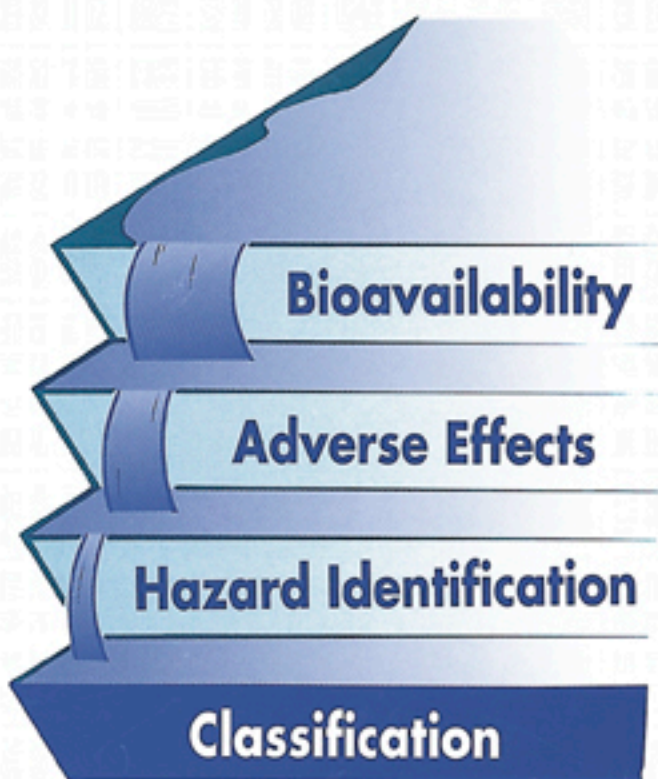


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# HAZARD IDENTIFICATION, HAZARD CLASSIFICATION AND RISK ASSESSMENT FOR METALS AND METAL COMPOUNDS IN THE AQUATIC ENVIRONMENT

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*by Peter M. Chapman, Ph.D.*



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**T**his paper has been published by the International Council on Metals and the Environment (ICME) as part of a series of publications discussing issues relevant to environmental and/or health-related policies affecting the mining and metals sector. It is believed that the topics examined are of concern, not only to the non-ferrous and precious metals mining and producing sectors, but also to others, including policy makers, regulators, educators and the public at large. ICME hopes that these publications provide insight into what are often difficult and complex issues. While the views expressed are those of the author, ICME welcomes questions and comments on this publication. Furthermore, the Council also appreciates suggestions regarding other issues of public importance for future publications.

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**A Publication by the International  
Council on Metals and the Environment**

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# FOREWORD

**T**oxicity, persistence and bioaccumulation are often identified as important parameters in aquatic hazard identification and risk assessment. However, since the body of knowledge for persistence and bioaccumulation was developed mainly for organic substances, further consideration of their relevance for hazard identification and risk assessment of metals and metal compounds was considered necessary.

For this purpose, two international meetings of experts were held. In September 1995, the OECD held a workshop in Ottawa, Canada, to recommend testing criteria for metals and metal compounds in the aquatic environment. This workshop was largely inspired by the view that criteria currently used for measuring aquatic toxicity were not appropriate for metals and metal compounds. A second technical workshop was held in Brussels, Belgium, in December 1995 under the auspices of the Canada/European Union Metals and Minerals Working Group. It addressed the issues of persistence and bioaccumulation as classification criteria for metals and metal compounds and proposed alternative approaches for their classification in water.

This publication summarizes the key conclusions of these international meetings and suggests a path forward for the hazard identification and risk assessment of metals and metal compounds that emphasizes: the importance of determining the bioavailable form of a metal or metal compound; the short-term acute effects; and, the long-term chronic effects. This publication also recommends that deficiency of essential elements be considered when developing a risk assessment methodology for metals and metal compounds in aqueous media.

Gary Nash  
Secretary General

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# EXECUTIVE SUMMARY

**T**he purpose of this report is to review the state of regulatory activities and the underlying science related to developing criteria for hazard identification so important to hazard classification and to risk assessment of metals and metal compounds entering the aquatic environment. This report incorporates the consensus achieved on these subjects at two recent international workshops (OECD, 1995; Canada/EU, 1996), and at other international meetings. Issues which remain are also detailed together with recommendations for their resolution.

Hazard identification and subsequent classification of metals and metal compounds in the aquatic environment can be accomplished within a similar (but not identical) framework to that currently being used for organic substances, pending resolution of the outstanding issues detailed herein. This involves, first, determining whether these substances are bioavailable such that adverse environmental effects may occur. If they are not bioavailable, there is no hazard. If they are bioavailable, then the potential to cause short-term adverse effects is determined by measuring the toxicity of the bioavailability fraction established by transformation. Hazard is determined in such cases using acute toxicity thresholds. If there is no acute toxicity, then whether or not the substance can cause long-term effects to aquatic biota is determined ideally by actual testing. Persistence, used as a modifier of toxicity for organic substances, is incorporated into transformation determinations. Bioaccumulation, also used as a modifier of toxicity for organic substances, is replaced by chronic toxicity.

Risk assessment of metals and metal compounds in the aquatic environment requires recognition of fundamental differences between inorganic metal compounds and organic compounds, including: metals and metal compounds are naturally occurring substances; some metals are essential for the health of organisms; speciation of metals governs bioavailability; and, a toxic metal species can originate from different metal substances. General consensus was that risk assessment of metals and metal compounds includes: "deficiency of essential metals" needs to be addressed; bioaccumulation data require a clear strategy before they can be used in decision-making; ingestion may be an important route of uptake for metals associated with particulates for some organisms; and, procedures and methods for testing with non-standardized organisms need to be determined.

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# I - INTRODUCTION

**H**armonization of substance classification and labelling criteria was identified as an international priority by the 1992 United Nations Conference for Environment and Development (UNCED Agenda 21, Chapter 19). As a result, international harmonization efforts related to ecosystem and human health are proceeding through the Organization for Economic Cooperation and Development (OECD - Advisory Group on Harmonization of Classification) under the auspices of the Intergovernmental Forum on Chemical Safety (IFCS), who have targeted 1997 for harmonization of classification criteria.<sup>1</sup> These efforts require agreement as to how to harmonize criteria for hazard identification and subsequent classification of organic and inorganic substances in use and transported on a worldwide basis, in other words, determining when substances might be “dangerous for the environment”. They also require good science in the decision-making process.

Ideally, harmonized international hazard identification resulting in classification would be based on simple, universal substance characteristics for which international agreement could be readily obtained. For instance, within Canada such simplicity is the basis of the Toxic Substances Management Policy (Environment Canada, 1995), which presently determines management options for any anthropogenic substances primarily on the basis of toxicity, modified by persistence and bioaccumulation.

However, such simple concepts are not necessarily applicable to all substances since all substances are not the same. In particular, intrinsic differences exist between organic substances and metals and metal compounds (e.g., Chapman et al., 1996a,b). The model of toxicity, modified by persistence and bioaccumulation, is not as directly applicable to metals and metal compounds as it is to organic substances.

Risk assessment methodologies are also not the same for organic substances and for metals and metal compounds. The purpose of this report is to review the state of the science and regulations as they apply to hazard identification, hazard classification and, ultimately, risk assessment for metals and metal compounds.

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<sup>1</sup> A more detailed summary of policies governing hazard identification, hazard classification and risk assessment, current as of December 1995, is provided in Parametrix (1995).

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## II - DEFINITIONS

### Hazard Identification and Risk Assessment

**H**azard identification and risk assessment are often used interchangeably, but in fact are different terms and should not be confused. Formal definitions are provided in OECD (1995) and Canada/EU (1996):

*Risk assessment* is the determination of the relationship between the predicted exposure/concentration and adverse effects in four major steps: hazard identification, dose-response assessment, exposure assessment and risk characterization.

*Hazard identification* is the identification of the adverse effects which a substance has an inherent capacity to cause. (This step is also referred to as “Effects Assessment” [Suter, 1993]).

*Dose-response assessment* is the estimation of the relationship between dose or concentration and the incidence and/or severity of an adverse effect.

*Exposure assessment* is the determination of the emissions, pathways and rates of movement of a substance in the environment, and its transformation or degradation, in order to estimate the concentrations/doses to which ecological systems, populations and organisms are or may be exposed.

*Risk characterization* is the estimation of the incidence and severity of the adverse effects likely to occur in an environmental compartment due to an actual or predicted exposure to a substance, i.e., integration of hazard identification, dose-response assessment and exposure assessment.

Hazard identification simply determines whether or not a substance could cause an adverse effect. Risk assessment incorporates hazard identification to determine the probability that an adverse effect could occur.

In the case of metals and metal compounds, the specific objective of hazard identification is to:

*recognize the **potential** to cause adverse effects in the environment under conditions of handling, transport (including releases such as spills) and usage.*

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Identification of a hazard does not mean it will necessarily be manifest. The science of toxicology is based on the premise that there is a dose or concentration above which effects occur, and below which effects do not occur. This premise dates back to Paracelsus, 1493-1541: “Sola dosis facit venenum” (there is no material which is not a poison depending on dose - Deichmann et al., 1986).

Thus, the objective of risk assessment is to determine the probability (not just possibility) of a hazard being manifest, specifically to relate an effect to an exposure. In other words, risk assessment attempts to answer the question of whether exposure to a substance in the environment exceeds the concentration at which an adverse effect may or will occur. US EPA (1992) defines risk assessment as “a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.” Risk assessment is a more complex and comprehensive process than hazard identification and incorporates hazard identification, dose-response assessment and exposure assessment as parts of the overall process (Suter, 1993).

## Hazard Classification

Hazard identification information is used in European hazard classification to determine whether substances may or may not be “dangerous for the environment”. The intent of existing hazard identification approaches such as European Union Directive 67/548/EEC (EU, 1967) is to classify substances to ensure that they are handled, transported, and used in the market place in an environmentally safe manner, with a full understanding of hazard. Hazard classification generally uses readily available information which conforms to simple criteria. As defined by OECD (1995):

*Hazard classification* is a procedure where inherent properties of a substance are classified as a means of providing information to, for example, a potential user of the substance.

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## III - CURRENT INTERNATIONAL CONSENSUS

A variety of fora are being used for international discussion and dialogue relative to developing consensus on hazard identification, classification and risk assessment. Two recent international workshops are particularly noteworthy relative to metals and metal compounds:

### Ottawa Workshop

An OECD Workshop held in Ottawa in September 1995 focused on aquatic toxicity testing of inorganic substances (OECD, 1995). This workshop addressed a need to review approaches for testing sparingly soluble inorganic substances (e.g., metals) for the purpose of classification criteria and to attempt to reach consensus on methodologies and interpretation of standard laboratory tests. Consensus was reached on the following points:

- Bioavailability is the key to hazard identification and to risk assessment since, if a substance is not bioavailable, it will not cause adverse toxicological effects to organisms.
- Hazard is currently determined based on acute toxicity, but long-term (chronic) toxicity needs to be considered.
- Aquatic toxicity testing should only be conducted to the solubility limit of the test material, with no vehicles or additives, and with the solid materials removed. This recommendation arose because of historic attempts to increase solubility limits in order to obtain a toxicity response, the possibility of physical effects from solids in the test containers, and the realization that the resulting toxicity responses were environmentally meaningless.
- Hazard identification criteria are not the same for organic chemicals as for metals and metal compounds. This consensus point recognizes differences between these two groups of substances. In particular, the toxicity of metals and metal compounds is almost always dependent on their ability to form metal ions (i.e., a change of valency state), which is not the situation with organic chemicals (or with other inorganic substances).

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- For risk assessments, which are based on comprehensive information, toxicity test results should be expressed as soluble concentrations and compared with the soluble fraction of that substance in the aquatic environment. This consensus item reflects the fact that, for risk assessments, the specific form of the substance released to the environment is less important than the soluble species which can occur. However, for hazard identification, which is based on data on intrinsic properties, and which is not comprehensive, the specific physical-chemical form of the substance is the most important parameter relative to the use of these data for hazard classification. This point is discussed further later in this report.

## Brussels Workshop

A European Union/Canada Working Group expert workshop held in Brussels in December 1995 focused on biodegradation/persistence and bioaccumulation/biomagnification of sparingly soluble inorganic substances (Canada/EU, 1996), and reached consensus on the following points:

- Bioavailability is the key to both aquatic hazard identification and risk assessment. Similar consensus was reached at the Ottawa workshop (OECD, 1995). In order for a substance to be toxic it must be bioavailable, but bioavailability does not imply toxicity.
- Persistence modifies toxicity (i.e., hazard), because it modifies exposure. As such, it is a secondary measure which historically has been incorrectly used as the sole surrogate for environmental fate, but which should not be the only descriptor for hazard identification.
- Bioaccumulation is not useful for hazard identification of metals for reasons including inability to predict adverse effects, and lack of predictive, standardized tests.
- Bioaccumulation data are useful for risk assessments relative to field data and natural tissue concentrations.

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# IV - HAZARD IDENTIFICATION OF METALS AND METAL COMPOUNDS IN THE AQUATIC ENVIRONMENT

**H**azard identification of organic and inorganic substances, is, as previously discussed, currently based on toxicity, persistence and bioaccumulation. Their relevance to hazard identification of metals and metal compounds is discussed below.

## Toxicity

Toxicity measurements are appropriate for hazard identification of all substances, including metals and metal compounds (OECD, 1995). They are a measure of adverse biological effects to individual organisms from bioavailable substances or from bioavailable forms of those substances. This measure is extrapolated to the protection of populations of organisms, communities and, ultimately, ecosystems. Ability to survive (acute toxicity) is the most important toxicity measure, and has been used to drive hazard identification. Chronic toxicity endpoints such as reproduction and growth are secondary measures for hazard identification. *Toxicity is a universal measure applicable to all substances.* However, not all substances will cause a toxic response.

## Persistence

Measures of persistence, based on biodegradation studies, are appropriate for hazard identification for many organic compounds but not for metals and metal compounds. Persistence of synthetic organic substances means that they may exist in the environment for long periods of time, thus increasing the duration of exposure to organisms and perhaps, depending on concentration and bioavailability, increasing the potential hazard. However, metals and metal compounds often exist in the environment for long periods of time in non-bioavailable forms.

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Persistence is a measure of the stability of a substance in a given medium over time. In water, it may be evaluated in several ways including measurements of the potential for biodegradation, hydrolysis, photolysis and chemical/biological transformation to occur. For organic substances, biodegradation has often (but not always) been the dominant process and is thought of as the most important, because it is the principal way in which an organic substance is broken down into its basic elements (carbon and hydrogen - usually as CO<sub>2</sub> and H<sub>2</sub>O). This process eliminates the substance from the aquatic system. There is no direct parallel for metals or metal compounds.

Persistence is one of several fate processes that can be measured to express the potential for the concentration of a substance to remain constant over time in a given medium. Biodegradation is a subset within a broad category of persistence studies that can be performed with a given substance to evaluate its potential to remain intact and potentially bioavailable for exposure to organisms. Other fate processes which act to change a substance's concentration over time include sorption processes, burial, volatility, physical advection and other transport mechanisms.

In general, the concept of persistence refers to the amount of parent substance remaining in the medium of interest. The concern is that if the substance is persistent and toxic, there is a potential for environmental effects, if the exposure level is high enough. For organic substances, biodegradation is a primary, but not the only, route of degradation of a substance in water. For metals and metal compounds, fate mechanisms other than biodegradation act to transform, bind, or transport the metal or metal compound such that the concentration of the bioavailable forms may decrease over time. Likewise, mechanisms such as oxidation exist which have the potential to increase metal concentrations. It is the net result of these processes together with the rate of input to the system that controls the total amount of metal in solution. It is generally recognized that metal concentrations in large bodies of water are controlled by the removal mechanisms which transform and transport metals to sediments (Biddinger et al., in press).

Considering these facts, the two previously mentioned workshops (OECD, 1995; Canada/EU, 1996) concluded that persistence, measured as the amount of substance removed via biodegradation, should not be used as a modifier of toxicity for classifying metals. A broader approach was advocated which considers factors which can maximize the potential for exposure and account for factors which can reduce exposure. In the current European classification system (EU, 1991), persistence is used as a modifier of toxicity for organic chemicals because degradation can reduce exposure. For metals, an analogous approach has been proposed whereby, for hazard identification, transformation studies would be used to evaluate the potential for metals and metal compounds to undergo transformation to more soluble bioavailable substances which would be more bioavailable (BIAC, 1996; Ethier, 1996). BIAC (1996) has also proposed that standardized

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studies be developed, for risk assessment, to evaluate the potential for metals to become less bioavailable through environmental fate processes such as sorption, precipitation, transformation and burial. In most cases, under natural conditions, these environmental fate processes will tend to decrease metal concentrations in aqueous environments (Canada/EU, 1996), and thus the hazard. The relationship between different transformation processes for hazard identification as compared to risk assessment is shown in Figure 1.

Thus, metals and metal compounds undergo *transformation which is a key environmental fate process* (Figure 1). The key question is whether a metal or metal compound transforms into a bioavailable cation and the rate and extent to which this occurs (OECD Metals Working Group, 1996). Accordingly, for hazard identification and subsequent classification, a standard procedure is needed to determine the rate and extent of transformation that a metal or metal compound undergoes in an aqueous environment (OECD, 1995). Such a procedure is currently being developed under the coordination of an OECD Working Group as discussed in Section V.

## Bioaccumulation

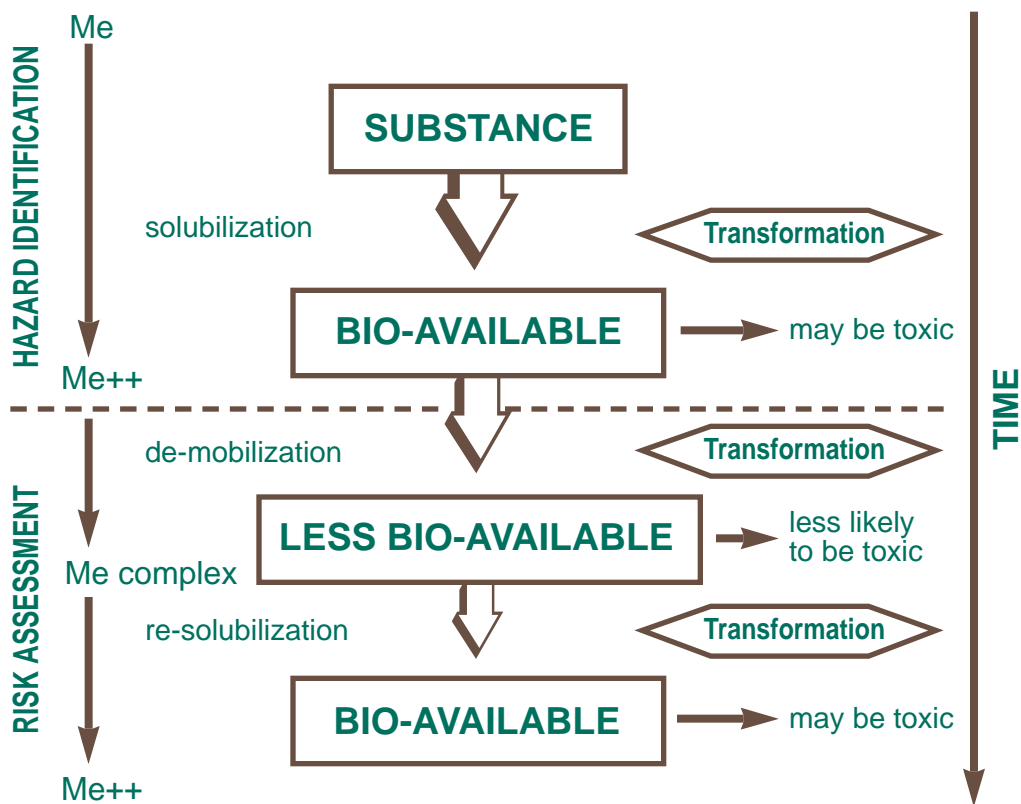
Measures of bioaccumulation, determined by laboratory experiments or octanol-water partition coefficients, are appropriate for hazard identification for many organic compounds but not for metals and metal compounds. Bioaccumulation of organic compounds occurs by passive diffusion and lipid solubility and, for organic substances, a test for the octanol/water partition coefficient is often an appropriate predictor of bioaccumulation potential. There is no simple test for bioaccumulation of metals and metal compounds.

The purpose of measuring bioaccumulation for organic compounds is to assess the potential for food-chain and/or longer-term effects (e.g., chronic toxicity). In risk assessment, bioaccumulation of organic compounds is a surrogate for possible effects via ingestion of prey, i.e., “secondary poisoning”. However, these purposes are not relevant to hazard identification of metals and metal compounds, and “...bioaccumulation of metals and metal compounds does not allow for the prediction of secondary poisoning to biota” (Canada/EU, 1996). Bioaccumulation is also incorrectly linked, for all substances, to biomagnification. Although biomagnification is a function of bioaccumulation, by definition it involves transfer through at least two trophic levels (“secondary poisoning” involves transfer through a single trophic level), is not predictable from bioaccumulation at a single trophic level, and does not appear to occur for metals and metal compounds other than methyl mercury (Chapman et al., 1996a). In general, it is “not a useful gen-

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eral criterion in the hazard identification of inorganic metal compounds or their constituent metal cations” (Canada/EU, 1996).

Bioaccumulation has, historically, been used incorrectly as a substitute for metal bioavailability. The reason this is incorrect is that many aquatic organisms possess the ability, through homeostasis mechanisms, to control their tissue metal levels. Because bioaccumulation of substances including metals and metal compounds can, depending on the rate and extent of uptake, result in long-term toxicity, the implicit purpose of measuring bioaccumulation for hazard identification is simply to determine potential for



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FIGURE 1. Differences Between Hazard Identification and Risk Assessment of Metals and Metal Compounds (Me) in the Aquatic Environment Relative to Different Transformation Processes. *Note that three different transformation processes are shown.*

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long-term effects. A more appropriate term, applicable to all substances, is their ability to cause long-term adverse effects. For hazard identification purposes, this is best determined through chronic toxicity data.

## Combined Measures

Based on international consensus at the OECD (1995) and Canada/EU (1996) workshops, the most important intrinsic property for hazard identification of metals and metal compounds is toxicity (acute and chronic), which incorporates bioavailability. Another apparent intrinsic property, total available surface area, is linked to bioavailability and toxicity (cf. Section V). Including a determination of transformation (to or from bioavailable forms, with consequent effects on exposure duration) effectively provides the same

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TABLE 1.  
Hazard Identification Framework

<b>Substances</b>	<b>Potential for Short-Term Adverse Effects (Acute Toxicity)</b>	<b>Determination of Bioavailable Forms</b>	<b>Potential for Long-Term Adverse Effects</b>
<b>Organic Chemicals</b>	Acute EC <sub>50</sub> in mg/L <sup>a</sup>	Degradability <sup>b</sup>	BCF, log K <sub>ow</sub> <sup>c</sup>
<b>Metals and Metal Compounds</b>	Acute EC <sub>50</sub> in mg/L <sup>d</sup>	Transformation <sup>e</sup>	Chronic EC <sub>50</sub> in mg/L <sup>d</sup>

a EC50 determined using the measured concentration of soluble material in test media.

b Degradability is the inverse of persistence.

c Measures of bioaccumulation.

d EC50 determined using the total amount of test material added to the test media.

e Transformation represents any physical-chemical reaction that would affect the bioavailability of metals and metal compounds. It can be operationally defined as the change of a substance from an insoluble form to a bioavailable form, or from a bioavailable form to an insoluble form. The measurements of interest are the rate and concentration of bioavailable species resulting from transformation at steady state. Steady state is defined as an acceptable approximation of equilibrium determined within a reasonable time frame within normal environmental conditions. Biological transformations such as methylation can be important in certain cases. However, this is an issue for risk assessment, not hazard identification.

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information for metals and metal compounds as is provided for organic chemicals by measuring toxicity, persistence and bioaccumulation (Table 1).

Aquatic toxicity measures for hazard identification of metals and metal compounds should involve, as for organic chemicals: measures of lethality (i.e.,  $EC_{50}$  values - concentration at which 50% die) and chronic toxicity measures (e.g.,  $EC_{\text{chronic}}$  values) in fresh and marine waters. The potential for metals to be transformed in the environment to more soluble and hence potentially more bioavailable substances, appears to be best measured by determining appropriate solubility factors and adjusting toxicity results accordingly (Allen and Batley, 1996). Solubility factors could be based on transformation studies measuring the amount of metal or metal compound available after a set period of time with testing conducted under relevant, natural conditions (Canada/EU, 1996), and should account for the rate and extent of dissolution relative to the amount of material added to solution. *Toxicity measurements should be multiplied by a "solubility factor", resulting in a final toxicity value (mg/l) used for hazard classification.* This procedure would address the issue that metals and metal compounds do not dissolve of themselves but rather undergo transformation whose rate and extent need to be considered relative to solubility.

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# V - HAZARD CLASSIFICATION OF METALS AND METAL COMPOUNDS IN THE AQUATIC ENVIRONMENT

## Legislation

**K**ey European Union (EU) legislation relative to hazard classification includes:

- The Dangerous Substances Directive (DSD - EU, 1967)
- The 7th Amendment to the DSD, introducing the concept of classification of substances which are “dangerous for the environment” (EU, 1991).
- The 12th Adaptation to Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances.

Because ecological (as opposed to human) toxicity legislation for hazard classification originated in Europe, the focus of this report is on European legislation, definition and application of hazard classification. However, there are differences between Europe and the rest of the world. Outside of Europe, hazard classification is used primarily for risk communication. In Europe, hazard classification serves as the foundation for the assessment, labelling and packaging of substances in the marketplace. It can also restrict transport, marketing/use and export/import of substances labelled as “dangerous for the environment” (UN Committee on the Transport of Dangerous Goods, 1995). This latter classification category is, at least for the present, unique to the European Union.

EU (1991) provides a means to compile relevant environmental information regarding a substance so as to determine the level of hazard by classification, resulting in labelling. As previously noted, the present EU system depends on acute ecological toxicity, bioaccumulation and biodegradation data to determine hazard. Very ecologically toxic substances ( $LC_{50} < 1.0$  mg/l) are labelled R50. Less ecologically toxic substances are labelled R51 or R52. Substances which either bioaccumulate (bioaccumulation factor

[BCF] > 100 or  $K_{ow}$  [log octanol-water partitioning coefficient] > 3.0) or are not readily biodegradable are labelled R53. The R50 designation is always used in conjunction with another R symbol, for instance R53. For example, a substance which is highly toxic to aquatic life (R50) and not readily biodegradable (R53) would be labelled R50/R53. The present classification scheme is shown in Table 2.

Hazardous properties vary significantly with physical form, for instance with the form of metal or metal substance. Based on EU (1967, 1991) and consensus emerging from the OECD Metals Working Group (1996), and the OECD Advisory Group on Harmonization of Classification<sup>2</sup> and Labelling Systems (1996), hazard classification criteria should:

TABLE 2.  
EU Criteria for Classifying Substances as “Dangerous for the Aquatic Environment” (simplified)

Acute Toxicity <sup>a</sup>	Very Toxic <sup>a</sup>	Toxic <sup>a</sup>	Harmful <sup>a</sup>	Bioaccumulation Potential	Not Readily Biodegradable
96h LC <sub>50</sub> Fish <sup>b</sup>	≤1 mg/L	>1 ≤ 10 mg/L	>10 ≤ 100 mg/L	Log $K_{ow}$ ≥ 3	as defined by OECD
48h EC <sub>50</sub> Daphnia <sup>b</sup>	≤1 mg/L	>1 ≤ 10 mg/L	>10 ≤ 100 mg/L	unless BCF ≤ 100	guidelines or
72h EC <sub>50</sub> Algae <sup>b</sup>	≤1 mg/L	>1 ≤ 10 mg/L	>10 ≤ 100 mg/L		BOD 5 / COD ≤ 0.5 <sup>c</sup>
Label	R50	R51	R52	R53	R53

a Toxicity as applied to the ecosystem, not to human health.

b The lowest value determines the classification.

c BOD = Biological Oxygen Demand  
COD = Chemical Oxygen Demand  
All other terms defined in text.

2 Hazard identification is based on intrinsic properties. Hazard classification is an arbitrary regulatory convention that uses hazard identification information to drive regulatory actions.

- 
- be transparent, leading to self-classification<sup>3</sup>;
  - avoid hazard classification on a case-by-case basis; and,
  - ensure that classification criteria are appropriate for the intrinsic properties of the substance being classified.

## Toxicity

Because aquatic acute toxicity is the primary driver for hazard identification and thus for subsequent hazard classification of metals and metal compounds, it is critical that toxicity test data be properly derived and appropriately reported. The range of test conditions is particularly important and can involve either a “worst case” condition or a range of conditions within “normal” conditions (OECD, 1995; Canada/EU, 1996). In order to establish the boundaries of the test conditions, the range of appropriate (i.e., to maintaining organism health), relevant (i.e., to possible exposure), naturally-occurring water quality parameters (e.g., hardness, pH) must be defined.

The OECD (1995) workshop noted that “solubilization” of metals and metal compounds is, in fact, a transformation reaction to form bioavailable metal ions rather than true “solubilization” in water. The rate and extent of this transformation to soluble and potentially bioavailable species is critical for hazard identification, and for subsequent hazard classification. However, the OECD (1995) workshop did not reach consensus as to the best means of relating the EC<sub>50</sub> of the soluble species to the total quantity of test material for hazard classification purposes. Specifically, two proposals were advanced. One proposal was that the soluble concentration, defined as the concentration in solution of the original substance that produced an EC<sub>50</sub>, be used for hazard identification. The other proposal was that an EC<sub>50</sub> be related to the total concentration, defined as the amount of the substance (i.e., of the material tested) required to produce the effect. The latter alternative would normalize the bioavailable fraction to the total mass of material required to provide that bioavailable fraction; the former would not, and thus ignores the role of kinetics in chemical reactions (OECD, 1995).

For hazard identification and subsequent classification, the total substance concentration intuitively appears to be the most appropriate approach. The ultimate objective is to determine the potential for a metal or metal compound to cause an adverse effect.

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<sup>3</sup> In general, in the European Union, pure substances are classified by the Technical Progress Committee (TPC). The supplier classifies only those substances not yet classified by the TPC.

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Whether this can occur relates to bioavailability, as agreed to by both OECD (1995) and Canada/EU (1996). Bioavailability can only occur with the release of soluble compounds. The problem is that this release often occurs at a very slow rate for metals and metal compounds and by different transport pathways as compared to, for instance, organic chemicals. Thus, the real question of concern is what measure of exposure will give the most appropriate and realistic description of hazard. Provided that an appropriate transformation protocol is used to measure the resulting transformed products, then toxicity test results should be classified on the basis of the total material subjected to the transformation protocol, not just the solubility products (cf. Allen and Batley, 1996). This is the reason that the Brussels Workshop (Canada/EU, 1996), as a high priority, recommended, as a high priority, "...that a standard method be developed for the determination of the solubility characteristics of sparingly soluble metals and inorganic compounds for the purpose of their hazard identification." They also recommended that, for toxicity testing, "...the result and its interpretation must be in terms of the parent metal compound."

The OECD Metals Working Group (1996) has endorsed the development of a dissolution protocol appropriate for testing metals and metal compounds, and is considering the most appropriate way to express the resulting toxicity data relative to hazard identification and subsequent classification. Canada is currently co-ordinating an international research effort to develop an appropriate dissolution protocol, based on work conducted by LISEC (1996a, b). LISEC (1996a) has developed a draft protocol for establishing the soluble fraction of metals and metal compounds and relating toxicity data on the soluble metal species to the parent substance. Testing conducted to date (LISEC, 1996b) has been done with coarse, fine and very fine zinc powders. Results indicate that "insoluble" zinc powders dissolve to a certain extent in toxicity testing media; equilibrium can be established; and, dissolution can be described by first order kinetics. Dissolution rate and the resulting equilibrium are related to the available reactive surface which is related to particle size. These results suggest the possibility of standardization relative to hazard classification based on different particle sizes, since total available surface area appears to be an intrinsic property for metals and possibly also for metal compounds, affecting bioavailability.

## Framework

There is a general consensus in the scientific community (e.g., OECD, 1995; Canada/EU, 1996) that hazard identification and subsequent classification for metals and metal compounds should probably "fit", to the extent possible, within an approach analogous to the EU approach (cf. Table 1).

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Within this approach, hazard classification requires answers to three specific questions:

1. Is a substance bioavailable such that adverse environmental effects may occur?
2. If bioavailable, is a substance likely to cause short-term adverse effects to aquatic organisms?
3. If bioavailable, but not exhibiting short-term adverse effects to aquatic organisms, is a substance likely to cause long-term adverse effects to aquatic organisms?

A framework for hazard classification of metals or metal compounds is proposed in Figure 2, which answers these three questions based on a scheme proposed by OECD (1995, page 8, Figure 1). This framework will appropriately identify and classify metals and metal compounds as hazardous (i.e., “dangerous for the environment”) or not, on the basis of solubility, and acute and chronic toxicity. Following this approach, one first determines whether bioavailable (i.e., soluble) forms are produced at levels of concern under normal environmental conditions. If not, there is no danger to the environment. If so, short-term (i.e., acute) toxicity is determined, and the dissolved equilibrium concentration resulting from the transformation is compared with the  $EC_{50}$  determined for the soluble fraction. If the substance is acutely toxic, then it is classified according to the level of acute toxicity observed (e.g., OECD considers a substance with an  $EC_{50} < 1.0$  mg/L to be dangerous for the environment based on acute toxicity alone, cf. EU criteria, Table 2). If the substance is not acutely toxic, whether appropriate long-term (i.e., chronic) toxicity data are available is determined. If the data are not available, and there is no intent to conduct studies to obtain the data, a safety net is applied relative to an appropriate hazard classification. If, however, data are available, or appropriate studies are conducted, this information is then used for hazard classification. The OECD Advisory Group on Harmonization of Classification and Labelling Systems (1996) is considering the use of a chronic toxicity safety net, including hazard classification criteria based on chronic toxicity to match the  $EC_{50}$  limits presently used for acute toxicity (Table 2).

Within this framework, it has been concluded (BIAC, 1996) that:

- Testing should neither be mandatory nor necessary where relevant existing information (e.g., acute and/or chronic toxicity test data) and professional judgement can be used to determine hazard. If relevant existing data or information are adequate for hazard identification and subsequent classification, further testing is unnecessary.
- Normal homeostasis mechanisms which control the uptake of essential metals (e.g., copper, zinc) in organisms cannot be ignored (van Tilborg and van Assche, 1995).

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Though the boundaries of these mechanisms are not presently fully understood, recognition of these mechanisms is required in hazard identification of essential elements. This may require the use of professional judgement to adequately determine hazard in these cases. It certainly requires that test organisms be cultured in appropriate media to meet their relevant requirements for essential metals.

- There should always be the opportunity to test further, where appropriate, to obtain more meaningful data. The proponent should always be allowed to conduct further studies (i.e., other than those required) if the information obtained can be used to provide more accurate and appropriate hazard identification and subsequent classification.
- Field data, including historical information, should be used preferentially, when available and appropriate, rather than laboratory data. Laboratory data are obtained under carefully controlled conditions and do not duplicate what occurs in the field, where biotic and abiotic interactions may occur; thus, appropriate field data are preferable for decision-making.
- Potential remobilization of metals and metal compounds needs to be addressed through risk assessment, not through hazard identification and subsequent classification (cf. Figure 1). Immobilization is a thermodynamically driven process reflective of the intrinsic properties of a substance and hence appropriate for inclusion in hazard identification and subsequent classification. In contrast, remobilization of metals built up over time in sediments is not an intrinsic property and, except in the case of extreme weather systems (e.g., hurricanes coinciding with very low tides in marine systems, catastrophic floods in freshwater systems), probably does not occur in the absence of human intervention (e.g., dredging).

## Proposed Hazard Classification of Metals and Metal Compounds

Table 3 outlines a classification system for metals and metal compounds which is based on the R-designations detailed in Table 1, the specific properties of metals and metal compounds, and the framework detailed in Figure 2. As for the present EU (1991) system, substances which have high acute toxicity (i.e., lowest LC/EC<sub>50</sub> values) are classified and labelled R50. Less acutely toxic substances are classified and labelled R51 or R52. Each of these designations incorporates solubility. Thus the inorganic equivalent of persistence, transformation to more bioavailable forms, is already part of the acute toxicity classification. The R53 label is used when there is no acute toxicity but chronic tox-

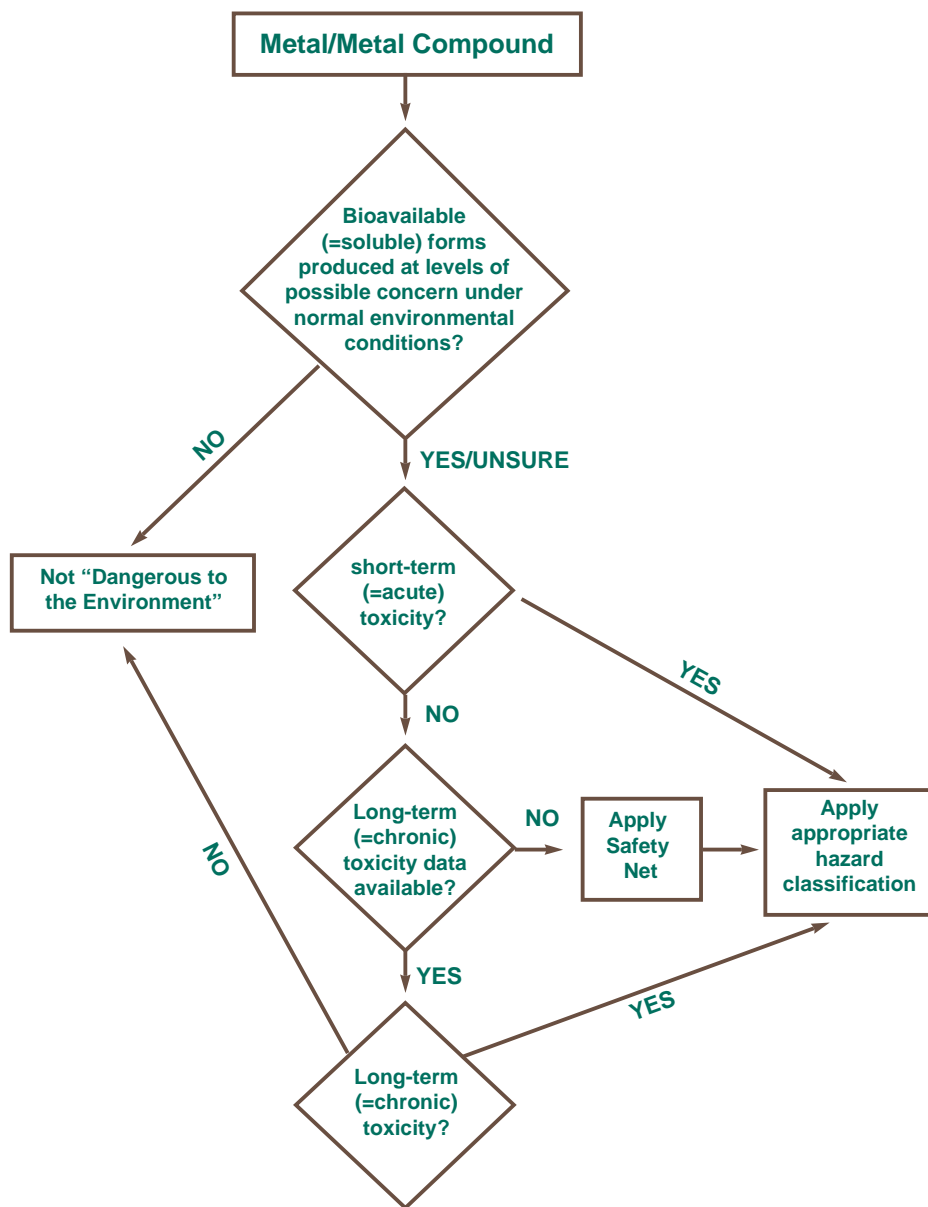


FIGURE 2.  
Hazard Classification of Metals and Metal Compounds in the Aquatic Environment.  
Modified from OECD (1995).

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icity exceeds a presently unspecified threshold or, in the absence of data, other information about the substance leads to application of a safety net.

It should be noted that, unlike the present EU (1991) system, acute toxicity is only determined based on fish and Daphnia; algae are only included for determining chronic toxicity. This distinction is appropriate because the multi-generational algal test is actually a chronic toxicity test (OECD Metals Working Group, 1996). Chronic fish and Daphnia tests could involve, respectively, full life-cycle testing (e.g., 7-d *Ceriodaphnia dubia* or equivalent) and early life-stage testing (e.g., 7-d fathead minnow development, or equivalent) to determine long-term toxicity (US EPA, 1994). OECD protocols presently exist for both Daphnia chronic testing and fish early life-stage testing.

It should be further noted that if, as appears to be the case (LISEC, 1996a,b), total available surface area is in fact an intrinsic parameter for metals and metal compounds, this could result in differences in classification for metals and metal compounds depending on their physical form.

TABLE 3.

Proposed Criteria for Classifying Metals and Metal Compounds as “Dangerous for the Aquatic Environment”

Acute Toxicity <sup>a</sup>	Very Toxic <sup>a</sup>	Toxic <sup>a</sup>	Harmful <sup>a</sup>	Chronic Toxicity	No Data	Data
96h LC <sub>50</sub> Fish <sup>b</sup>	≤1 mg/L	>1 ≤ 10 mg/L	>10 ≤ 100 mg/L	EC <sub>chronic</sub> Fish <sup>b</sup>	Safety Net Applied <sup>c</sup>	≤ Chronic Toxicity Threshold <sup>d</sup>
48h EC <sub>50</sub> Daphnia <sup>b</sup>	≤1 mg/L	>1 ≤ 10 mg/L	>10 ≤ 100 mg/L	EC <sub>chronic</sub> Daphnia <sup>b</sup>		
				72h EC <sub>50</sub> Algae <sup>b</sup>		
Label:	R50	R51	R52	Label:	R53	R53

- a Toxicity values incorporate a solubility factor, need to consider the apparent intrinsic property of total available surface area (see Table 1 and text), and only apply to the ecosystem, not to human health.
- b The lowest value determines the classification.
- c Safety net characteristics remain to be determined but should involve an assessment of whether chronic toxicity is possible. Such an assessment, in the absence of actual data, would involve best professional judgement considering the physical-chemical characteristics of the metal or metal compound and the results of acute toxicity testing. If there is uncertainty, an R53 label should be applied.
- d Chronic toxicity threshold remains to be determined but should be based on the level of chronic toxicity which can adversely affect the ecosystem. For instance, 40 to 50% reductions in growth in the laboratory may be indicative of potentially significant effects on survival and reproduction in the field (Kubitz et al., 1996). An EC<sub>chronic</sub> ≤0.1 mg/L, 10-fold less than the lowest acute toxicity threshold, could be used as a conservative threshold in the absence of information on ecosystem effects.

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# VI - RISK ASSESSMENT OF METALS AND METAL COMPOUNDS IN THE AQUATIC ENVIRONMENT

**A** risk assessment is a process which considers the probability and degree of harm that a hazardous substance poses, considering level of exposure and both short-term (i.e., acute) and long-term (i.e., chronic) time scales. US EPA (1992) notes that “a risk does not exist unless (1) the stressor has the inherent ability to cause one or more adverse effects, and (2) it co-occurs with or contacts an ecological component (i.e., organisms, populations, communities, or ecosystems) long enough and at a sufficient intensity to elicit the identified adverse effect.” Risk assessments are generally performed on two spatial scales: local, encompassing a narrow range of environmental conditions; and, regional, encompassing a wide range of environmental conditions.

Risk assessment, in the European context, is based on comparing the predicted environmental concentration (PEC) of a substance with its predicted no effect concentration (PNEC). PECs are measured, but PNECs require the use of professional judgement, generally either by applying a safety factor to the lowest measured no observed effect concentration (NOEC) or to the use of statistical extrapolation of toxicity data fitted to a logistic curve to derive a maximum tolerable concentration (MTC) (Sloof, 1992). Similarly, in North America, the ratio of a substance’s expected environmental concentration is compared to its no-adverse-effect level, termed the ecological benchmark concentration (Parkhurst et al., 1994). However, as risk assessments evolve, they are moving away from strict reliance on these quotient approaches, to probabilistic risk assessments expressing the results as a distribution of toxicity values rather than a single point estimate (SETAC, 1994; Solomon et al., 1996), and will probably further evolve to Bayesian analyses (HERA, 1996).

The annexes to the EC guidance document note fundamental differences between metals and organic compounds relative to risk assessments. These differences include, but are not restricted to, the following observations:

- Metals and some metal compounds are natural substances. Thus natural “pollution” occurs, for example, in highly mineralized areas never subjected to mining activities (Thornton, 1996; Rasmussen, 1996a,b).

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- Some metals are essential for the health of organisms. Thus toxicity can occur due to both deficiency and excess. Van Tilborg and van Assche (1996) have proposed changes to the way risk assessments are conducted for essential metals based on this reality.
  - Speciation of metals governs bioavailability. Thus total metals concentrations provide no information on bioavailability and can be misleading when used for decision-making.
  - A toxic form of a metal can originate from different metal substances. Thus the focus should be on the metal species that are bioavailable and that can, in excess, result in toxicity.

General consensus, arising from the OECD (1995) and Canada/EU (1996) workshops, and subsequent international meetings, exists on the following key points regarding risk assessments for metals and metal compounds:

- Normal homeostatic mechanisms exist and control uptake and tissue storage of metals essential to the survival of organisms (e.g., zinc, copper). These mechanisms and the conditions under which they can be altered need to be considered in any risk assessment involving essential metals. Ultimately, tests need to be developed and applied to measure metal “deficiency” toxicity. Test organisms should originate from, and be cultivated within, the optimum natural concentration range for these essential metals.
- Bioaccumulation of a metal cation by an organism can be measured, in a risk assessment, by direct analysis of tissue and comparison of concentrations with those in the exposure media (e.g., water, sediment). These data are metal- and organism-specific. Interpretation of these data is complicated by homeostasis mechanisms whose boundaries are not presently well understood. A clear strategy is required for using bioaccumulation data in decision-making.
- For hazard identification, it is assumed that uptake from water is the primary mechanism for accumulation of the bioavailable fraction of metals and metal compounds. However, for risk assessment, ingestion may also be an important route of uptake for metals associated with particulates, in some cases, for some organisms.
- The criteria for selecting organisms for risk assessments differ from those for hazard identification. Hazard identification and subsequent classification are based on testing with standardized organisms; however, risk assessment allows for testing with site-specific organisms under site-specific conditions. To do this effectively requires additional development of criteria for organism selection and use, and determining when non-standardized organisms may be used, including quality assurance/quality control (QA/QC) considerations.

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## VII - FUTURE DIRECTIONS

**H**azard classification of metals and metal compounds requires, in particular: clear definition of the safety net strategy for cases where chronic toxicity data are not available; and, definition of a chronic toxicity threshold below which a metal or metal compound would be classified (i.e., R53) (cf. Table 3). Summarized below are the areas that have been identified in this report as requiring further work in support of developing criteria for hazard identification, hazard classification and risk assessment:

1. Clarification is required of the relationship between toxicity measurements of the soluble species and the solubility characteristics of the parent metal or metal compound. Similar clarification is being sought for other poorly water-soluble compounds (e.g., Carvalho et al., 1995). Basically, further determinations of the kinetics of dissolution are necessary, including how to “translate” dissolution kinetic data into an appropriate classification of metals and metal compounds.
2. A general dissolution protocol (i.e., a transformation measurement) is needed for determining the soluble fraction of a metal or metal compound which is relevant for assessing its aquatic toxicity for hazard identification and subsequent classification (OECD, 1995). Work to develop such a protocol is currently underway and is being coordinated by the Canadian government. This protocol will allow for hazard identification of metals and metal compounds based on their intrinsic tendency to transform into bioavailable species.
3. The range of appropriate (i.e., to maintaining organism health), relevant (i.e., to possible exposure), naturally-occurring water quality parameters (e.g., hardness, pH) must be determined to establish boundaries for bioavailability (e.g., toxicity) testing.
4. Tests for defining toxicity due to deficiencies in essential metals need to be developed and applied to test organisms. Specifically, there is a need to determine how the “deficiency border” of essential elements can be defined and measured. Test organisms should originate from, and be cultivated within, the optimum natural concentration range for essential metals.
5. Criteria should be developed to evaluate the appropriateness of non-standardized test organism(s) for particular risk assessments.
6. The relationship of dissolved (i.e., soluble) metal concentrations in natural waters and sediments needs to be defined relative to physico-chemical parameters.
7. A clear strategy is required for using (or not using) bioaccumulation data in decision-making resulting from risk assessment of metals and metal compounds.

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## VIII - SUMMARY

A decision framework and criteria are proposed for hazard classification of metals and metal compounds within the context of existing international regulations and initiatives. The framework determines: whether these substances are bioavailable to levels of concern; if so, whether short-term (acute) or long-term (chronic) adverse effects are likely to occur. Hazardous substances will be classified as such, substances which are not hazardous will also be properly classified. Finalizing this decision framework requires, in addition to testing and validation: continued development of a general dissolution protocol for obtaining the soluble fraction of a metal or metal compound which is relevant for assessing its aquatic toxicity (OECD, 1995); and, establishing a standardized protocol for determining chemical solubility factors (Canada/EU, 1996). The proposed classification criteria use the same R- designations as currently used by the EU (1992), follow the decision framework, and consider the specific properties of metals and metal compounds. Finalizing the hazard classification criteria requires, in particular, determination of chronic toxicity thresholds and “safety net” characteristics, and specific test conditions.

Risk assessment specific to metals and metal compounds is discussed, including differences between these substances and organic compounds, and current international consensus (OECD, 1995; Canada/EU, 1996). Particular future information needs for risk assessment of metals and metal compounds include hazard classification criteria for non-standardized test organisms, approaches and methods to test for essential metals deficiency, solubility in natural waters related to physico-chemical parameters, and a strategy for using bioaccumulation data in decision-making.

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## NOTES

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## VII - FUTURE DIRECTIONS

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#### **T HEAD DISSOLUTION PROTOCOL (I.E., A TRANSFORMATION**

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TABLE LIST should be developed to evaluate the appropriateness of non-standardized test organism(s) for particular risk assessments.





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This report summarizes a great deal of information derived from a variety of sources. It also details some major advances in hazard identification approaches (e.g., BIAC, 1996; Ethier, 1996) for which credit belongs to a wide group of individuals, of whom the author is only one. Thus this report should not be construed as solely the work of the author. However, the contents of the report are solely the author's responsibility, and the opinions expressed are similarly his responsibility.

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