



Metal-specific tools and use communication

Eurometaux

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Outline

1. Basic aspect and challenges for metals
Why are metals and inorganic (metal) compounds different from organic substances in relation to Hazard and Risk assessment/characterisation for chemicals management
2. Methodologies for assessing hazards and risk from metals and inorganic (metal) compounds in the CSR
 - ✓ MERAG & HERAG
 - ✓ ECHA metals guidance document
 - ✓ CLP guidance on the classification of metals: Annex 4
3. Metal industry tools & useful guidance notes
 - ✓ Exposure tools (MEASE)
 - ✓ SPERCs
 - ✓ Multi-metallic questionnaire
 - ✓ MECLAS

1. Introduction

- Metals and inorganic metal-compounds possess properties that make them “different” from organic substances
- Require a number basic aspects and challenges to be considered:

- Chemicals of **natural origin** and in use for a long time

*natural
background*

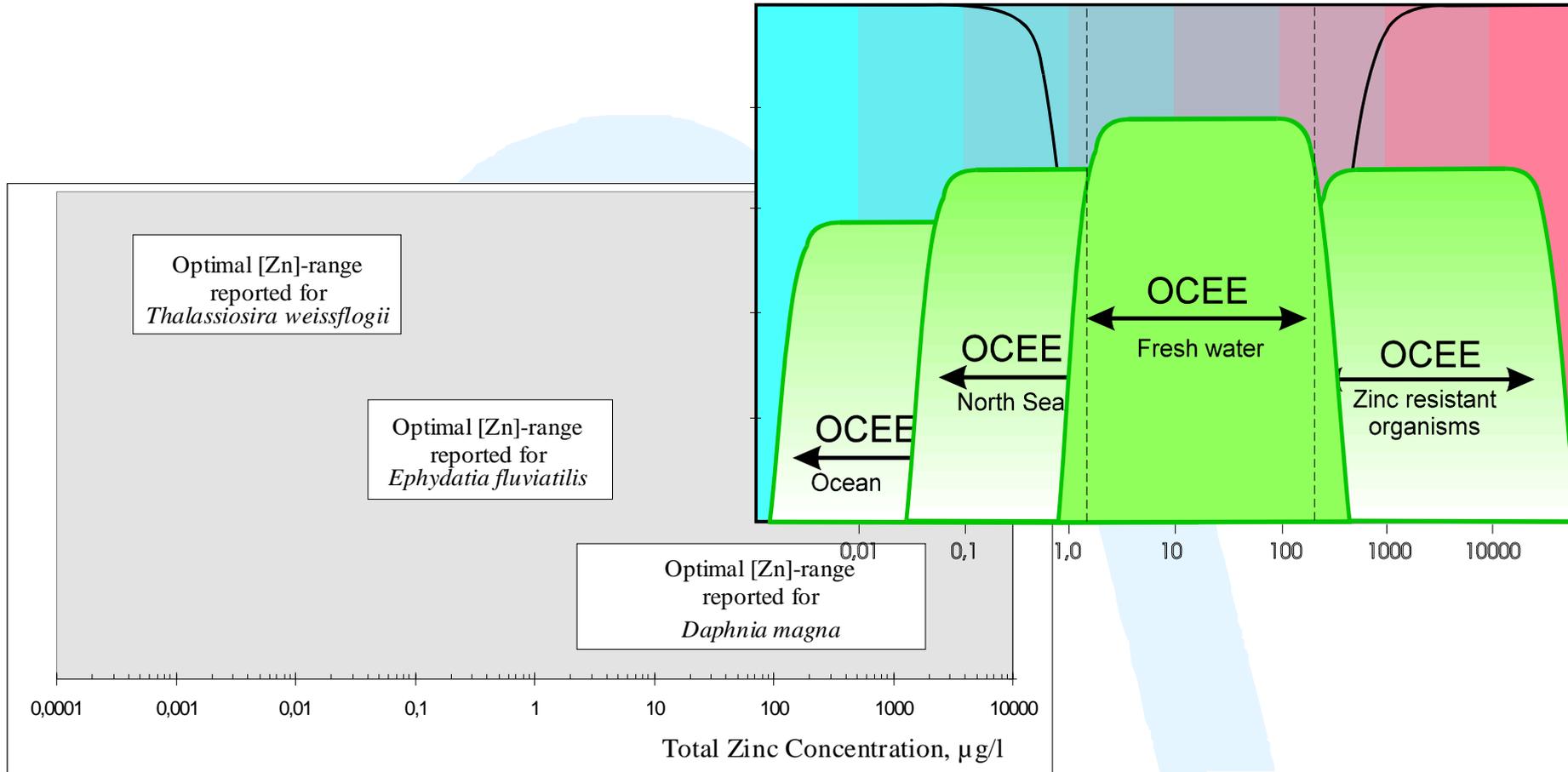
*historical
emissions*

- Data sets can be (very) **data-rich** <-> **data poor**
- **Chemical Speciation** is of paramount importance
- **Adsorption/desorption behaviour** of a metals highly variable
- **Differences in (bio)availability**

- Some metals are very **difficult to test**
- Metals can be **toxic** for several endpoints while equally being an **essential** element
- Metals are used in **complex materials** that may change their properties including their hazard profiles...
- Metals may change from a **bioavailable form** to **non-bioavailable** form
- Some metals have **good monitoring** data sets

1. Introduction

Importance of natural background *for effects assessment* ?



Metals Risk assessment and characterisation are complex
Requiring a number of iterations of data



2. Methodologies for the assessing hazards and risk for metals and inorganic (metal) compounds

Introduction

The increasing regulatory challenges in the metals and mining industry:

- ✓ chemicals management
- ✓ hazard classification
- ✓ environmental, health & quality standards
- ✓ ...



The need for globally harmonised state-of-the-art approaches in the metals and mining industry for Hazard and risk assessment

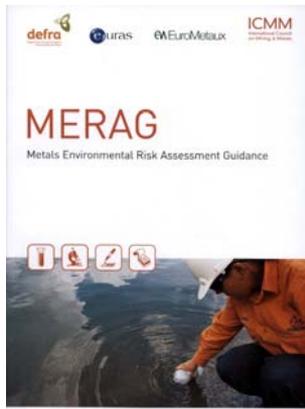


Consolidation of experience and learning lessons in risk assessment of metals (a.o. ESR) in two projects (2005-2008):

- **MERAG : Metals environmental Risk Assessment Guidance**
- **HERAG : Metals Health Risk Assessment Guidance**

Metals Environmental Risk Assessment Guidance (MERAG)

HEalth Risk Assessment Guidance (HERAG)

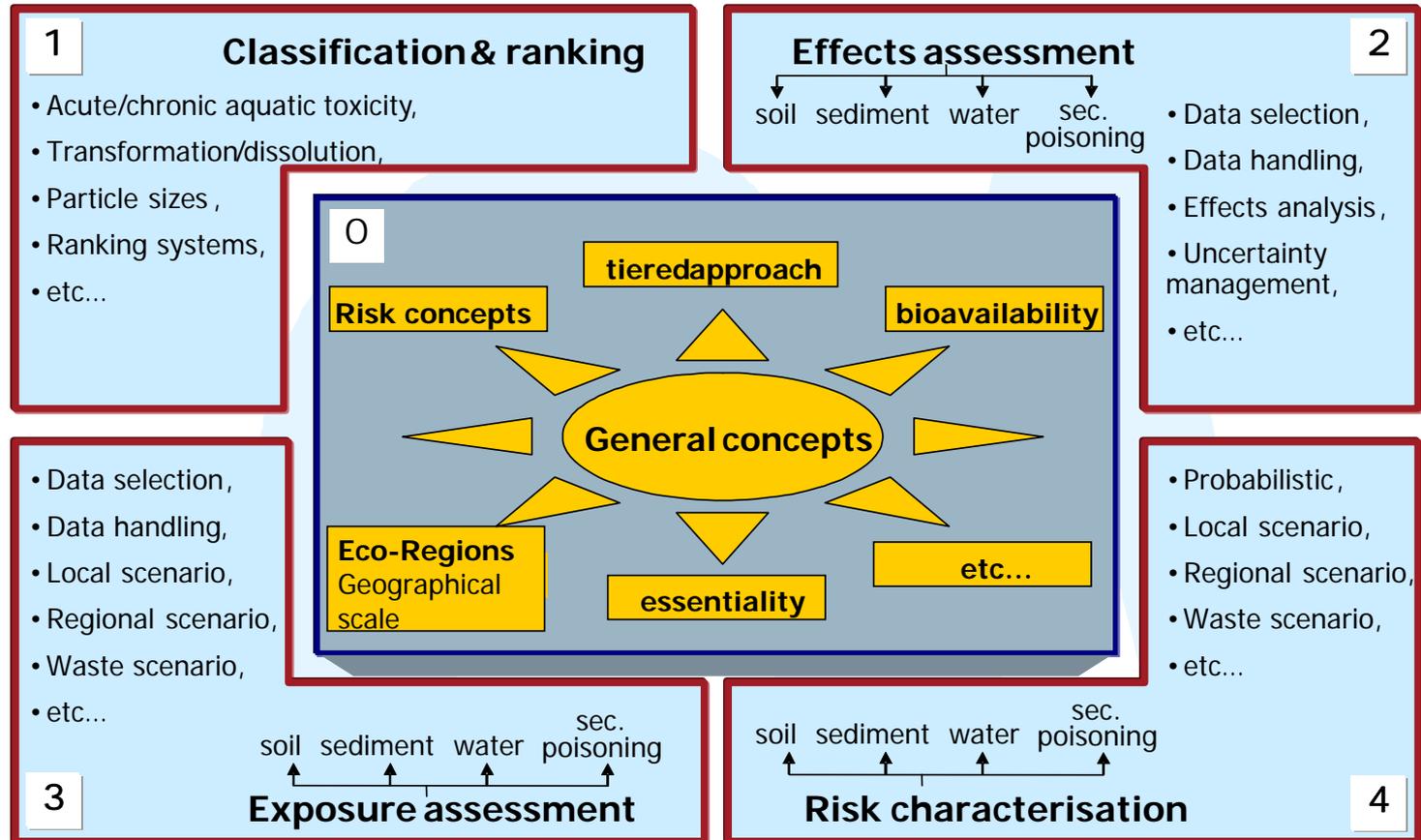


- Fact sheet 1: Risk characterization
- Fact sheet 2: Exposure assessment
- Fact sheet 3: Effects assessment
- Fact sheet 4: Marine risk assessment
- Fact sheet 5: Bioavailability water sediment
- Fact sheet 6: Bioavailability soil
- Fact sheet 7: Uncertainty analysis
- Fact sheet 8: Classification



- Fact sheet 1: Assessment of occupational dermal exposure and dermal absorption
- Fact sheet 2: Assessment of occupational inhalation exposure and systemic inhalation absorption
- Fact sheet 3: Indirect exposure via the environment and consumer exposure
- Fact sheet 4: Gastrointestinal uptake and absorption, and catalogue of toxico-kinetic models
- Fact sheet 5: mutagenicity
- Fact sheet 6: Quality screening procedures of health literature
- Fact sheet 7: Essentiality
- Fact sheet 8: Choice of assessment factors

2. Methodologies for the hazards and risk from metals and inorganic (metal) compounds: MeRAG



2. Methodologies for the hazards and risk from metals and inorganic (metal) compounds

- The MERAG, HERAG and metals annex principles have been applied in the metals sector consortia in both the context of REACH and CLP
- In order to ensure that metals and inorganic (metal) compounds are assessed in a correct manner, industry has extensively invested in:
 - Training of industry (EU and beyond)
 - Training of consultants specialised in Metals
 - Authorities

Communication
up and down

3. Metal industry tools & other useful guidance notes

Metal Environmental Release Categories: SPERCs

- A multi-metallic questionnaire to gather information on uses and exposure in a harmonised way

○ Specific Emission Release Categories (SPERCs) for metals

- based on large underlying database of measured release factors (air and water)
- Reviewed against the 2010 REACH registration data for metal and metal compounds
- Background guidance document explaining the approach followed is also available

Life-cycle stage	Substance	Linked to ERC	Default release to air (incl.RMMs)	Default release to water (incl. on-site RMMs)	SPERC fact sheet
Production	metal	1	0.03 %	0.01 %	Download version 1.2
Production	metal compounds	1	0.03 %	0.02 %	Download version 1.1
Formulation	alloy	2,3	0.007 %	0.003 %	Download version 1.1
Formulation	metal compounds	2,3	0.004 %	0.5 %	Download version 1.1
use-shape	metal	12a	0.02%	0.01 %	Download version 1.2
Use-intermediate	metal/alloy	6a	0.03 %	0.02 %	See SPERC Production of metal compound
Use-Metallic coating	metal + metal compounds	5	0.4 %	0.6 %	Download version 1.1
Use-batteries	metal + metal compounds		0.002 %	0.003 %	Download version 1.1
Use	metal compounds	4-7	0.1 %	0.6 %	Download version 1.1 (further refinements are ongoing)
Service life	metal	8-11	Use ERC	Use ERC	
Service life	metal compounds	8-11	Use ERC	Use ERC	
Waste	metal				Under development
Waste	metal compounds				Under development

3. Metal industry tools & guidance documents

Exposure modeling tool: MEASE

1st tier screening tool for the estimation of occupational inhalation and dermal exposure to metals and inorganic substances at the workplace: MEASE

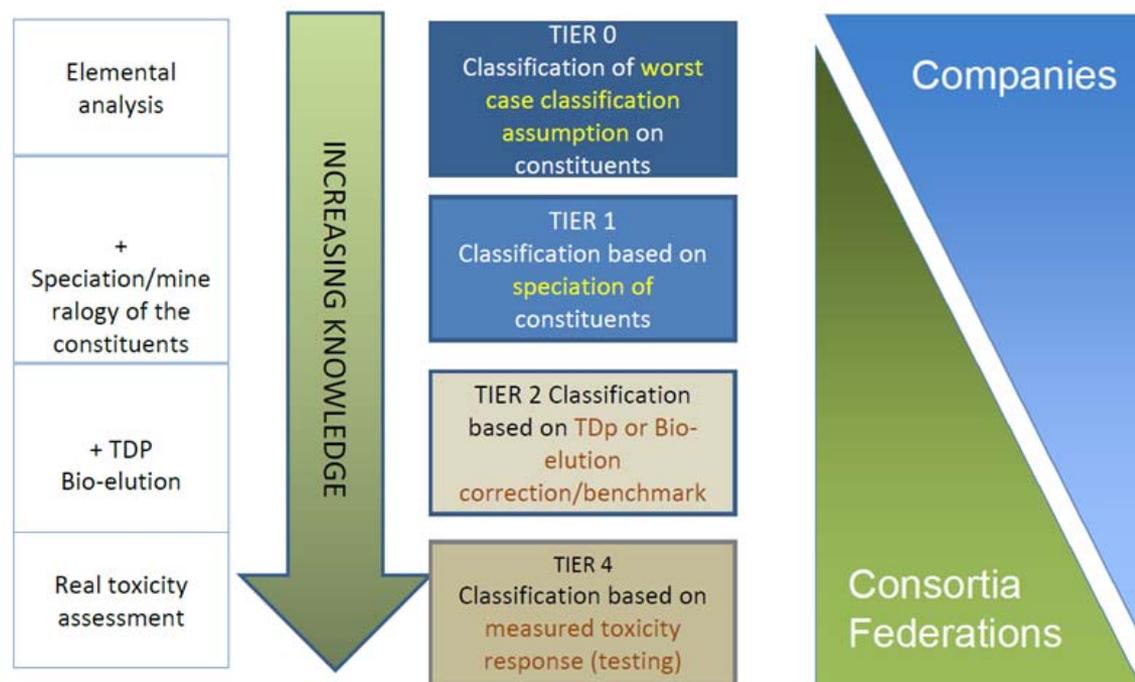


- Provide conservative estimates of exposure to identify (screen) unproblematic PROCs to save resources
- Specific assumptions and possible deviation of default (generic) parameters adapted to metals and inorganics
- Referred to in ECHA Guidance R14

3. Metal industry tools & guidance document

Hazard Classification : MeClas

- Inorganic sector industry has many complex metal materials
- For all these UVCB substances a hazard classification has to be derived either for the purpose of REACH and/ or CLP
- An internet based tool was developed to allow the correct assessment of the classification



4. Useful links

- ☞ REACH Metals gateway: www.reach-metals.eu
 - ✓ Central info-point to retrieve information on EM network metals consortia
 - ✓ Links to the tools or hyperlinks to tools and guidance notes addressed in this presentation
 - ✗ SPERCs
 - ✗ MEASE
 - ✗ Multi-metallic questionnaire
- ☞ ICMM HERAG and MERAG principles and fact sheets
 - <http://www.icmm.com/page/1185/metals-environmental-risk-assessment-guidance-merag>
 - <http://www.icmm.com/page/1213/health-risk-assessment-guidance-for-metals-herag>
- ☞ MECLAS: www.MECLAS.eu
- ☞ ECHA Guidance documents
 - ✓ R13-2 Environmental risk assessment of metals and metal compounds:
http://echa.europa.eu/documents/10162/17224/information_requirements_r7_13_2_en.pdf
 - ✓ R14 occupation exposure estimation
http://echa.europa.eu/documents/10162/17224/information_requirements_r14_en.pdf
 - ✓ Guidance on the application of the CLP criteria
http://echa.europa.eu/documents/10162/17217/clp_en.pdf