RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Nickel Oxide

EC No 215-215-7 and 234-323-5

CAS No 1313-99-1 and 11099-02-8

Member State: France

Dated: August 2016

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude other Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Nickel monoxide (NiO) belongs to the family of nickel compounds including nickel metal, nickel salts, organometallic nickel substances, etc. More than a hundred are classified under the CLP Regulation. At least 26 nickel compounds are registered under REACH, 16 as full dossiers (REACH Article 10), 8 as intermediate dossiers (REACH article 18) and 2 with both full and intermediate dossiers. Additional registrations can also be expected. From those 26 nickel compounds, 6 have been selected by the French Competent Authority for further assessment (nickel sulphate, hydroxycarbonate, dichloride, dinitrate, bis(hydrogen)phosphate and monoxide). Risk management option analyses (RMOA) have been carried out on NiSO4 and NiO as both salts cover substantially the majority of the uses reported for Ni compounds. ***Therefore the conclusion of these two RMOAs is also valid for the other Nickel compounds.***

Classification and labelling

NiO is currently classified under Annex VI of the CLP Regulation (EC No.1272/2008) as follows.

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
028-003-00-2	Nickel oxide	215-215-7	1313-99-1	Skin Sens. 1 Carc. 1A STOT RE 1 Aquatic chronic 4	H317 H350i H372 H413	none	none

Information on any previous risk assessment, risk reduction strategy and RMO analyses

No previous risk assessment has been specifically carried out on nickel oxide, but on others nickel compounds.

Previous risk assessment carried out under Council Regulation 793/93

A risk assessment has been carried out in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances for 5 nickel compounds (nickel metal, nickel sulphate, nickel dichloride, nickel dinitrate and nickel carbonate) but not for nickel oxide specifically. For further information on this risk assessment, please refer to the conclusion document on nickel sulphate or the risk assessment report (RAR) itself.

However, some pieces of information can be found on NiO in the available RAR dated May 2009 since several of the 5 covered compounds were at that time also involved in uses that are reported for nickel oxide, such as catalysts manufacturing.

Moreover, the following statements/conclusions from the RAR, that covers all nickel compounds because of their similar classification under Annex VI of the CLP regulation, are relevant for NiO. The main risks identified by the risk assessment reports that need to be addressed are related to occupational inhalation exposure. Catalyst production which is the main use of nickel oxide in terms of used volume was one of the scenario considered to be at risk for nickel compounds in the RAR.

Based on the information and the classification available at that time (identified uses and exposure levels, hazard characterization and subsequent classification, agreed DNELs, etc.), risks were identified for workers based on inhalation exposure (to nickel salts) and on the following health effects:

- acute inhalational toxicity (short-term peak exposures to nickel salts),
- respiratory sensitisation (occupational asthma following inhalation exposure to nickel salts),
- chronic inhalational toxicity (full-shift exposure),
- inhalational carcinogenicity (for all scenarios except those where the exposure is purely to metallic nickel),
- reproductive toxicity (fertility and developmental toxicity following inhalation).

Note that there was no concern for workers after oral exposure, as it was assumed that this is prevented by personal hygiene measures.

Previous risk reduction strategy carried out under Council Regulation 793/93

In order to identify appropriate measures to address the risks to human health raised in the risk assessment report, a risk reduction strategy with respect to human health was prepared by Denmark in 2007 in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

The report stated that nickel and nickel compounds were already widely regulated under EU legislation. The following risk reduction measures were proposed in relation to obligations under Community law:

- to set occupational exposure limits for nickel metal and nickel compounds in the form of inhalable dust/aerosols under Directive 98/24/EC (chemicals at work) or Directive 2004/37/EC (carcinogens at work) as appropriate,
- to establish at Community level an occupational exposure limit or limits for welding fumes, according to Directive 98/24/EC or Directive 2004/37/EC as appropriate, taking into account information in the nickel RAR, as well as other risk assessments on chromium(VI) compounds and zinc,
- to establish at Community level an occupational exposure limit or limits for welding fumes, according to Directive 98/24/EC or Directive 2004/37/EC as appropriate, taking into account information in the nickel RAR, as well as other risk assessments on chromium(VI) compounds and zinc,
- to consider the validity of derogations for the use of $NiSO_4$ and NiCl2 under Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

The following measures were proposed in relation to non-regulatory outcomes:

- practical sector-specific guidance of a non-binding nature should be drawn up by the Commission for uses of nickel identified as a concern in the risk assessment, as foreseen under Article 12(2) of Directive 98/24/EC,
- consideration of an exchange of information organised by the Commission to ensure proper guidance to severely nickel-sensitised individuals through the Community,
- the effects of Directive 94/27/EC (relating to restrictions on the marketing and use of certain dangerous substances and preparations) as amended and the associated EN 1811 standard should be monitored in the wider EU population to ensure that the threshold set in the Directive is adequate to prevent new cases of

nickel allergy and is also sufficient to prevent elicitation of symptoms in a significant proportion of nickel-sensitised individuals caused by the release of nickel from objects in direct and prolonged contact with the skin and piercing posts.

Previous RMO analysis carried out on environment by Denmark

A risk assessment for the environment and human exposed via the environment has been conducted by Denmark under Council Regulation 793/93 on nickel (metal) and nickel compounds (nickel sulphate, nickel [hydroxy]carbonate, nickel chloride, nickel dinitrate). This report is dated May 2008.

The work was completed in 2012 on the sediment compartment on the basis of new information that was formerly required in COM Reg. 466/2008 on the chronic effects (and potential risks) to freshwaters sediment organisms. A conclusion of substance evaluation (for those five compounds) drafted the 19th of December 2012 was made available to Member States according to transitional measures described in Article 135, 136 and 48 of the REACH regulation. This conclusion is regarded as a risk management option analysis that complete the existing environmental risk assessment for nickel compounds.

Denmark considers that no risk management measure is appropriate under the REACH Regulation but expresses the need for other community-wide measures. It is thus proposed:

- the establishment of an EQS freshwater sediment under the Water Framework Directive (WFD) including potential use of an AVS-based bioavailability normalisation approach,
- that further Guidance is being developed under WFD for refined assessment when initially $EQS_{freshwater\ sediment}$ seems to be exceeded. It is proposed to base such a further development on the refinement approach of the summary report which includes bioavailability normalisation and refinement of the emission/exposure assessment,
- a revision of the BREF note for nickel plating to also protecting specifically the freshwater sediment compartment under the Industrial Emission Directive.

Denmark also recommends registrants of nickel to update nickel registration dossiers without undue delay taking into account:

- the new hazard data on freshwater sediment organisms,
- that an assessment factor of 2 is recommended to derive $PNEC_{freshwater\ sediment}$= 47 mg Ni/kg sed. dw,
- the use of the established bioavailability approach i.e. the prescribed use of AVS normalisation models and/or reducing exposure and/or refining emission/exposure assessment if initially calculated $RCR_{freshwater\ sediment}$ >1 to prove safe use (i.e. $RCR_{freshwater\ sediment}$ <1 for refined assessment).

Denmark finally expresses the need for action at national level by Member States Competent Authorities (in future if/when $EQS_{freshwater\ sediment}$ and bioavailability normalisation approach have been adopted under the WFD and employed by registrants under REACH):

- implement BAT in relevant industrial sector,
- monitor if the proposed EQS for freshwater sediment is complied with for all industrial nickel emitting local sites,
- enforce compliance under REACH and the Water Framework Directive.

The French Member State Competent Authority (MSCA FR) agrees with the conclusions of the environmental risk assessment and RMOA conducted by Denmark and considers that no further development of the proposed environmental risk management option is needed.
Therefore the present RMOA has not considered further the environmental risk.

Current legal requirements for nickel and nickel compounds under REACH and other EU legislations

Nickel metal and nickel compounds are existing substances with a long history of production, uses and also hazard and risk characterization. Therefore a number of general and targeted legislative controls are currently in place in the EU. Only those that explicitly cover nickel oxide directly or indirectly are listed below.

EU general legislations on dangerous chemicals covering nickel compounds

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations).

Directive 94/27/EC of 30 June 1994 (amending for the 12th time Directive 76/769/EEC) and Directive 94/60/EC of 20 December 1994 (amending for the 14th time Directive 76/769/EEC) relating to restrictions on the marketing and use of certain dangerous substances and preparations (also called Nickel Directive).

EU workplace legislation regarding occupational health and safety

Directive 90/394/EEC Protection of Workers from Risks to Exposure to Carcinogens at Work and, in its codified version, Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work (informal and binding OELs) and Directive 89/391/EC, Framework Directive (called OSH "Framework directive").

In addition to the OEL legislation and to Directive 2004/37/EC, the risks at the workplace arising from exposure to hazardous substances are controlled at European level by a number of Directives (see below) related to the protection of occupational safety and health. They impose minimum standards for health and safety of workers and provide a framework of directions and safeguards to ensure that the risks in the workplace to health from hazardous substances are managed. Most of them cover indirectly nickel and its compounds regarding to their classification as hazardous substances.

- Directive 2001/58/EC on "Safety Data Sheets" and Directive 1999/45/EC relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets).
- Directive 89/656/EEC on the use of personal protective equipment (PPE).
- Directive 92/85/EC (pregnant workers directive) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
- Directive 94/33/EC (young workers directive) on the protection of young people at work.

EU legislation regarding consumer protection

The following is provided for information only and not developed further since this RMOA

only addresses the occupational risk and not the risk for consumers, considered non-existent for NiO particularly.

Regulation (EC) No 552/2009 amending the REACH Regulation (EC) No 1907/2006 as regards to Annex XVII: restrictions concerning substances classified Carc. 1A/1B, Muta. 1A/1B and/or repr. 1A/1B under Annex VI of the CLP which shall not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the general public.

Regarding NiO specifically, Annex XVII of REACH as amended by Commission regulation 552/2009 provides that nickel and its compounds shall not be used:

- in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0.2 µg/cm2/week (migration limit),
- in articles intended to come into direct and prolonged contact with the skin such as: earrings, necklaces, bracelets and chains, anklets, finger rings, wrist, watch cases, watch straps and tighteners, rivet buttons, tighteners, rivets, zippers and metal marks, when these are used, in garments, if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm2 / week,
- in articles referred to in point (b) where these have a nickel-free coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0.5 µg/cm2 / week for a period of at least two years of normal use of the article.

Regulation (EC) No 1223/2009 on cosmetic products that came into force on 11 July 2013 strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector (Nickel and nickel compounds, entries 455 to 460 of the Annex- are included in the Annex II "List of substances prohibited in cosmetic products").

Directive 2009/48/EC on toys' safety: chemicals that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under the CLP Regulation No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

<u>EU legislation regarding protection of the environment and/or covering human health safety through environmental exposure</u>

The following is provided for information only and not developed further since this document only covers the human health risk and not the risk for the environment that is considered already framed by the Danish RMOA.

The following environmental legislations may directly or indirectly cover Ni compounds including NiO:

- Directive 2010/75/EC on industrial emissions (IED) replacing Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC).
- Directive 96/82/EC on the control of major accident hazards involving dangerous substances (Seveso II Directive).
- Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (4th Daughter Directive).
- Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking water).
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive).

- Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (Ground water Directive).
- Directive 2008/105/EC on environmental quality standards in the field of water policy (EQS or Priority Substances Directive).
- Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.
- Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Batteries Directive).
- Directive 2008/103/EC amending Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators as regards placing batteries and accumulators on the market.

Focus on current instruments setting occupational exposure limit values

- *SCOEL recommendation for nickels' occupational exposure limit values (OELs)*

The Scientific Committee on Occupational Exposure Limits (SCOEL) has adopted in June 2001 the following recommendation on indicative OELs for nickel and inorganic nickel compounds.

Exposure to nickel compounds is associated with an increased cancer risk in the lung and nasal cavity, as well as with inflammatory responses/fibrosis in the lung. Since mechanistic data indicate an indirect genotoxic mode of action, nickel is considered a carcinogen with a practical threshold. The proposed OELs are based on protection from inflammatory effects in the lung, but according to available evidence, it should also protect against carcinogenic effects.

Based on available long-term inhalation studies in rats showing severe lung damage (fibrosis and inflammation) and taking into account the differences between rats and humans with respect to particle deposition in the alveolar region (higher deposition in humans as compared in rats due to potential toxicodynamic differences) an OEL of 0.005 mg/m3 is proposed for the respirable fraction (<10 µm).

In addition to chronic inflammation of the lung, the proposed OEL also needs to protect from nickel-induced carcinogenicity. Since epidemiological evidence suggests not only the induction of lung tumours, which may be provoked by respirable particle sizes, but also of nasal tumours, and particles at the workplace are not limited to the respirable fraction, exposure towards inhalable nickel particles needs to be limited for carcinogenic nickel species as well. Based on the available epidemiological studies, an OEL of 0.01 mg Ni/m3 is proposed for the inhalable fraction (<100 µm) of water soluble as well as poorly water soluble nickel compounds (metallic nickel is excluded) in order to protect from nickel-induced carcinogenicity.

- *Indicative occupational exposure limit values (IOELVs) or binding occupational exposure limit values (BOELVs)*

An EU framework for the setting of Indicative Occupational Exposure Limit Values (IOELVs) is defined, *inter alia*, in Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Binding Occupational Exposure Limit Values (BOELVs) are developed, which take into account not only risk assessment, but also socio-economic and technical feasibility and may be then set under the Carcinogens Directive (2004/37/EC).

Any chemical agent for which an IOEL value is set at European level, Member States must establish a national exposure limit value, taking into account the Community indicative limit value, determining its nature in accordance with national legislation and practice.

Any chemical agent for which a BOELV value is established at European level, Member

States must establish an corresponding national binding OEL value which can be stricter, but cannot exceed the Community limit value.

There are currently no IOELV nor BOELV for nickel and its compounds. However a number of Member States have already set formal national OELs for nickel and nickel compounds. Those in force national OELs in force generally group the nickel compounds for which OELs apply as either water-insoluble inorganic nickel compounds or as water-soluble nickel species. Since they are part of national legislation, there may be differences across European countries in relation to the legal or advisory framework which affects the way the limit is interpreted and applied. In addition, the legal duties imposed may vary.

Those national OELs, even close, are not harmonized between Member States and are over the SCOEL recommendation of 0.01 mg Ni/m3, except for the nickel carbonyl species and except for Denmark, such as shown below.

Country	OEL (mg Ni/m^3) as Ni	Comments
France	1.0	Nickel carbonate, Nickel dihydroxyde, Nickel subsulfide, Nickel oxide, Nickel sulfide, Nickel trioxyde: 8-h time weighted average exposure limit value
	0.1	Nickel sulphate
	0.12	Nickel carbonyle
Germany[1]	0.5	metallic nickel, nickel carbonate
	0.5	nickel dioxide, nickel sulphide and sulphidic ores
	0.05	nickel compounds as inhalable droplets (e.g. nickel sulphate, nickel chloride, nickel acetate).
Sweden	0.5	metallic nickel
	0.1 ppm total dust	nickel compounds
	0.007	nickel carbonyl (equivalent to 0.001 ppm)
	0.1 ppm total dust	trinickel disulfide
Poland	0.25	nickel and its compounds
Belgium	1	Nickel metal
	0.2	Insoluble nickel compounds
	0.12 (0.05 ppm)	nickel carbonyl
	0.1	Nickel subsulfide
	1	Nickel sulfide (dust and smoke)
Norway	0.007 (0.001 ppm)	Nickel carbonyl and nickel tetracarbonyl
	0.05	Nickel metal and other nickel compounds
Finland	1	Nickel metal
	0.1	Other nickel compounds (except nickel carbonyl)
	0.007 (0.01 ppm)	Nickel carbonyl (8 h)
	0.021 (0.003 ppm)	Nickel carbonyl (15 min)
United Kingdom	0.5	nickel metal and water- insoluble nickel compounds
	0.1	water- soluble nickel compounds
	0.24	nickel carbonyl
The Netherlands	1.0	metallic nickel
	0.1	nickel oxide, nickel carbonate
	0.1	soluble nickel compounds
	0.12	nickel carbonyl
Denmark	0.05	metallic nickel
	0.05	insoluble nickel compounds
	0.01	soluble nickel compounds
	0.007	nickel carbonyl
Austria	0.05	nickel metal and alloys, nickel sulphide, sulphidic ores, oxidic nickel and nickel carbonates in inhalable dust, as well as any nickel compound in the form of inhalable droplets
	0.05	soluble nickel compounds
Ireland	1.0	insoluble Ni compounds

[1] Reported values were in force until 2006 but are no more valid; new threshold values are currently discussed

	0.1	soluble Ni compounds
	0.12	nickel carbonyl
Italy	1.5	Ni metal
	0.2	insoluble Ni compounds
	0.1	nickel subsulfide
Luxembourg		Cf. German OELs
Portugal	1.0	insoluble Ni compounds
Spain	1.0	insoluble Ni compounds
	0.1	soluble Ni compounds
	0.12	nickel carbonyl

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	X
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

3.1.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

At the date of the RMOA this option is considered as not appropriate. However, this option should be re-assessed in the future for further consideration, taking into account the progress regarding the implementation of the other measure (binding inhalable occupational exposure limit of 0.01 mg and 0.005 Ni/m3 respectively for the inhalable and respirable fractions) or when new data will be available.

3.1.3 Restriction

3.1.4 Other Union-wide regulatory risk management measures

Nickel oxide is used in 7 main applications: manufacturing of NiO-containing catalyst precursors, of Ni-based powders, of Ni-containing electronics and thermally functioning ceramics, of frits for glass and enamel production, of pigments for enamel and ceramics production, of stainless steel and special alloys of NiZn cores and solids from NiO powders. NiO as such is not manufactured within the EU but imported, except NiO produced as an intermediate from other nickel compounds and used for the manufacturing of NiO-containing catalysts precursors and Ni-based catalysts.

For the purpose of the RMOA, a level of risk has been estimated. Based on the considered appropriate DNEL by MSCA-FR (0.01 mg NiO/m^3) which differs from the registrants' DNEL (0.05 mg NiO/m^3), risk is estimated unacceptable for 7 GES over 10. A risk management action is needed and the objective of a risk reduction strategy (RRS) would be to formally set a binding inhalable occupational exposure limit of 0.01 mg NiO/m^3 and to keep exposure below this limit at the workplace.

In conclusion, from the currently identified legislation covering directly or indirectly the risk from the manufacturing and uses of NiO, a risk management option considered relevant for further processing is a binding OEL under Directive 2004/37/EC at 0,01 mg NiO/m^3.

As said previously, Risk management option analyses (RMOA) have been carried out on NiSO4 and NiO as both salts cover substantially the majority of the uses reported for Ni compounds. ***Therefore the conclusion of these two RMOAs is also valid for the other Nickel compounds.***

The French authorities consider that a binding OEL under Directive 2004/37/EC at 0.01 mg/m^3 for nickel compounds are today the adequate risk management options to address the risk identified.

By legally enforcing BOELVs for nickel compounds around 2015 or 2016, Directive 2004/37/EC could be seen as a relevant preliminary measure, where the risk can be technically managed by lowering or if possible preventing exposure. Obligations imposed to operators are clear and could in theory be technically achievable.

It is also considered proportionate as:

- uses/processes for which the risk is considered already managed by a relevant exposure control will be maintained,
- Industry will have to implement without delay significant technical adaptations of processes for at least part of exposure scenarios that are currently seen at risk because of high and uncontrolled exposure,
- a more drastic measure will be decided later on if needed, based on results from on-site surveys and national controls.

The implementation of a BOEL, this measure will also require registrants to revise and update their registration dossiers under REACH with a relevant chemical safety assessment showing that risks are adequately controlled; responsibility under REACH is therefore still kept on the operators.

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
BOEL for all nickel compounds classified as CMR 1A-1B at 0.01 and 0.005 mg/m3 respectively for the inhalable and respirable fractions.	2017	COMMISSION