.2.1 – manufacturing sites. It mentions New Caledonia as one of the largest mining countries. However, New Caledonia is not considered a country. One suggestion could be to add "*(French overseas territory)"* after New Caledonia.
- Section 3.3.2 – import and export of Ni metal. Page 31. There is some Danish wording in the last paragraph on INSG.
- Section 3.5 – summary and conclusions. Page 34, first paragraph. Cfr remark above that nickel is used in many more sectors than what is described here.

Waste Management

- Section 4.5.2 – Batteries. Page 39: It is mentioned that batteries contain nickel oxide which is incorrect. According to the REACH dossiers, the nickel compounds used in battery production are Ni metal, nitrate, sulphate and dihydroxide. The only compound present in the final battery is Ni dihydroxide. Ni oxide is not used at all, so we would suggest deleting "nickel oxides" and leave only "hydroxides".
- Same section, page 39. There is reference to the "Regulation" but the legislation on batteries is a Directive, not a Regulation as correctly mentioned in the previous sentence.
- Section 4.6: Summary and Conclusions. Page 40, first paragraph. "Pure non-contaminated alloys shall not be regarded as … " It may be useful to add as example stainless steel, e.g. "Pure non-contaminated alloys, *such as stainless steel*, shall not be regarded as … "

Environmental Effects and Exposure

- Section 5.1 – environmental hazard. Page 41. The first paragraph mentions that nickel metal powder bears a classification as aquatic chronic 3. This should be defined, i.e., Ni powder < 1.0 mm in diameter

- Same section, page 41. It is mentioned that nickel metal is not classified as environmentally toxic. The wording needs clarification here - ENV classification is not expressed as "environmentally toxic".

- Same section, page 41. The first paragraph mentions that "nickel metal is poorly soluble in water and the studies of the ecotoxicity of nickel are therefore less relevant to nickel metal." It may be helpful to state something like the following: "Environmental classification of sparingly soluble metal substances and metals is performed by comparing exposure data that is obtained from the Transformation/Dissolution Protocol (as described in Annex 10 of UN GHS) with established ecotoxicity reference values (ERVs) for Ni. The chronic ERV for Ni is 2.4 µg Ni/L."

- Same section, page 41 – table 5.1. It appears that the data presented in this table are not normalized. The EU RA used a bioavailability normalization approach that was based on normalizing ecotoxicity data for different bioavailability scenarios, i.e., the seven eco-regions. The normalized geometric means for the seven scenarios used in the EU RA are presented in Annex G.10. We suggest using the geometric means for one of the scenarios for this document. Otherwise the values presented in Table 5.1 cannot be found in the EU RA, and this may create confusion.

- Same section, page 42. "In 2012 a revised EQS was adopted …" The revised EQS Directive was adopted and published in the EU OJ in 2013. Hence we would suggest to replace the sentence with: "*In 2013, a revised EQS was published …*"

- Same section, page 42. Reference to EQS values and bioavailable fraction. It should be noted that only the freshwater EQS is bioavailability based. Furthermore, stating that the EQS refers to the bioavailable fraction is not entirely precise. A clearer way of expressing this would be to say that the freshwater EQS is bioavailability-based. It may also be helpful to state that the EQS relies on a tiered approach. The reference EQS is 4 µg bioavailable Ni/L. If the ambient dissolved concentration is greater than 4 µg Ni/L, then the bioavailability-based EQS is calculated based on local water chemistry, and the bioavailability-based EQS is then compared to the ambient dissolved Ni concentration.

- Same section, page 42 – PNEC values. It may be helpful to explain the difference between the FW PNEC in the Ni REACH dossier and the EQS. The FW PNEC represents a reasonably worst case (RWC), which is defined in the EU RA process as the 10th percentile of waters in terms of bioavailability. The WFD calls for protection of all waters, and therefore needs to cover the bioavailability of waters that fall below the 10th percentile.

- Same section, page 42 – PNEC values. Replace "application factors of 1" with "*assessment* factors of 1".

- In general, information other than PNECs is available to consider in risk characterizations, especially when the PNEC is determined through the application of Assessment Factors. For example, in the case of the sediment risk characterization, it is mentioned that several sites show Ni concentrations greater than the reported PNEC of 47 mg Ni/kg. The background Ni concentrations can be considered in this assessment. Also, it should be kept in mind that the lowest EC10 of any test species was 139 mg Ni/kg, which was obtained for *Hyalella azteca* in a high bioavailability sediment. This information should be considered when evaluating observed sediment concentrations.

- Section 5.1.2 – bioavailability of the freshwater environment. Page 43 – suggest to delete the comment in brackets (measured as the concentration of Ca2CO3) and we suggest that the following be used instead: "evidence suggests that both Ca2+ and Mg2+ can inhibit Ni2+ toxicity".

- Same section, page 44. Reference is made to 374 evaluated surface water samples, but then the last sentence in this paragraph only refers to 264 samples. Maybe it would help to say that there were 374 sites, and for (which?) reason, 264 out of the 374 were compared to the EQS.

- Section 5.1.3 – marine environment. Reference to the updated value in the EQS directive in 2012. Same remark as above as the Directive was published in the OJ in 2013.

- Section 5.1.4 - Sediments. Page 45, last paragraph. Replace “application factor” with “*assessment* factor”.

- Section 5.1.7 – conclusion on toxicity in the environment. Page 46. BLM is referred to as “bio-ligand modelling”, however the correct term is “Biotic Ligand Model”. In the same sentence we would propose to delete the wording “”estimating of the bioavailable fraction” and replace with “are available for *predicting the toxicity* of nickel in freshwater". All of the models discussed in this document - BLMs, AVS-based sediment models, CEC-based soil models - are used to predict toxicity. They are not used to estimate bioavailable fractions. The bioavailable fraction is included in the estimations of toxicity, but it is not accurate to say that these models estimate the bioavailable fraction.

- Section 5.2 – Exposure assessment and monitoring data. Page 46: “according to the FOREGS database, the nickel concentration in EU freshwater streams … “. It's important to state that this refers to the dissolved nickel concentration in EU freshwater streams. In several areas, "total nickel" is used. "Total nickel" refers to both dissolved and particulate Ni. Only dissolved Ni is relevant in terms of both exposure and effects.

- Same section, page 47: Paragraph below table 5.5. It is unclear how this information is related to the information presented in the 1st paragraph of Section 5.2, where FOREGS data are also mentioned. Could you please clarify?

- Section 5.3.1 – freshwater systems. Page 48: “concentrations of nickel that exceeds the EQS are, however, not uncommon … “.This seems to contradict the information presented on p.

44, where it is reported that only 8.7% of sites exceed the reference EQS of 4 µg Ni/L (23 out of 264) and that bioavailability normalization reduced the exceedance rate to 2% of sites.

- Same section, page 48: the conclusion that the average level of the total nickel concentrations is below the EQS. This may need some clarification as total Ni concentrations are not the focus. Bioavailable Ni concentrations are the focus. The first level of comparison should be between measured dissolved Ni to the reference EQS of 4 µg Ni/L.
- Section 5.3.2 – sediments. Page 48: correlation to the sulphur content measures as AVS. It should read *reduced sulfide*, not sulphur.
- Same section, page 48: reference to PNEC at 47mg Ni/kg mentioned that this does not take the bioavailibility in sediments into account. It may be necessary to explain why no bioavailability normalization was performed. The HC5 that results when the 90P AVS values are used in the bioavailability model is 300 mg Ni/kg. A range of PNECs is possible, and this needs to be considered before making conclusions of risk. Also, the lowest EC10 from any species tested in the least bioavailable sediment was 139 mg Ni/kg. This is reported in the Ni REACH dossier (and in the literature). Hence more information may need to be considered before making conclusions of risk.
- Section 5.4 – summary and conclusions. Page 49, "in the aquatic freshwater compartment, the nickel ion is highly toxic". Some additional information may be helpful to show the complete picture. For example, it could be stated that the most sensitive groups of aquatic organisms to Ni include snails, cladocerans, and vascular plants (Lemna). On the other hand, fish and amphibians are not particularly sensitive to Ni exposure.
- Same section, page 49. Reference to pH, DOC & Calcium. We suggest to delete "calcium" and replace with "*hardness (Ca and Mg)*".
- Same section, page 49: "user friendly tools have been developed that allow the estimate the bioavailable fraction". Same comment as above, please replace with "… *that allow to estimate toxicity as a function of water chemistry."*
- Same section, page 49: paragraph 3 states that the high end of observed concentration range lie above the PBEC value and indicate a risk" – we suggest to replace with "… and indicate a *potential* risk*."*
- Same section, page 49, 4th paragraph first sentence refers to the sediment compartment. However a risk characterization of the sediment compartment was not performed in the EU RAR hence we wonder whether this actually is a mistake and should read soil compartment?

Human health effects and exposure

- Section 6.1 – human health hazard. Page 50. Classification as "suspected of causing cancer". We suggest to add as a clarification "*by inhalation*"

- Same section, page 50: classification as STOT RE 1. We suggest to clarify that this is by inhalation and that lungs are the affected organ.
- Section 6.2.1 – absorption. Page 50. Dermal absorption of nickel metal. It should be noted that the human data on nickel metal already account for the amount dissolved in sweat and hence would be more reliable than the *in vitro* data of release of nickel ion in synthetic sweat.
- Same section, page 50: exposure by inhalation. The following text is unclear:

  > *The exposure by inhalation depends on the particle size, where particle with an aerodynamic diameter over 1 – 5 µm have the greatest probability of settling in the nasopharyngeal regions (inhalable fraction) and particles with aerodynamic diameters below 1 – 5 µm are most likely to settle in the tracheobronchial and pulmonary regions.The inhalable aerosol fraction includes particles with diameter > 5µm.*

  Particles with aerodynamic diameter (AD) below 10 µm are considered to be in the respirable aerosol fraction (50% penetration for particles of 4 µm AD), which is a subfraction of the inhalable aerosol fraction. The inhalable aerosol fraction can include particles up to 100 µm in AD
- Section 6.2.2 – acute toxicity. Reference is made to a 4-week study. However, such as study is not considered as acute. Perhaps the wording should be changed to consider this study as a sub-chronic study.
- Section 6.2.4 – sensitization. Page 51: The document notes that the prevalence of nickel sensitisation has declined. It would be helpful to have a reference provided for the values presented for prevalence of nickel sensitization. These values are important for Denmark as the first country to adopt this type of regulation for dermal nickel sensitisation.
- Same section, page 51. The cut-off release rate of 0.5µg Ni/cm2/week is considered protective of all non-sensitized individuals but also of most sensitized individuals. Only for nickel sensitized individuals is the release rate of 0.5 µg Ni/cm2/week considered not to protect all individuals, but rather a significant proportion of individuals.
- Same section, page 51: cut-off release rate: it should be noted that this value is to be measured by the most recent EN1811 standardized protocol.
- Section 6.2.5 – repeated dose toxicity. Page 51: reference to studies on rats and mice. However, there are no chronic inhalation exposure studies in mice with nickel metal.
- Same section, page 51: the last paragraph mentions a 13-day inhalation study with rats. However, it probably should read 13 *weeks*.
- Same section, page 52, last paragraph refers to the current SCOEL recommendation for the respirable fraction. The value of 0.005 mg Ni/m3 respirable fraction applies also to water soluble Ni compounds, not only to poorly soluble Ni compounds and Ni metal.

- Section 6.2.7 – carcinogenicity. Page 52, second paragraph. The difference between soluble Ni compounds and Ni metal is that for Ni metal the epidemiological data matches the animal data (both negative). For sulfidic and oxidic Ni compounds the epidemiological data also matches the animal data (both positive). Thus soluble Ni compounds stand out as the only form of Ni where there is a discrepancy between the animal and the human data.
- Same section, page 52. The IARC current carcinogen classification of nickel metal is incorrectly reported as Group 1 when it is Group 2B. The discussion thus hints at a discrepancy of opinions between SCOEL and IARC when in reality there is not much of a gap: CLP and IARC both consider nickel metal as suspect carcinogen at most; SCOEL does not consider it as a known human carcinogenic.
- Same section, page 52: IARC 2012 is not in the reference list.
- Section 6.2.9 – conclusion on toxicity to humans. Page 53. Again there is a reference to the respirable SCOEL recommendation which is also for soluble nickel compounds (see previous comments on this).
- Same section, page 52: the reference with respect to IARC is incorrect – see previous comment on this point.
- Page 53. It appears there is an error on section numbers; from 6.2.9 goes to 6.1.
- Section 6.1.1.1 – dermal exposure. Page 55, reference to the EN1811 to test the release under conditions similar to sweat, saliva and other body fluids. However, EN1811 only specifies sweat, not saliva or other fluids.
- Section 6.1.1.4 – ambient air. Page 56, it is mentioned that urban air samples show that 19% of the measured nickel content is in metal form. However we could not find a source for this information in. The EURA report in section 4.1.1.1.3 states that "Respiratory exposure to nickel metal occurs only in occupational exposure context". Most of urban Ni will be in oxidic or sulphate form with < 10% as metallic. We would recommend to check the source of the “19%” as it seems out of line with existing published data (e.g., see Oller et al., 2014)
- Section 6.1.1.6 – conclusion of consumer exposure. Page 57: One additional clarification could be made: these values do not consider the differential absorption of Ni from water versus food, versus air versus soil (as nicely indicated in Fig 6.1).
- Section 6.2.1 – consumer. Page 57. Dermal sensitisation should be added as a local effect for which there are no risk to the general population.
- Section 6.2.2 – workers. Page 59, reference to the Danish OEL of 0.01mg/m3. We were under the impression that there are 2 Ni OELs in Denmark: 0.01 mg/m3 which applies to water soluble compounds and 0.05 mg/m3 which is for insoluble Ni compounds and Ni metal. If none of these 2 values is defined as respirable, they would be comparable to the SCOEL 0.01 mg Ni/m3 or the REACH DNEL of 0.05 mg Ni/m3.
- Section 6.3 – summary of health effects. Page 59: it should be noted that the allergic reaction is dermal sensitization.

- Same section, page 59. Reference to the recent standardized EN1811 protocol should be added to measure the release rate.
- Same section, page 59. The reference with respect to IARC is incorrect – see previous comment on this point.
- Same section, page 60: "Exposure to nickel metal in the work environment may lead to inflammatory lesions in the respiratory tract and may possible be carcinogenic as well. " While this is factually correct, we would nevertheless suggest to replace this sentence with the sentence on page 9 which is more reflective of how groups like SCOEL have considered nickel metal: "exposure to nickel metal in the work environment may lead to inflammatory lesions in the respiratory tract. Nickel metal is, however, not regarded as a carcinogen in humans"

Information on alternatives

- Section 7.1.1 – alternatives to nickel in steel and alloys. Page 61. All stainless steels share a minimum percentage of about 10% chromium. In fact it is minimum 10.5% chromium.
- Same section, page 61. There is reference to the nickel price which drives materials with lower content of nickel. We would suggest to bring this more into perspective, in view of the cyclic nature of metal prices. For instance, currently the nickel price is not as high as a couple of years ago hence this statement may not directly reflect current market practices.
- Same section, page 61. There is mention that the price drives the market to a number of alternative materials including composites or coated carbon steels. However we are not aware of stainless steel applications being lost to composites or coated carbon steels.
- Same section, page 62 – concluding paragraph. This section ignores the very important role that nickel-stabilized austenitic stainless steels play in alloys for low (cryogenic) applications and where non-magnetic properties are required.