Non-Ferrous Metals
Consultative Forum on
Sustainable Development

SCIENCE, RESEARCH AND DEVELOPMENT WORKING GROUP

Report on Risk Assessment of Non-Ferrous Metals and Sustainable Development

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RISK ASSESSMENT OF NON-FERROUS METALS AND SUSTAINABLE DEVELOPMENT

Remit of the Science Working Group

The Science and Research Working Group of the Non-Ferrous Metals Consultative Forum on Sustainable Development (NFMSD) was formed as the result the Forum's first meeting, held in Brussels in 2000. The Forum identified the need to share credible scientific research on non-ferrous metals in a timely manner. In April 2001 the Science and Research Working Group held its inaugural meeting and defined its work priorities:

- Developing a Net Based Science Network - to include contact details and affiliations of scientists known to be working in the field of science and the sustainable development of non-ferrous metals.

- Principles for the Life Cycle Analysis of Metals - with focus on materials flow guidelines, harmonisation of methodology and data issues in relation to sustainable development.

- Stock-take of Metals/Science Related Sustainable Development Initiatives - with identification of the scientific programs content in any other Sustainable Development initiatives that are currently under way.

- Guiding Principles for Risk Assessment - include a stock take of work already done, and then elaboration of guiding principles for improving risk assessment. It was also decided to address issues such as what constitutes an acceptable level of risk, and how risk assessment may contribute rationality in decision making. A need was also identified to improve data as well as communication and educational issues in relation to risk assessment.

This paper is the result of the Working Group's discussions on both guiding principles and policy aspects of risk assessment.

The Working Group's Approach to Risk Assessment of Non-Ferrous Metals

The Group acknowledged that risk assessment of the production and use of non-ferrous metals is just one, albeit important, approach to maintaining a sustainable non-ferrous metals industry. However, it was felt that value could be added by exploring the scientific challenges presented by risk assessment for non-ferrous metals. In particular the Group agreed that there needed to be methodologies applied to non-ferrous metals that take into account their natural occurrence and essentiality. Approaches to non-ferrous metals regulation based on frameworks developed for organic chemicals were considered to be inappropriate.

The Group identified the hazard identification stage for non-ferrous metals as particularly important in ensuring meaningful risk assessments were completed and appropriate methodology was used. It was agreed that non-ferrous metals could be toxic to varying degrees, but that the risk they posed varied greatly, for example with concentration and chemical form. In this respect the Group highlighted the role that sound risk assessment and then reduction and management strategies could play in preventing adverse effects from exposure.

Over the course of its meetings the Group has elaborated a six-point approach towards the key principles that should guide risk assessment for non-ferrous metals. These guidelines are developed in Part One of this paper. Discussions that took place during the Porto Forum in November 2001 highlighted the need for the Group's work to also encompass risk assessment for non-ferrous metals in the context of decision making.

The Group acknowledged that during the risk assessment processes followed in many jurisdictions local community groups and public interest groups often felt that the burden of proof to establish that existing environmental protection legislation may be sufficient lay with them. It was also recognised that the difference in scientific approach between biologists/ecotoxicologists and chemists needed to be debated.

In response the Group concentrated its efforts on three main areas relating to the complexity of the risk assessment process and policy formulation for all stakeholders. Part Two of this paper therefore looks at the issues of process (how to engage all stakeholders), methodology (how regulators may approach the problem of uncertainty in data sets) and bias (how to explore the issue of subjectivity within non-ferrous metals risk assessment policy).

Risk Assessment of Non-Ferrous Metals in the Context of Sustainable Development

One important conclusion of the Group's work on risk assessment of non-ferrous metals has been that regulatory systems are moving towards the use of policy tools that recognise that environmental harm may occur through production, use, disposal and recycling of non-ferrous metals. The life cycle management approach to understanding production, use, disposal and recycling of products associated with a particular non-ferrous metal (in particular product stewardship) is underlain by the conduct of a comprehensive risk assessment. This represents an important factor in understanding how risk assessment of non-ferrous metals falls within the context of Sustainable Development.

Recommendations

As the Group discusses the linkage between risk assessment, life cycle management and product stewardship further, a number of options for future work may be appropriate, including for example:

- Formulating a mechanism to make Governments, regulatory agencies and other stakeholders more aware of the specific requirements for risk assessment of non-ferrous metals and facilitate a continued dialogue amongst stakeholders

- Organising a Working Group and/or Workshop of stakeholders to assess the current state of knowledge in the science of bio-availability of metals and its incorporation in risk assessment

- Organising a Working Group and/or Workshop which would address the issue of risk assessment methodology and models for non-ferrous metals and the related policy considerations

- Further work to elaborate how knowledge gained in advancing science for risk assessment can be used in improving life cycle assessment approaches for non ferrous metals.

PART ONE - SCIENTIFIC CONSIDERATIONS

1.1 Introduction

Minerals and metals are naturally occurring substances that have played and continue to play an essential role in the development of human societies.

Throughout history, the development of societies has advanced with the discovery of new uses of minerals and metals. During the Stone Age, minerals such as chert, flint and quartzite were used for tools, weapons or for barter. As civilisations progressed from the Stone Age through to the Copper Age (at about 6000 BC), native copper was formed into decorative shapes and used for more efficient tools. During the Bronze Age it was discovered how to enhance the properties of copper by mixing it with tin. It was then discovered that metal tools could be made harder and more corrosion resistant by mixing copper and tin and copper and zinc. The science of metallurgy began, leading to the discovery of many of the metallic alloys that are still in use today.

Non-ferrous metals are a vital and integral part of our modern society and their unique properties and availability benefit every facet of our lives.

In addition to being indispensable materials for the development and welfare of society, trace amounts of certain metals are essential to all life forms. At the same time, however, the extraction, processing and in some cases the particular use or application of certain metals can have, and has in the past, resulted in adverse effects on human health and the environment. It is in this context that policy decisions regarding the safe use of metals must be based on sound scientific principles within a risk assessment framework that takes into consideration the unique properties of metals.

1.2 The role and importance of risk assessment in sustainable risk management policies

Good policy depends on good science. Policy decisions on the use of non-ferrous metals therefore require a sound scientific assessment of the risks associated with the life cycle of metal, production and use. Policy decisions made solely on the basis of hazard can lead to outcomes that do not have a rational basis and are costly to society:

- Hazard means only that a material has a property that has the potential in certain circumstances to lead to harm but takes no account of actual exposures. Hazard by itself does not provide a rational basis for making policies on use of materials.
- Risk is the likelihood, chance or probability that a potential hazard will actually cause harm and encompasses a measure of the magnitude of this

harm under defined site-specific or regional exposure conditions for a defined population.

Sound decision making recognises the importance of applying risk assessment to proposed substitute materials in circumstances where risk is identified for a particular metal use. Risk assessment of substitutes and comparative life cycle assessment are therefore valuable tools in building sustainable risk management policies and in guiding materials selection in industry.

A risk assessment of the production and use of a specific non-ferrous metal is just one, albeit important, approach to maintaining a sustainable non-ferrous metal industry. Metal-metal interactions and other health and environmental impacts may not be adequately addressed through risk assessments of this type and other tools (e.g. life cycle assessment, codes of practice, etc) should augment metal-specific risk assessment.

1.3 Hazard Identification and Risk Assessment

Risk assessment is a scientific process for identifying, estimating and evaluating the risks presented by a particular material under specific conditions and circumstances. There are guidance documents that set out the principles for risk assessment. These were developed by individual jurisdictions such as the US National Research Council and the European Union or by intergovernmental organisations such as the Organisation for Economic Co-Operations and Development (OECD) and the International Programme on Chemical Safety (IPCS). The IPCS and OECD have developed a framework for co-operation in the field of risk assessment methodologies, which ensures complementarity, mutual support and mutual involvement in the projects conducted by each organization.

Risk assessments typically include four steps:

i) dose-response assessment,
ii) hazard identification,
iii) exposure assessment and
iv) risk characterisation

An important step for any meaningful risk assessment is the hazard identification stage. It is this stage of risk assessment that is the cause for debate in terms of the appropriate hazard criteria for metals. Most screening methodologies for the hazard identification for chemicals were developed with organic substances in mind. As a result they rely on persistence (as a surrogate for biodegradability), bioaccumulative (to measure exposure) and toxicity (to measure the harm).

For metals, such “PBT” criteria have been demonstrated to be inappropriate for hazard identification given that, as naturally occurring elements, metals are by definition persistent. Metals are elements and it is neither possible nor desirable to eliminate them. In fact, the persistence of metals facilitates their re-use and recycling.

Moreover, many metals act as essential micro-nutrients and are required for the normal function of biological systems. They are essential in small amounts for the normal health and development of plants, animals and humans. Trace elements such as cobalt, copper, iron, manganese, selenium, molybdenum and zinc are necessary for the normal development of plants and animals. In many cases, metals are added to animal feed and to pharmaceutical products. Potash and phosphates are used as fertilizers to grow healthy plants.

Table 1 - Metals classified by their known essentiality to living organisms

Essential	**Non-essential**
Chromium	Arsenic
Cobalt	Antimony
Copper	Cadmium
Iron	Lead
Manganese	Mercury
Molybdenum	Thallium
Nickel	Tin
Selenium	Silver
Zinc	

Metals and other elements are only available to living organisms if they are in a form that is bioavailable. Harmful effects may occur if the concentration of the bioavailable form of the metal is either insufficient to meet the organism's needs, or significantly more than biologically required concentrations. For example, copper and zinc are essential elements for the normal healthy growth and reproduction of all higher plants and animals. Copper and zinc deficiency in soils can have a serious impact on crop yields and on animal health. In plants, copper and zinc are essential components of several proteins, mostly enzymes, which have varied but important metabolic functions. In certain regions, copper and zinc have to be applied to soils to achieve minimum requirements. In animal health, copper and zinc are essential elements in a number of enzymes critical for human health.

Just as minerals and metals can be essential for biological systems, they can also be harmful in excess. Metals are toxic to varying degrees, but the hazard they pose varies greatly with concentration, chemical form and to some extent the organisms individual tolerance. Adverse effects can be prevented through an improved scientific understanding of the role and behaviour of these substances, through the implementation of sound risk reduction and management strategies. The health effects and benefits of metals and their compounds are well documented, particularly in terms of human exposure and the workplace. Today, extensive regulatory regimes are in place in many countries to closely monitor and control those metal exposures and emissions.

1.4 Metals Classification and Risk Management

Minerals and metals are often classified as chemicals in many domestic and international regulations. As a result, approaches to metals and environment issues often use models that were originally developed for organic chemicals but that are not appropriate for inorganic substances such as metals. Indeed, the concepts of banning, substitution and virtual elimination find their origins in risk-management approaches for synthetic organic chemicals. Such approaches for minerals and metals have led to inappropriate actions and the creation of unnecessary public concern.

There is a common misconception that any amount of a metal in the environment is contamination arising from human activity. This does not reflect the fact that minerals and metals are an integral component of the earth and that natural background levels of metals can vary widely from place to place, reflecting their natural distribution. Unfortunately, these misconceptions can drive regulatory policy decisions and have led to a number of international environmental policy and regulatory initiatives that threaten the use of minerals and metals in general.

Bans, substitutions and market access restrictions are generally presented by some as the preferred option for resolving environmental issues involving minerals and metals. Objective approaches based on sound science, risk assessment; risk-benefit analysis and risk management options should be the preferred approach. International awareness that naturally occurring inorganic substances require different approaches from synthetic organic substances is developing within the OECD and the United Nations. Work is still necessary however, to establish the appropriate protocols for the hazard classification for metals that will meet the needs of regulators, risk assessors, industry and the general public.

The scientific challenges presented by risk assessment for non-ferrous metals have been brought into focus by the EU's risk assessment for zinc. A summary of experiences with respect to a voluntary risk assessment of lead is provided in Annex I. The EU's risk assessment process for zinc has highlighted the need to:

- Develop and use a methodology that takes account of homeostatic regulation, natural background occurrence and variations in concentration of metals in the environment
- Use data only from organisms originating from the habitat type for which the risk assessment is being made (as ecotypic differentiation might have evolved a tolerance or need for the metal that might be different from that of individuals of the same species from other regions and exposed to different background concentrations).

- Include bioavailability in quantitative risk assessment methodologies
- Utilise up-to-date information on metal production and use patterns in exposure assessment
- Ensure testing for effects assessment takes place on species that have been kept in the appropriate abiotic conditions (in particular background concentration of the metal under study).

1.5 Some Limiting Factors

<u>A need for accurate and comparable measurement</u>

The increasing need for accurate measurement of environmental concentrations has been identified as a limiting factor in conducting risk assessment and for comparison between both place and time. The extent to which this issue presents a limitation on conduct and use of risk assessments for metals requires further examination.

<u>The time required for risk assessment</u>

One of the main criticisms of risk assessment as a policy tool is that it takes too long to conclude. There are concerns that damage to health and environment may occur during the conduct of the assessment. It has been suggested that improved prioritisation of substances identified for risk assessment may alleviate these concerns. Furthermore, the concept of voluntary risk assessment – conducted by industry under a regulatory framework – has been proposed as an alternative approach in Europe and would expedite risk assessment processes without sacrificing scientific rigor. An overview of the concept of voluntary risk assessment is set out in Annex II.

1.6 Guiding principles for risk assessment of non-ferrous metals

Experience to date suggests the following key guiding principles for conduct of risk assessment for non-ferrous metals:

- Recognition that risk assessment methodologies that have been developed for man-made chemicals are not suitable for direct application to non-ferrous metals;

- Methodologies that are applied to non-ferrous metals must take account of their natural occurrence and essentiality;

- Metals must be assessed according to species or compound under consideration;

- Local differences in the environment, such as soil pH, and natural background levels need to be taken into consideration;

- The incorporation of bioavailability in assessments of exposure of non-ferrous metals is necessary to accurately establish risks associated with environmental exposure.

- Conclusions of risk assessments generated in one region/scenario require careful examination and extrapolation before it becomes possible to extrapolate those conclusions to other regions/scenarios.

1.7 Communications issues and recommendations for consideration by the Consultative Forum

The working group also noted several important challenges in communicating (i) the need for sound scientific risk assessment for non-ferrous metals and (ii) the outcomes of risk assessments.

It is recommended that:

➢ A mechanism is established to make Governments, regulatory agencies and other stakeholders more aware of the specific requirements for risk assessment of non-ferrous metals that are set out in this paper.

➢ Action is taken to promote the message that it is not sensible to apply conclusions of a risk assessment from one area to another area without considerable further work. The context and background to conclusions to risk assessments generated in one region/scenario require careful examination and extrapolation before it becomes possible to extrapolate those conclusions to other regions/scenarios. Induction of cholera outbreaks through misinterpretation of the perceived need to reduce chlorine in drinking water has been cited as an example.

PART TWO: POLICY CONSIDERATIONS

2.1 Introduction

Risk assessment has emerged as a tool favoured by policy makers to assess environmental impacts relating to the use and disposal of non-ferrous metals. It allows the construction of a framework within which governments can define their policies regulating the safe use of non-ferrous metals. Risk assessment techniques used to define exposure to a hazard and calculate an individual's or ecosystem's risks include elements of uncertainty, and are the subject of much on-going debate.

It can be argued that risk assessment is one among many possible approaches to regulating the safe use of non-ferrous metals. The focus of this part of the paper is to describe the way in which regulators are currently using risk assessment and air the views of some stakeholders regarding the assumptions that support policy stances.

2.2 Risk Assessment as a Tool in Decision Making

When the Science Working Group began its discussions on risk assessment in April 2001 a number of fundamental issues that addressed the need to consider the place of risk assessments of metals in relation to their sustainability were raised. During the discussions that took place a resonating theme to emerge was the need to demonstrate the specificity of metals in risk assessments to policy makers. It was also acknowledged that the difference in scientific approach adopted by chemists and biologists/ecotoxicologists needed to be acknowledged.

The Group highlighted that metals are different from the organic chemicals upon which most risk assessments have been centered, and that regulatory policy should reflect this fact. At the same time, differences in scientific approach to aspects of risk assessment such as bioavailability implied that policy discussions needed in some way to be aware of a range of scientific opinions. Bodies such as the International Programme for Chemical Safety (IPCS) have brought together chemists and ecotoxicologists in an attempt to engage them in dialogues and to understand the separate thought processes at work.

As a policy tool, risk assessment has the advantage of having a well-established set of principles. Although these principles have been developed within individual jurisdictions the participation of the IPCS and the Organisation for Economic Co-operation and Development (OECD) has resulted in a framework for a shared and standardised approach to risk assessment methodology. Mutual support in projects across different jurisdictions has tended to reinforce further the logic for using risk assessment as a uniformly applicable policy tool. Regular national consultation exercises on improving frameworks for risk characterisation and hazard classification show that the present set of risk assessment principles is not set in stone. Such consultation reveals that existing frameworks need to be developed further to deliver the higher level of certainty in analysis that society now demands.

Risk assessment of non-ferrous metals is a complex subject. The complexity is magnified because of the specialised data gathering necessary to support the science developing in relation to the bio-availability of non-ferrous metals to organisms originating from the habitat for which the risk assessment is being made. As a consequence the whole of the risk assessment process can appear to be inaccessible to local communities who often feel in the front line of concern about risk characterisation and hazard classification for non-ferrous metals.

Issues relating to the complexity and inaccessibility of the risk assessment process can be grouped into several categories:

- Process: how to engage all stakeholders and address fundamental issues such as who has the burden of proof to show harm;

- Methodology: how to treat the problem of uncertainty in data sets and risk models to ensure that all the assumptions used have been aired in a transparent way;

- Bias: how to explore the subjectivity within non-ferrous metals risk assessment that results in a policy decision determining what problems are important and how these should be handled.

2.3 The Burden of Proof

As environmental legislation has been developed, the focus has been on end of pipe solutions restricting emissions to the environment. Regulators have sought to provide environmental protection through pollution control devices such as scrubbers, filters and water treatment plants. The control devices are intended to curb environmental damage so that emissions fall below limits stipulated by the regulator. These limits are arrived at scientifically and often approximate to minimum standards that are set in international arenas. Some stakeholders feel that the current regulatory system bases its determinants only upon science, thus omitting many essential human values.

Local community groups and public interest groups often feel that the burden of proof to establish that existing environmental legislation may be insufficient lies with them. They talk of emission limits being decided in a "top down way" and believe that current risk assessment practices are based on a "prove harm" system of regulation that requires that harm must occur before action can be taken. They feel that science often cannot define "harm" very clearly; much less prove that it has occurred.

Industry shares concerns relating to risk assessment, but these are of a different nature. Indeed, there are currently proposals on the table to reverse the burden of proof from regulators to industry in a number of jurisdictions. There is already a view among the non-ferrous metals industry that it is finding itself facing tighter environmental controls based on data derived using methodologies better suited to risk assessments of organic chemicals.

Some of these concerns are being addressed through consultation exercises being carried out by environmental regulators. In the United States for example, the Environmental Protection Agency (EPA) has launched a draft Action Plan to establish a process for developing guidance for risk assessments (REF). The idea is to ensure a consistent application of scientific principles for assessing hazard and risk for metals. The EPA is also encouraging transparency through articulation of the assumptions and uncertainties inherent in the risk assessment process. Bearing in mind local communities, the draft Action Plan also emphasises the need for flexibility to address program-specific issues.

Open, meaningful consultation is important to ensure that the general public, academia and local communities such as residents living near plants and workers that are affected by policy choices are included in the decision - making process. It is particularly important that the conclusions reached using risk assessment are not viewed as being biased toward industry, based on scientific data inadequate in scope. In some jurisdictions the general public and community groups are involved in the decision-making process - new draft legislation is published for public review. By definition, the methodology of risk assessment is based on limited scientific data. Therefore, the preventive approach is used to protect the public interest. There is a perception among public interest groups that all stakeholders need to address the limitations of current risk assessment procedures along with the perception that the prevailing standards of proof are unrealistic. However, understanding the current limitations of risk assessment should lead to further development of the risk assessment methodology as well as more effective risk management options.

Risk assessments are based on the use of sound science, but there are practical limits (e.g. available data, methodologies, time, financial support etc) to the science that can be applied and science does not operate in a vacuum. The regulatory system ultimately reflects the values of society. Risk assessment as a policy tool should address concerns that environmental harm is occurring through the production, use and recycling of non-ferrous metals.

2.4 Approaches to Uncertainty

Risk assessments are subject to a number of limiting factors and the Science Working Group identified the problems of the length of time to completion and the need for accurate and comparable measurement. The latter lies at the heart of different approaches towards the science currently used in risk assessments and its ability to provide clear answers to important questions about the potential environmental hazards associated with non-ferrous metals.

Among public interest groups there is the belief that science cannot yet offer a sound understanding of complex biological systems and the way in which organisms may be interconnected. They also point to the potential for cumulative and interactive impacts of multiple hazards. However, there does not appear to be any scientific methodology that would currently allow a practical multi-pollutant assessment. Faced with this uncertainty it is felt that policy makers should rely on sound decision making, open discussion (with all stakeholder groups) and public values in addition to available scientific information. To do otherwise could increase the risk of irreversible harm to the ecosystem and human health if the regulatory system demands incontrovertible scientific evidence of harm. One response to this inevitable scientific uncertainty is to avoid practices that have the potential to cause severe damage, even in cases where there may be no scientific proof of harm. This is the heart of the precautionary principle.

Regulators have acknowledged concerns about the uncertainty relating to risk assessment of non-ferrous metals. In some jurisdictions (such as the European Union) their approach, particularly in relation to bio-availability, has been to call for additional research within strictly set timetables. Research on bioavailability will further the understanding of ecotoxicology of non-ferrous metals. The non-ferrous metals industry has reacted by commissioning independent research vetted by scientific review panels also composed of independent experts. More collaboration and coordination between industry-funded research and governmental and academia research is needed. A more complete and open presentation from scientists on the limitations in risk assessment may also promote precautionary actions from government decision-makers and industry when potential risks and uncertainties are large.

The scientific approach to uncertainty both used by industry- and non-industry-funded research can be characterised as working to resolve problems relating to methodology, data sets and the risk models used. For example, there is an important overriding premise - namely non-ferrous metals as inorganic compounds and naturally occurring elements cannot be assessed in the same way as man-made compounds. For industry the uncertainty lies in the ability to replicate adequately in the laboratory the ability of organisms to adapt to different natural background concentrations and to model the effects of both toxicity and deficiency in the case of essential elements, e.g., copper and zinc.

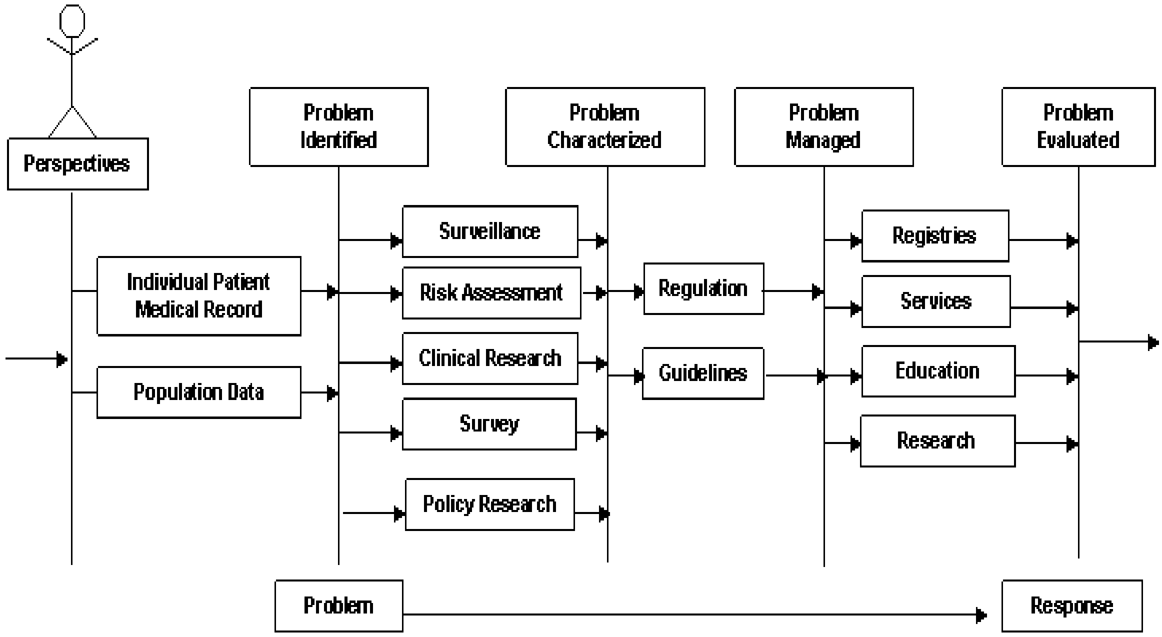
2.5 The Approach to Risk

The approach to risk establishes which problems are important and how they should be handled. The non-ferrous metals industry's view of risk may not be aligned with that of local communities based on differing interpretations of levels of uncertainty about the potential for environmental harm resulting from metals production, use and recycling. It is the role of the industry to utilise a community-based participatory approach in building effective relationship with communities that in turn will help to address issues of concern in a constructive and effective manner. It is the role of government, to establish the process of exchanging the different viewpoints of interested parties (policy-makers, industry, academia, affected communities, and the general public). One of the approaches that could be of interest for all stakeholders is to utilise life-cycle assessment. This approach is currently under development by the scientific community worldwide.

One of the biggest challenges faced by policy makers is how to regulate to meet the concern about the risks posed by bioaccessible metal concentrations without harming usage of metals such as copper, nickel and zinc that are known to be essential for living organisms. The approach to risk followed by most regulators asserts that humans have an assimilative capacity to absorb and decompose chemicals with negligible effects as long as exposure remains below a threshold at which toxic effects become significant. This is not the case for bioaccessible metal compounds. In some countries where they are ecological assessment-based (e.g. Russia, Sweden), the thresholds are usually significantly lower.

Harmonisation of environmental regulation is currently taking place, accompanied by a debate among public interest groups over the idea of "thresholds" as bases on which to set discharge limits and exposure limits relating to the ability to measure exposure and understand how ecosystems work. As scientific understanding has improved over time most thresholds set by regulators have fallen. Levels of acceptable risk vary over time and between different stakeholders. Inevitably there is a degree of subjectivity involved, but the approach to risk followed in a democratic process should reflect the will of society and its changing priorities. Therefore, the collaboration of all stakeholders (governments, industry, academia, and the public) is critical in developing a comprehensive approach on sustainability of non-ferrous metal production, use and recycling. One methodological approach to assessing risk is shown in Figure 1.

Figure 1: Unified Modelling Languale Sequence Diagram for Problem States



(Source: Anna O. Orlova, Harold Lehmann. 2002. A UML-based Meta-Framework for System Design in Public Health Informatics. Amer. Medical Iinformatics Association, Nov.9-13, 2002, San-Antonio, Texas, USA.)

2.6 Conclusions

- Non-ferrous metals as inorganic compounds and naturally occurring elements cannot be assessed in the same way as man-made chemicals

Risk assessment of non-ferrous metals is a relatively new phenomenon based on an existing framework developed by IPCS and the OECD for organic chemicals. It benefits from an agreed standardised approach across jurisdictions, but has experienced problems in application due to the need to gather new data and to take into account the essentiality of some non-ferrous metals to living organisms.

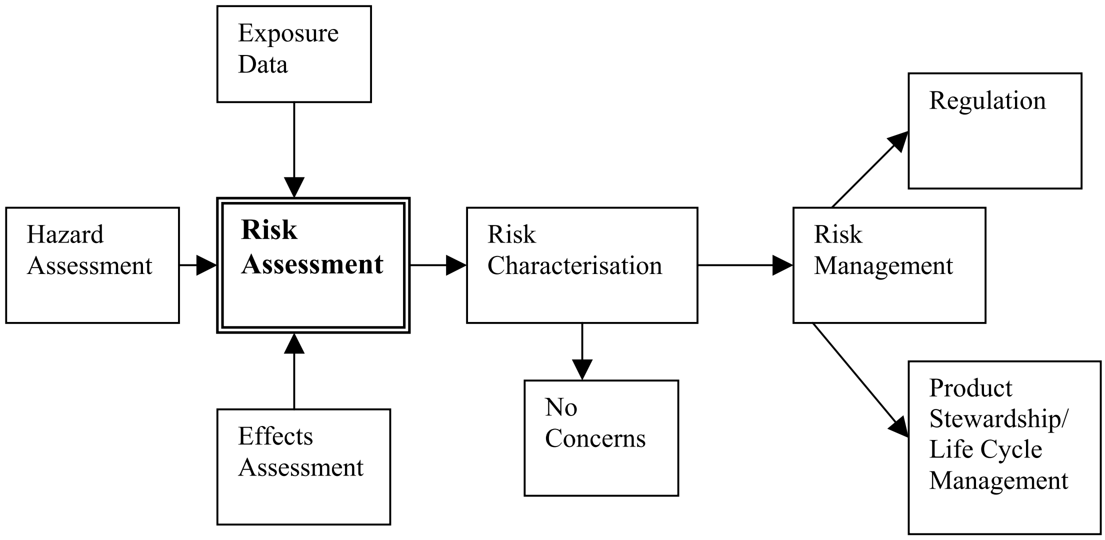
- The complexity of risk assessment has led some stakeholders to feel disenfranchised from the process. Local community groups and public interest groups often feel that the burden of proof to establish that existing environmental protection legislation may be insufficient lies with them. They rarely have the resources to generate the level of information to prove scientifically if harm is occurring to humans and/or the environment

There are also differences in interpretation over acceptable levels of risk and the degree of uncertainty apparent in current scientific understanding of how metals exposure affects complex ecosystems relating to environmental and ecological risk assessments.

- The approach to risk followed in a democratic process should reflect the will of society and its changing priorities

Risk assessment methodologies are evolving, and the risks posed by pollutants have been re-characterised over time. One result is that thresholds (limits) have fallen.

Figure 2: Risk Assessment and its Role in Developing Effective Regulatory and Voluntary Initiatives for a Sustainable Non-Ferrous Metals Sector



There is no risk management without prior risk assessment (as shown in Figure 2). Risk assessment is one basis for developing regulation in order to manage risk. Further evaluation of risk management activities would help to improve society's risk management decisions to control and eliminate risks associated with certain problems (or products). In some cases, the product itself could be eliminated as a result of risk assessment and management practices. In other cases, proper risk management practices (e.g. closed loop recycling) may allow continued usage of products for long-term sustainability.

- Faced with uncertainty, policy makers should rely on sound judgement, open discussion and public values in addition to the scientific information that is available.

In most jurisdictions the risk assessment process ends at a point where risk has been characterised and quantified. The process under which governments follow the principle of precautionary action designed to prevent harm when the exact nature of the harm is not proven may be pursued as part of an approach to risk management.

One approach to deal with uncertainty is to apply the precautionary principle that places the burden of proof on the proponent of an activity - production, rather than on the public as end user. Advocates of this approach point out that if properly applied, it is an open process that includes potentially affected parties and which involves an examination of a full range of alternatives. The comprehensive approach should include elements of societal/economic risks arising from, for example, sudden changes in production structure.

ANNEX I

Voluntary Risk Assessment Initiatives

The current system for conducting risk assessments in Europe whereby EU Member States have sole responsibility for carrying out the detailed work required has been heavily criticised. Of the large numbers of substances that are of concern in Europe (approximately 120 on the EU Working List and 30,000 existing substances with a production exceeding one tonne per year) only a handful have so far been assessed and there is a general recognition that the efficiency of the system must be significantly improved.

In order to address these issues the European Commission has proposed wide ranging changes to Chemicals Policy in the EU. A central theme of these proposals is a reversal in the burden of proof from the regulators to industry. In the light of these growing calls for industry to take greater responsibility for the assessment of its products, the European lead and copper industries have made definitive commitments to conduct voluntary risk assessments on the production and use of their materials across the EU. However, although a voluntary approach to risk assessment can help to overcome some of the shortcomings of the official process it also raises new concerns, primarily the question of how to ensure that a risk assessment conducted by industry is credible in the eyes of regulators and other stakeholders.

One way of creating trust is for industry to follow the official technical procedures for risk assessment in the European Union as set out in EU Council Regulation 793/93, Commission Regulation 1488/94 and the supporting Technical Guidance Documents (TGD). However, as the name suggests, the TGD provides only guidance on conducting a risk assessment and Member States must use expert judgement in its implementation. In order to ensure that there is no accusation of bias when implementing the TGD, industry has worked with the European Commission and Member States to develop a protocol for carrying out the voluntary risk assessments. The process encompasses the following core principles:

Industry: Industry is responsible for the management and funding of the risk assessment, with day-to-day coordination conducted by the relevant trade association. The industry will retain independent consultants to conduct the risk assessment and will establish a Scientific Review Panel (again comprising independent experts) to keep under review the protocols, analyses, results and conclusions.

Sponsoring Countries: One or possibly two sponsoring countries will assume the role of monitoring the progress of the risk assessment and advising the industry on key aspects of the project. The sponsors will be consulted on matters such as the appointment of consultants and members of the Scientific

Review Panel, and can participate on the Panel as an observer in order to monitor the review process. They can produce comments or questions to the industry, giving the opportunity to industry to answer or to supply further information. If they choose, the sponsoring country may then report to other Member States (at the Competent Authority or Technical Meeting level as appropriate) on industry's progress, highlighting where differences of opinion have been resolved or remain.

Scientific Review Panel: Independent experts in relevant health and environmental disciplines will be retained by industry to form a Scientific Review Panel. This Panel will meet periodically to review the protocols and analyses being employed in the risk assessment and to ensure that these methodologies are appropriate. The presence on this Panel of a representative of the sponsor countries should provide the sponsors with confidence in the processes employed, without requiring the investment of excessive manpower and expense that is a serious constraint for rapporteurs involved in formal risk assessments. The Panel will similarly review the results and conclusions of the risk assessment. By using independent consultants, a scientific review panel and by involving the Authorities in the process it is hoped that all stakeholders can have confidence in the process without shouldering the considerable burden of work that is required.