Secretariat

**Committee of Experts on the Transport of Dangerous Goods
and on the Globally Harmonized System of Classification
and Labelling of Chemicals**

**Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals**

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Item 5 (a) of the provisional agenda
Development of guidance:
Alignment of Annex 9 (section 9.7) and Annex 10
with the criteria in Chapter 4.1

Revision of GHS Annex 9 (section 9.7) and Annex 10 to align them with the criteria in Chapter 4.1 and the generic environmental hazard guidance

Transmitted by the International Council on Mining and Metals (ICMM) on behalf of the informal working group*

Introduction

1.   This document summarises the work of the informal working group on "the alignment of Annex 9 (section 9.7) and Annex 10 (on metals and metal compounds) to the criteria in Chapter 4.1 and the generic environmental hazard guidance", and, with informal document INF.6, presents a proposal for revision of these annexes to ensure their alignment with the GHS text, for consideration by the Sub-Committee.

Background

2.   The terms of reference for the work of informal working group (informal document INF.25, (twenty-fourth session)) set out the following tasks:

(a)   to complete the review of Annex 9 section A9.7 (Environmental classification of metals and metal compounds) and Annex 10 (Transformation-Dissolution of metals and metal compounds in aqueous media) for inclusion under a future revised edition of the GHS to ensure that the classification strategy, guidance and tools on metals and metal compounds are in line with the long-term aquatic classification scheme introduced by the third revised edition of the GHS text.

(b)   To report progress to the GHS Sub-Committee as appropriate. The latest status update is informal document INF.10 (forty-second session).

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*   A/75/6 (Sect.20), para. 20.51.

3.   The main changes that were considered to amend the basis for hazard categories towards the long-term aquatic classification endpoint for metals and metal compounds include:

(a)   For Annex 9, section A9.7:

(i)   extension of the classification strategy and guidance for metals, and poorly soluble metal compounds towards the long-term aquatic classification endpoint

(ii)   extension of the effects data interpretation for data rich substances, to the long-term aquatic classification endpoint

(iii)   review of the application of M factors for the acute and long-term aquatic classification endpoint

(b)   For Annex 10: extension of the Transformation/Dissolution protocol (TDp) to lower doses (0.1 and 0.01 mg/L at 28 days) - which could include testing and modelling guidance

4.   The correspondence group progressed the work item in two phases between 2011 and 2014, and then between 2020 and 2022. The work has been summarized in informal documents INF.25 (twenty-fourth session), INF.33 (twenty-eighth session), INF.9/Rev.1 (thirty-ninth session), INF.17 (fourth-first session) and INF.10 (fourth-second session). Discussions in the informal correspondence group are detailed, and the group has worked diligently over several years to address its mandate and to resolve issues and challenges, with a focus on completing the group's work on the two annexes in the 2020-2022 biennium. After each call ICMM, as lead, revised the draft text of annexes and prepared papers on specific topics to take forward the discussions, taking into account verbal and written comments and information provided by members of the group.

5.   Paragraphs 6 to 13 below provide the Sub-Committee with an indication of the nature of the work that has been undertaken, the issues that have been identified, and the solutions that have been adopted. The changes made to Annex 9 (section 9.7) and Annex 10 are summarised in the annex to this document. For clarity the full text of the annexes as revised is set out in informal document INF.6 with an indication of where the text has changed relative to the ninth revised edition of GHS.

Issues and outcomes

6.   Between 2011 and 2014, the informal correspondence group activities were informed, in part, by the experience gained from redrafting the European Union guidance for the implementation of the third revised edition of the GHS under the Classification, Labelling and Packaging Regulation (CLP Regulation). This European Union guidance proved a useful resource as it includes an updated classification strategy, scheme and guidance for metals and metal compounds. It was published in April 2012.

7.   The group changes proposed in the annex of this document are in line with its mandate and do not introduce any new technical concepts beyond those already contained in the GHS. Some of the additions proposed by members of the group during their discussions were beyond the mandate of the group, and the group therefore agreed not to consider them further.

8.   The work resumed in 2020 starting with a full and detailed review of the comments and changes that had been tabled by the different experts to date. By the end of 2020, the group agreed that most of the proposed changes discussed to that point were acceptable in principle. A limited number of open issues was identified: the role of the screening test for metal compounds, the approach for the default classification category Aquatic Chronic 4, clarifying the correlation between Transformation/Dissolution and toxicity at varying pH, and a consistent definition of the ecotoxicity reference values (ERV). The latter two issues were quickly resolved by written procedure. The former two were the subject of further discussions in 2021 and 2022.

9.   During 2022, the group discussed the use of the screening test further, and considered the loading rate, the application field, the function, and the relevancy. Initial views from participants diverged related to the loading rate, with some participants suggesting that the loading rate must be set at a fixed value (100 mg/L) and others suggesting it could be linked to the loading rates considered in the acute classification scheme for the Transformation/Dissolution tests. Initial views expressed by participants also diverged on the application field of the screening test, i.e. whether additional data could be useful to identify a metal compound as readily or poorly soluble. After discussion, the group reached consensus on the basis of the following premises:

(a)   The screening test is only applicable to metal compounds, and the aim is to differentiate between readily soluble and poorly soluble compounds

(b)   The screening test was developed with this aim in mind, and therefore the testing conditions of the screening test are different from the full test. The testing conditions (including the loading rate) are therefore unrelated to the use of full Transformation/Dissolution data in the classification schemes. The full Transformation/Dissolution test is normally not used for identifying readily and poorly soluble metal compounds.

10.   Regarding the role of the default classification category Aquatic Chronic 4 (safety net classification), the group first worked to ensure that the approach is fully consistent with Chapter 4.1, section 4.1.2 of the ninth revised edition of the GHS. On this basis, the group concretely agreed that:

(a)   There is no safety net classification foreseen in the acute classification.

(b)   The classification schemes should first assess whether a metal or metal compound meets the criteria for classification as Chronic 1, 2, or 3. If this is not the case, it should then be assessed whether Chronic 4 applies.

(c)   The GHS is designed to work based on existing data. If Transformation/Dissolution data are not available, the GHS should therefore not mandate additional testing.

11.   The agreement that no safety net classification is foreseen in the acute classification prompted a further discussion by the group around how to deal with cases when no Transformation/Dissolution data are available. Having considered four different cases where this may occur and the possible classification outcomes, the group agreed on a limited set of additional changes to Annex 9, sub-section A9.7.5.2 in the GHS. The group agreed that these proposed changes resolve the final open issue that had been identified in this biennium and allowing the issue of cases when no Transformation/Dissolution data are available to be dealt with adequately and effectively.

12.   Having considered the issues outlined in paragraph 3 (a) of this document, the informal correspondence group's proposed changes to Annex 9, section 9.7 of the GHS can be summarised as follows:

(a)   In A9.7.1 *Introduction*, the amendments put forward aim to clarify the applicability of A9.7 to metals and metal compounds.

(b)   In A9.7.2.1 *Interpretation of aquatic toxicity data*, further details are added to clarify key elements to be considered for a more effective assessment including references to more recent and readily accessible test methodologies (also included in A9 Appendix VI Section 5 metals and metal compounds).

(c)   In A9.7.2.2. *Interpretation of solubility data*, refinements are introduced to clarify the applicability of a screening test using the Transformation/Dissolution protocol detailed in Annex 10.

(d)   In A9.7.4 *Bioaccumulation*, new paragraphs are proposed to clarify the applicability of bioaccumulation approaches to metals and metal compounds.

(e)   A9.7.5 *Application of classification criteria to metals and metal compounds* sees the most extensive changes. New sub-sections are proposed for each classification scheme in line with the proposed extension of the scope of Annex 9.7, by using ecotoxicity reference values (ERV) for both acute $(L(E)C_{50})$ and chronic $(NOEC/EC_X)$ ecotoxicity assessments. Accordingly, the existing Figure A9.7.1 is replaced by 5 new decision trees that can be found under the following figures:

(i)   A.9.7.1 (short-term hazard classification of metals);

(ii)   A.9.7.2 and A9.7.3 (long-term hazard classification of metals);

(iii)   A.9.7.4 (short-term hazard classification of metal compounds);

(iv)   A.9.7.5 (long-term hazard classification of metal compounds).

(f)   Refinements to A9.7.5.4 *Particle size and surface area* are proposed to address metal compounds of variable solubility taking into consideration the impact of particle size and surface area.

(g)   A new section A9.7.5.5. Setting M factors for metals and inorganic metal compounds based on acute and chronic ERV, outlined in Table 9.7.1 M factors for readily soluble metal compounds, is proposed.

13.   Having considered the issues outlined in paragraph 3 (b) of this document, the informal correspondence group's proposed changes to Annex 10 consist of refinements reflecting the changes proposed in Annex 9, section A9.7 supported by additional testing methodologies outlined in the Appendix of Annex 10 under references 12 to 16.

14.   The changes proposed to Annex 9, section A9.7 and Annex 10 in this document reflect all the discussions and agreements by the informal correspondence group, in particular those summarized in paragraphs 6 to13 above.

Action and next steps

15.   The Sub-Committee is invited to consider the proposed revised Annex 9 (Section 9.7) and Annex 10 as set out in the annex to this document and in informal document INF.6.

Annex

Proposed amendments to annexes 9 and 10 of the GHS

Amendments to Annex 9

A9.7.1.1   Replace the last but one sentence ("This section does not take into account….or persistence hazards") with the following:

"This section does not take into account the non-metallic ion (e.g. CN-) of metal compounds, which may be toxic."

The last sentence of this paragraph remains the same.

Add a new paragraph:

"A9.7.1.1.1 Organometallic compounds (OM) (e.g. methyl mercury or tributyltin,…) and Organo Metallic Salts (OMS) may also be of concern given that they may pose bioaccumulation or persistence hazards in case they do not quickly dissociate or dissolve in water. Unless they act as a significant source of the metal ion (as a result of the dissociation and/or degradation processes), the organic moieties and the inorganic components should be assessed individually (OECD 2015). They are therefore excluded from the guidance of this section and should be classified according to the general guidance provided in section 4. Alternatively, those metal compounds that contain an organic component but that dissociate or dissolve easily in water as the metal ion should be treated in the same way as metal compounds and classified according to this annex (e.g. Zinc acetate, ...)."

A9.7.1.6   In the second sentence, replace the text between brackets with the following: "(e.g. partitioning or chemical speciation to a non-soluble and hence not-bioavailable form)."

In the third sentence, replace "in assessing chronic classification" by "in assessing long-term (chronic) classification"

A9.7.1.8   In the first sentence, replace "to cause toxicity at the level of the $L(E)C_{50}$," by "to cause toxicity at the level of the ecotoxicity reference value (ERV), being the acute ERV (expressed as $L(E)C_{50}$), and/or the chronic ERV (expressed as the NOEC/ECx),"

A9.7.1.9   Amend to the introductory paragraph to read as follows:

"This section deals with metals and metal compounds. For how this guidance applies to OMs and OMSs, see A9.7.1.1. Within the context of this guidance document, metals and metal compounds are characterized as follows:"

A9.7.2.1.1   Add the following new paragraphs:

"A9.7.2.1.1.1 Ecotoxicity data of soluble inorganic compounds are used and combined to derive the acute and chronic ecotoxicity reference value of the dissolved metal ion (ERV or ERV_{ion}). The ecotoxicity of soluble inorganic metal compounds is dependent on the physico-chemistry of the medium, irrespective of the original metal species released in the environment.

A9.7.2.1.1.2 When evaluating ecotoxicity data and deriving ERVs, the general "weight of evidence" principle is also applicable to metals (see section A9.3.4).

A9.7.2.1.1.3 The ecotoxicity data selected should be evaluated for their adequacy. Adequacy covers here both the reliability (inherent quality of a test relating to test methodology and the way that the performance and results of a test are described) and the relevance (extent to which a test is appropriate to be used for the derivation of an ecotoxicity reference value) of the available ecotoxicity data (see section A9.2.6 and A9.3.6).

(a)   Under the reliability criteria, metal specific considerations include the description of some abiotic parameters in the test conditions for enabling the consideration of the bioavailable metal concentration and free metal ion concentration:

(i) Description of the physical test conditions: in addition to the general parameters (O_2, T°, pH, …), measurements of abiotic parameters such as dissolved organic carbon (DOC), hardness, alkalinity of the water that govern the speciation and hence the metal bioavailability are recommended.

(ii) Description of test materials and methods: to calculate the free metal ion concentration with speciation models the concentrations of dissolved major ions and cations (e.g. aluminium, iron, magnesium, and calcium) are recommended.

(iii) Concentration-effect relationship; hormesis: sometimes an increased performance in growth or reproduction is seen at low metal doses that exceed the control values, referred to as hormesis. Such effects can occur especially with major trace nutrients such as iron, zinc and copper but can also occur with a wide variety of non-essential substances. In such cases, positive effects should not be considered in the derivation of acute ERVs and especially chronic ERVs. Other models than the conventional log-logistic dose-response model should be used to fit the dose-response curve and consideration should be given to the adequacy of the control diet/exposure. Due to the essential nutritional needs, caution is needed with regards to extrapolation of the dose-response curve (e.g. to derive an acute or chronic ERV) below the lowest tested concentration.

(b) Under the relevancy criteria, certain considerations need to be made, related to the relevancy of the test substance and to acclimatisation/adaptation:

(i) Relevance of the test substance: tests conducted with soluble metal salts should be used for the purpose of deriving acute and chronic ERVs. The ecotoxicity adapted from organic metal compounds exposure should not be used.

(ii) Acclimatisation/adaptation: For essential metals, the culture medium should contain a minimal concentration not causing deficiency for the test species used. This is especially relevant for organisms used for chronic toxicity tests where the margin between essentiality and toxicity may become small. For this reason a proper description of culture conditions related to the level of essential metals is required."

A9.7.2.1.2.1 Add the following text at the end of the existing paragraph:

"For the classification of metals and metal compounds, Transformation/Dissolution (T/D) testing is carried out over a pH range (see A10.2.3.2). If evidence is available that the aquatic toxicity of the dissolved metal depends on pH, then T/D data and aquatic toxicity are compared at a similar pH. If such evidence is not available, then the aquatic toxicity cannot be grouped according to pH. The highest aquatic toxicity observed is then compared to the T/D data obtained at the pH which causes maximum transformation and dissolution."

A9.7.2.1.2.2 Delete "or economic" at the end of the paragraph.

A9.7.2.1.2.3 In the second sentence, replace "(Tipping, 1994)" with "(Tipping, 1994; Tipping et al., 2011)".

Amend the third and fourth sentence to read as follows: "Alternatively, the Biotic Ligand Model (BLM) allows for the calculation of the concentration of metal ion responsible for the toxic effect at the level of the organism, which may be affected by the DOC concentration, the pH, and the concentrations of competing ions such as calcium and magnesium. Such models may be investigated to better understand the impact of test medium composition on metal toxicity. The BLM model has at present been validated for specific metals, organisms, and end-points "(Santore and Di Toro, 1999; Garman et al., 2020)."

Add the following text at the end of the current paragraph: "In case a metal-specific BLM is available covering an appropriate pH range, a comparison of aquatic toxicity data can be made using the entire effects database for different reference pH values, relevant to the T/D data."

A9.7.2.2.2   Replace the last sentence with the following: "Where these are the only information available and the solubility data cannot provide a clear answer on the solubility rate and equilibrium, it is highly recommended that solubility data be generated using the Transformation/Dissolution (T/D) protocol (Annex 10)."

A9.7.2.2.3 and A9.7.2.2.4   Replace with the following:

"A9.7.2.2.3   Screening test for assessing solubility of metal compounds

In the absence of solubility data for metal compounds, a screening test for assessing solubility should be performed as described in the Transformation/Dissolution protocol (Annex 10). The screening test is conducted at the high loading rate (100 mg/L) and under rapid and vigorous agitation for 24 h. The function of the screening test is:

(a)   To identify those metal compounds which undergo either dissolution or rapid transformation such that their ecotoxicity potential is indistinguishable from soluble forms in that they may be classified based on the dissolved ion concentration.

(b)   To verify the pH dependency of the dissolution, in preparation of the full T/D test. Where data at different pH are available from the screening test, then the full test should at least be conducted at the pH which maximises the solubility. Where data are not available over the full pH range, a check should be made that this maximum solubility has been achieved by reference to suitable thermodynamic speciation models or other suitable methods (see A9.7.2.1.2.3). In the absence of suitable data or models, it is highly recommended that solubility data are generated to cover the full pH range. It should be noted that this screening test is only intended to be used for metal compounds. Metals should be assessed at the level of the full test (see A9.7.2.2.4).

A9.7.2.2.4   Full test for assessing solubility of metals and metal compounds

A9.7.2.2.4.1   The full test should at least be carried out at the pH[6] that maximizes the concentration of dissolved metal ions in solution. The pH may be chosen following the same guidance as given for the screening test.

A9.7.2.2.4.2   Based on the data from the full test, it is possible to generate a concentration of the metal ions in solution after 7 days for each of the three loadings (i.e. 1 mg/l as "low", 10 mg/l as "medium" and 100 mg/l as "high") used in the test. If the purpose of the test is to assess the long-term (chronic) hazard of the substance, then the loadings[7] should be 0.01 mg/l, 0.1 mg/l or 1 mg/l depending on the transformation rate, and the duration of the test should be extended to 28 days."

Insert the following new footnotes "6" and "7":

"[6] *The Transformation/Dissolution protocol specifies a pH range of 6 to 8.5 for the 7-day test and 5.5 to 8.5 for the 28-day test. Considering the difficulty in carrying out transformation/dissolution tests at pH 5.5, OECD only validated the test in the pH range of 6 to 8.5.*"

"[7] *Lower loading rates than 1 mg/l may not be practically feasible for each case. While T/D testing at lower loading rates is in principle the best way forward it is technically often not feasible. Extensive experience with the T/D protocol demonstrated that reliable predictions can be made for other loading rates. In order to make maximal use of existing T/D data, the 28-day results for the lower loading rates (0.1 and 0.01 mg/l) can therefore often be derived by extrapolation from evidence at other loading rates. This approach should be justified on a case-by-case basis and supported by reliable information on the T/D at different loading rates. It should be further noted that the relationship between loading*

rate and dissolved metal concentration may not be linear. Therefore, extrapolating T/D data to lower loadings should preferably be made by using the equations of section A.10.6.1 or alternatively by extrapolating in a precautionary way."

A9.7.2.3   Amend to read as follows:

"A9.7.2.3   Comparison of aquatic toxicity data and solubility data

A decision on how to classify the substance will be made by comparing aquatic toxicity data and solubility data. Depending on the available data, two approaches can be followed:

(a)   If limited information on the T/D at different pH levels is available, or if the aquatic toxicity of the dissolved metal does not depend on pH, then the lowest ERV and the highest T/D result, each potentially derived at different pH levels, should provide the basis for classification (this should be used as the default approach).

(b)   If evidence is available that the aquatic toxicity of the dissolved metal depends on pH, and sufficient toxicity data are available at varying pH levels, then a split of the acute and chronic ERVs can be performed according to the pH band. If in addition T/D data at different pH levels are available, then the classification may be derived by comparing T/D data with the ERV at corresponding pH levels, meaning that toxicity data and T/D data are in this case always compared at the same pH band. This split of the effects data into pH bands would apply in an equal way to the acute and the chronic effects data sets. The most stringent classification outcome across all pH bands should be used."

A9.7.4.1   Amend to read as follows:

"A9.7.4.1   While log K_{ow} is a good predictor of BCF for certain types of organic compounds e.g. non-polar organic substances, it is irrelevant for inorganic substances such as inorganic metal compounds because metals, in contrast to organic substances, are not lipophilic and are generally not transported through cellular membranes by passive processes. Uptake of metal ions typically occurs through active processes."

A9.7.4.3   Amend the end of the fourth sentence and insert a new fifth sentence as follows: "…in organisms in which the metal is essential (homeostasis). Removal and sequestration processes that minimise toxicity are complemented by an ability to up-regulate concentrations for essentiality.".

The rest of the paragraph remains unchanged ("Since nutritional requirement of the organisms… bioconcentration and environmental concern.").

A9.7.4.4   Insert a new paragraph A9.7.4.4 to read as follows:

"A9.7.4.4   For essential elements, measured BCFs decline as external concentrations increase because the internal concentrations are regulated by the organism. Non-essential metals are also actively regulated to some extent and therefore also for nonessential metals, an inverse relationship between the metal concentration and the external concentration may be observed (McGeer et al., 2003). When external concentrations are so high that they exceed a threshold level, or overwhelm the regulatory mechanism, this can cause harm to the organism. BCF and BAF may be used to estimate metal accumulation by:

(a)   Considering information on essentiality and homeostasis of metals/metal compounds. As a result of such regulation, the "bioaccumulative" criterion is not applicable to metals.

(b)   Assessing bioconcentration factors for non-essential metals, should preferably be done from BCF studies using environmentally relevant concentrations in the test media.".

A9.7.5.1.1   Amend to read as follows:

"A9.7.5.1.1   Short-term (acute) and long-term (chronic) hazards are assessed individually for metals and metal compounds. For long-term hazards preference should be given in applying the approach based on chronic toxicity data. Such evidence is often available for the readily soluble metal salts. The schemes for the determination of short-term and long-term aquatic hazards of metals and metal compounds are described below and summarized in the figures:

(a)   A9.7.1 (short-term hazard classification of metals);

(b)   A9.7.2 and A9.7.3 (long-term hazard classification of metals);

(c)   A9.7.4 (short-term hazard classification of metal compounds);

(d)   A9.7.5 (long-term hazard classification of metal compounds).

A9.7.5.1.1.1   There are several stages in these schemes where data are used for decision purposes. It is not the intention of the classification schemes to generate new data. In the absence of valid data, it will be necessary to use all available data and expert judgement.

A9.7.5.1.1.2   In the following sections, the reference to the acute and chronic ERVs refers to the data point(s) that will be used to select the hazard categories for the metal or metal compound.".

A9.7.5.1.2   Amend to read as follows:

"A9.7.5.1.2   When considering acute and chronic ERVs for metal compounds ($ERV_{compound}$), it is important to ensure that the data point to be used as the justification for the classification is expressed in the weight of the molecule of the metal compound to be classified. This is known as correcting for molecular weight. Thus while most metal data are expressed in, for example, mg/l of the dissolved metal ion (abbreviated ERV_{ion}), this value will need to be adjusted to the corresponding weight of the metal compound. Thus:

$$ERV_{compound} = ERV_{ion} \text{ x}$$

(Molecular weight of metal compound / Σ atomic weight of the atom(s) of the metal in the compound)

where:

$$ERV_{compound} = ERV \text{ of the metal compound}$$

$$ERV_{ion} = ERV \text{ of the dissolved metal ion}"$$

A9.7.5.2 to A9.7.5.2.4.2   Replace with the following text:

"A9.7.5.2   *Classification strategy for metals*

A9.7.5.2.1   *Short-term (acute) aquatic hazard of metals*

A9.7.5.2.1.1   The scheme for determining the short-term (acute) aquatic hazard of metals is described in this section and summarized in Figure A9.7.1.

A9.7.5.2.1.2   Where the acute ERV of the dissolved metal ion is greater than 100 mg/l, the metals need not be considered further in the classification scheme.

A9.7.5.2.1.3   Where the acute ERV of the dissolved metal ions is ≤ 100 mg/l, consideration must be given to the data available on the rate and extent to which these ions can be generated from the metal. Such data, to be valid and useable, should have been generated using the Transformation/Dissolution protocol (Annex 10).

A9.7.5.2.1.4   Where 7-day data from the Transformation/Dissolution protocol are available, then, the results should be used to aid classification according to the following rules. Classify the metal as:

(a)   Category Acute 1 if the dissolved metal ion concentration at the low loading rate is ≥ acute ERV. Assign an Acute M factor according to Table A9.7.1;

(b)   Category Acute 2 if the dissolved metal ion concentration at the low loading rate is < acute ERV, but at the medium loading rate it is ≥ acute ERV;

(c)   Category Acute 3 if the dissolved metal ion concentration at the low and the medium loading rates is < acute ERV, but at the high loading rate it is ≥ acute ERV.

Do not classify the metal for short-term aquatic hazard if the dissolved metal concentration at all loading rates is below the acute ERV.

**Figure A9.7.1: Classification strategy for determining
the short-term (acute) aquatic hazard of metals**
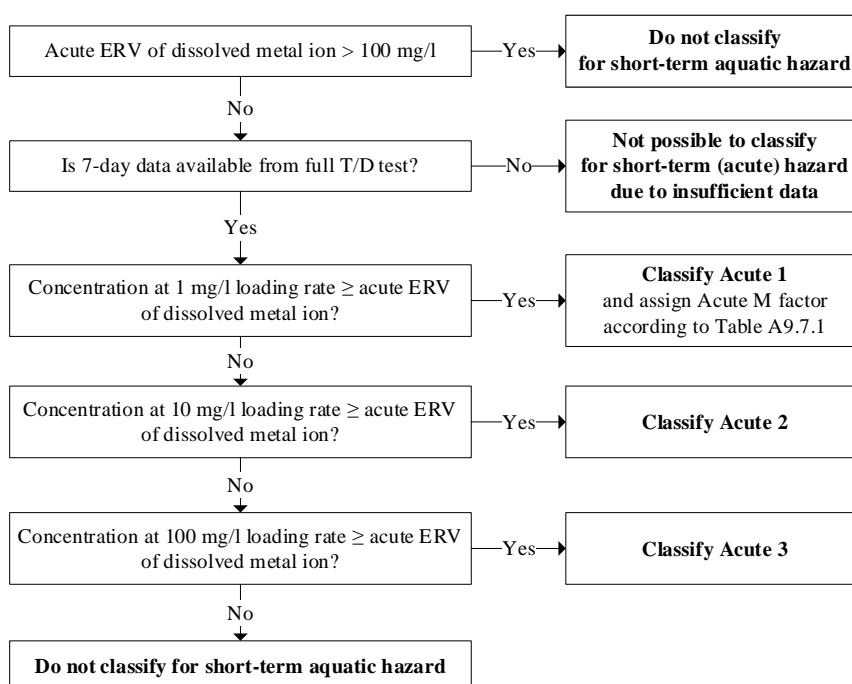
A9.7.5.2.2   *Long-term (chronic) aquatic hazard of metals*

The scheme for determining the long-term (chronic) aquatic hazard of metals is described in this section and summarised in figures A9.7.2 and A9.7.3. Metals can be classified for long-term aquatic hazard using chronic toxicity data when available or using the surrogate approach in absence of appropriate chronic toxicity data.

A9.7.5.2.2.1 Approach based on available chronic toxicity data

A9.7.5.2.2.1.1   Where the chronic ERV of the dissolved metal ion is greater than 1 mg/l, the metal need not be considered further in the classification scheme.

A9.7.5.2.2.1.2   Where the chronic ERV of the dissolved metal ion is less than or equal to 1 mg/l, consideration must be given to the available data on the rate and extent to which these ions can be generated from the metal. To be valid and useable, such data should have been generated or calculated using the Transformation/Dissolution protocol (Annex 10) for 28 days (see section A9.7.2.2.4). If such data are unavailable, the surrogate approach should be used (see section A9.7.5.2.2.2). Where 28-day T/D data are available, then classify the metal as:

(a)   Category Chronic 1 if the dissolved metal ion concentration obtained at a loading rate of 0.1 mg/l (0.01 mg/l if there is evidence of rapid environmental transformation) is greater than or equal to the chronic ERV. Assign a Chronic M factor according to Table A9.7.1;

(b) Category Chronic 2 if the dissolved metal ion concentration obtained at a loading rate of 1 mg/l (0.1 mg/l if there is evidence of rapid environmental transformation) is greater than or equal to the chronic ERV;

(c) Category Chronic 3 if the dissolved metal ion concentration obtained at a loading rate of 1 mg/l is greater than the chronic ERV and there is evidence of rapid environmental transformation.

A9.7.5.2.2.1.3   Classify the metal as category Chronic 4 if the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern (see section 4.1.2.2).

A9.7.5.2.2.1.4   Do not classify the metal for long-term aquatic hazard if the dissolved metal ion concentration obtained from the 28-day Transformation/Dissolution test at a loading rate of 1 mg/l is less than the chronic ERV of the dissolved metal ion.

Figure A9.7.2: Classification strategy for determining long-term aquatic hazard of metals on the basis of chronic data
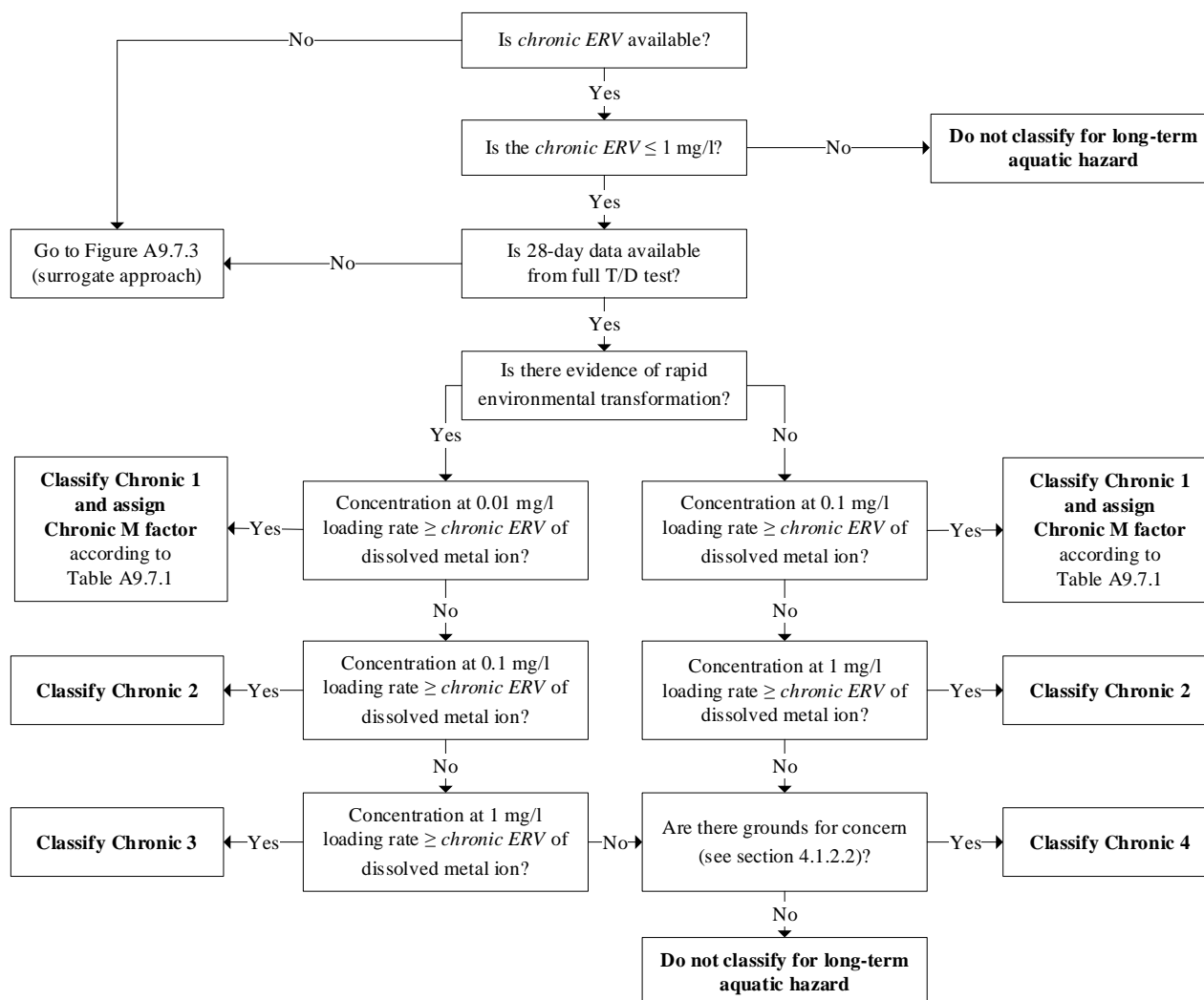
A9.7.5.2.2.2   The surrogate approach

A9.7.5.2.2.2.1   Where appropriate chronic toxicity data and/or T/D data are not available, but the metal is classified for short-term (acute) aquatic hazard, then classify the metal as (unless there is evidence of rapid environmental transformation and no bioaccumulation):

(a)   Category Chronic 1 if the metal is classified for short-term (acute) aquatic hazard as category Acute 1. Assign the same M factor as for category Acute 1.

(b)   Category Chronic 2 if the metal is classified for short-term (acute) aquatic hazard as category Acute 2.

(c)   Category Chronic 3 if the metal is classified for short-term (acute) aquatic hazard as category Acute 3.

A9.7.5.2.2.2.2   In the lack of a short-term aquatic hazard classification due to missing T/D data, and there is no clear data of sufficient validity to show that the transformation of metal ions will not occur, the safety net classification (Chronic 4) should be applied when the known classifiable toxicity of these soluble forms is considered to produce sufficient concern. For example, this is the case when the acute ERV_{ion} is equal to or below 100 mg/L, and/or if the chronic ERV_{ion} is equal to or below 1mg/L. In these cases, testing according to the Transformation/Dissolution protocol may be considered.

A9.7.5.2.2.2.3   Do not classify the metal for long-term aquatic hazard if the metal is not classified for short-term aquatic hazard and if there are no grounds for concern.

Figure A9.7.3: Classification strategy for determining long-term aquatic hazard of metals in absence of appropriate chronic toxicity reference data and/or 28-day Transformation/Dissolution data

"
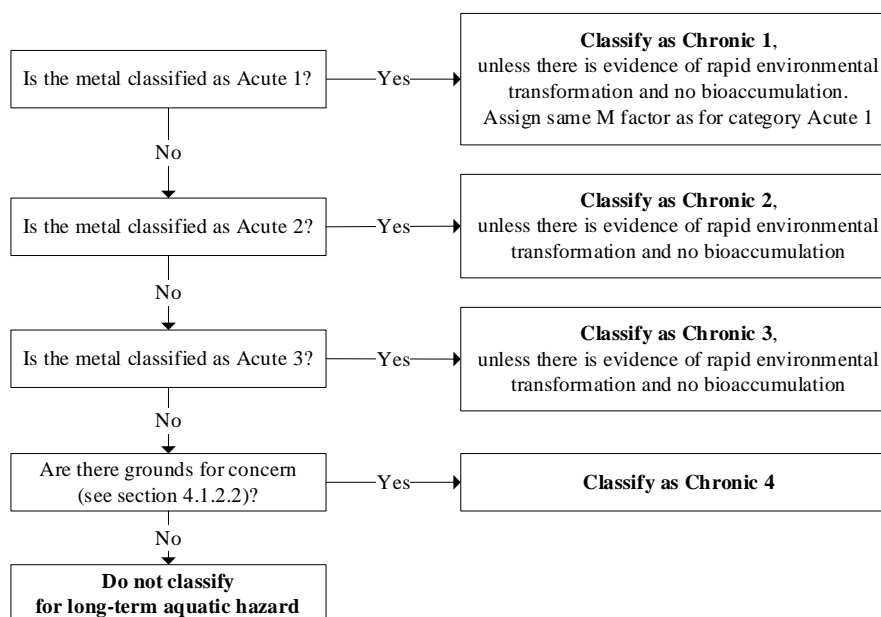
A9.7.5.3 to A9.7.5.3.3.3   Replace with the following text:

"A9.7.5.3   Classification strategy for metal compounds

Metal compounds will be considered as readily soluble if the water solubility (measured e.g. through a screening test according to the T/D protocol, or estimated e.g. from the solubility product), expressed as the concentration of dissolved metal ion, is greater than or equal to the acute ERV_{ion}. In the context of the classification criteria, metal compounds will also be considered as readily soluble if such data are unavailable, i.e. there are no clear data of sufficient validity to show that the transformation to metal ions will not occur. Care should be exercised for compounds whose solubility is close to the acute ERV as the conditions under which solubility is measured could differ significantly from those of the acute toxicity test. In these cases the results of the screening test are preferred. Metal compounds will be considered as poorly soluble if the water solubility (measured e.g. through a screening test, or estimated e.g. from the solubility product), expressed as the concentration of dissolved metal ion, is less than the acute ERV_{ion}.

A9.7.5.3.1 *Short-term (acute) aquatic hazard of metal compounds*

A9.7.5.3.1.1 Readily soluble metal compounds are classified on the basis of the acute $ERV_{compound}$. Classify the readily soluble metal compound as:

(a) Category Acute 1 if the acute $ERV_{compound}$ is equal to or less than 1 mg/l column and no Assign an Acute M factor according to Table A9.7.1;

(b) Category Acute 2 if the acute $ERV_{compound}$ is greater than 1 mg/1 but less than or equal to 10 mg/l;

(c) Category Acute 3 if the acute $ERV_{compound}$ is greater than 10 mg/1 but less than or equal to 100 mg/l.

Do not classify the readily soluble metal compound for short-term aquatic hazard if the acute $ERV_{compound}$ is larger than 100 mg/l.

A9.7.5.3.1.2 Poorly soluble metal compounds are classified on the basis of the acute ERV of the dissolved metal ion and 7-day Transformation/Dissolution data. Classify the poorly soluble metal compound as:

(a) Category Acute 1 if the dissolved metal ion concentration at the low loading rate is equal to or greater than the acute ERV_{ion}, and assign Acute M factor according to Table A9.7.1;

(b) Category Acute 2 if the dissolved metal ion concentration at the medium loading rate is equal to or greater than the acute ERV_{ion};

(c) Category Acute 3 if the dissolved metal ion concentration at the high loading rate is equal to or greater than the acute ERV_{ion}.

Do not classify the poorly soluble metal compound for short-term (acute) aquatic hazard if the dissolved metal ion concentration is below the acute ERV of the dissolved metal ion at all loading rates.

Figure A9.7.4: Classification strategy for determining the short-term (acute) aquatic hazard of metal compounds
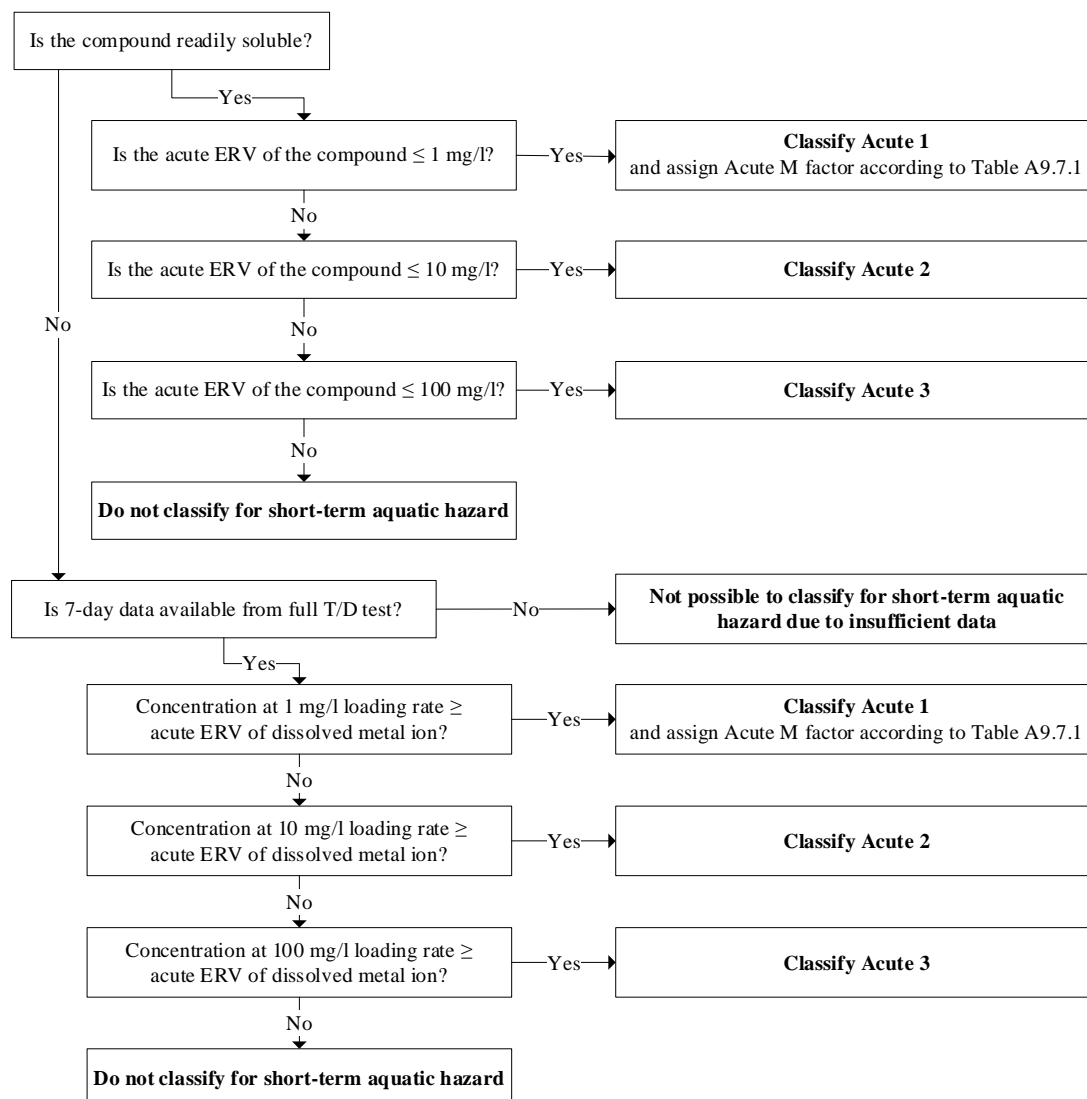
A9.7.5.3.2   *Long-term (chronic) aquatic hazard of metal compounds*

The scheme for determining the long-term (chronic) aquatic hazard of metal compounds is described in this section and summarised in Figure A9.7.5. Metal compounds can be classified for long-term aquatic hazard using chronic toxicity data when available, or using the surrogate approach in absence of appropriate chronic toxicity data.

A9.7.5.3.2.1 Approach based on available chronic toxicity data

A9.7.5.3.2.1.1 Where the chronic $ERV_{Compound}$ is greater than 1 mg/l, the metal compound need not to be considered further in the classification scheme for long-term hazard.

A9.7.5.3.2.1.2 Readily soluble metal compounds are classified on the basis of the chronic $ERV_{compound}$. If there is no evidence of rapid environmental transformation, then classify the readily soluble metal compound as:

> (a)   Category Chronic 1 if the chronic $ERV_{compound}$ is equal to or less than 0.1 mg/l (0.01 mg/l if there is evidence of rapid environmental transformation). Assign a chronic M factor according to Table A9.7.1;

> (b) Category Chronic 2 if the chronic ERV$_{compound}$ is equal to or less than 1 mg/l (0.1 mg/l if there is evidence of rapid environmental transformation);
>
> (c) Category Chronic 3 if the chronic ERV$_{compound}$ is equal to or less than 1 mg/L and there is evidence of rapid environmental transformation;
>
> (d) Category Chronic 4 if the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern (see section 4.1.2.2)

A9.7.5.3.2.1.3 Poorly soluble metal compounds: Consideration must be given to the data available on the rate and extent to which these ions can be generated from the metal compound. For such rate and extent data, to be valid and useable, they should have been generated using the Transformation/Dissolution protocol for a 28-day period. Where such 28-day T/D data are unavailable, the surrogate approach should be used (see section A9.7.5.3.2.2). Where 28-day T/D data are available, then classify the poorly soluble metal compound as:

> (a) Category Chronic 1 if the dissolved metal ion concentration obtained at a loading rate of 0.1 mg/l (0.01 mg/l if there is evidence of rapid environmental transformation) is greater than or equal to the chronic ERV of the dissolved metal ion. Assign a chronic M factor according to Table A9.7.1;
>
> (b) Category Chronic 2 if the dissolved metal ion concentration obtained at a loading rate of 1 mg/l (0.1 mg/l if there is evidence of rapid environmental transformation) is greater than or equal to the chronic ERV of the dissolved metal ion.;
>
> (c) Category Chronic 3 if the dissolved metal ion concentration obtained at a loading rate of 1 mg/l is greater than or equal to the chronic ERV of the dissolved metal ion and there is evidence of rapid environmental transformation;
>
> (d) Category Chronic 4 if the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern (see section 4.1.2.2)

Do not classify the poorly soluble metal compound for long-term (chronic) aquatic hazard if the dissolved metal ion concentration obtained from the 28-day Transformation/Dissolution test at a loading rate of 1 mg/l is less than the chronic ERV of the dissolved metal ion.

Figure A9.7.5: Classification strategy for determining long-term aquatic hazard of metal compounds on the basis of chronic data

```
                                    ┌──────────────────────────┐              ┌──────────────────────────┐
                                    │ Is chronic ERV available?│──── No ─────▶│ Go to Figure A9.7.3      │
                                    └──────────────────────────┘              │ (surrogate approach)     │
                                              │                               └──────────────────────────┘
                                             Yes
                                              ▼
┌──────────────────────┐            ┌──────────────────────────────────┐
│ Do not classify      │◀─── No ────│ Is chronic ERV_compound ≤ 1 mg/l?│
│ for long-term hazard │            └──────────────────────────────────┘
└──────────────────────┘                      │
                                             Yes
                                              ▼
                                    ┌────────────────────────────────────┐
                                    │ Is the metal compound readily       │
                                    │ soluble?                             │
                                    └────────────────────────────────────┘
```

Is chronic ERV available? — No → **Go to Figure A9.7.3 (surrogate approach)**

Yes

Is chronic $ERV_{compound} \leq 1$ mg/l? — No → **Do not classify for long-term hazard**

Yes

Is the metal compound readily soluble? — No (to "Is 28-day data available from full T/D test?")

Yes

Is there evidence of rapid environmental transformation?

Yes:
- Is the chronic $ERV_{compound} \leq 0.01$ mg/l? — Yes → **Classify Chronic 1 and assign chronic M factor according to Table A9.7.1**
  - No → Is the chronic $ERV_{compound} \leq 0.1$ mg/l? — Yes → **Classify Chronic 2**
    - No → Is the chronic $ERV_{compound} \leq 1$ mg/l? — Yes → **Classify Chronic 3**
      - No →

No:
- Is the chronic $ERV_{compound} \leq 0.1$ mg/l? — Yes → **Classify Chronic 1 and assign chronic M factor according to Table A9.7.1**
  - No → Is the chronic $ERV_{compound} \leq 1$ mg/l? — Yes → **Classify Chronic 2**
    - No → Are there grounds for concern (see section 4.1.2.2)? — Yes → **Classify Chronic 4**
      - No → **Do not classify for long-term aquatic hazard**

Is 28-day data available from full T/D test? — No → **Go to Figure A9.7.3 (surrogate approach)**

Yes

Is there evidence of rapid environmental transformation?

Yes:
- Concentration at 0.01 mg/l loading rate ≥ chronic ERV of dissolved metal ion? — Yes → **Classify Chronic 1 and assign chronic M factor according to Table A9.7.1**
  - No → Concentration at 0.1 mg/l loading rate ≥ chronic ERV of dissolved metal ion? — Yes → **Classify Chronic 2**
    - No → Concentration at 1 mg/l loading rate ≥ chronic ERV of dissolved metal ion? — Yes → **Classify Chronic 3**
      - No →

No:
- Concentration at 0.1 mg/l loading rate ≥ chronic ERV of dissolved metal ion? — Yes → **Classify Chronic 1 and assign chronic M factor according to Table A9.7.1**
  - No → Concentration at 1 mg/l loading rate ≥ chronic ERV of dissolved metal ion? — Yes → **Classify Chronic 2**
    - No → Are there grounds for concern (see section 4.1.2.2)? — Yes → **Classify Chronic 4**
      - No → **Do not classify for long-term aquatic hazard**

A9.7.5.3.3.2   The surrogate approach

Where appropriate chronic toxicity data and/or T/D data are not available, but the metal compound is classified for short-term (acute) aquatic hazard, then the metal compound is classified according to the surrogate approach. The surrogate approach for metal compounds is identical to that for metals (see section A9.7.5.2.2.2)."

A9.7.5.4.3 Add the following paragraph after the current table in A9.7.5.4.3 to reads as follows:

"Massive forms will usually be tested as 1 mm particles. Alternatively, the T/D testing of materials with different surface areas may result in highly reliable dissolution kinetic equations that allows to define the "Critical Particle Diameter" (CPD) for appropriate loadings for the acute and long-term hazard assessment."

A9.7.5.4.4 Replace A9.7.5.4.4 with the following:

"A9.7.5.4.4 For some forms of metals, it may be possible, using the Transformation/Dissolution protocol (OECD 2001), to obtain a correlation between the concentration of the metal ion after a specified time interval as a function of the surface area loadings of the forms tested. Such correlations should be established for the relevant pH ranges as specified in the Transformation/Dissolution protocol. In such cases, it could then be possible to estimate the level of dissolved metal ion concentration of the metal with different particles, using the critical surface area approach (Skeaff et. al., 2000) (See reference in appendix VI, part 5, Metals and metal compounds). From this correlation and a linkage to the appropriate toxicity data at corresponding pH level, it is possible to determine a "Critical Surface Area" (CSA) of the substance that delivers the L(E)C50 to the dissolution medium and then to convert the CSA to a Critical Particle Diameter (CPD) (see example). This CPD at appropriate mass loadings for acute and long-term hazard assessment can then be used to:

(a)   determine the classification category of powders based on the finest representative powder on the market and

(b)   determine an accurate classification of the massive metal by applying a 1 mm (default) diameter.

A9.7.5.4.4.1   Within the CSA approach an equation is developed to predict metal ion release (based on previously measured metal ion release from different loadings of the metal), which is correlated to measured surface area, and a corresponding calculated equivalent particle diameter. The basis of the CSA approach is that the release of metal ions is dependent on the surface area of the substance, with this release being predictable once the relationship has been established. The CSA as the surface area loading (mm²/l) to a medium that delivers a selected ecotoxicity reference value to that medium. The term SA is the measured specific surface area (m²/g) of the metal sample. The measured specific critical surface area (SA_{crit}) (m²/g) is the measured specific surface areas for the corresponding low, medium and high loadings which are associated with the respective acute and long-term aquatic toxicity classification categories in the classification scheme for metals and metal compounds. A typical equation for this relationship for a given substance, aquatic medium, pH and retention time is:

$$\log(C_{Me(aq)}, mg/l) = a + b \log(A_{meas})$$

$C_{Me(aq)}$ = total dissolved concentration of metal ion (mg/l) at a particular length of test time (i.e. 168 hours for short-term hazard assessment) under certain conditions (i.e. pH, specified medium, etc.), as determined by Transformation/Dissolution testing of different surface area loadings

a, b = regression coefficients

A_{meas} = initial surface area loading (mm²/l) [equals (measured specific surface area, SA, in m²/g) X (substance mass loading in g/l) X 10^6], where SA was measured with the BET nitrogen adsorption-desorption technique."

Figure A9.7.1 Delete

A9.7.5.5   Insert a new sub-section A9.7.5.5 to read as follows:

"A9.7.5.5   Setting M factors for metals and inorganic metal compounds

A9.7.5.5.1   For the hazard class "Hazardous to the Aquatic Environment", where the application of the normal cut-off values or concentrations limits may lead to an "under-classification" of the mixture, the M factor concept is used. The M factors are used in application of the summation method for the classification of mixtures containing substances that are classified as very ecotoxic. The concept of M factors has been established to give an increased weight to very toxic substances when classifying mixtures. This ensures that the magnitude of their toxicity is not lost in the derivation of the mixtures classification. M factors are only applicable to the concentration of a substance classified as hazardous to the aquatic environment (Categories Acute 1 and Chronic 1) and are used to derive by the summation method the classification of a mixture in which the substance is present. They are, however, substance specific and it is important that they are established when classifying substances. It is important to note that separate Acute and Chronic M factors should be derived and these may not necessarily be of the same value, depending how each was determined (e.g. the basis of the separate acute and chronic ERV values).

A9.7.5.5.2   For readily soluble metal compounds M factors are applied as for organic substances (see table A9.7.1).

A9.7.5.5.3   For poorly soluble metal compounds and metals M factors are applied based on the ratio of the dissolved metal ion concentration (obtained from T/D testing after respectively 7 and 28 days for the loading that was used to establish the classification of Category Acute 1 or Category Chronic 1) and the ERV of the dissolved metal ion. If that ratio is below 10 then an M factor of 1 is applied; if that ratio is ≥ 10 and < 100 then an M factor of 10 is applied; if that ratio is ≥ 100 and < 1000 then an M factor of 100 is applied… (continue this approach in factor 10 intervals).

Table A9.7.1 M factors for readily soluble metal compounds

<u>**Acute ERV$_{compound}$ (mg/L)**</u>	<u>**Acute Multiplication factors (M)**</u>
<u>$0.1 <$ Acute ERV ≤ 1</u>	<u>1</u>
<u>$0.01 <$ Acute ERV ≤ 0.1</u>	<u>10</u>
<u>$0.001 <$ Acute ERV ≤ 0.01</u>	100
<u>$0.0001 <$ Acute ERV ≤ 0.001</u>	1000
<u>Continue in factor 10 intervals</u>	

<u>**Chronic ERV$_{compound}$ (mg/L)**</u>	<u>**Chronic Multiplication factors (M)**</u>	
	<u>**No rapid environmental transformation**</u>	<u>**Rapid environmental transformation**</u>
<u>$0.01 <$ Chronic ERV ≤ 0.1</u>	<u>1</u>	<u>-</u>
<u>$0.001 <$ Chronic ERV ≤ 0.01</u>	<u>10</u>	<u>1</u>
<u>$0.0001 <$ Chronic ERV ≤ 0.001</u>	100	<u>10</u>
<u>$0.00001 <$ Chronic ERV ≤ 0.0001</u>	1000	100
<u>Continue in factor 10 intervals</u>		

"

In Annex 9, Appendix VI, insert the following references under 5. Metals and metal compounds:

"Garman, E.R., Meyer, J.S., Bergeron, C.M., Blewett, T.A., Clements, W.H., Elias, M.C., Farley, K.J., Gissi, F. and Ryan, A.C. (2020), Validation of Bioavailability-Based Toxicity Models for Metals. Environmental Toxicology & Chemistry, 39: 101-117.

OECD (2015). Guidance on selecting a strategy for assessing the ecological risk of organometallic and organic metal salt substances based on their environmental fate. OECD Series on Testing and Assessment nr. 212. OECD, Paris, France.

Tipping, E., Lofts, S., and Sonke, J.E. (2011). Humic Ion-Binding Model VII: a revised parameterisation of cation-binding by humic substances. Environmental Chemistry 8 225—235.

Amendments to Annex 10

A10.1 Amend the end of the paragraph to read as follows:

"This test guidance is the outcome of an international effort under the OECD to develop an approach for the toxicity testing and data interpretation of metals and sparingly soluble inorganic metal compound (reference 1, this annex and section A9.7 of Annex 9). The experimental work on several metals and metal compounds upon which this Test Guidance is based has been conducted and reported (references 5 to 15, this annex). This test guidance has subsequently also been published as a guidance document by the OECD (reference 16).".

A10.1.2   Replace the term "dissolution/transformation" in the last sentence with Transformation/Dissolution".

A10.1.4   Insert the following new paragraph:

"A10.1.4   This test guidance is not applicable to organometal compounds."

A10.2.2.1   Amend the end of the last sentence to read as follows: "is indistinguishable from soluble forms, and to verify the pH dependency of the dissolution, in preparation of the full T/D test (See A9.7.2.3)."

A10.2.3.1   Amend the end of the paragraph to read as follows: ", "using a loading of 1 mg/l, 0.1 mg/l, or 0.01 mg/l depending on the transformation rate.".

A10.2.3.2   Amend the last sentence to read as follows:

"except for the 28-day full test where the pH range of 5.5 to 8.5 is recommended if technically feasible to take into consideration possible long-term effects on acidic lakes."

A10.2.3.3   In the first sentence, replace "while massive are tested" with "while massive forms are tested".

Add the following sentence at the end of the end of the existing paragraph: "The tested material should also be free from oxidation/corrosion layers due to storage, given the latter may disturb the transformation rate. Appropriate pre-treatment of the samples is recommended."

A10.4 (f)   Amend the end of the sentence to read "or equivalent technique, and particle size distribution;".

A10.5   In sub-paragraph (d), delete "radial impeller".

Amend sub-paragraph (e) to read as follows:

"(e) appropriate filters (e.g._0.2 µm Acrodisc) or centrifuge for solids-liquid separation (A10.5.1.10) filter should be flushed at least three times with fresh medium to avoid elevated trace metals in the sample at time 0;"

Amend sub-paragraph (k) to read: "analytical equipment for metal analysis (e.g. atomic adsorption spectrometry, inductively coupled plasma mass spectrometry) of acceptable accuracy, preferably with a limit of quantification (LOQ) five times lower than the lowest chronic ecotoxicity reference value or the lowest acute ecotoxicity reference value if only a 7-day test is conducted;"

A10.5.1.2   Replace the text between brackets in the first sentence with " (e.g. HCl or aqua regia)"

Insert the following new second sentence: "Specific attention to the type of glassware is required for metals that can be released from the glass."

The rest of the paragraph ("The test vessel volume …in 2.8 l flasks") remains unchanged.

A10.5.1.4   Amend to read as follows:

"A10.5.1.4   The concentration of total organic carbon in the medium before adding the substance, should not exceed 2.0 mg/l."

A10.5.1.5   In the first paragraph, replace "transformation of the metal compound" with "transformation of the metal or metal compound"

A10.5.1.7   Insert the following new note 3 under Table A10.1:

> "***NOTE 3:***   *Equilibration via headspace is recommended given CO_2 gas bubbling does not guarantee equal distribution between different test vessels.*"

In footnote 2, replace the term "dissolution/transformation" with "Transformation/Dissolution".

A10.5.1.9   Amend to read as follows:

"A10.5.1.9   During the full Transformation/Dissolution test, agitation should be used which is sufficient to maintain the flow of aqueous medium over the test substance while maintaining the integrity of the surface of the test substance and of any solid reaction product coatings formed during the test. For 1 l of aqueous medium, this may be accomplished by the use of a 1.0 to 3.0 l flask capped with a rubber stopper and placed on an orbital or laboratory shaker set at 100 r.p.m. Other methods of gentle agitation may be used provided they meet the criteria of surface integrity and homogeneous solution.".

A10.5.1.10   Amend the end of the first sentence of the paragraph to read: "…which will in turn depend on particle size distributions, the shape of the particles and particle density."

Replace the last sentence by:

"Alternative techniques may be considered in case of finer particles. If there is concern that particles will remain in suspension, then filtration efficiency should be checked prior to any testing. Options that could be considered to increase filtration efficiency include centrifugation followed by filtration, or waiting for about 5 minutes for the suspension to settle prior to taking a solution sample.".

A10.5.2.1 Amend the first paragraph to read as follows:

"A suitable validated analytical method for the total dissolved metal analysis is essential to the study. The analytical detection limit should preferably be 5 times lower than the appropriate chronic ecotoxicity reference value, or the acute ecotoxicity reference value in case a 7-day test is conducted.".

A10.5.2.3.1   Delete "(e.g. 37-44 µm)" and add the following sentence at the end of the paragraph: "This variability may be higher at the lower loadings."

A10.5.2.3.3   Amend the end of the final sentence in the second paragraph to read as follows: "with target pH 1 and analysed for total dissolved metal concentration."

A10.5.2.3.5   Amend the final sentence to read as follows: "It is a requirement to check the specific surface area of powder samples."

A10.5.3.1   Amend the heading to read as follows: "*Screening Transformation/Dissolution test – sparingly soluble metal compounds*".

A10.5.3.1.1   In the last sentence, in the text between brackets, replace "addition of the solids" with "addition of the test material"

A10.5.3.1.2   Amend the end of the first sentence to read as follows: "rapidly and vigorously (e.g. on an orbital shaker at 200 rpm, if feasible)."

A10.5.3.2 Amend the heading to read as follows:

"A10.5.3.2   *Full Transformation/Dissolution test - metals and metal compounds*"

A10.5.3.2.2   Amend as follows:

"For 7-day test, substance loadings of 1, 10 and 100 mg/l, respectively, are added to the test vessels (number of which depends on the reproducibility as established in sub-section A10.5.2.3), containing the aqueous medium. The test vessels are closed (but allowing for equilibration with air if required) and agitated as described in A10.5.1.9. If a 28-day test is to be conducted, then the loading may be 0.01 mg/l, 0.1 mg/l or 1 mg/l depending on the transformation rate. The test with 1 mg/l loading may be extended to 28 days, provided that

the same pH value is to be chosen for both 7 day and 28-day tests. The 7-day tests are only conducted at pH ranges of 6 up to 8.5, while a somewhat broader pH range of 5.5 and 6to 8.5 is recommended if technically feasible for the 28-day tests. A concurrent control test with no substance loaded (i.e. a blank test solution) is required. At established time intervals (e.g. 2 hours, 6 hours, 1, 4 and 7 days for the short-term test and additionally at e.g. 14, 21 and 28 days for the long-term test), the temperature, pH and dissolved O_2 concentrations are measured in each test vessel, and at least two samples (e.g. 10 - 15 ml) are drawn by syringe from each test vessel. The solid and dissolved fractions…. [*the rest of the text remains unchanged*]."

A10.6.2.1 Insert the following new paragraph at the end of the section:

"The release rate may also be expressed relative to the surface area of the test substance (e.g. µg/mm2) to allow for a comparison of the release rates between different surface loadings or particle sizes."

Renumber the current sub-section "A10.6.2.1 Long term test" as A10.6.2.2 and amend as follows:

"A10.6.2.2   *Long-term test*

The dissolved metal concentrations, measured from the 1 mg/l loading during the 28-day test, are plotted versus time and the transformation/dissolution kinetics determined, if possible, as described in A10.6.2.1.".

Annex 10, Appendix

Insert the following new references:

12.   Skeaff, J.M., Hardy, D.J. and King, P. (2008), A new approach to the hazard classification of alloys based on transformation/dissolution. Integr Environ Assess Manag, 4: 75-93. https://doi.org/10.1897/IEAM_2007-050.1

13.   Skeaff, J., Adams, W.J., Rodriguez, P., Brouwers, T. and Waeterschoot, H. (2011), Advances in metals classification under the United Nations globally harmonized system of classification and labeling. Integr Environ Assess Manag, 7: 559-576. https://doi.org/10.1002/ieam.194

14.   Skeaff, J.M. and Beaudoin, R. (2015), Transformation/dissolution characteristics of a nickel matte and nickel concentrates for acute and chronic hazard classification. Integr Environ Assess Manag, 11: 130-142. https://doi.org/10.1002/ieam.1573

15.   Huntsman-Mapila, P., Skeaff, J.M., Pawlak, M. and Beaudoin, R. (2016), Addressing aquatic hazard classification for metals, metal compounds and alloys in marine systems, Marine Pollution Bulletin 109:550-557. https://doi.org/10.1016/j.marpolbul.2016.03.055

16.   OECD Environment Health and Safety Publications; Series on Testing and Assessment n° 29. Guidance document on Transformation Dissolution of Metals and Metal Compounds in Aqueous media, July 2001.

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