7 November 2019

COMMENTS ON

ÖKO-INSTITUT DRAFT RoHS ANNEX II DOSSIER FOR NICKEL SULPHATE AND NICKEL SULFAMATE (VERSION 2, 25/09/2019) AND SUBSTANCE INVENTORY

STAKEHOLDER CONSULTATION 2 (2019)

Comments provided by:

Nickel Institute
Brussels, Belgium

For additional information:

Dr. Mark Mistry
Senior Manager Public Policy, Nickel Institute
mmistry@nickelinstitute.org

Mr. Marco Vallini
Manager Public Policy, Nickel Institute
mvallini@nickelinstitute.org

Introduction

Nickel Institute*(NI) takes note of the "2019 Stakeholder consultation 2" launched by the Öko-Institut in the context of the "Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)". We welcome the opportunity to respond to the consultation and provide comments. In the following contribution, we would like to submit general and specific comments on the draft Report for nickel sulphate and nickel sulfamate (Report 6) as well as on the revised RoHS Substance Inventory.

General comments on draft Report on Nickel sulfate and Nickel sulfamate

The NI welcomes the acknowledgment that:

- the two nickel salts (nickel sulphate and nickel sulfamate) are process chemicals used in the production phase (i.e. surface treatment) and are not present in the final EEE and are therefore not relevant substances for a RoHS restriction. This aspect was also acknowledged in the 2014 Öko-Institut study on the "Review of the List of Restricted Substances under RoHS 2".

The NI welcomes and supports the consequential and logic conclusion that:

- it is not recommended to restrict the two nickel salts, as there would be no benefits in terms of health and environmental protection, while there could be unnecessary costs for public authorities and companies (testing, administrative burdens, etc.).

At the same time, we do not agree with the statement in the draft Report (page 32) that a future assessment under RoHS of "Nickel and its compounds" would be recommended "to clarify the range of expected impacts of nickel metal and nickel^{2+} ions during use and/or waste management (…)". This statement is not justified for the following reasons:

- First of all, nickel metal has a different and lower harmonised hazard classification than nickel compounds. Most importantly, nickel metal is not classified as a CMR Cat. 1A-1B under the CLP Regulation. For the sake of clarity, the report should at least acknowledge this important difference.

- A grouping of nickel metal and nickel compounds is neither justified nor appropriate in this context. The RoHS Methodology indicates that substance grouping could be relevant when a certain group of chemicals "*exhibit the same hazard properties and where similar exposure could arise*" (page 20). This is not the case of nickel and nickel compounds, which have a different harmonised hazard classification under the CLP Regulation. In addition, nickel metal

* Nickel Institute (NI) is the global association of the world's primary nickel producers. NI is the centre of excellence for information on nickel and nickel-containing materials. NiPERA Inc., the separately incorporated science division of NI, undertakes leading edge nickel scientific research relevant to human health and the environment. NI's identification number in the EU Transparency Register is 77947983421-21.

Nickel Institute – Brussels Office
Rue Belliard, 12 – B-1040 Brussels, Belgium – Tel: +32 2 290 32 00 – Fax: + 32 2 290 32 20
Email: brussels@nickelinstitute.org – Web: www.nickelinstitute.org

and compounds not only release Ni ions to different degrees but the process of metal release is different (corrosion versus dissolutions).

- Nickel metal and nickel compounds have many different uses and applications. Nickel compounds such as nickel sulphate and sulfamate are not present in the final EEE, while metallic nickel can be present in e.g. plated surfaces under a chromium finishing as well as in stainless steel and other alloys which are used in EEE.

- Previous extensive assessments by public authorities such as the EU Risk Assessment Report (2008) and the Danish EPA "Survey of nickel metal" (2015) did not identify any concern that would require EU regulatory action on nickel metal (and nickel compounds) under RoHS.

- Potential residual risks from the use of nickel and nickel compounds are already thoroughly addressed and managed by existing EU regulations in the field of chemicals (e.g. REACH), environmental policy (EQS Directive, Industrial Emissions Directive, etc.) as well as existing and upcoming EU regulation on workplace legislation (e.g. 4th revision of Directive 2004/37EC).

For all these reasons, we conclude that the recommendation that "Nickel and its compounds should be assessed in the future" is not justified.

Comments on revised Substance Inventory

With regard to the Substance Inventory, we have the following complementary remarks:

- We note that nickel metal (CAS N° 7440-02-0) appears as the first substance in the revised Inventory and it has apparently been pre-assessed as "Overall Priority Group I". It is not clear, however, what approach has been followed to come to this assessment. In particular, we do not understand why nickel metal has been assigned to the "Hazard Group I" category in the Inventory. As noted earlier, nickel metal has a different and lower hazard classification compared to inorganic nickel compounds and compared to other substances which are found in this Hazard Group I.

- The harmonised hazard classification of nickel metal in the CLP Regulation does not seem to fulfil the "Criteria A" which would justify assigning a substance to Human Health or Environmental "Hazard Group I" according to the RoHS Methodology itself.

- We note that the Inventory still includes nickel compounds that are not expected to be present in the final EEE (e.g. nickel sulfate; nickel sulfamate). In order to align the Inventory with the overall conclusions of the draft Report, nickel sulphate and nickel sulfamate should be removed from the Inventory list.

Specific comments on draft Report on Nickel sulfate and Nickel sulfamate

We noted that the draft Report includes some errors and statements which are not supported by any data. Here below in the Annex, we provide constructively some comments and suggested edits, which we believe would make the Report more accurate and balanced, if addressed.

ANNEX

Section CONTEXT and SCOPE of the DOSSIER / substance assessment

Page 8, Paragraph 3: "*Though a grouping of "nickel and its compounds" appears in the regulatory context, e.g. in the context of occupational exposure limits for nickel and its compounds, a grouping was not proposed for this assessment for the following reasons*: […]"

Nickel Institute (NI) Comment: Nickel and Nickel compounds are rarely / hardly ever grouped in the regulatory context. It should be clarified that in the context of EU OELs setting, for example, the grouping was only done for the scientific evaluation but it was not done for the outcome. There is no grouping of nickel metal and nickel compounds in the subsequent EU regulatory processes, which follow two different legal frameworks: Directive 98/24/EC to set OELs for nickel metal and Directive 2004/37/EC to set OELs for classified inorganic nickel compounds. This is due to the fact that nickel metal has a lower hazard classification than nickel compounds. Nickel metal is not classified as CMR 1A-1B and it is therefore not in the scope of Directive 2004/37/EC.

Possible suggested edit (text in green):
"Though a grouping of "nickel and its compounds" appears in the regulatory context, e.g. in the context of the scientific evaluation of occupational exposure limits for nickel and its compounds, a grouping was not proposed for this assessment for the following reasons: […]"

Section 1.2. Classification and labelling status

Page 12, Paragraph 2: "*To summarize the table shown below, it is understood based on the harmonised classification that both nickel sulphate and nickel sulfamate are considered as CMR substances. This means that exposure to these substances could lead to impacts on human health and/or the health of other species, e.g., cancer, genetic defects and/or impacts on the reproductive system and organs*.

NI Comment: It should be acknowledged that Nickel compounds are carcinogens (only by inhalation) with a mode of action based threshold, as noted also in the ECHA RAC Opinion on occupational exposure limits (2018).

Possible suggested edit (text in green):
"To summarize the table shown below, it is understood based on the harmonised classification that both nickel sulphate and nickel sulfamate are considered as CMR substances. This means that exposure to these substances above a certain threshold could lead to impacts on human health and/or the health of other species, e.g., cancer, genetic defects and/or impacts on the reproductive system and organs."

Section 1.2.2 Self-classification(s)

Page 14, Paragraph 5 on nickel sulfate: "*84 notifiers additionally classify nickel sulphate for the human health hazard Eye irritation 2 (H319 – causes serious eye irritation)*".

Nickel Institute – Brussels Office
Rue Belliard, 12 – B-1040 Brussels, Belgium – Tel: +32 2 290 32 00 – Fax: + 32 2 290 32 20
Email: brussels@nickelinstitute.org – Web: www.nickelinstitute.org

NI comment: It is not clear where the number "84" comes from. We have checked the ECHA C&L inventory and we only found 48 notifiers (out of 1367) classifying the substance as Eye Irritant 2. In addition, the information displayed on the ECHA website under "View details" indicates that these notified self-classifications are affected by the presence of impurities or additives in the substance and do not necessarily reflect the intrinsic properties of the pure substance.

Page 14, Paragraph 7: "*To summarise, on the basis of the self-classifications, another hazard pathway additional to the ones mentioned above may be contact with eyes, potentially affecting both human health and health of other species*".

NI comment: As noted in our previous comment, these self-classifications in the ECHA C&L inventory are affected by the presence of impurities or additives in the substance and do not necessarily reflect the intrinsic properties of the pure substance. Pure nickel sulfate is not an eye irritant.

Section 1.3.1 Regulation of substances under REACH

Page 14, Paragraph 5 on nickel sulfate: "*Based on the RMOA, a binding occupational exposure limit value (BOELV) was proposed by the French authorities at 0.01 µg/m3 for nickel compounds*."

NI Comment: There is an error in the unit of measurement. The correct unit of measurement is "mg". The correct value is 0,01 mg/m³. This error must be corrected to avoid confusion.

Suggested edit: "Based on the RMOA, a binding occupational exposure limit value (BOELV) was proposed by the French authorities at 0.01 ~~µ~~mg/m3 for nickel compounds (based on a 2011 SCOEL recommendation that was later superseded by the 2018 ECHA recommendation)."

Section 1.3.2. Other legislative measures

Page 16 , 3rd bullet point: "*Any compound of nickel (including the metals in metallic form, as far as these are classified as dangerous substances) is categorised as "heavy metal" and leads to the classification of hazardous waste according to the Commission Decision 2000/532/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste*".

NI Comment: It is not correct to state that all forms of nickel lead to nickel-containing materials being classified as hazardous waste. There are some exemptions under EU legislation for "pure metal alloys in their massive form".

Possible suggested edit (text in green): "Any nickel-containing ~~compound~~ substance ~~of nickel~~ (including the metals in metallic form, as far as these are classified as dangerous substances) ~~is categorised as "heavy metal" and~~ can lead~~s~~ to the classification of hazardous waste according to the Commission Decision 2000/532/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste. However, the concentration limits defined in Annex III to Directive 2008/98/EC do not apply to metal alloys in their massive form, in accordance with Commission Decision 2014/995/EU amending Decision 2000/532/EC on the list of waste".

Section 2.4 Potential impacts of the substance on the environment and on health during the use of EEE

Page 20, first and second paragraphs: "*Seeing that both nickel sulphate and nickel sulfamate are understood not to be present in EEE, impacts would not be expected in relation to these substances in the use phase of such EEE. It is, however, noted that the application of these substances in plating processes used in the manufacture of EEE components results in the presence of nickel or other nickel compounds in the relevant EEE. It is possible that the presence of these compounds may result in impacts on health and/or the environment during the use phase of such equipment. However, the investigation of the potential for such impacts is beyond the scope of this assessment*".

NI Comment:
The paragraph is unclear. In the first sentence it is stated that impacts would not be expected in the use phase, as the substances "are understood not to be present". Then, it is stated that the "presence of these compounds may result in impacts during the use phase". This statement is contradictory and it is not supported by any evidence. Previous extensive assessments by public authorities such as the EU Risk Assessment Report (2008), the Danish EPA "Survey of nickel metal" (2015) did not identify any concern that would require EU regulatory action under RoHS. To address potential residual risks from the industrial use of nickel compounds (in plating and other sectors), the Commission is developing binding occupational exposure limits for classified inorganic nickel compounds under the next revision of Directive 2004/37/EC, expected in 2020. In parallel, possible environmental impacts from plating are expected to be addressed by the upcoming revision of the EU "Surface treatment of metals and plastics BREF" under the Industrial Emissions Directive.

Possible suggested edit (text in green): "It is, however, noted that the application of these substances in plating processes used in the manufacture of EEE components results in the presence of nickel or other nickel compounds in the relevant EEE. It is possible that the presence of these compounds may result in impacts on health and/or the environment during the use phase of such equipment. However, it should be noted that, to address potential residual risks from the industrial use of nickel compounds in plating (and other sectors), the Commission is developing EU binding occupational exposure limits for inorganic nickel compounds (classified as CMR 1A-1B) under the next revision of Directive 2004/37/EC, expected in 2020. In parallel, possible environmental impacts from plating are expected to be addressed under the upcoming revision of the "Surface treatment of metals and plastics BREF" under the Industrial Emissions Directive. However, the investigation of the potential for such impacts is beyond the scope of this assessment. ".

Section 3. Human Health Hazard Profile

Page 21, paragraph 1: "*The toxicological summary in the registration dossier provided in the ECHA database show the same results for nickel sulphate and nickel sulfamate (the guidance values are given in terms of mg nickel and not as mg substance). It is therefore assumed that the nickel ion is the entity being mostly relevant for the human health. In the regulatory context, it is commonly referred to a group "nickel and its compounds"*.

NI comments: It should be mentioned and clarified in the Report that nickel metal has a different and lower hazard classification compared to inorganic nickel compounds. This is an important aspect that should be acknowledged.

Possible suggested edit (text in green): "The toxicological summary in the registration dossier provided in the ECHA database show the same results for nickel sulphate and nickel sulfamate (the guidance values are given in terms of mg nickel and not as mg substance). It is therefore assumed that the nickel ion is the entity being mostly relevant for the human health. In the regulatory context, it is commonly referred to a group "nickel and its compounds". It should however be noted that nickel metal has a different and lower hazard classification than inorganic nickel compounds".

Section 3. Human Health Hazard Profile

Page 23, paragraph 1: "*To conclude on human health, nickel and its compounds being present in the EEE waste stream might exhibit a risk for workers e.g. in shredding plastic with decorative nickel plating. However, the nickel in the decorative plastic may result from the use of other nickel salts than the two nickel salts in scope of this assessment*".

NI Comment: these conclusions and assumptions are not supported by any evidence or data in the dossier. The conclusion seems to be based only on the hazard classification of nickel compounds. It should be noted, however, that no risks were identified for shredding processes in the REACH chemical safety assessment of the waste life-cycle stage (documented in the joint Chemical Safety Report), which is based on the Best Available Techniques (BAT) Reference Document (BREF) for Waste Treatment (JRC, 2018). Moreover, it should be acknowledged that nickel metal and inorganic nickel compounds have different hazard classifications. It should also be noted that potential residual risks for workers from nickel compounds are expected to be addressed by the binding OEL that the Commission is planning to propose under the next revision of Directive 2004/37/EC in 2020.

Section 9. DESCRIPTION OF SOCIO ECONOMIC IMPACTS – 9.3. Impact on EEE producers

Page 31, paragraph: "(…) *KEMI (2015) also points out that "nickel compounds are hazardous to human and environment and are found to a great extent in EEE products, it is of interest to analyze them more extensively in order to make an assessment of their risks in EEE products*.".

NI Comment: It is unclear how this paragraph fits in Section 9.3, which is supposed to assess the socio-economic impacts on EEE producers? It addition, the sentence contradicts what stated many times in the draft report (e.g. that "the compounds do not remain present in the final product" (page 30) as well as the quoted conclusion by KEMI (2015) that "nickel sulfate and nickel sulfamate as process chemicals for electroplating are not relevant for inclusion in RoHS" (page 31).

Section 9.7. Total socio-economic impact

Page 32, paragraph 3 : "*It is noted that a possible restriction of nickel and its compounds can be expected to be more effective in terms of preventing possible impacts on environment and health in the use and waste phase of products, that are related to nickel plating of components using nickel sulphate and nickel sulfamate*.[…]".

NI Comment: This statement is not supported by any evidence or data in the dossier. How can this assumption be made if an analysis has not been performed? There is no information in the draft

report on the socio-economic impacts (potential impacts for the European industrial value chain; feasibility; competitiveness of manufacturers and SMEs, etc.) or potential benefits.

Section 10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

Page 33, Paragraph 1: "*In the final coating, the nickel salts are understood to be converted into nickel metal or nickel2+ ions, depending on the process*".

NI Comment: Nickel compounds, and more precisely the common nickel salts used in surface treatment technologies, such as electrolytic plating and electroless technologies (e.g. Ni sulphamate, Ni sulphate), contain Ni^{2+} cations ionically bonded to their respective anions. The nickel salts (solid) are dissolved and dissociated into their ions in the bath and then are reduced to nickel metal on the plated surface. It is important to clarify that in the final coating the nickel salts are converted into nickel metal.

Possible suggested edit: "In the final coating, the nickel salts are understood to be converted into nickel metal ~~or nickel2+ ions, depending on the process~~. "

Section 10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

Page 33, Paragraph 2: "*In parallel, the assessment would recommend a future assessment under RoHS of nickel and its compounds in order to clarify the range of expected impacts of nickel metal and nickel2+ ions during use and/or waste management and whether a RoHS restriction of this group would allow preventing such impacts*".

NI Comment: This conclusive statement is not supported by any evidence in the draft Report. In addition, it should be acknowledged clearly that nickel metal has a different and lower hazard classification than nickel compounds. This aspect is not mentioned anywhere in the draft Report. It is an important point which should be acknowledged.

In addition, it should be noted that previous extensive assessments by public authorities such as the EU Risk Assessment Report (2008), the Danish EPA "Survey of nickel metal" (2015) as well as the RMOAs under REACH (2016) did not identify any concern that would require EU regulatory action under RoHS. Previous assessments recommended the establishments of occupational exposure limit (OEL) values under EU workplace legislation as the most effective and efficient risk management measure to address any potential residual risk from the use of nickel compounds. The OEL process is ongoing and a legislative proposal from the Commission is expected in 2020. In parallel, possible environmental impacts from e.g. plating are expected to be addressed by the upcoming revision of the EU "Surface treatment of metals and plastics BREF" as well as other relevant BREFs in the context of the Industrial Emissions Directive.

Nickel Institute – Brussels Office
Rue Belliard, 12 – B-1040 Brussels, Belgium – Tel: +32 2 290 32 00 – Fax: + 32 2 290 32 20
Email: brussels@nickelinstitute.org – Web: www.nickelinstitute.org