

The EU approach to nickel compounds classification and its downstream consequences

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Legal Background

- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging entered into force on 20 January 2009
- Incorporates the UN Globally Harmonised System (GHS)
- Replaces the current EU system on classification, packaging and labelling of chemicals has been developed over the last 40 years and is set out in three key instruments
 - Directive 67/548/EEC (Dangerous Substances Directive)
 - 30th and 31st ATP
 - Directive 1999/45/EC (Dangerous Preparations Directive)
 - Title XI of REACH (Classification & Labelling)



CLP – Transitional Provisions

■ 3 phases

- From entry into force: voluntary basis
- 1 December 2010: substances
- 1 June 2015: mixtures

■ Self-classification for substances not listed in Annex VI



Technical Annexes

■ Annexes on technical details

- ➔ **Annex I:** Classification and labelling requirements for hazardous substances and mixtures (hazard based approach); criteria, woe, exp., expert judgment
- ➔ **Annex II:** Special rules for labelling and packaging
- ➔ **Annex III:** List of Hazard Statements (23 languages)
- ➔ **Annex IV:** List of Precautionary Statements (23 languages)
- ➔ **Annex V:** Pictograms
- ➔ **Annex VI:** Harmonised List of Hazardous Substances (translation of the current Annex I of Directive 67/548/EEC)
- ➔ **Annex VII:** Translation Table for classification



Classification of Nickel compounds

■ Danish EPA proposal

- Risk assessment for 5 Nickel compounds
- Proposal for harmonised classification for Nickel compounds

■ Added value for harmonised classification

- Different classification for the same substance
- Lack of data: non classification
- Internal market: If only nickel compounds with epidemiological data are classified as carcinogens this might lead to market distortions, since all the other nickel compounds could be seen as safer and lead to unjustified substitution of the classified nickel compounds. This would not be beneficial for either the regulatory community or the industries concerned.



Category approach

- **Definition:** Technique for grouping closely related chemicals that are then considered as a category.

■ Basic principles:

- Importance of other ions (counter ions)
- Certain compounds may not fit the pattern
- Lack of data should not always be a barrier to classification.

■ Category Approach:

- Not a new approach: e.g.: Directive 73/146/EEC: Arsenic and its compounds; Mercury and its compounds.
- Main assumption: Ni^{++} is responsible for the effects to be assessed.
- Water solubility is used as a measure of similarity between compounds.
- Data available from animal, human and other sources is used to validate that chemicals with similar water solubility in fact have similar toxic effects.
- Collected existing information: epidemiological studies, *in vitro/in vivo* studies, water solubility....



Categorisation of Nickel compounds

■ 8 sub-categories:

- soluble compounds: water solubility $> 10^{-2}$ mol/L
- sparingly soluble compounds: water-solubility in the range 10^{-4} - 10^{-2} mol/L.
- 'insoluble' compounds: water solubility $< 10^{-4}$ mol/L
- nickel oxide and mixed nickel oxides
- metallic nickel and metallic nickel compounds
- nickel carbonyl
- nickel compounds specifically excluded from the category
- nickel compounds not included in the category



EU procedure (2005-2009)

- Experts from Member States/Industry: TC C&L: Exclusion of some compounds (complex nickel oxide compounds, metal-metal compounds) and toxic properties (acute toxicity, irritation /corrosivity)
- TC C&L: recommendation to the Kom
- Inter-service consultation
- Vote by MS: Unanimity
- WTO (TBT agreement): trade impact, flawed science. No new scientific info
- European Parliament: vote against a resolution supported by some MEPs
- Adoption by the Commission/Publication (1st ATP to the CLP Regulation published in September 2009)



Classification of Soluble nickel compounds

- Carcinogen. Cat. 1;
- Toxic for the reproduction. Cat. 2;
- Mutagenic. Cat. 3;
- Toxic by inhalation (prolonged exposure);
- May cause sensitisation by inhalation and skin contact;
- Very toxic for the aquatic organisms;



Classification of Springly soluble nickel compounds

- Carcinogen. Cat. 1;
- Toxic by inhalation (prolonged exposure);
- May cause sensitisation by inhalation and skin contact;
- Very toxic for the aquatic organisms;



Classification of Insoluble nickel compounds

- Carcinogen. Cat. 1;
- Toxic by inhalation (prolonged exposure);
- May cause sensitisation by skin contact;
- Very toxic for the aquatic organisms;



Classification of nickel oxides

- Carcinogen. Cat. 1;
- Toxic by inhalation (prolonged exposure);
- May cause sensitisation by skin contact;
- May cause long-term adverse effects in the aquatic env.



Classification of Ni metal

- Carcinogen. Cat. 3;
- Toxic by inhalation (prolonged exposure);
- May cause sensitisation by skin contact;
- Harmful for the aquatic organisms (nickel powder; particle diameter < 1 mm)



IARC Conclusion

- The Working Group reaffirmed the classification of beryllium and its compounds, cadmium and its compounds, chromium (VI) compounds, and nickel compounds as “carcinogenic to humans” (Group 1). Studies involved complex occupational exposures to a metal and its compounds, making it impossible to separately assess their carcinogenicity” in Lancet in May 2009.
- Confirm the EU methodology



Downstream consequences

- Existing harmonised classification/Self-classification
- Regulation 1272/2008 : Nickel compounds and mixtures containing them have to be labelled with the symbol and hazard and precautionary statements (including for export) + updating the SDS by Dec. 2010
- REACH: registration deadline: 30 November 2010 (CMR, > 1 t/y)
- REACH: CMR substances do not **automatically** need an authorisation to be used or placed on the market.
- All CMR substances, including Nickel compounds, are potential candidates for authorisation, but have to go through a process of nomination, prioritisation and scientific/socio-economic evaluation. Third countries and other stakeholders have the possibility to provide input to the process.



Downstream consequences

- Commission proposal for including Nickel compounds in **Annex XVII of REACH**: prohibits the sale to the general public of Ni compounds or of mixtures containing them in concentration above 0.1%, that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR)
- Does not concern **articles** containing Ni compounds
- Does not concern **metallic form**
- **Cosmetic directive**: prohibits the sale to the general public of cosmetic product containing Ni compounds in concentration above 0.1% (CMR).



Downstream consequences

- **CMR directive: SCOEL limit for Nickel compounds (under discussion)**
- **Workers Protection (Directive 89/391/EEC)**
 - Ensuring the safety and health of workers
 - Risk assessments
 - Principle of prevention including the substitution of the dangerous substances by the non-dangerous or less dangerous
- **Directives: Pregnant and breastfeeding workers, Young workers, Personal work equipment.**



Downstream consequences

- **Hazardous wastes directive**
- **Seveso directive**
- **End of life vehicles directive**
- **Safety of toys directive**
- **Eco-labelling**

But self-classified nickel compounds were already under their scope.



Follow-up

- Commission's openness to discuss further with experts from Nickel industry and from WTO countries the proposed classification of nickel compounds (e.g., bio-elution...).
- Thank you.



Oller et al. 2008.

Inhalation carcinogenicity study with nickel metal powder in Wistar rats:

5. *Intracellular dissolution.* Once inside the target cells, the physico-chemical properties of Ni-containing particles will determine the extent to which Ni (II) ion is released and becomes available at nuclear sites. In the case of nickel metal particles, an oxidation reaction has to occur (rather than simple dissolution) for Ni (II) ion to be released.

