



**Asia-Pacific
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OECD Role in International Acceptance of Data

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OECD Role in International Acceptance of Data

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Foundation of OECD Test Guidelines

- **1981 Council Act on the Mutual Acceptance of Data:**
 - “Decides that data generated in the testing of chemicals in an OECD member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other member countries for purpose of assessment and other uses related to the protection of human health and the environment.”
- **1997 Council Act:**
 - Opening MAD to non member economies

Benefit of Mutual Acceptance of Data

- **For governments:**
 - Harmonisation of tests and approaches to testing
 - Ability to share data across countries
 - Comparable level of human health and environmental protection across countries
 - Reduction in animal use and suffering
- **For industry:**
 - Avoids duplicative testing
 - Reduction of non-tariff barriers to trade

Total savings to governments and industry exceeds €150 million per year

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Cooperative Chemical Assessment Program

- Elaboration and dissemination of OECD-wide agreed conclusions on hazards of existing industrial chemicals
- Save resources, increase the number of international assessments
- Use of initial assessments by member countries and chemical industry for priority setting, classification, risk assessment, risk management
- More than 1500 chemicals have been assessed

www.oecd.org/env/hazard

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Cooperative Chemical Assessment Program

- Assessment reports for metals are available for antimony, cadmium, cobalt, copper, nickel and zinc
- These assessments provide countries with high quality and often very extensive effects and risk data sets for key metals and their compounds, useful for national chemicals management programmes
- The assessments have highlighted a number of specificities not addressed (yet) by existing OECD guidance documents

Examples of such specificities are: Natural occurrence, essentiality, speciation and bioavailability, acclimatisation, bioaccumulation regulation...

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OECD Workshop on Metals Specificities

- Objectives
 - Share regional experience in dealing with metal specific environmental hazard assessment
 - Review existing guidance for metals specific hazard assessment concepts
 - Understand and apply metal and inorganic specific tools and approaches
 - Identify opportunities for harmonisation of approaches across countries/regions

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Main Recommendations

- **Bioavailability** should be taken into account for hazard and risk assessment in order to focus on interspecies sensitivity
- A tiered approach can be used, ensuring that first tier assessments use effects data where bioavailability is maximised
- **Biotic Ligand Models (BLMs)** can be used to estimate bioavailability
- For some metals, one parameter dominates and a simplified bioavailability correction model would be sufficient

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Main Recommendations

- The **mechanistic understanding** of bioavailability models would increase their regulatory acceptance
- Bioavailability models have a **specific applicability domain** and have to cover soil/water parameters and background relevant for the region where they are applied
- **Checks with regional specific species** may be needed

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Main Recommendations

- **Building blocks for environmental effects assessment strategies for metals were identified with attention on:**
 1. Aspects specifically for metals (e.g. data relevancy criteria and data normalisation)
 2. Aspects more generically for data rich substances (data aggregation, species sensitivity distributions, ...). More concept and guidance development is needed for the soil and sediment compartments
 3. Release and toxicity of metal ions from substances are the basis for read-across

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Main Recommendations

- **The potential for bioaccumulation and bioconcentration raised specific concern.**
 - BCFs (and BAF) are inversely related to environmental concentrations
 - Use of a single value for assessing risks from secondary poisoning has to be carefully considered
 - Measures of tissue concentrations along the food chain provide a useful way to assess secondary poisoning

Need to improve the interpretation of BCF and BAF data for metals as well as the assessment of secondary poisoning mechanisms and pathways

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OECD Guidance on Grouping of Chemicals, Second Edition

- **Grouping of chemicals:**
 - Formation of a chemical category or identification of (a) chemical analogue(s) to extend the use of measured data to similar untested chemicals, providing reliable estimates that are adequate for classification and labelling and/or risk assessment without further testing.
 - When grouping metal compounds the main assumption is that toxicological and ecotoxicological properties are likely to be similar or follow a similar pattern as a result of the presence of a common metal ion.

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OECD Guidance on Grouping of Chemicals, Second Edition *(continued)*

- **Grouping of chemicals: *(continued)***
 - The bioavailability of the metal ion (or a redox form of this ion) at target sites in addition to the metal's potency, will determine the occurrence and severity of effects
 - The most simplistic approach assumes that the metal ion availability will normally be reduced with decreasing water-solubility and consequently present a reduced bioavailability

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Read-across: Factors to be Considered

- Chemical speciation and valence, different valences may result in differences in MoA
- Organometallic compounds might have a different MoA than metal ion(s)
- Metals (elemental form, zero valence) might have different properties than metal ions
- Effect of some metal containing UVCB are not adequately described by their metal content
- Route of exposure may result in different MoA, toxicity, and effects

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Read-across: Factors to be Considered

- The crystalline structure of insoluble metal compounds could influence the hazard profile
- Particle size of the substance influences the deposition behaviour in the respiratory tract, rates of dissolution and corrosion
- Counter ions might influence the toxicity

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Guidance on Selecting a Strategy for Assessing the Ecological Risk of Organometallic (OM) and Organic Metal Salt (OMS) Substances Based on Their Environmental Fate

- Help determine whether an OM or OMS should be assessed as part of inorganic moiety assessments or individually in its original form
- A step by step approach for examining available information on environmental fate and toxicity of the substances and their transformation products to identify the best path forward for ecological risk assessment
- This document informs the planning/grouping/prioritization of OM and OMS assessments

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Content of the Guidance Document

- OM and OMS can potentially transform (e.g. dissolve/dissociate/degrade) under environmental conditions to release the following transformation products: organic moiety, inorganic or metal moiety, new OM
- There are many intrinsic properties (e.g. classifications of metals/ligands) and extrinsic properties (e.g. pH, redox potential) that can influence the environmental transformation of OM/OMS

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Content of the Guidance Document

(continued)

- Various considerations are presented to help the evaluator determine which are the predominant transformation processes and products for an OM/OMS, if any, which in turn informs the selection of an assessment strategy
- The approach can be limited by the extent of empirical data availability, but the guidance provides options for dealing with data scarcity
- Document includes illustrative examples using actual OM and OMS

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Development of Environmental Hazard and Risk Assessment Guidance

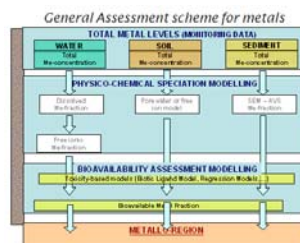
- **Aim:** "to translate hazard and risk assessment guidance for metals and inorganics that is being developed/updated by BIAAC members (metals, mining, inorganics sector), into an accessible format that can be used by all OECD members"



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Proposed OECD Guidance

- **Block 1 (principal work components of this project):**
Data handling, read-across and bio-availability correction
- **Block 2 (to be introduced in a special workshop session):**
Bioaccumulation and bio-magnification assessment for metals and inorganic metal compounds
- **Block 3 (potential phase 2 follow-on work):**
Specific risk assessment/characterisation approaches and sensitivity assessment techniques



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Guidance on the Incorporation of Bioavailability Concepts for Assessing the Chemical Ecological Risk and/or Environmental Quality Standard Setting of Metals and Inorganic Metal Compounds

- Provide insight in the key scientific principles
- Provide a tiered approach and a step-by-step explanation that can be used to implement bioavailability into a risk assessment context for the water, sediment and soil compartments.
- Key message: Bioavailability correction provides an efficient solution that allows one to avoid costly local testing/local-specific assessment

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Benefits for Countries

- Application of metal-specific concepts can lead to more environmentally relevant standards, greater environmental protection and a reduction in costs of implementation
- Tools and concepts have been peer-reviewed and used extensively in developing metals effects files
- Formal inclusion of the concepts into OECD guidance would make it easier for other countries to incorporate them into their own regulatory systems
- Guidance would provide OECD countries the certainty that all metal files have been developed and scrutinised on a commonly agreed basis - thus encouraging the use of these extensive data sets more widely.

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