PART 4

ENVIRONMENTAL HAZARDS

CHAPTER 4.1

HAZARDOUS TO THE AQUATIC ENVIRONMENT

4.1.1 Definitions and general considerations

4.1.1.1 *Definitions*

Acute aquatic toxicity means the intrinsic property of a substance to be injurious to an organism in a short-term aquatic exposure to that substance.

Availability of a substance means the extent to which this substance becomes a soluble or disaggregate species. For metal availability, the extent to which the metal ion portion of a metal (M°) compound can disaggregate from the rest of the compound (molecule).

Bioavailability (or biological availability) means the extent to which a substance is taken up by an organism, and distributed to an area within the organism. It is dependent upon physico-chemical properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. Availability is not a prerequisite for bioavailability.

Bioaccumulation means net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (i.e. air, water, sediment/soil and food).

Bioconcentration means net result of uptake, transformation and elimination of a substance in an organism due to waterborne exposure.

Chronic aquatic toxicity means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism.

Complex mixtures or multi-component substances or complex substances means mixtures comprising a complex mix of individual substances with different solubilities and physico-chemical properties. In most cases, they can be characterized as a homologous series of substances with a certain range of carbon chain length/number of degree of substitution.

Degradation means the decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water and salts.

ECx means the concentration associated with x% response.

Long-term (chronic) hazard, for classification purposes, means the hazard of a chemical caused by its chronic toxicity following long-term exposure in the aquatic environment.

NOEC (No Observed Effect Concentration) means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control.

Short-term (acute) hazard, for classification purposes, means the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that chemical.

4.1.1.2 *Basic elements*

4.1.1.2.1 The basic elements for use within the harmonized system are:

(a) acute aquatic toxicity;

(b) chronic aquatic toxicity;

(c) potential for or actual bioaccumulation; and

(d) degradation (biotic or abiotic) for organic chemicals.

4.1.1.2.2 While data from internationally harmonized test methods are preferred, in practice, data from national methods may also be used where they are considered as equivalent. In general, it has been agreed that freshwater and marine species toxicity data can be considered as equivalent data and are preferably to be derived using OECD Test Guidelines or equivalent according to the principles of Good Laboratory Practices (GLP). Where such data are not available classification should be based on the best available data.

4.1.1.3 ***Acute aquatic toxicity***

Acute aquatic toxicity would normally be determined using a fish 96 hour LC_{50} (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC_{50} (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC_{50} (OECD Test Guideline 201 or equivalent). These species are considered as surrogate for all aquatic organisms and data on other species such as Lemna may also be considered if the test methodology is suitable.

4.1.1.4 ***Chronic aquatic toxicity***

Chronic toxicity data are less available than acute data and the range of testing procedures less standardized. Data generated according to the OECD Test Guidelines 210 (Fish Early Life Stage), or 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) can be accepted (see also Annex 9, para. A9.3.3.2). Other validated and internationally accepted tests could also be used. The NOECs or other equivalent ECx should be used.

4.1.1.5 ***Bioaccumulation potential***

The potential for bioaccumulation would normally be determined by using the octanol/water partition coefficient, usually reported as a log K_{ow} determined by OECD Test Guideline 107, 117 or 123. While this represents a potential to bioaccumulate, an experimentally determined Bioconcentration Factor (BCF) provides a better measure and should be used in preference when available. A BCF should be determined according to OECD Test Guideline 305.

4.1.1.6 ***Rapid degradability***

4.1.1.6.1 Environmental degradation may be biotic or abiotic (e.g. hydrolysis) and the criteria used reflect this fact (see 4.1.2.11.3). Ready biodegradation can most easily be defined using the biodegradability tests (A-F) of OECD Test Guideline 301. A pass level in these tests can be considered as indicative of rapid degradation in most environments. These are freshwater tests and thus the use of the results from OECD Test Guideline 306 which is more suitable for marine environments has also been included. Where such data are not available, a BOD(5 days)/COD ratio ≥ 0.5 is considered as indicative of rapid degradation.

4.1.1.6.2 Abiotic degradation such as hydrolysis, primary degradation, both abiotic and biotic, degradation in non-aquatic media and proven rapid degradation in the environment may all be considered in defining rapid degradability. Special guidance on data interpretation is provided in the Guidance Document (Annex 9).

4.1.1.7 ***Other considerations***

4.1.1.7.1 The harmonized system for classifying substances for the hazards they present to the aquatic environment is based on a consideration of existing systems listed in 4.1.1.7.3. The aquatic environment may be considered in terms of the aquatic organisms that live in the water, and the aquatic ecosystem of which they are part. To that extent, the proposal does not address aquatic pollutants for which there may be a need to consider effects beyond the aquatic environment such as the impacts on human health etc. The basis, therefore, of the identification of hazard is the aquatic toxicity of the substance, although this may be modified by further information on the degradation and bioaccumulation behaviour.

4.1.1.7.2 While the scheme is intended to apply to all substances and mixtures, it is recognized that for some substances, e.g. metals, poorly soluble substances, etc., special guidance will be necessary. Two guidance documents (see annexes 9 and 10) have been prepared to cover issues such as data interpretation and the application of the criteria defined below to such groups of substances. Considering the complexity of this endpoint and the breadth of the application of the system, the Guidance Documents are considered an important element in the operation of the harmonized scheme.

4.1.1.7.3 Consideration has been given to existing classification systems as currently in use, including the European Union supply and use scheme, the revised GESAMP hazard evaluation procedure, IMO scheme for marine pollutants, the European road and rail transport scheme (ADR/RID), the Canadian and United States of America pesticide systems and the United States of America land transport scheme. The harmonized scheme is considered suitable for use for packaged goods in both supply and use and multimodal transport schemes, and elements of it may

be used for bulk land transport and bulk marine transport under MARPOL 73/78 Annex II insofar as this uses aquatic toxicity.

4.1.2 Classification criteria for substances

4.1.2.1 Whilst the harmonized classification system consists of three short-term (acute) classification categories and four long-term (chronic) classification categories, the core part of the harmonized classification system for substances consists of three short-term (acute) classification categories and three long-term (chronic) classification categories (see Table 4.1.1 (a) and (b)). The short-term (acute) and the long-term (chronic) classification categories are applied independently. The criteria for classification of a substance in Acute 1 to 3 are defined on the basis of the acute toxicity data only (EC_{50} or LC_{50}). The criteria for classification of a substance into Chronic 1 to 3 follow a tiered approach where the first step is to see if available information on chronic toxicity merits long-term hazard classification. In absence of adequate chronic toxicity data, the subsequent step is to combine two types of information, i.e. acute toxicity data and environmental fate data (degradability and bioaccumulation data) (see Figure 4.1.1).

4.1.2.2 The system also introduces a "safety net" classification (Chronic 4) for use when the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern. The precise criteria are not defined with one exception: for poorly water soluble substances for which no toxicity has been demonstrated, classification can occur if the substance is both not rapidly degraded and has a potential to bioaccumulate. It is considered that for such poorly soluble substances, the toxicity may not have been adequately assessed in the short-term test due to the low exposure levels and potentially slow uptake into the organism. The need for this classification can be negated by demonstrating that the substance does not require classification for aquatic long-term (chronic) hazards.

4.1.2.3 Substances with acute toxicities well below 1 mg/l or chronic toxicities well below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) contribute as ingredients of a mixture to the toxicity of the mixture even at a low concentration and should be given increased weight in applying the summation method (see Note 2 to Table 4.1.1 and paragraph 4.1.3.5.5.5).

4.1.2.4 Substances classified under the following criteria (Table 4.1.1) will be categorized as "hazardous to the aquatic environment". These criteria describe in detail the classification categories. They are diagrammatically summarized in Table 4.1.2.

Table 4.1.1: Categories for substances hazardous to the aquatic environment *(Note 1)*

(a) Short-term (acute) aquatic hazard

Category Acute 1: *(Note 2)*	
96 hr LC_{50} (for fish)	≤ 1 mg/l and/or
48 hr EC_{50} (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/l *(Note 3)*
Category Acute 1 may be subdivided for some regulatory systems to include a lower band at $L(E)C_{50}$ ≤ 0.1 mg/l	
Category Acute 2:	
96 hr LC_{50} (for fish)	>1 but ≤ 10 mg/l and/or
48 hr EC_{50} (for crustacea)	>1 but ≤ 10 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	>1 but ≤ 10 mg/l *(Note 3)*
Category Acute 3:	
96 hr LC_{50} (for fish)	>10 but ≤ 100 mg/l and/or
48 hr EC_{50} (for crustacea)	>10 but ≤ 100 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	>10 but ≤ 100 mg/l *(Note 3)*
Some regulatory systems may extend this range beyond an $L(E)C_{50}$ of 100 mg/l through the introduction of another category.	

(Cont'd on next page)

Table 4.1.1: Categories for substances hazardous to the aquatic environment *(Note 1) (cont'd)*

(b) Long-term (chronic) aquatic hazard *(see also figure 4.1.1)*

(i) Non-rapidly degradable substances (Note 4) for which there are adequate chronic toxicity data available

Category Chronic 1: (*Note 2*)	
Chronic NOEC or EC_x (for fish)	≤ 0.1 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	≤ 0.1 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	≤ 0.1 mg/l
Category Chronic 2:	
Chronic NOEC or EC_x (for fish)	≤ 1 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	≤ 1 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	≤ 1 mg/l

(ii) Rapidly degradable substances for which there are adequate chronic toxicity data available

Category Chronic 1: *(Note 2)*	
Chronic NOEC or EC_x (for fish)	≤ 0.01 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	≤ 0.01 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	≤ 0.01 mg/l
Category Chronic 2:	
Chronic NOEC or EC_x (for fish)	≤ 0.1 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	≤ 0.1 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	≤ 0.1 mg/l
Category Chronic 3:	
Chronic NOEC or EC_x (for fish)	≤ 1 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	≤ 1 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	≤ 1 mg/l

(iii) Substances for which adequate chronic toxicity data are not available

Category Chronic 1: *(Note 2)*	
96 hr LC_{50} (for fish)	≤ 1 mg/l and/or
48 hr EC_{50} (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/l *(Note 3)*
and the substance is not rapidly degradable and/or (or, if absent, the log $K_{ow} \geq 4$). *(Notes 4 and 5)*	the experimentally determined BCF is ≥ 500
Category Chronic 2:	
96 hr LC_{50} (for fish)	> 1 but ≤ 10 mg/l and/or
48 hr EC_{50} (for crustacea)	> 1 but ≤ 10 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	> 1 but ≤ 10 mg/l *(Note 3)*
and the substance is not rapidly degradable and/or (or, if absent, the log $K_{ow} \geq 4$). *(Notes 4 and 5)*	the experimentally determined BCF is ≥ 500
Category Chronic 3:	
96 hr LC_{50} (for fish)	> 10 but ≤ 100 mg/l and/or
48 hr EC_{50} (for crustacea)	> 10 but ≤ 100 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	> 10 but ≤ 100 mg/l *(Note 3)*
and the substance is not rapidly degradable and/or (or, if absent, the log $K_{ow} \geq 4$). *(Notes 4 and 5).*	the experimentally determined BCF is ≥ 500

(c) "Safety net" classification

Category Chronic 4:

Poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, and which are not rapidly degradable and have a log $K_{ow} \geq 4$, indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence would include an experimentally determined BCF < 500, or a chronic toxicity NOECs > 1 mg/l, or evidence of rapid degradation in the environment.

NOTE 1: *The organisms fish, crustacea and algae are tested as surrogate species covering a range of trophic levels and taxa, and the test methods are highly standardized. Data on other organisms may also be considered, however, provided they represent equivalent species and test endpoints.*

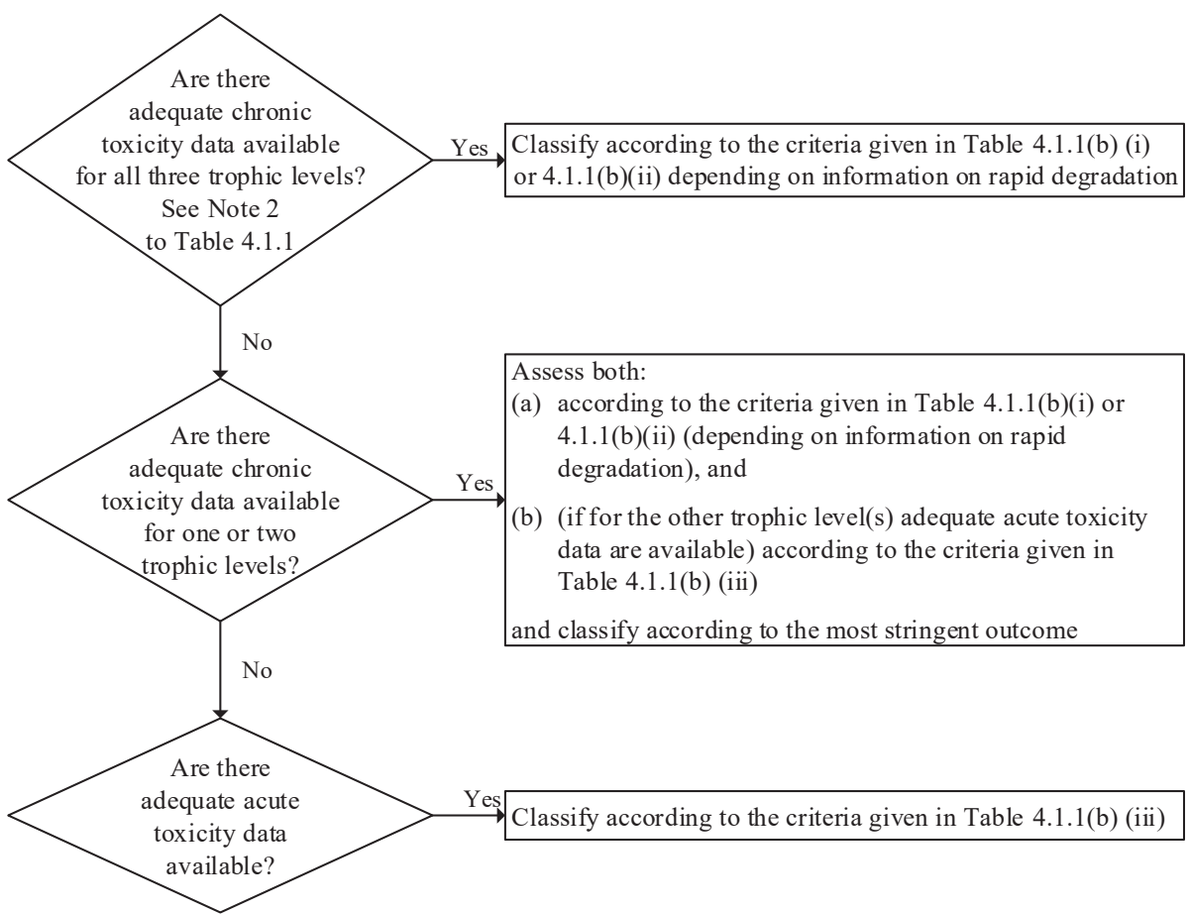
NOTE 2: *When classifying substances as Acute 1 and/or Chronic 1 it is necessary at the same time to indicate an appropriate M factor (see 4.1.3.5.5.5) to apply the summation method.*

NOTE 3: *Where the algal toxicity ErC_{50} [= EC_{50} (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgment should be used in deciding if classification should be applied. Classification should be based on the ErC_{50}. In circumstances where the basis of the EC_{50} is not specified and no ErC_{50} is recorded, classification should be based on the lowest EC_{50} available.*

NOTE 4: *Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation. When no useful data on degradability are available, either experimentally determined or estimated data, the substance should be regarded as not rapidly degradable.*

NOTE 5: *Potential to bioaccumulate, based on an experimentally derived BCF ≥ 500 or, if absent, a log K_{ow} ≥ 4, provided log K_{ow} is an appropriate descriptor for the bioaccumulation potential of the substance. Measured log K_{ow} values take precedence over estimated values and measured BCF values take precedence over log K_{ow} values.*

Figure 4.1.1: Categories for substances long-term (chronic) hazardous to the aquatic environment



4.1.2.5 The system for classification recognizes that the core intrinsic hazard to aquatic organisms is represented by both the acute and chronic toxicity of a substance, the relative importance of which is determined by the specific regulatory system in operation. Distinction can be made between the short-term (acute) hazard and the long-term (chronic) hazard and therefore separate hazard categories are defined for both properties representing a gradation in the level of hazard identified. The lowest of the available toxicity values between and within the different trophic levels (fish, crustacean, algae) will normally be used to define the appropriate hazard category(ies). There may be

circumstances, however, when a weight of evidence approach may be used. Acute toxicity data are the most readily available and the tests used are the most standardized.

4.1.2.6 Acute toxicity represents a key property in defining the hazard where transport of large quantities of a substance may give rise to short-term dangers arising from accidents or major spillages. Hazards categories up to $L(E)C_{50}$ values of 100 mg/l are thus defined although categories up to 1000 mg/l may be used in certain regulatory frameworks. The category Acute 1 may be further sub-divided to include an additional category for acute toxicity $L(E)C_{50} \leq 0.1$ mg/l in certain regulatory systems such as that defined by MARPOL 73/78 Annex II. It is anticipated that their use would be restricted to regulatory systems concerning bulk transport.

4.1.2.7 For packaged substances it is considered that the principal hazard is defined by chronic toxicity, although acute toxicity at $L(E)C_{50}$ levels ≤ 1 mg/l are also considered hazardous. Levels of substances up to 1 mg/l are considered as possible in the aquatic environment following normal use and disposal. At toxicity levels above this, it is considered that the acute toxicity itself does not describe the principal hazard, which arises from low concentrations causing effects over a longer time scale. Thus, a number of hazard categories are defined which are based on levels of chronic aquatic toxicity. Chronic toxicity data are not available for many substances, however, and in those cases it is necessary to use the available data on acute toxicity to estimate this property. The intrinsic properties of a lack of rapid degradability and/or a potential to bioconcentrate in combination with acute toxicity may be used to assign a substance to a long-term (chronic) hazard category. Where chronic toxicity is available showing NOECs greater than water solubility or greater than 1 mg/l, this would indicate that no classification in any of the long-term (chronic) hazard categories Chronic 1 to 3 would be necessary. Equally, for substances with an $L(E)C_{50} > 100$ mg/l, the toxicity is considered as insufficient to warrant classification in most regulatory systems.

4.1.2.8 Recognition is given to the classification goals of MARPOL 73/78 Annex II, which covers the transport of bulk quantities in ships tanks, which are aimed at regulating operational discharges from ships and assigning of suitable ship types. They go beyond that of protecting aquatic ecosystems, although that clearly is included. Additional hazard categories may thus be used which take account of factors such as physico-chemical properties and mammalian toxicity.

4.1.2.9 ***Aquatic toxicity***

4.1.2.9.1 The organisms fish, crustacea and algae are tested as surrogate species covering a range of trophic levels and taxa, and the test methods are highly standardized. Data on other organisms may also be considered, however, provided they represent equivalent species and test endpoints. The algal growth inhibition test is a chronic test but the EC_{50} is treated as an acute value for classification purposes. This EC_{50} should normally be based on growth rate inhibition. If only the EC_{50} based on reduction in biomass is available, or it is not indicated which EC_{50} is reported, this value may be used in the same way.

4.1.2.9.2 Aquatic toxicity testing, by its nature, involves the dissolution of the substance under test in the water media used and the maintenance of a stable bioavailable exposure concentration over the course of the test. Some substances are difficult to test under standard procedures and thus special guidance will be developed on data interpretation for these substances and how the data should be used when applying the classification criteria.

4.1.2.10 ***Bioaccumulation***

It is the bioaccumulation of substances within the aquatic organisms that can give rise to toxic effects over longer time scales even when actual water concentrations are low. The potential to bioaccumulate is determined by the partitioning between n-octanol and water. The relationship between the partition coefficient of an organic substance and its bioconcentration as measured by the BCF in fish has considerable scientific literature support. Using a cut-off value of log $K_{ow} \geq 4$ is intended to identify only those substances with a real potential to bioconcentrate. In recognition that the log K_{ow} is only an imperfect surrogate for a measured BCF, such a measured value would always take precedence. A BCF in fish of < 500 is considered as indicative of a low level of bioconcentration. Some relationships can be observed between chronic toxicity and bioaccumulation potential, as toxicity is related to the body burden.

4.1.2.11 ***Rapid degradability***

4.1.2.11.1 Substances that rapidly degrade can be quickly removed from the environment. While effects can occur, particularly in the event of a spillage or accident, they will be localized and of short duration. The absence of rapid degradation in the environment can mean that a substance in the water has the potential to exert toxicity over a wide temporal and spatial scale. One way of demonstrating rapid degradation utilizes the biodegradation screening tests designed to determine whether a substance is “readily biodegradable”. Thus a substance which passes this screening test is one that is likely to biodegrade “rapidly” in the aquatic environment, and is thus unlikely to be persistent. However, a

fail in the screening test does not necessarily mean that the substance will not degrade rapidly in the environment. Thus a further criterion was added which would allow the use of data to show that the substance did actually degrade biotically or abiotically in the aquatic environment by > 70% in 28 days. Thus, if degradation could be demonstrated under environmentally realistic conditions, then the definition of "rapid degradability" would have been met. Many degradation data are available in the form of degradation half-lives and these can also be used in defining rapid degradation. Details regarding the interpretation of these data are further elaborated in the guidance document of Annex 9. Some tests measure the ultimate biodegradation of the substance, i.e. full mineralization is achieved. Primary biodegradation would not normally qualify in the assessment of rapid degradability unless it can be demonstrated that the degradation products do not fulfill the criteria for classification as hazardous to the aquatic environment.

4.1.2.11.2 It must be recognized that environmental degradation may be biotic or abiotic (e.g. hydrolysis) and the criteria used reflect this fact. Equally, it must be recognized that failing the ready biodegradability criteria in the OECD tests does not mean that the substance will not be degraded rapidly in the real environment. Thus where such rapid degradation can be shown, the substance should be considered as rapidly degradable. Hydrolysis can be considered if the hydrolysis products do not fulfil the criteria for classification as hazardous to the aquatic environment. A specific definition of rapid degradability is shown below. Other evidence of rapid degradation in the environment may also be considered and may be of particular importance where the substances are inhibitory to microbial activity at the concentration levels used in standard testing. The range of available data and guidance on its interpretation are provided in the guidance document of Annex 9.

4.1.2.11.3 Substances are considered rapidly degradable in the environment if the following criteria hold true:

(a) if in 28-day ready biodegradation studies, the following levels of degradation are achieved:

(i) tests based on dissolved organic carbon: 70%;

(ii) tests based on oxygen depletion or carbon dioxide generation: 60% of theoretical maxima;

These levels of biodegradation must be achieved within 10 days of the start of degradation which point is taken as the time when 10% of the substance has been degraded, unless the substance is identified as a complex, multi-component substance with structurally similar constituents. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days as explained in Annex 9 (A9.4.2.2.3).

(b) if, in those cases where only BOD and COD data are available, when the ratio of BOD_5/COD is ≥ 0.5; or

(c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level >70% within a 28-day period.

4.1.2.12 ***Inorganic compounds and metals***

4.1.2.12.1 For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Equally the use of bioaccumulation data should be treated with care. Specific guidance will be provided on how these data for such materials may be used in meeting the requirements of the classification criteria.

4.1.2.12.2 Poorly soluble inorganic compounds and metals may be acutely or chronically toxic in the aquatic environment depending on the intrinsic toxicity of the bioavailable inorganic species and the rate and amount of this species which may enter solution. A protocol for testing these poorly soluble materials is included in Annex 10. All evidence must be weighed in a classification decision. This would be especially true for metals showing borderline results in the Transformation/Dissolution Protocol.

4.1.2.13 ***Use of QSARs***

While experimentally derived test data are preferred, where no experimental data are available, validated Quantitative Structure Activity Relationships (QSARs) for aquatic toxicity and log K_{ow} may be used in the classification process. Such validated QSARs may be used without modification to the agreed criteria, if restricted to chemicals for which their mode of action and applicability are well characterized. Reliable calculated toxicity and log

K_{ow} values should be valuable in the safety net context. QSARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation.

4.1.2.14 *The classification criteria for substances diagrammatically summarized*

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories			
Short-term (acute) hazard (*Note 1*)	**Long-term (chronic) hazard** (***Note 2***)		
	Adequate chronic toxicity data available		**Adequate chronic toxicity data not available** (*Note 1*)
	Non-rapidly degradable substances (*Note 3*)	**Rapidly degradable substances** (*Note 3*)	
Category: Acute 1 $L(E)C_{50} \leq 1.00$	**Category: Chronic 1** NOEC or $EC_x \leq 0.1$	**Category: Chronic 1** NOEC or $EC_x \leq 0.01$	**Category: Chronic 1** $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	**Category: Chronic 2** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 2** $0.01 <$ NOEC or $EC_x \leq 0.1$	**Category: Chronic 2** $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		**Category: Chronic 3** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 3** $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
	Category: Chronic 4 *(Note 4)* Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF ≥ 500 or, if absent log Kow ≥ 4, unless NOECs > 1 mg/l		

NOTE 1: *Acute toxicity band based on $L(E)C_{50}$ values in mg/l for fish, crustacea and/or algae or other aquatic plants (or QSAR estimation if no experimental data).*

NOTE 2: *Substances are classified in the various chronic categories unless there are adequate chronic toxicity data available for all three trophic levels above the water solubility or above 1 mg/l. ("Adequate" means that the data sufficiently cover the endpoint of concern. Generally this would mean measured test data, but in order to avoid unnecessary testing it can, on a case-by-case basis, also be estimated data, e.g. (Q)SAR, or for obvious cases expert judgment).*

NOTE 3: *Chronic toxicity band based on NOEC or equivalent EC_x values in mg/l for fish or crustacea or other recognized measures for chronic toxicity.*

NOTE 4: *The system also introduces a "safety net" classification (referred to as category Chronic 4) for use when the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern.*

NOTE 5: *For poorly soluble substances for which no acute toxicity has been demonstrated at the solubility limit, and are both not rapidly degraded and have a potential to bioaccumulate, this category should apply unless it can be demonstrated that the substance does not require classification for aquatic long-term (chronic) hazards.*

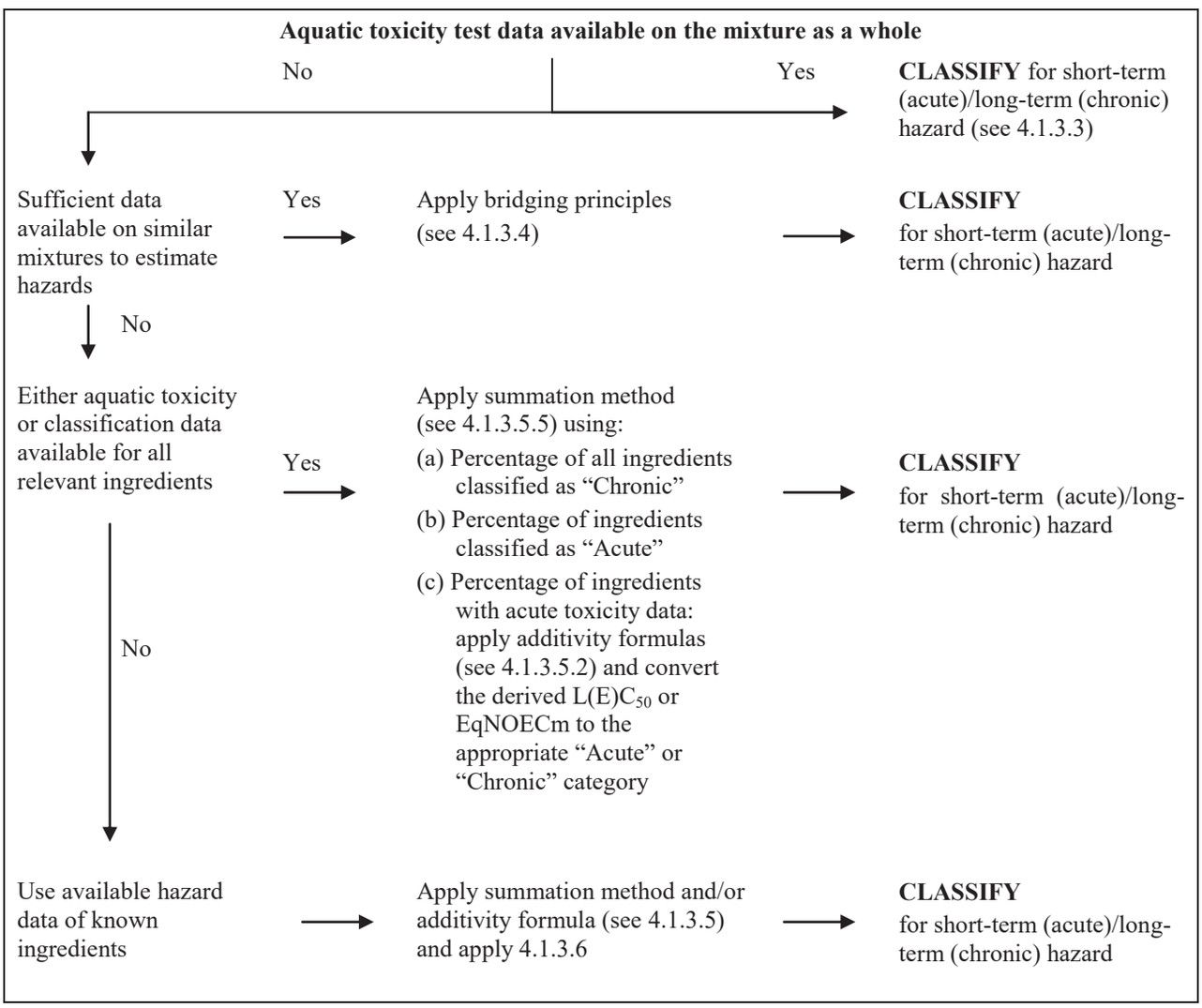
4.1.3 Classification criteria for mixtures

4.1.3.1 The classification system for mixtures covers all classification categories which are used for substances, meaning categories Acute 1 to 3 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following assumption has been made and is applied where appropriate:

The "relevant ingredients" of a mixture are those which are present in a concentration equal to or greater than 0.1% (w/w) for ingredients classified as Acute and/or Chronic 1 and equal to or greater than 1% (w/w) for other ingredients, unless there is a presumption (e.g. in the case of highly toxic ingredients) that an ingredient present at a concentration less than 0.1% can still be relevant for classifying the mixture for aquatic environmental hazards.

4.1.3.2 The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its ingredients. Elements of the tiered approach include classification based on tested mixtures, classification based on bridging principles, the use of "summation of classified ingredients" and/or an "additivity formula". Figure 4.1.2 outlines the process to be followed.

Figure 4.1.2: Tiered approach to classification of mixtures for short-term (acute) and long-term (chronic) aquatic environmental hazards



4.1.3.3 ***Classification of mixtures when toxicity data are available for the complete mixture***

4.1.3.3.1 When the mixture as a whole has been tested to determine its aquatic toxicity, this information can be used for classifying the mixture according to the criteria that have been agreed for substances. The classification should normally be based on the data for fish, crustacea and algae/plants (see 4.1.1.3 and 4.1.1.4). When adequate acute or chronic data for the mixture as a whole are lacking, "bridging principles" or "summation method" should be applied (see paragraphs 4.1.3.4 and 4.1.3.5 and decision logic 4.1.5.2.2).

4.1.3.3.2 The long-term (chronic) hazard classification of mixtures requires additional information on degradability and in certain cases bioaccumulation. There are no degradability and bioaccumulation data for mixtures as a whole. Degradability and bioaccumulation tests for mixtures are not used as they are usually difficult to interpret, and such tests may be meaningful only for single substances.

4.1.3.3.3 *Classification for categories Acute 1, 2 and 3*

(a) When there are adequate acute toxicity test data (LC_{50} or EC_{50}) available for the mixture as a whole showing $L(E)C_{50} \leq 100$ mg/l:

Classify the mixture as Acute 1, 2 or 3 in accordance with Table 4.1.1(a)

(b) When there are acute toxicity test data (LC_{50}(s) or EC_{50}(s) available for the mixture as a whole showing $L(E)C_{50}$(s) >100 mg/l, or above the water solubility:

No need to classify for short-term (acute) hazard

4.1.3.3.4 *Classification for categories Chronic 1, 2 and 3*

(a) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x or NOEC of the tested mixture ≤ 1mg/l:

(i) Classify the mixture as Chronic 1, 2 or 3 in accordance with Table 4.1.1 (b)(ii) (rapidly degradable) if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable;

(ii) Classify the mixture as Chronic 1, 2 or 3 in all other cases in accordance with Table 4.1.1 (b)(i) (non-rapidly degradable);

(b) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x(s) or NOEC(s) of the tested mixture > 1 mg/l or above the water solubility:

No need to classify for long-term (chronic) hazard, unless there are nevertheless reasons for concern

4.1.3.3.5 *Classification for category Chronic 4*

If there are nevertheless reasons for concern:

Classify the mixture as Chronic 4 (safety net classification) in accordance with Table 4.1.1(c).

4.1.3.4 ***Classification of mixtures when toxicity data are not available for the complete mixture: bridging principles***

4.1.3.4.1 Where the mixture itself has not been tested to determine its aquatic environmental hazard, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, this data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

4.1.3.4.2 *Dilution*

Where a new mixture is formed by diluting a tested mixture or a substance with a diluent which has an equivalent or lower aquatic hazard classification than the least toxic original ingredient and which is not expected to affect the aquatic hazards of other ingredients, then the resulting mixture may be classified as equivalent to the original tested mixture or substance. Alternatively, the method explained in 4.1.3.5 could be applied.

4.1.3.4.3 *Batching*

The aquatic hazard classification of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the aquatic hazard classification of the untested batch has changed. If the latter occurs, new classification is necessary.

4.1.3.4.4 *Concentration of mixtures which are classified with the most severe classification categories (Chronic 1 and Acute 1)*

If a tested mixture is classified as Chronic 1 and/or Acute 1, and the ingredients of the mixture which are classified as Chronic 1 and/or Acute 1 are further concentrated, the more concentrated untested mixture should be classified with the same classification category as the original tested mixture without additional testing.

4.1.3.4.5 *Interpolation within one hazard category*

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same hazard category and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same hazard category as A and B.

4.1.3.4.6 *Substantially similar mixtures*

Given the following:

(a) Two mixtures: (i) A + B;

(ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

(d) Data on aquatic hazards for A and C are available and are substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the aquatic toxicity of B.

If mixture (i) or (ii) is already classified based on test data, then the other mixture can be assigned the same hazard category.

4.1.3.5 *Classification of mixtures when toxicity data are available for all ingredients or only for some ingredients of the mixture*

4.1.3.5.1 The classification of a mixture is based on summation of the concentrations of its classified ingredients. The percentage of ingredients classified as “Acute” or “Chronic” will feed straight into the summation method. Details of the summation method are described in 4.1.3.5.5.

4.1.3.5.2 Mixtures can be made of a combination of both ingredients that are classified (as Acute 1, 2, 3 and/or Chronic 1, 2, 3, 4) and those for which adequate toxicity test data is available. When adequate toxicity data are available for more than one ingredient in the mixture, the combined toxicity of those ingredients may be calculated using the following additivity formulas (a) or (b), depending on the nature of the toxicity data:

(a) Based on acute aquatic toxicity:

$$\frac{\sum Ci}{L(E)C_{50_m}} = \sum_n \frac{Ci}{L(E)C_{50_i}}$$

where:

C_i = concentration of ingredient i (weight percentage);

$L(E)C_{50_i}$ = LC_{50} or EC_{50} for ingredient i, in (mg/l);

n = number of ingredients, and i is running from 1 to n;

$L(E)C_{50_m}$ = $L(E)C_{50}$ of the part of the mixture with test data;

The calculated toxicity may be used to assign that portion of the mixture a short-term (acute) hazard category which is then subsequently used in applying the summation method;

(b) Based on chronic aquatic toxicity:

$$\frac{\sum Ci + \sum Cj}{EqNOEC_m} = \sum_n \frac{Ci}{NOECi} + \sum_n \frac{Cj}{0.1 \times NOECj}$$

where:

C_i = concentration of ingredient i (weight percentage) covering the rapidly degradable ingredients;

Cj = concentration of ingredient j (weight percentage) covering the non-rapidly degradable ingredients;

$NOEC_i$ = NOEC (or other recognized measures for chronic toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/l;

NOECj = NOEC (or other recognized measures for chronic toxicity) for ingredient j covering the non-rapidly degradable ingredients, in mg/l;

n = number of ingredients, and i and j are running from 1 to n;

$EqNOEC_m$ = Equivalent NOEC of the part of the mixture with test data;

The equivalent toxicity thus reflects the fact that non-rapidly degrading substances are classified one hazard category level more “severe” than rapidly degrading substances.

The calculated equivalent toxicity may be used to assign that portion of the mixture a long-term (chronic) hazard category, in accordance with the criteria for rapidly degradable substances (Table 4.1.1(b)(ii)), which is then subsequently used in applying the summation method.

4.1.3.5.3 When applying the additivity formula for part of the mixture, it is preferable to calculate the toxicity of this part of the mixture using for each ingredient toxicity values that relate to the same taxonomic group (i.e. fish, crustacean or algae) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three groups). However, when toxicity data for each ingredient are not available in the same taxonomic group, the toxicity value of each ingredient should be selected in the same manner that toxicity values are selected for the classification of substances, i.e. the higher toxicity (from the most sensitive test organism) is used. The calculated acute and chronic toxicity may then be used to classify this part of the mixture as Acute 1, 2 or 3 and/or Chronic 1, 2 or 3 using the same criteria described for substances.

4.1.3.5.4 If a mixture is classified in more than one way, the method yielding the more conservative result should be used.

4.1.3.5.5 *Summation method*

4.1.3.5.5.1 Rationale

4.1.3.5.5.1.1 In case of the ingredient classification categories Acute 1/Chronic 1 to Acute 3/Chronic 3, the underlying toxicity criteria differ by a factor of 10 in moving from one category to another. Ingredients with a classification in a high toxicity band may therefore contribute to the classification of a mixture in a lower band. The calculation of these classification categories therefore needs to consider the contribution of all ingredients classified Acute 1/Chronic 1 to Acute 3/Chronic 3 together.

4.1.3.5.5.1.2 When a mixture contains ingredients classified as Acute 1 or Chronic 1, attention should be paid to the fact that such ingredients, when their acute toxicity is well below 1 mg/l and/or chronic toxicity is well below 0.1 mg/l (if non rapidly degradable) and 0.01 mg/l (if rapidly degradable) contribute to the toxicity of the mixture even at a low concentration (see also *Classification of hazardous substances and mixtures* in Chapter 1.3, paragraph 1.3.3.2.1). Active ingredients in pesticides often possess such high aquatic toxicity but also some other substances like organometallic compounds. Under these circumstances the application of the normal cut-off values/concentration limits may lead to an "under-classification" of the mixture. Therefore, multiplying factors should be applied to account for highly toxic ingredients, as described in 4.1.3.5.5.5.

4.1.3.5.5.2 Classification procedure

In general a more severe classification for mixtures overrides a less severe classification, e.g. a classification with Chronic 1 overrides a classification with Chronic 2. As a consequence the classification procedure is already completed if the result of the classification is Chronic 1. A more severe classification than Chronic 1 is not possible, therefore it is not necessary to undergo the further classification procedure.

4.1.3.5.5.3 Classification for categories Acute 1, 2 and 3

4.1.3.5.5.3.1 First, all ingredients classified as Acute 1 are considered. If the sum of the concentrations (in %) of these ingredients multiplied by their corresponding M factor is ≥ 25% the whole mixture is classified as Acute 1. If the result of the calculation is a classification of the mixture as Acute 1, the classification process is completed.

4.1.3.5.5.3.2 In cases where the mixture is not classified as Acute 1, classification of the mixture as Acute 2 is considered. A mixture is classified as Acute 2 if 10 times the sum of the concentrations (in %) of all ingredients classified as Acute 1 multiplied by their corresponding M factor plus the sum of the concentrations (in %) of all ingredients classified as Acute 2 is ≥ 25%. If the result of the calculation is classification of the mixture as Acute 2, the classification process is completed.

4.1.3.5.5.3.3 In cases where the mixture is not classified either as Acute 1 or Acute 2, classification of the mixture as Acute 3 is considered. A mixture is classified as Acute 3 if 100 times the sum of the concentrations (in %) of all ingredients classified as Acute 1 multiplied by their corresponding M factor plus 10 times the sum of the concentrations (in %) of all ingredients classified as Acute 2 plus the sum of the concentrations (in %) of all ingredients classified as Acute 3 is ≥ 25%.

4.1.3.5.5.3.4 The classification of mixtures for short-term (acute) hazards based on this summation of the concentrations of classified ingredients is summarized in Table 4.1.3.

Table 4.1.3: Classification of a mixture for short-term (acute) hazards based on summation of the concentrations of classified ingredients

Sum of the concentrations (in %) of ingredients classified as:		**Mixture is classified as:**
Acute 1 × M[a]	≥ 25%	Acute 1
(M × 10 × Acute 1) + Acute 2	≥ 25%	Acute 2
(M × 100 × Acute 1) + (10 × Acute 2) + Acute 3	≥ 25%	Acute 3

[a] *For explanation of the M factor, see 4.1.3.5.5.5.*

4.1.3.5.5.4 Classification for categories Chronic 1, 2, 3 and 4

4.1.3.5.5.4.1 First, all ingredients classified as Chronic 1 are considered. If the sum of the concentrations (in %) of these ingredients multiplied by their corresponding M factor is ≥ 25% the mixture is classified as Chronic 1. If the result of the calculation is a classification of the mixture as Chronic 1 the classification procedure is completed.

4.1.3.5.5.4.2 In cases where the mixture is not classified as Chronic 1, classification of the mixture as Chronic 2 is considered. A mixture is classified as Chronic 2 if 10 times the sum of the concentrations (in %) of all ingredients classified as Chronic 1 multiplied by their corresponding M factor plus the sum of the concentrations (in %) of all ingredients classified as Chronic 2 is ≥ 25%. If the result of the calculation is classification of the mixture as Chronic 2, the classification process is completed.

4.1.3.5.5.4.3 In cases where the mixture is not classified either as Chronic 1 or Chronic 2, classification of the mixture as Chronic 3 is considered. A mixture is classified as Chronic 3 if 100 times the sum of the concentrations (in %) of all ingredients classified as Chronic 1 multiplied by their corresponding M factor plus 10 times the sum of the concentrations (in %) of all ingredients classified as Chronic 2 plus the sum of the concentrations (in %) of all ingredients classified as Chronic 3 is ≥ 25%.

4.1.3.5.5.4.4 If the mixture is still not classified in either category Chronic 1, 2 or 3, classification of the mixture as Chronic 4 should be considered. A mixture is classified as Chronic 4 if the sum of the concentrations (in %) of ingredients classified as Chronic 1, 2, 3 and 4 is ≥ 25%.

4.1.3.5.5.4.5 The classification of mixtures for long-term (chronic) hazards based on this summation of the concentrations of classified ingredients is summarized in Table 4.1.4.

Table 4.1.4: Classification of a mixture for long-term (chronic) hazards based on summation of the concentrations of classified ingredients

Sum of the concentrations (in %) of ingredients classified as:		**Mixture is classified as:**
Chronic 1 × M[a]	≥ 25%	Chronic 1
(M × 10 × Chronic 1) + Chronic 2	≥ 25%	Chronic 2
(M × 100 × Chronic 1) + (10 × Chronic 2)+ Chronic 3	≥ 25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4	≥ 25%	Chronic 4

[a] *For explanation of the M factor, see 4.1.3.5.5.5.*

4.1.3.5.5.5 Mixtures with highly toxic ingredients

Acute 1 or Chronic 1 ingredients with acute toxicities well below 1 mg/l and/or chronic toxicities well below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) may influence the toxicity of the mixture and should be given increased weight in applying the summation method. When a mixture contains ingredients classified as Acute or Chronic 1, the tiered approach described in 4.1.3.5.5.3 and 4.1.3.5.5.4 should be applied using a weighted sum by multiplying the concentrations of Acute 1 and Chronic 1 ingredients by a factor, instead of merely adding up the percentages. This means that the concentration of "Acute 1" in the left column of Table 4.1.3 and the concentration of "Chronic 1" in the left column of Table 4.1.4 are multiplied by the appropriate multiplying factor. The multiplying factors to be applied to these ingredients are defined using the toxicity value, as summarized in Table 4.1.5 below. Therefore, in order to classify a mixture containing Acute/Chronic 1 ingredients, the classifier needs to be informed of the value of the M factor in order to apply the summation method. Alternatively, the additivity formula (see 4.1.3.5.2) may be used when toxicity data are available for all highly toxic ingredients in the mixture and there is convincing evidence that all other ingredients, including those for which specific acute and/or chronic toxicity data are not available, are of low or no toxicity and do not significantly contribute to the environmental hazard of the mixture.

Table 4.1.5: Multiplying factors for highly toxic ingredients of mixtures

Acute toxicity	M factor	Chronic toxicity	M factor	
$L(E)C_{50}$ value		**NOEC value**	**NRD[a] ingredients**	**RD[b] ingredients**
$0.1 < L(E)C_{50} \leq 1$	1	$0.01 < NOEC \leq 0.1$	1	-
$0.01 < L(E)C_{50} \leq 0.1$	10	$0.001 < NOEC \leq 0.01$	10	1
$0.001 < L(E)C_{50} \leq 0.01$	100	$0.0001 < NOEC \leq 0.001$	100	10
$0.0001 < L(E)C_{50} \leq 0.001$	1000	$0.00001 < NOEC \leq 0.0001$	1000	100
$0.00001 < L(E)C_{50} \leq 0.0001$	10000	$0.000001 < NOEC \leq 0.00001$	10000	1000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

[a] *Non-rapidly degradable*
[b] *Rapidly degratdable*

4.1.3.6 *Classification of mixtures with ingredients without any useable information*

In the event that no useable information on acute and/or chronic aquatic toxicity is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: "× % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment". The competent authority can decide to specify that the additional statement is communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier.

4.1.4 Hazard communication

General and specific considerations concerning labelling requirements are provided in *Hazard communication: Labelling* (Chapter 1.4). Annex 1 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

Table 4.1.6: Label elements for hazardous to the aquatic environment

SHORT-TERM (ACUTE) AQUATIC HAZARD

	Category 1	Category 2	Category 3
Symbol	Environment	*No symbol*	*No symbol*
Signal word	Warning	*No signal word*	*No signal word*
Hazard statement	Very toxic to aquatic life	Toxic to aquatic life	Harmful to aquatic life

LONG-TERM (CHRONIC) AQUATIC HAZARD

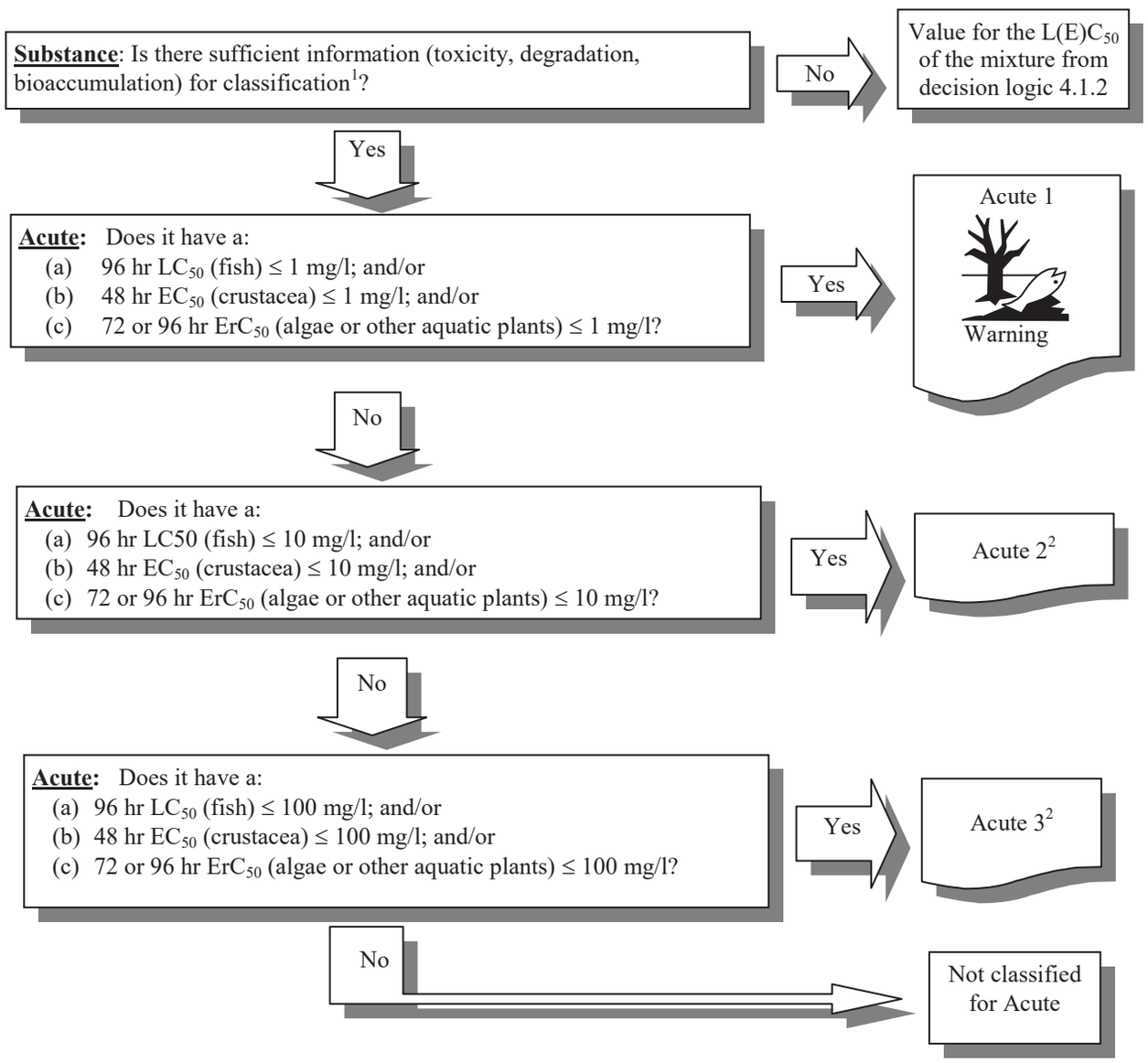
	Category 1	Category 2	Category 3	Category 4
Symbol	Environment	Environment	*No symbol*	*No symbol*
Signal word	Warning	*No signal word*	*No signal word*	*No signal word*
Hazard statement	Very toxic to aquatic life with long lasting effects	Toxic to aquatic life with long lasting effects	Harmful to aquatic life with long lasting effects	May cause long lasting harmful effects to aquatic life

4.1.5 Decision logic for substances and mixtures hazardous to the aquatic environment

The decision logics which follow are not part of the harmonized classification system but are provided here as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of the decision logic.

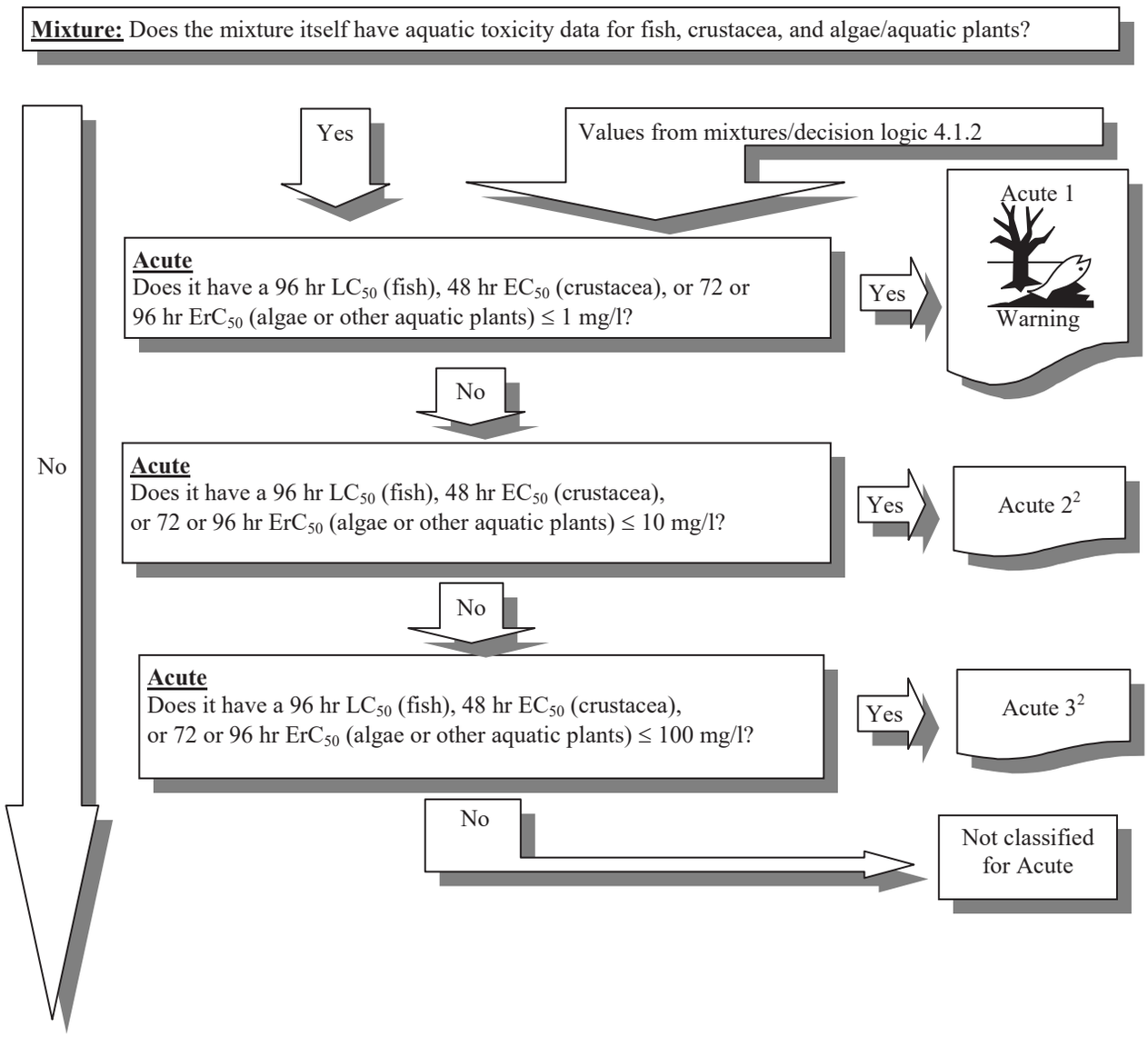
4.1.5.1 *Short-term (acute) aquatic hazard classification*

4.1.5.1.1 *Decision logic 4.1.1 for substances and mixtures hazardous to the aquatic environment*

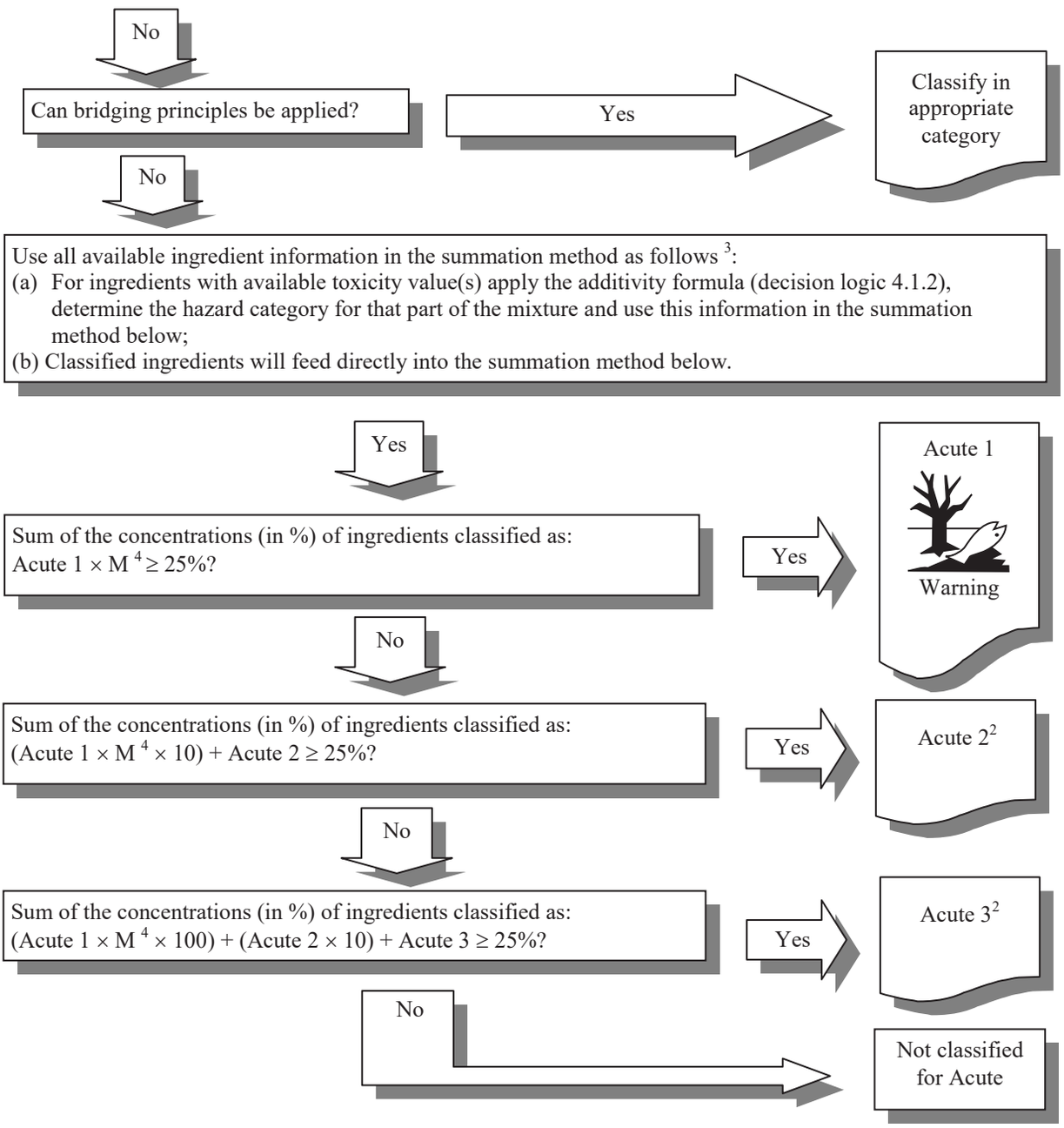


[1] *Classification can be based on either measured data and/or calculated data (see 4.1.2.13 and Annex 9) and/or analogy decisions (see A9.6.4.5 in Annex 9).*

[2] *Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.*



[2] *Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.*



[2] *Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.*

[3] *If not all ingredients have information, include the statement "x % of the mixture consists of ingredients(s) of unknown hazards to the aquatic environment" on the label. The competent authority can decide to specify that the additional statement be communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier. Alternatively, in the case of a mixture with highly toxic ingredients, if toxicity values are available for these highly toxic ingredients and all other ingredients do not significantly contribute to the hazard of the mixture, then the additivity formula may be applied (see 4.1.3.5.5.5). In this case and other cases where toxicity values are available for all ingredients, the short-term (acute) classification may be made solely on the basis of the additivity formula.*

[4] *For explanation of M factor see 4.1.3.5.5.5.*

4.1.5.1.2 *Decision logic 4.1.2 for mixtures (additivity formula)*

Apply the additivity formula:

$$\frac{\sum C_i}{L(E)C_{50_m}} = \sum_n \frac{C_i}{L(E)C_{50_i}}$$

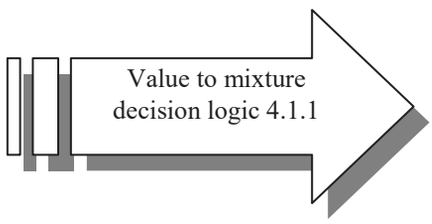
where:

C_i = concentration of ingredient i (weight percentage)

$L(E)C_{50_i}$ = (mg/l) LC_{50} or EC_{50} for ingredient i

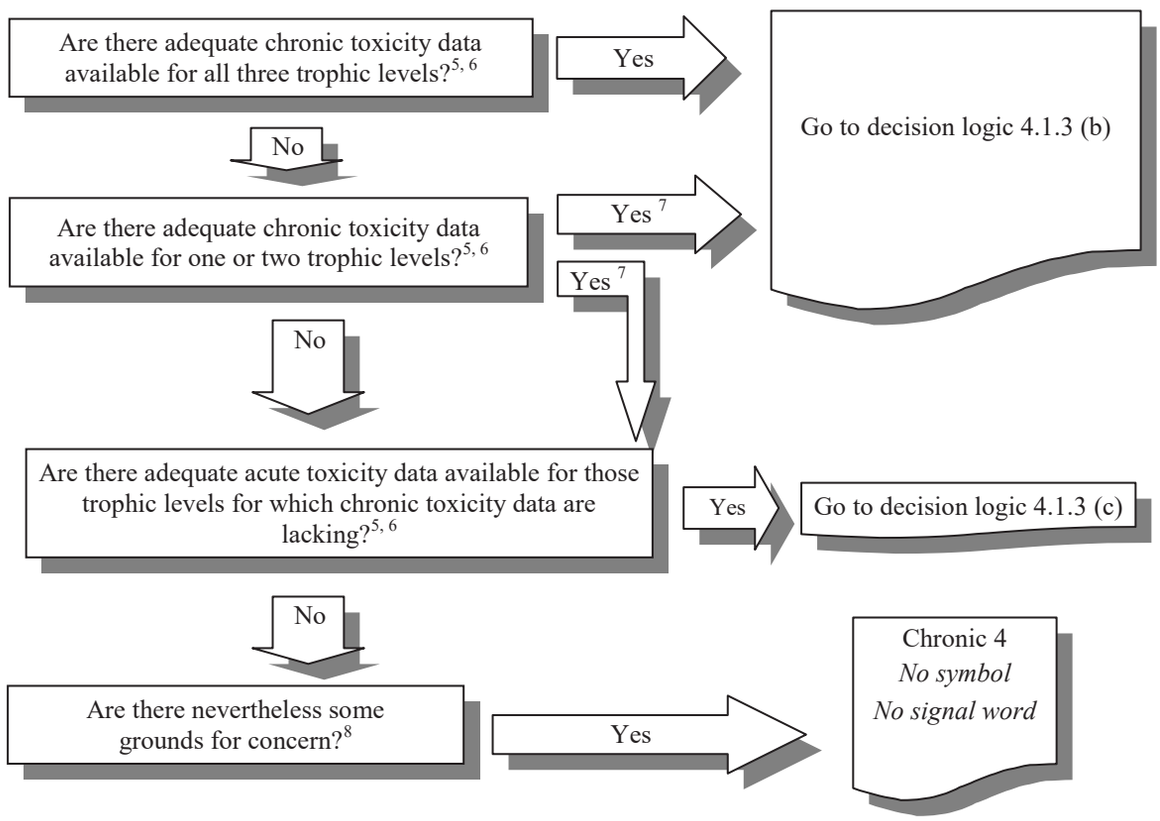
n = number of ingredients, and i is running from 1 to n

$L(E)C_{50_m}$ = $L(E)C_{50}$ of the part of the mixture with test data



4.1.5.2 *Long-term (chronic) aquatic hazard classification*

4.1.5.2.1 *Decision logic 4.1.3 (a) for substances*



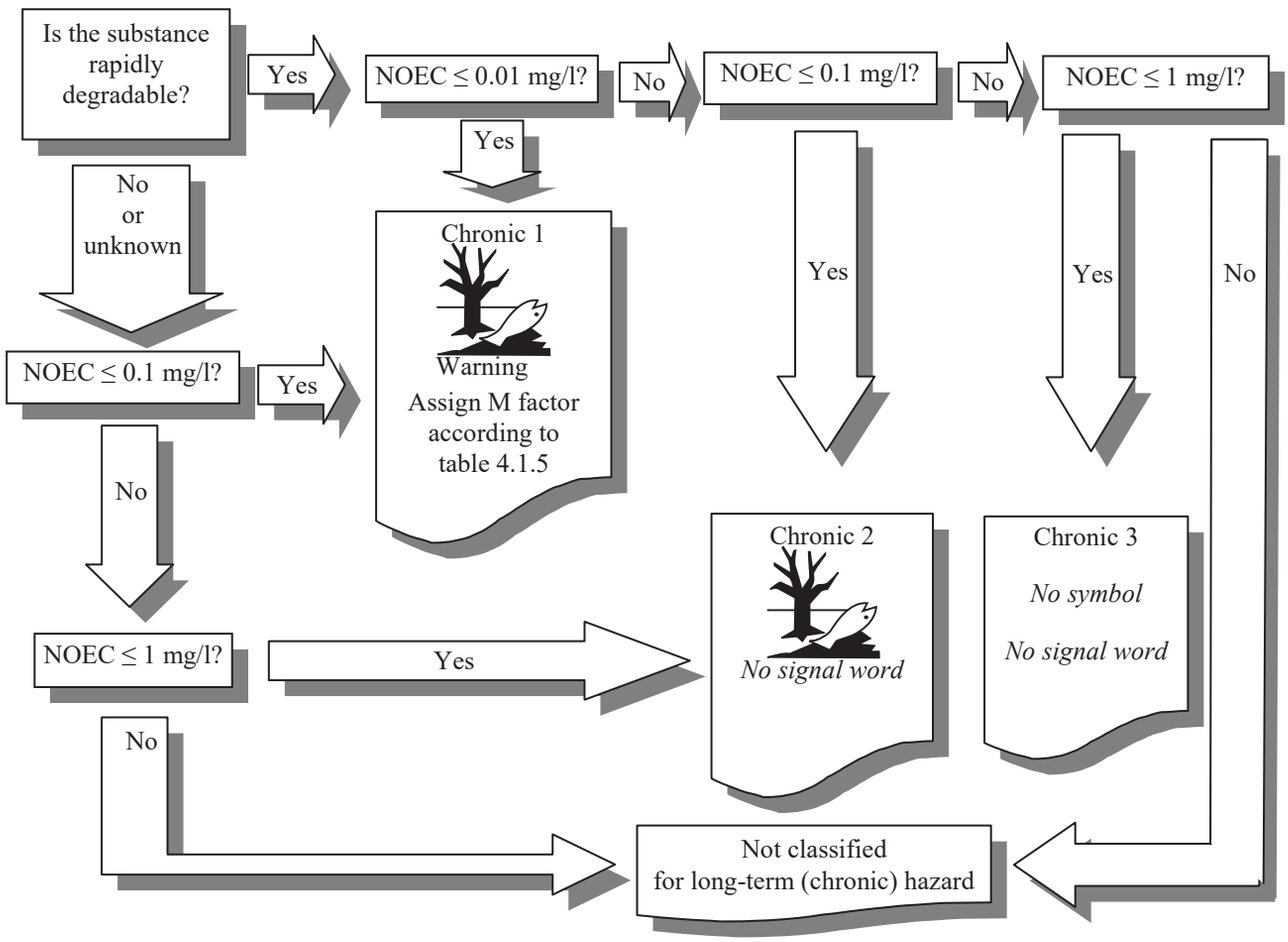
[5] *Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent (see 4.1.1.2.2 and A9.3.2 of Annex 9).*

[6] *See Figure 4.1.1.*

[7] *Follow the flowchart in both ways and choose the most stringent classification outcome.*

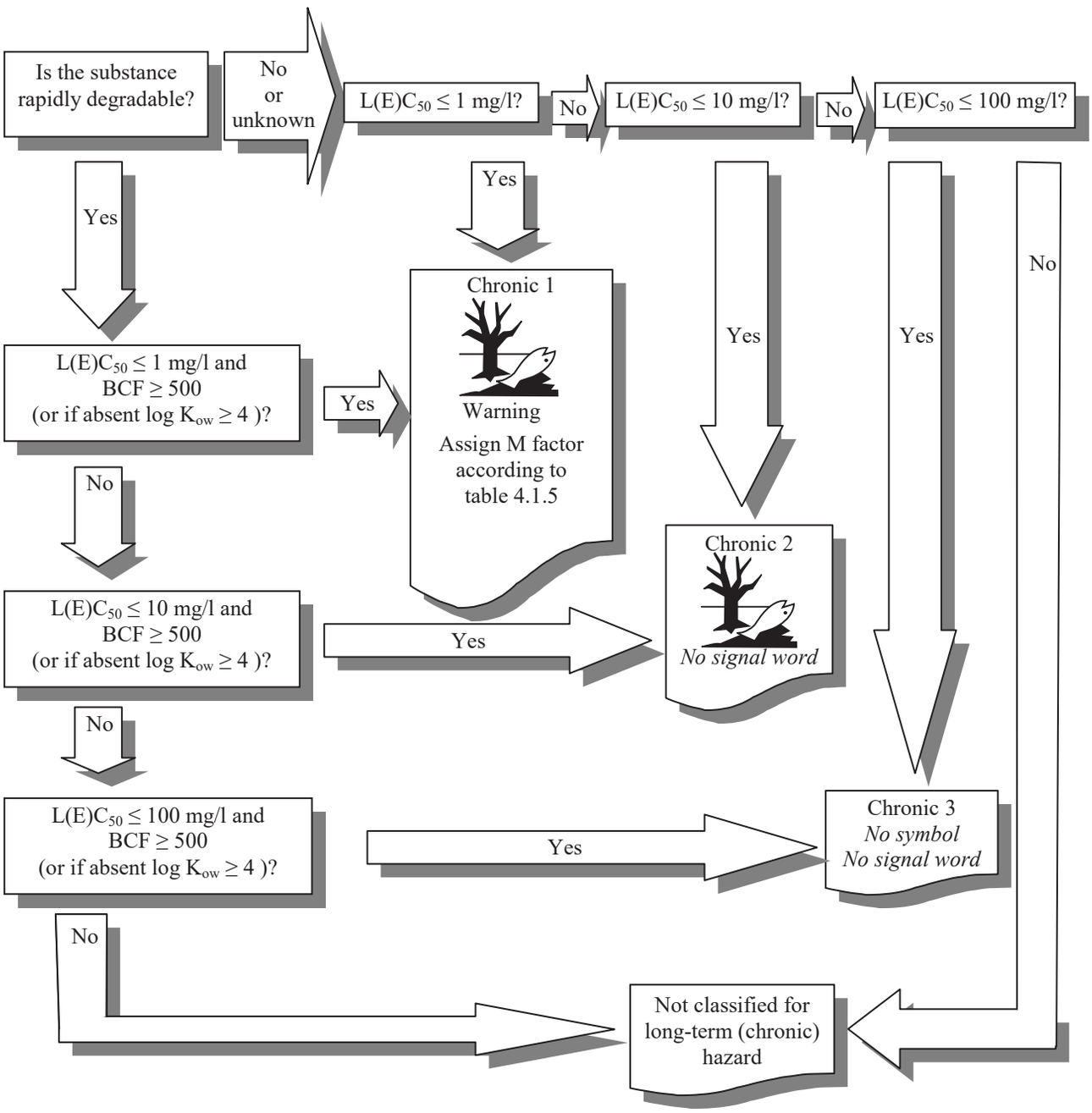
[8] *Note that the system also introduces a "safety net" classification (referred to as Category: Chronic 4) for use when the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern.*

4.1.5.2.2 *Decision logic 4.1.3 (b) for substances (when adequate chronic toxicity data are available for all three trophic levels)*[5]



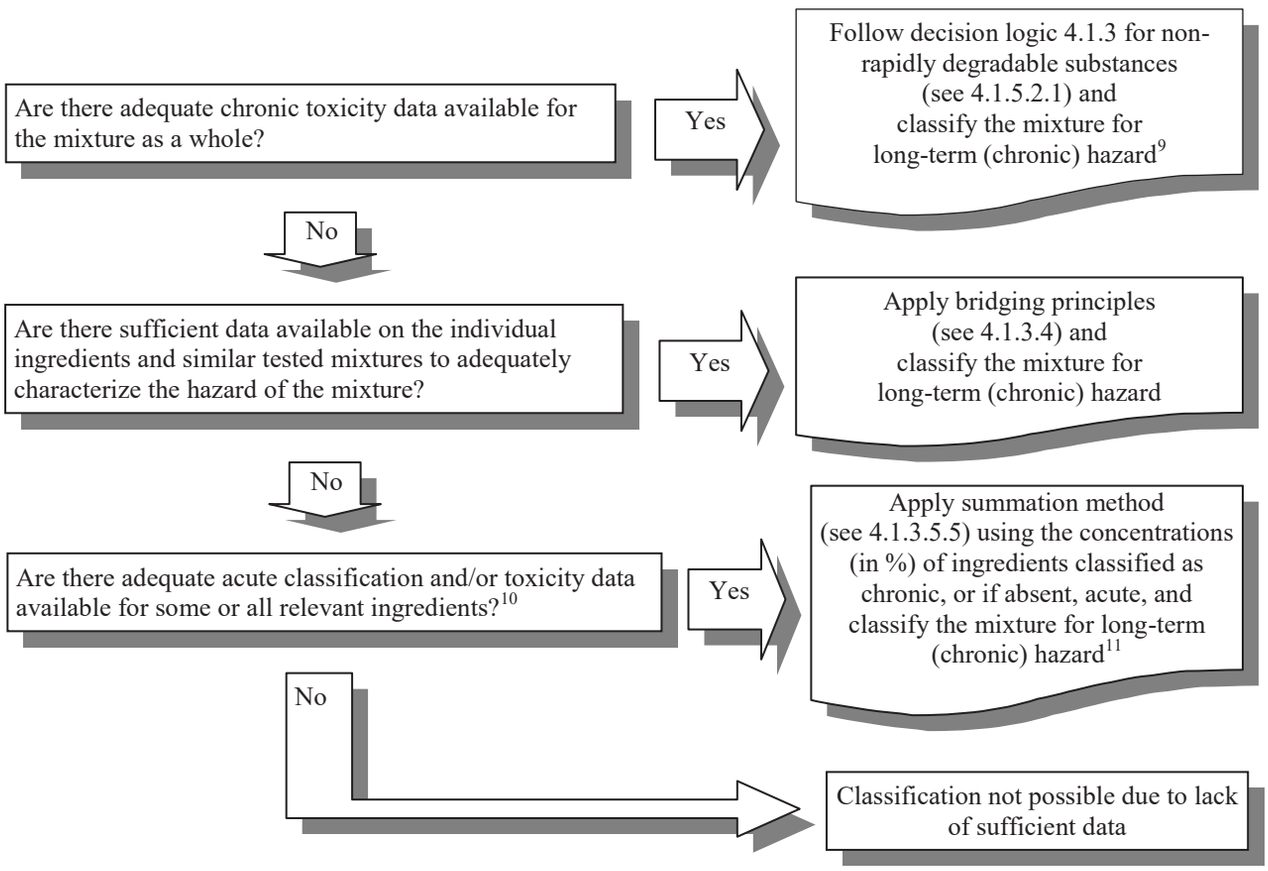
[5] *Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent (see 4.1.1.2.2 and A9.3.2 of Annex 9).*

4.1.5.2.3 *Decision logic 4.1.3 (c) for substances (when adequate chronic toxicity data not are available for all three trophic levels)*[5]



[5] *Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent (see 4.1.1.2.2 and A9.3.2 of Annex 9).*

4.1.5.2.4 *Decision logic 4.1.4 for mixtures*



[9] *Degradability and bioaccumulation tests for mixtures are not used as they are usually difficult to interpret, and such tests may be meaningful only for single substances. The mixture is therefore by default regarded as non-rapidly degradable. However, if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable the mixture can, for classification purposes, be regarded as rapidly degradable.*

[10] *In the event that no useable information on acute and/or chronic aquatic toxicity is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: "× % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment". The competent authority can decide to specify that the additional statement be communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier.*

[11] *When adequate toxicity data are available for more than one ingredient in the mixture, the combined toxicity of those ingredients may be calculated using the additivity formulas (a) or (b) in 4.1.3.5.2, depending on the nature of the toxicity data. The calculated toxicity may be used to assign that portion of the mixture a short-term (acute) or long-term (chronic) hazard category which is then subsequently used in applying the summation method. (It is preferable to calculate the toxicity of this part of the mixture using for each ingredient a toxicity value that relate to the same taxonomic group (e.g. fish, crustacea or algae) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three groups) (see 4.1.3.5.3)).*

CHAPTER 4.2

HAZARDOUS TO THE OZONE LAYER

4.2.1 Definitions

Ozone Depleting Potential (ODP) is an integrative quantity, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11.

Montreal Protocol is the Montreal Protocol on Substances that Deplete the Ozone Layer as either adjusted and/or amended by the Parties to the Protocol.

4.2.2 Classification criteria[1]

A substance or mixture shall be classified as Category 1 according to the following table:

Table 4.2.1: Criteria for substances and mixtures hazardous to the ozone layer

Category	Criteria
1	Any of the controlled substances listed in Annexes to the Montreal Protocol; or Any mixture containing at least one ingredient listed in the Annexes to the Montreal Protocol, at a concentration ≥ 0.1%

4.2.3 Hazard communication

General and specific considerations concerning labelling requirements are provided in *Hazard Communication: Labelling* (Chapter 1.4). Annex 1 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

Table 4.2.2: Label elements for substances and mixtures hazardous to the ozone layer

	Category 1
Symbol	Exclamation mark
Signal word	Warning
Hazard statement	Harms public health and the environment by destroying ozone in the upper atmosphere

[1] *The criteria in this chapter are intended to be applied to substances and mixtures. Equipment, articles or appliances (such as refrigeration or air conditioning equipment) containing substances hazardous to the ozone layer are beyond the scope of these criteria. Consistent with 1.1.2.5 (a)(iii) regarding pharmaceutical products, GHS classification and labelling criteria do not apply to medical inhalers at the point of intentional intake.*

4.2.4 Decision logic for substances and mixtures hazardous to the ozone layer

The decision logic which follows is not part of the harmonized classification system but is provided here as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of the decision logic.

Decision logic 4.2.1