



Eurometaux
European Association of Metals

ICMM
International Council
on Mining & Metals

METALS ENVIRONMENTAL RISK ASSESSMENT GUIDANCE

MERAG

Overview 2016



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Main front cover image

Chilubi Island, Zambia

The light-toned sand island stands out from the dark waters of Lake Bangweulu. The waters are crowded by areas of aquatic vegetation and wetland (reeds, papyrus, and floating grass). Lake Bangweulu is rich enough to supply fish for the copper-mining towns to the west.

Foreword

The Metals Environmental Risk Assessment Guidance (MERAG) document was published in 2007 as the result of extensive collaboration between industry, the scientific community and governments to consolidate the knowledge that had been built on how best to assess metals.

Since its publication, MERAG has been instrumental in ensuring that minerals and metals are produced and used safely around the world. This spans a broad range of applications: from its use in official guidance to the EU's landmark Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach) regulation in Europe, to the UN's Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and even the regulations that govern marine transport of cargoes.

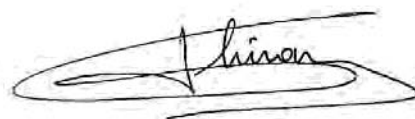
MERAG set out the critical requirements for appropriate assessment of metals in a series of fact sheets, which were peer reviewed by leading independent scientists. These were intended to be living documents in recognition that the science would evolve as concepts were applied and refined, and new approaches would emerge.

Accordingly, over the past two years we have renewed the collaboration that gave rise to MERAG, screened the original document and conducted a thorough update of the fact sheets as needed. Six of the original eight have been updated and a new fact sheet added – on applying a weight-of-evidence approach. These have all been subject to independent review once more, and all are now freely available for all to use, adapt and apply to their own scenarios at their operations or in creating their policies and regulation.

As before, our intention is that this guidance will evolve as new concepts develop and experience is gained in applying them. Accordingly, we welcome feedback and encourage the users and readers of MERAG to provide us with examples of its application that we can share as appropriate.



Tom Butler
Chief Executive Officer, ICM



Guy Thiran
Director-General, Eurometaux

Introduction

Understanding the potential environmental risks posed by metals is a key factor in ensuring that they are produced and used safely. For mining and metals companies this is an important aspect of materials stewardship and of chemicals management, whereby companies are extending their interest beyond the plant gate and considering the whole life cycle of their materials.

Background

The Metals Environmental Risk Assessment Guidance (MERAG) presents the most advanced and appropriate scientific concepts for assessing the risk posed by the presence of metals and inorganic metal compounds in the environment.

The MERAG project was initiated in 2004 in order to consolidate the advancement in science for minerals and metals risk assessment that was taking place around the globe – most notably in the EU – at that time. A consolidated background publication accompanied by a series of peer-reviewed fact sheets was released in 2007. It was acknowledged that MERAG would need to be a living document to be able to incorporate the further advancements in science that would take place. Indeed, the eight years since it was published have seen considerable progress in metals-specific science and the sophistication of its application.

In that time, the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) has been introduced by many countries around the world; the landmark Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach) regulation in the EU has been implemented, with many other countries following a similar path; and, most global jurisdictions are now implementing more rigorous systems of hazard and risk assessment. All of this experience has led to new scientific concepts, more user-friendly tools and the generation of an enormous amount of substance-specific data that can be universally applied.

About MERAG and this overview

This publication is intended as a brief introduction to MERAG.

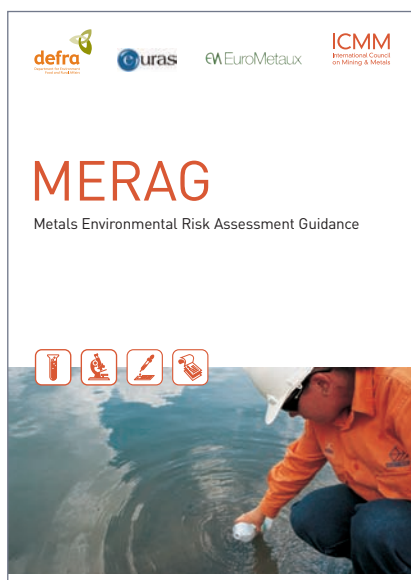
The target audience for the guidance is professionals in the field of environmental science, particularly those working with decision-makers in the public or private sectors. MERAG's goal is to deliver the basic material to make risk assessments for metals more ecologically relevant – and to provide the reader with material to adapt to their local, national or regional assessments.

The aim of this update is to promote the advances that have been made since the original publication in 2007, and to encourage further integration of metals-specific approaches into risk assessment frameworks. Since the original guidance was released, MERAG concepts have been applied successfully in risk assessments around the world. Indeed, this process has been continual since 2007 with MERAG incorporated into a number of national frameworks or assessment systems. For example:

- In the European Union, MERAG was used as a basis for developing guidance on how to assess metals under Reach.¹ This was borne out of collaboration with the European industry and has yielded a wealth of data and knowledge that has subsequently been used to inform decision-making globally.
- Involvement of United States Environmental Protection Agency (EPA) staff in reviewing the original MERAG fact sheets in 2007 meant that MERAG became a key resource in the development of EPA's Framework for Metals Risk Assessment.
- Annexes 9.7 and 10 of the United Nations' GHS for hazard classification and labelling provide specific guidance on assessment of metals and inorganic metal compounds. Recently, a UN correspondence group has been applying advances contained in the MERAG fact sheets to update guidance for long-term aquatic toxicity assessment for metals.

¹ European Chemicals Agency, *Guidance on Information Requirements and Chemical Safety Assessment. Appendix R.7.13-2: Environmental Risk Assessment for Metals and Metal Compounds*, Helsinki, European Chemicals Agency, 2008. http://echa.europa.eu/documents/10162/13632/information_requirements_r7_13_2_en.pdf.

- In 2015, MERAG was agreed to be a relevant basis for guidance development by the OECD. Work is proceeding in its Task Force on Hazard Assessment, which has identified those concepts most suitable for inclusion into OECD resources and reviewed initial draft guidance.
- The year 2015 also saw the first activity to build capacity for improved assessment of metals delivered through the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue. A workshop held during the Third Senior Officials' Meeting in the Philippines in August provided training to over 60 regulatory and industry personnel from 15 APEC economies.
- MERAG is an important element of meeting industry commitments to the UN's Strategic Approach to International Chemicals Management – as described in the ICMM *Minerals and Metals Management 2020* action plan.²



MERAG was originally released in 2007 to improve ecological risk assessment for metals

Use of data developed from MERAG to comply with EU Reach regulation

“For the International Molybdenum Association, MERAG provided the vital route map to generate its environmental risk assessment for molybdenum and 11 molybdenum compounds for compliance with the EU Reach regulation. As a substance that did not already have an EU voluntary risk assessment in place prior to Reach, the MERAG framework and its detailed guidance very significantly both facilitated and accelerated the core task of comprehensively risk assessing molybdenum in the environment, as well as assisting to identify the research and data components that were needed for this robust process.”

“The resulting molybdate data set³ subsequently received Mutual Acceptance of Data status by the OECD in 2014. Such status is a valuable asset to the molybdenum industry at regulatory level as it enhances the international relevance of the data set to include OECD member countries, where it is the starting point for environmental legislative developments or reviews about molybdenum. MERAG was a key enabler for these achievements.”

Sandra Carey, HSE Executive
International Molybdenum Association

This practical application of MERAG has naturally led to further research and refinement of concepts and often the development of user-friendly tools and models to apply them. It has also led to the generation of large amounts of high-quality data. The 2016 update of MERAG takes all of that experience into account. It is an extensive update that builds upon rigorous scientific development, practical experience and knowledge of how to best handle large amounts of data.

The critical concepts are presented in the series of independently reviewed MERAG fact sheets. These are described in Section 2 of this document and can be freely downloaded from www.icmm.com or www.arche-consulting.be. It is hoped that these concepts will enable regulators and scientists to create new or adapt local, national or regional risk assessment systems accordingly.

² ICMM, *Minerals and Metals Management 2020: Responsible and Integrative Chemicals Management in the Mining and Metals Supply Chain*, London, ICMM, 2009. www.icmm.com/document/584.

³ http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?id=5c88d62f-4401-4cad-b521-521a4bd710f3.

Introduction

Concept development and review process

MERAG represents the state-of-the-science for metals risk assessment. The concepts and guidance laid out in the fact sheets have been developed by researchers – both within the metals industry and in the broader community of academic and commercial environmental toxicologists and chemists.

To ensure that MERAG is an unbiased representation of the available science, the project has been run in partnership with the UK government's Department for Environment, Food & Rural Affairs (DEFRA). This partnership has been important in providing objective review and ensuring that the guidance has relevance for regulatory decision-making.

The updated fact sheets were reviewed at an open workshop in November 2014 with extensive input from the UK's Hazardous Substances Advisory Committee, Government of Canada and several EU member states. Further to this process, in 2015 members of the OECD's Task Force on Hazard Assessment have reviewed many MERAG concepts in the process of creating their own guidance based upon it.

This process is intended to provide confidence in the approaches outlined and ensure their suitability for application globally.

The future of MERAG

We recognise that science will not cease to develop upon the release of this guidance. It is our intention that this publication, through periodic update and addition to the fact-sheet series, will continue to provide a solid basis for improvement in risk assessment processes for metals, and we encourage all parties to use the material freely.

We also welcome feedback and encourage the users and readers of this guidance document to provide us with further examples of best practice, which we can share as appropriate in future documents or through other knowledge-sharing activities.

“The Hazardous Substances Advisory Committee welcomed the opportunity to assist Eurometaux and ICMM in updating the MERAG documents, building on a partnership that was first established in 2005. The MERAG fact sheets constitute an important guide to current thinking regarding the most appropriate ways of conducting environmental hazard and risk assessment for metals.”

Lesley Stanley
UK Hazardous Substances Advisory Committee



1

The need for specific approaches

Escondida Mine, Chile

The image displays shortwave infrared bands and highlights the different rock types present on the surface, as well as the changes caused by mining.

The need for specific approaches

Minerals and metals are natural components of the earth and exist in many forms – each with specific chemical characteristics that define their interaction with the environment and with living organisms.

What makes metals different?

The properties of metals and other natural inorganic substances that set them apart from organic chemicals include their natural occurrence, essentiality, homeostatic control mechanisms and acclimatization to diverse natural environments.

Understanding the hazards and risks posed by metals and inorganics, and managing them adequately, requires specific knowledge and scientific concepts because of these unique properties.

Examples of the considerations that must be taken into account for metals risk assessment are outlined in Table 1 (adapted from United States Environmental Protection Agency 2007).⁴

Implications for risk assessment

Questions related to the specific impact of metals on the environment and the need to establish ready and accessible metal-specific tools and data sets in order to make informed, science-based decisions have been raised by many stakeholders – including governments, nongovernmental organisations, companies and industry associations.

The field of regulatory risk assessment evolved primarily from the study of organic chemicals – notably due to concerns over the use of dioxins and polychlorinated biphenyls from the 1960s onwards. Consequently, the majority of risk assessment guidance and scientific frameworks were created for organic chemicals.

In many cases, such guidance and frameworks fail to adequately address specific characteristics that must be taken into account to perform accurate hazard and risk assessments for inorganic substances, including minerals and metals.

MERAG presents the result of extensive and current research activities and builds on the foundations of metals risk assessment that began over 20 years ago.

“We appreciated the constructive partnership with the metals sector in building appropriate risk assessment and hazard classification guidance for metals and metal compounds, a group that is technically not easy to deal with. The MERAG and HERAG publications certainly fostered the scientific/technical debate in the EU and were a good basis for ECHA to build practical guidance.”

Jack de Bruijn
Directorate of Risk Management,
European Chemicals Agency

⁴ United States Environmental Protection Agency, Framework for Metals Risk Assessment, Washington, DC, US Environmental Protection Agency, 2007. <http://www2.epa.gov/risk/framework-metals-risk-assessment>.

Table 1: Key properties of metals and inorganic metal compounds that dictate the necessity of specific assessment concepts

Properties of minerals and metals	Implications for risk assessment
<p>The environmental chemistry of metals strongly influences their fate and effects on human and ecological receptors</p>	<p>Unlike organic chemicals, metals are neither created nor destroyed by biological or chemical processes. However, these processes can transform metals from one species to another (valence states) and can convert them between inorganic and organic forms. Metals also are present in various sizes, from small particles to large masses.</p> <p>The form of the metal (chemical species, compound, matrix and particle size) influences the metal's bioavailability, fate and effects. The form of the metal is influenced by environmental properties such as pH, particle size, moisture, redox potential, organic matter, cation exchange capacity and acid-volatile sulphides.</p> <p>Certain forms of metals are used for evaluating exposure and effects. For example, the free metal ion is used for exposure assessments based on competitive binding of metal to specific sites of action. Information developed on the fate and effects of one form of a metal may not be directly applicable to other forms.</p>
<p>Metals are naturally occurring constituents in the environment and vary in concentrations across geographic regions</p>	<p>Humans, other animals and plants have evolved in the presence of metals and are adapted to various levels of metals. Many animals and plants exhibit geographic distributions that reflect variable requirements for and/or tolerance to certain metals. These regional differences in requirements and tolerances should be kept in mind when conducting toxicity tests, evaluating risks and extrapolating across regions that differ naturally in metals levels.</p> <p>Depending on the purpose of the risk assessment, care should be taken to understand and distinguish among naturally occurring levels, current background levels (ie natural and anthropogenic sources) and contributions to current levels from specific activities of concern.</p>
<p>Some metals are essential for maintaining proper health of humans, animals, plants and micro-organisms</p>	<p>Adverse nutritional effects can occur if essential metals are not available in sufficient amounts. Nutritional deficits can be inherently adverse and can increase the vulnerability of humans and other organisms to other stressors, including those associated with other metals.</p> <p>Excess amounts of essential metals can result in adverse effects if they overwhelm an organism's homeostatic mechanisms. Such homeostatic controls do not apply at the point of contact between the organism and the environmental exposure.</p> <p>Essentiality thus should be viewed as part of the overall dose-response relationship for those metals shown to be essential, and the shape of this relationship can vary among organisms. For a given population, "reference doses" designed to protect from toxicity of excess should not be set below doses identified as essential. Essential doses are typically life-stage and gender specific.</p>

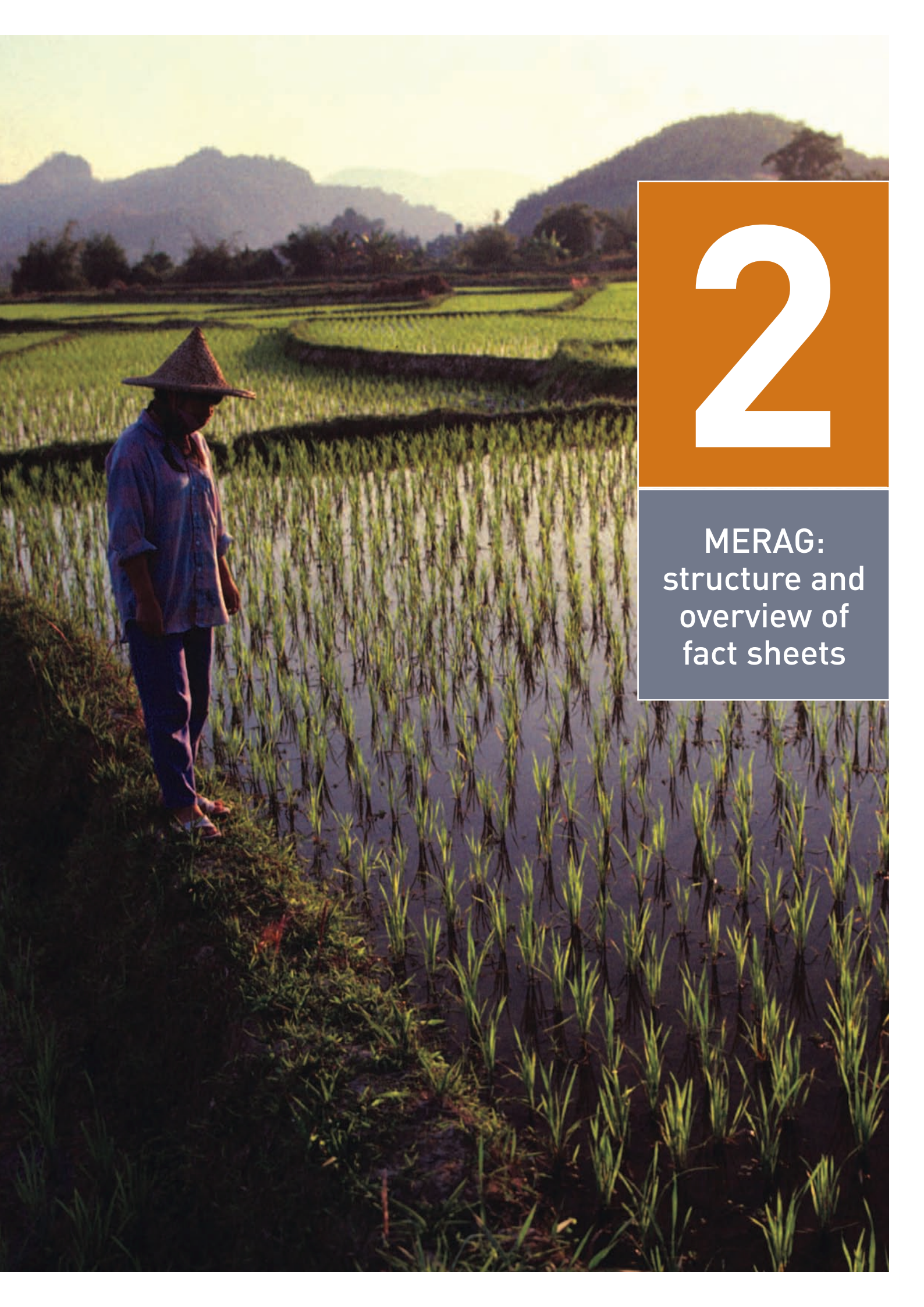
Table continued
on page 10

The need for specific approaches

Table 1: Key properties of metals and inorganic metal compounds that dictate the necessity of specific assessment concepts *continued*

Properties of minerals and metals	Implications for risk assessment
Many metals are data rich	Collecting data and screening them for environmental or human health risks can be complex, yet it provides comprehensive information to help make science-based decisions. Many governments and regulators have therefore underscored the need to improve concepts and assessment tools for metals as well as to ensure the availability and accessibility of screened data sets.
All environmental media have naturally occurring mixtures of metals, and metals are often introduced into the environment as mixtures	<p>Some metals act additively when they are present together, others act independently of each other, and still others are antagonistic or synergistic. Such interactions are important aspects of assessing exposure and effects; this is one of the latest areas of scientific focus and will be reflected in future MERAG publications.</p> <p>Interactions among metals within organisms may occur when they compete for binding locations on specific enzymes or receptors during the processes of absorption, excretion or sequestration, or at the target site. The presence and amount of other metals are important when conducting and interpreting laboratory tests.</p>

“Many governments and regulators have underscored the need to improve concepts and assessment tools for metals as well as to ensure the availability and accessibility of screened data sets.”



2

MERAG:
structure and
overview of
fact sheets

MERAG: structure and overview of fact sheets

MERAG addresses the specific properties of metals and other naturally occurring inorganic substances. It summarizes existing knowledge and approaches and describes how they can be built into accepted frameworks for risk assessment.

Themes and building blocks

MERAG's fact sheets have been created to address the key challenges for the assessment of metals as outlined in the previous section.

The guidance is structured so that metals-specific concepts are built into the traditional building blocks needed for environmental risk assessment (illustrated in Figure 1). They can be summarised as:

General concepts and principles

Environmental risk assessments of metals are characterised by a set of unique properties that require additional specific considerations – for example, they are naturally occurring substances, some of them are essential, etc. The purpose of this building block is to give an overview of the main concepts and scientific principles underlying or supporting the metal-specific methodologies that have been developed in the guidance document. Concepts such as natural background, essentiality and bioavailability are discussed in depth.

Classification

This building block is related to issues of the classification or prioritisation of metals. Guidance is given on how to interpret transformation and dissolution data and which effects data are suited for incorporation in classification or prioritisation schemes.

Effects assessment

This building block is mainly concerned with setting up ecologically relevant threshold values for protecting a particular environmental compartment. In this regard, depending on the data richness, specific recommendations are provided on how to select or handle toxicity data and on how to derive or validate environmental threshold values such as the predicted no-effect concentration (PNEC).

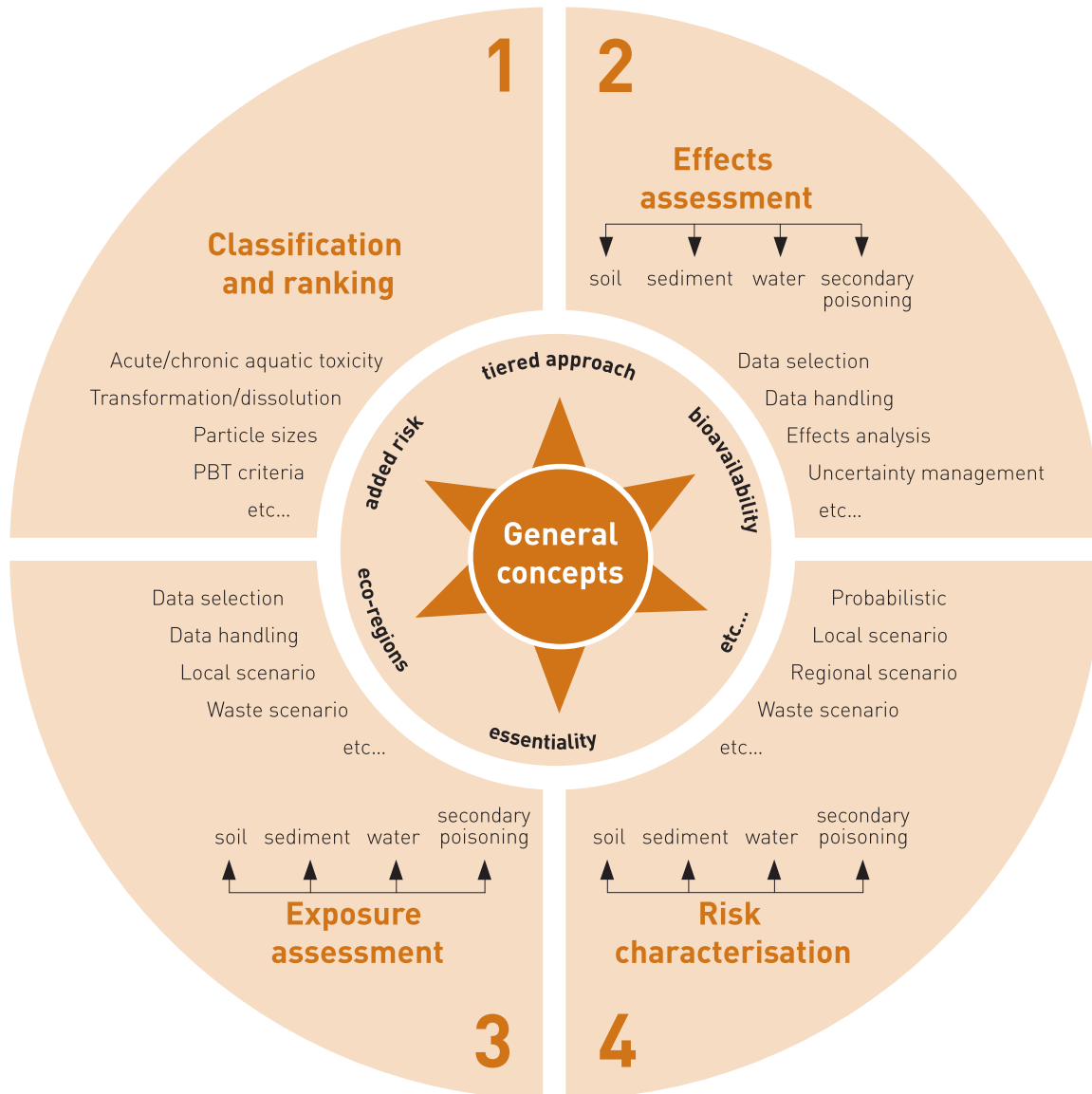
Exposure assessment

Basic recommendations on how to perform continental, regional and site-specific exposure assessments are covered by this building block. Emphasis is on the proper data selection and handling in order to derive reliable and relevant environmental concentrations from both modelled and measured data.

Risk characterisation

Finally, attention is given to how environmental risks from metals can be assessed in the most appropriate way, depending on the availability of data. In this regard the way bioavailability corrections could be incorporated in the process has been developed. The usefulness and applicability of newly developed approaches such as probabilistic risk assessments for data-rich substances are also highlighted, together with methodologies quantifying the uncertainty embedded in any risk assessment process.

Figure 1: MERAG's conceptual building blocks



“The guidance is structured so that metals-specific concepts are built into the traditional building blocks needed for environmental risk assessment.”

MERAG: structure and overview of fact sheets

MERAG fact sheets

The building blocks have been tackled in a series of fact sheets as described below.

The proposed tiered approaches in the fact sheets are focused on data collection, testing strategies and risk characterisation, and are aimed at facilitating the risk assessment process and the setting of environmentally relevant quality criteria. The tiers enable the reader to find the appropriate level of guidance for the data richness of the metal being assessed.

In addition to the detailed guidance provided in the fact sheets, the original MERAG background document provides an overview of the main concepts and underlying scientific principles referred to in the fact sheets. While some areas have advanced since its publication, the background document is still a worthy introduction for the new reader.

Fact sheet 1

Risk characterisation: general aspects

Updated May 2016

Within a risk assessment, environmental risks are often estimated in a deterministic manner using single-point estimates for both exposure and effects. Although this approach has its merits for data-poor substances, for data-rich metals this method may not consider the entirety of the available data set. Accordingly, the use of probabilistic approaches is explored in this fact sheet. Finally, due to the presence of a natural background and the adaptation/acclimation of biological species, pragmatic approaches have been presented, such as the use of the “added risk approach” and “biogeochemical regions”.

This fact sheet presents the components of a risk characterisation strategy that will anticipate future compliance obligations while ensuring that the best option for managing the potential risks presented is considered.



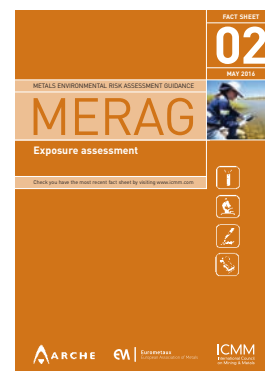
Fact sheet 2

Exposure assessment

Updated May 2016

Metal concentrations in the environment are the result of the natural background, historical contamination and local and diffuse emissions associated with the use pattern and life cycle of the metal (ie from mining to waste disposal). Due to the inherent variation of metal concentration in the natural environment (eg different natural background concentrations) and the variations of anthropogenic input, large differences in metal levels can be observed in different locations.

This fact sheet considers both diffuse source emissions and local industrial emissions. Exposure concentrations of metals can be both modelled and measured. If used in parallel, these approaches may provide the most comprehensive understanding, as long as the specific characteristics of metals have been reflected in the choice of the model input parameters and in how the monitoring data have been collected and processed. Detailed guidance is provided on how to take these metal-specific elements into account within an exposure assessment.



Fact sheet 3

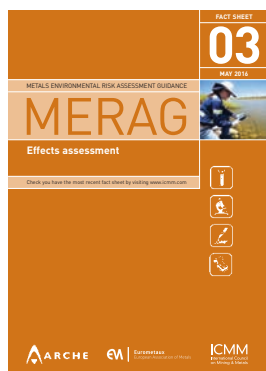
Effects assessment

(data compilation, selection and derivation of PNEC values for the risk assessment of different environmental compartments – water, soil and sediment)

Updated May 2016

In selecting data for the derivation of environmental threshold values such as predicted no effects concentrations (PNECs) or environmental quality standards (EQSs), it is imperative that the most relevant and reliable data are selected. Because metals are naturally occurring, and their deficiency/toxicity is driven by natural background levels and/or physico-chemical test conditions, there is a need to take metal specificities into account.

This fact sheet describes relevance and reliability criteria tailored to the needs of collecting and evaluating metals ecotoxicity data. It also covers the methodologies that can be used to derive environmental threshold values for metals depending on data availability. As some metals are data rich, the use of statistical approaches (eg species sensitivity distributions) has been explained in detail.



Fact sheet 4

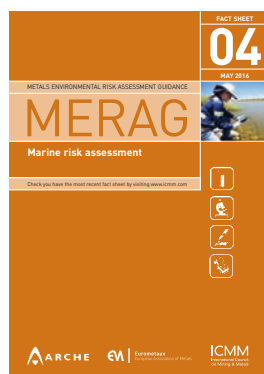
Marine risk assessment

(for metals and metal compounds in the aquatic environment)

Updated May 2016

Despite the fact that marine ecosystems are a part of the largest aquatic system on the planet, most risk assessment methodologies and environmental quality standards setting are based on the inland aquatic environment – particularly where it is considered at risk from urban or industrial development. The need to extend the existing risk assessment approaches and principles to assess the potential risks of a substance entering into the marine environment has been acknowledged only recently by regulatory bodies and industry.

This fact sheet reviews the characteristics of the marine environment, the derivation of ecotoxicity thresholds (PNEC or EQS) for marine species, incorporation of bioavailability and risk characterisation.



Fact sheet 5

Incorporation of bioavailability for water, soils and sediments

Updated May 2016 and incorporating previous fact sheet 6

The degree to which metals are available and cause toxicity to aquatic, sediment-burying and terrestrial organisms is determined by the site-specific geochemical conditions that control the speciation/precipitation and/or complexation of metals. In the aquatic environment these processes are generally controlled by pH and dissolved organic carbon concentration. Furthermore, several cations (including calcium, magnesium, sodium and potassium) are known to compete with metal ions for binding to the site of toxic action and hence reduce metal toxicity. In sediments sulphides, organic carbon and iron/manganese (oxy)hydroxides play a mitigating role as they provide important binding/absorption phases. For the soil compartment it has been demonstrated that clay minerals and organic carbon content, together with soil pH, are the main drivers determining the bioavailability of metals.

This fact sheet covers different bioavailability tools/concepts that can be applied in a tiered approach to improve environmental assessments. This helps to increase the realism of the assessment and to better understand the likelihood of the occurrence of adverse effects due to metal contamination.



MERAG: structure and overview of fact sheets

Fact sheet 7

Uncertainty analysis

Published 2007

Any risk assessment carries with it uncertainty. The current risk assessment schemes are largely deterministic, and uncertainty is most often accounted for by means of worst-case assumptions and assessment factors, which are implicitly embedded in calculation schemes and rules. However, combining risk and uncertainty into a single measure makes the risk assessment less transparent to a risk manager or decision-maker, and they have no idea how conservative or realistic the risk outcomes actually are. There is, therefore, a need for a proper and transparent treatment of sources of variability and uncertainty during the risk assessment process.

One way to classify uncertainty is to differentiate it into uncertainty due to variability and uncertainty due to limited knowledge. This fact sheet explores how these can be addressed through sensitivity analysis and the use of appropriate statistical techniques – particularly for data-rich substances.



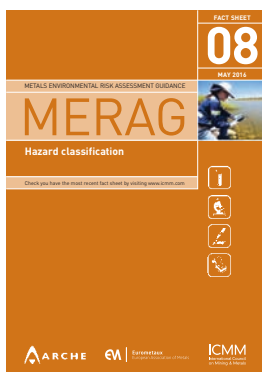
Fact sheet 8

Hazard classification

Updated May 2016
(alloys and complex materials sections due end 2016)

The general strategy for classifying chemical substances, compounds and mixtures for the aquatic environment is hazard-based, and takes into account the intrinsic properties (aquatic toxicity, solubility, degradation and bioaccumulation) of the substance or, in the case of a mixture, those of its components. For sparingly soluble metal compounds (SSMCs) and inorganic complex materials (eg ores, concentrates, alloys) the interpretation of these properties is not straightforward. A metal's toxicity and its resulting classification are determined by the effect of the soluble ion, and not by the total fraction of metal in the material. Consequently, the identification and quantification of the metal fractions that contribute to the hazard is one of the main challenges for the environmental classification of SSMCs and complex inorganic materials.

This fact sheet provides guidance on how to incorporate key metal-specific concepts into hazard assessments, including bioavailability (via transformation/dissolution testing), particle size and both the increased or decreased release of metals from alloys or mixtures.



Fact sheet 9

Weight of evidence

Published May 2016

The precautionary principle paradigm states that if an action has a suspected risk of causing harm to the public or to the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. This approach allows policy-makers to make decisions in situations when extensive scientific knowledge on the matter is lacking. However, when more scientific evidence is available, the weight-of-evidence approach can help policy-makers make a more balanced decision on potential harm caused by the use of a substance.

The weight-of-evidence approach is a phrase that has often been used in recent years in the field of environmental assessment, but it constitutes neither a scientifically well-defined nor an agreed formalised concept characterised by defined tools and procedures. This fact sheet demonstrates how the approach can be successfully applied in the context of an ecological risk assessment so that multiple and differing types of data can be used to support conclusions on dominant stressors, biological impairment or risk.





3

Practical
examples of
MERAG's
application

Amsterdam, The Netherlands

A network of canals encircles the medieval city center of Amsterdam. Amsterdam's designers created a port city that inspired planners in England, Sweden and Russia.

Practical examples of MERAG's application

The following case studies, selected from across the life cycle – from mining to end use – are just a sample of the projects being undertaken by our member companies and associations. They give a flavour of how concepts from MERAG can be used for practical assessment and contain some examples of where user-friendly tools have been created.

Applying MERAG through the life cycle of minerals and metals

Once a methodology or tool achieves maturity, adoption becomes universal among leading companies, and provokes further innovation. It can also become a model for regulatory bodies to standardise what was initially innovative and an advancement in performance.

These instruments are making quantitative and qualitative differences. The impact of this is that there has been a systematic reduction in the likelihood of human and environmental risks being exaggerated, underestimated or entirely missed.

Case study 1

Application of MERAG concepts at a copper mine site in the United States

The issue

There is a need to understand, in areas impacted by mining operations, the short- and long-term impacts of the presence and bioavailability of metals of concern at levels above background. The findings could then be used as the basis for investments in management and remediation commensurate with the risk.

The response

The bioavailability of arsenic, copper, lead and selenium in soils, surface waters and wetlands was assessed. The principles laid out in the ICMM/Eurometaux MERAG fact sheets on bioavailability, exposure assessment, effects assessment, uncertainty analysis and risk characterisation were used to make decisions regarding possible effects on birds, other wildlife and the aquatic resources of impacted areas for purposes of determining remedial actions. Metal monitoring was performed across 35,000ha. The outcome of the risk assessment identified a limited number of areas where arsenic and lead soil removals were required; a groundwater plume requiring monitoring; selenium sediment concentrations in wetlands placing shorebirds (American avocets and black-necked stilts) at low levels of risk; and an artesian well containing selenium that required treatment. Soil and sediment removals were completed and a treatment system (fluidised-bed bioreactor) was built to remove selenium from the artesian well discharge.

The outcome

A remediation response commensurate to the risk was identified with a high level of scientific and technical confidence.

Case study 2

Preventing pollution of the marine environment in the transport of mined products

The issue

Marine trade is vital to the world economy and is capable of moving vast amounts of material and merchandise at low unit cost. However, a number of environmental concerns have been identified in recent years, including concern that cargo residues that may be discharged when holds are washed out in preparation for the next cargo could harm the marine environment.

The response

Non-ferrous ores and concentrates, some with known ecotoxic potentials, are important marine cargoes, and it is essential to know when residues in wash waters from holds pose unacceptable risks requiring active management. Metal concentrates – obtained from mining operations and shipped in bulk to the metal-producing industries (smelters/refiners) – were a prime candidate for regulatory attention. On January 1st 2013 the International Maritime Organization brought in changes to MARPOL (International Convention for the Prevention of Pollution from Ships) that aims to prevent the pollution of the marine environment from solid bulk cargoes.

The challenge for ICMM members was then to apply the latest science to determine the real hazards posed to the environment by the complex mixture of minerals that make up a concentrate. This meant looking to each constituent mineral in a range of concentrates from around the world and modelling the degree to which metal ions would be released (the driver for ecotoxicity) consistent with the criteria defined in the MARPOL Convention. The predictive power of tools such as MERAG and the Metals Classification Tool (MeClas) and early engagement by all concerned parties was brought to bear.

The outcome

The testing and modelling carried out by mining companies and facilitated by metals commodity associations determines quickly and accurately whether there is insufficient release of metal ions to cause toxicity – meaning that risk management measures can be targeted where they are really needed.

Case study 3

Characterising complex products – the Metals Classification Tool (MeClas)

The issue

The United Nations' Globally Harmonised System (GHS) for hazard classification and labelling includes specific rulings for metals, metal compounds and alloys. However, these are complex and not available from any (commercial) assessment tools or software. In addition, hazard data sets for metals – while usable at the worldwide level – are often large and complicated, and access to them can be an issue.

The response

To address those challenges, Arche and Eurometaux have developed an automated system for the hazard identification and classification/labelling of complex inorganic materials like ores and concentrates, complex intermediates, slags and alloys under the GHS. The MeClas tool is a web-based, flexible and user-friendly hazard identification tool. It recognises the specific properties and assessment techniques for inorganics and uses the most up-to-date information on (eco)toxicity references and self-classifications available. The tool was launched in 2010 and extensively used for the EU's Reach registration and the notifications under the EU Classification, Labelling and Packaging regulation that concluded in 2010. In view of the 2015 deadlines for classification of mixtures, the tool has recently been improved to address the specificities of various alloys. In addition, the GHS database of industry self-classifications and the United States' implementation of GHS mixture rules have been included.

The outcome

Two decades of research, testing and validation are in regular use. MeClas is regularly updated, and can be downloaded without cost for non-commercial use. More information on the principles behind the methodologies can be found at www.meclas.eu.

Practical examples of MERAG's application

Case study 4

Accurately modelling metal releases to the environment

The issue

There is a long history and experience with assessing organic chemicals and compounds and ways of measuring and evaluating environmental impacts on different biota in air and bodies of water. With increasing attention being paid to metals and metallic compounds, it was found that methodologies developed for organics often gave wildly inaccurate or improbable predictions of releases and thus predictions of environmental exposures and impacts.

The response

Specific environmental release categories (Spercs) for metals and metal compounds were developed by Eurometaux and Arche to provide a realistic approach for characterising the environmental releases of metals and metal compounds from the manufacture, processing and downstream uses in the EU. The metal Spercs are based on a database of more than 1,300 recent (1993–2010) site-specific measured release factors to air and water of 18 different metals and their compounds. The sites were in various member states of the EU. The first version of the metal Spercs was published in 2010 and used extensively in the development of the 2010 Reach registrations. The Spercs underwent a review process conducted by Luskow et al. (2010)⁵ on behalf of the Federal Environment Agency of Germany, and a second version of the metal Spercs was published for the purpose of the 2013 Reach registration deadline. The metal Spercs were also included in a further validation exercise led by the European Chemicals Agency to identify “best practices” in the use of Spercs.

The outcome

Although developed in the European Union, the metal Spercs principles and methodology approach can be used in other regions, and in other chemical management systems that include metals and metallic compounds. This potential was examined in a peer-reviewed publication (Verdonck et al. 2014).⁶ It has also been proposed to include the metal Spercs in an OECD project aimed at making a “cross-walk” between the Emission Scenario Documents developed by several countries and the EU Spercs. The metal Spercs are downloadable for non-commercial use without cost from www.arche-consulting.be/Metal-CSA-toolbox/spercs-tool-for-metals.

“We recognise that risk assessment for metals poses some unique challenges and the MERAG project has proved a valuable foundation for the OECD in building our guidance and approaches.”

Bob Diderich
Head of Division Environment, Health and Safety
OECD

⁵ H. Luskow, O. Wirth, A. Reihlen and D. Jepsen, Standardisation of Emission Factors for the Exposure Assessment under Reach, Dessau, Germany, Federal Environment Agency, Germany. Project no. 363 01 300 (UFOPLAN), 2010.

⁶ F.A.M. Verdonck, F. Van Assche, K. Hicks, J. Mertens, A. Voigt and V. Verougstraete, Development of Realistic Environmental Release Factors Based on Measured Data: Approach and Lessons from the EU Metal Industry, Integrated Environmental Assessment and Management, 10(4) (2014), 529–38.



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Further
information

Further information

Mining and metals industry associations

Cobalt Development Institute
www.thecdi.com

European Precious Metals Federation
www.epmf.be

International Aluminium Institute
www.world-aluminium.org

International Antimony Association
www.antimony.com

International Cadmium Association
www.cadmium.org

International Copper Association
www.copperalliance.org

International Lead Association
www.ila-lead.org

International Manganese Institute
www.manganese.org

International Molybdenum Association
www.imoa.info

International Zinc Association
www.zinc.org

Nickel Institute
www.nickelinstitute.org

Vanitec
www.vanitec.org

Tools for metals hazard and risk assessment

Since the initial development of MERAG and the repeated application of metals-specific tools and concepts, many have been incorporated into user-friendly tools and models. Below is a list of some commonly used tools with information on how they can be accessed and brief descriptions of typical scenarios to which they apply.

bio-met

www.bio-met.net

bio-met is a quick, user-friendly and unified chronic biotic ligand model (BLM) normalisation tool based on full BLM calculations. It was developed by Arche and WCA Environment (see www.wca-environment.com). The tool requires the input of basic abiotic water parameters to provide BLM normalised values for several metals.

Specific environmental release categories (Spercs)

www.arche-consulting.be/en/our-tools/spercs-tool-for-metals

Spercs can be used as an advanced tier instrument to characterise the environmental releases from manufacture, processing and downstream uses of the metal in environmental safety assessments. They are supported by a database of more than 1,300 recent (1993–2010) site-specific measured release factors to air and water of 18 different metals (and their compounds), with the sites being in various EU member states.

Soil PNEC calculator

www.arche-consulting.be/en/our-tools/soil-pnec-calculator

The soil PNEC calculator is an Excel-based spreadsheet allowing straightforward calculation of soil-specific ecological quality standards and corresponding risk characterisation for various metals, based on their predicted no-effect concentrations (PNECs) for soil organisms, and it considers key aspects such as bioavailability.

MeClas

www.meclas.eu

MeClas is a web-based system for the hazard identification and classification and labelling of complex inorganic materials. It is particularly useful in the consideration of ores and concentrates, complex intermediates, slags and alloys under the EU Classification, Labelling and Packaging regulation and the United Nations' GHS.

Acknowledgments

Authors

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Contributors

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Eurometaux constitutes the interface between the European non-ferrous metals industry and the European authorities and international or intergovernmental bodies. It is committed to establishing dialogue with the latter in order to ensure early consultation in all fields of policy and legislation that may affect industry and to asserting the sector's views and positions in this respect. It asserts the contribution of the European industry and its products to sustainable development, as well as this industry's views and positions, whenever the opportunity to do so arises across all sectors of society. In doing so, Eurometaux is the industry's voice on all regulatory matters.

Arche

Arche was founded by key experts in the field of environmental toxicology, exposure modelling and the preparation of risk assessment dossiers in general. Arche has built up in-depth knowledge on assessing risks of chemicals during both the predecessor of the Reach regulation (EU Regulation 67/1488 on new and existing substances) and the preparation of chemical safety assessments/reports in the framework of the Reach regulation.

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