Environmental assessment of metals and inorganics under REACH

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HISTORICAL BACKGROUND

Council Regulation 793/93 provided the framework for the evaluation and control of the risk of existing substances.

Member States were preparing Risk Assessment Reports and they were examined by the Technical Committee and the Commission.

RARs: Zinc, Chromium, Nickel, Cadmium and Aluminium

In addition industry could establish voluntary risk assessment for not prioritised substances.

RARs: Copper, Lead
Paradigm of REACH

- Burden of proof: from public authorities to industry
- From focus on Risk Assessment to Risk Management Measures
- From full testing to selective testing (ITS)
- Attitude: from reactive to pro-active

Key elements of REACH

Registration of manufactured/imported chemical substances > 1 tonne/year (staggered dead-lines over 11 years)
Evaluation of some registered substances
Authorisation for use of substances of very high concern
Restrictions: “Safety net”
Chemicals Agency to efficiently manage the system
Guidance on information requirements

Appendix R.7.13-2: Environmental risk assessment for metals and metal compounds

• Experience from the past assessments included (past examples considered)
• Metal-specific aspects: GD aims to assist the Registrant in how to perform the chemical safety assessment for metals and metal compounds
• Tiered approach advocated → data availability depends on the type of metal/metal compounds
• Some refinements tools applicable only for data rich metals (e.g. Ni, Cu, Zn)
• The guidance does not explicitly cover organometallic compounds unless they act, through their degradation products, as significant source of metal ion
Issues for specific recognition

• Metals are a class of chemicals of natural origin and have been in use for a long time. Subsequently natural background and historical emissions should be taken into account in a Chemical Safety Assessment (CSA).

• Metal data sets can be data-rich, requiring extensive data treatment (e.g. statistical, probabilistic tools);

• Speciation is of paramount importance and highly depends on environmental conditions and chemistry;

• Solubility of certain metals/metal compounds (!)

• The adsorption/desorption behaviour of a metal strongly depends on prevailing environmental conditions.

• Differences in bioavailability
Guidance on effect assessment

Metal-specific points to be considered in hazard assessment

• Data collection (data rich vs. data poor metals)
  - Proper description of the physico-chemical test conditions that influence the speciation and bioavailability whenever possible
  - Strong preference to use measured data of the metal concentrations in the test media
  - For sparingly soluble metals, measured data on the dissolved fraction are always required

• Read-across from other inorganic compound of the same metal (driven by a bioavailable metal fraction that is causing the effect)

• QSAR

• PNEC derivation for metals and metal compounds (data rich vs. data poor metals)
Incorporation of bioavailability in the aquatic effects assessment
(Use of dissolved concentrations, speciation models, Biotic Ligand Models)

Incorporation of bioavailability in the sediment effects assessment
(Organic carbon normalisation, SEM-AVS normalisation)

Incorporation of bioavailability in the terrestrial effects assessment

Bioaccumulation of metals and metal compounds
(Regulation of internal concentration of melats by active regulation and storage)

Secondary poisoning
Risk driven assessment

Exposure assessment

- Local exposure assessment vs. regional exposure assessment
- CHESAR tool
- Guidance on metal-specific aspects in exposure modelling
  
  *(Adjusting multimedia fate models for metals, modelling of adsorption/desorption processes)*

- Guidance on metal-specific aspects in selecting measured data
  
  *(Natural background and historical contamination)*

- Guidance on the incorporation of bioavailability in the exposure assessment
  
  *(The use of the’ ecoregion driven approach’)*
Risk characterisation

It is imperative for metals that both PEC and PNEC are based on similar level of bioavailability

- Guidance on the risk characterisation for the aquatic, sediment and soil compartment
- Guidance for generic PNEC derivation (for sediments and soil EPM when no ecotox data available)
- Bioavailability correction → derivation of more field-relevant and site-specific PNEC

Guidance on the risk characterisation for secondary poisoning
Registration of metals
some statistics

– ECHA has received about 6500 Registration dossiers for metals and metal compounds
– More than 4500 of these dossiers registered for the highest tonnage band (over 1000 tpa)
– Most registrations submitted jointly
– About 450 lead registrants
Key Messages from ongoing REACH evaluations

• Provide sufficient information on substance identity
• Provide adequate justification for QSAR, Read across, grouping and weight of evidence cases
• Ensure good quality for robust study summaries
• Check the exposure scenarios and CSR for consistency and completeness
Conclusions

- Most of the main principles as included in the background papers for the workshop are included in the REACH guidance.
- Their use have to be transparently documented and justified based on solid scientific argumentation in the registration dossiers.
- Their applicability to specific metals and metals compounds may differ depending on the data availability and ‘scope’ of some of the proposed models and hence needs to be assessed on a case-by-case basis.
Thank you for your attention!