



Secretariat

Distr.
GENERAL

ST/SG/AC.10/C.4/2008/14
3 October 2008

ENGLISH
Original: ENGLISH AND FRENCH

**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

Sixteenth session
Geneva, 10-12 (a.m) December 2008
Item 2 of the provisional agenda

**UPDATING OF THE SECOND REVISED EDITION OF THE GLOBALLY HARMONIZED
SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)**

Draft amendments to the second revised edition of the GHS

Note by the secretariat¹

This document contains the draft amendments to the second revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals (ST/SG/AC.10/30/Rev.2), adopted by the Sub-Committee of Experts at its thirteenth, fourteenth and fifteenth sessions.

¹ In accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.4/24, Annex 2 and ST/SG/AC.10/34, para. 14).

Draft amendments to the second revised edition of the Globally Harmonized System of classification and labelling of chemicals (GHS)

Chapter 1.2

Add the following note after the definition of “oxidizing gas”:

"NOTE: “Gases which cause or contribute to the combustion of other material more than air does” means pure gases or gas mixtures with an oxidizing power greater than 23.5% as determined by a method specified in ISO 10156:1996 or 10156-2:2005”.

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

Chapter 2.3

2.3.2.2 Add a new Note at the end to read as follows:

"NOTE: Aerosols not submitted to the flammability classification procedures in this Chapter should be classified as extremely flammable (Category 1)."

(Ref. Doc.: ST/SG/AC.10/C.4/26, Annex 1)

Chapter 2.4

2.4.2 Replace current note under table 2.4.1 with the following:

"NOTE: “Gases which cause or contribute to the combustion of other material more than air does” means pure gases or gas mixtures with an oxidizing power greater than 23.5% as determined by a method specified in ISO 10156:1996 or 10156-2:2005”.

Consequential amendment: See amendments to chapter 1.2.

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

Chapter 2.6

2.6.2 In Note 2 to table 2.6.1, insert "and not more than 60 °C" after "more than 35 °C".

(Ref. Doc.: ST/SG/AC.10/C.4/30, Annex 1)

2.6.4.2.2 At the end of the introductory text preceding sub-paragraphs (a) to (d) replace “below, is at least 5 °C greater than the relevant classification criterion and provided that:” with “below, is at least 5 °C⁴ greater than the relevant classification criterion (23 °C and 60 °C, respectively) and provided that:”

In (b), replace “flash point (closed-cup as given in 2.6.4.2.5 below)” with “lower explosion limit” and add “as well as a method for calculating the lower explosion limit of the mixture;” at the end, after the text between brackets.

Amend (c) to read as follows:

“(c) The temperature dependence of the saturated vapour pressure and of the activity coefficient is known for each component as present in the mixture;”

Amend the text of footnote 3 to read as follows:

“³ Up to now, the calculation method is validated for mixtures containing up to six volatile components. These components may be flammable liquids like hydrocarbons, ethers, alcohols, esters (except acrylates), and water. It is however not yet validated for mixtures containing halogenated, sulphurous, and/or phosphoric compounds as well as reactive acrylates.”

Insert a new footnote “4” to read as follows:

“⁴ If the calculated flash point is less than 5°C greater than the relevant classification criterion, the calculation method may not be used and the flash point should be determined experimentally.”

(Ref. Doc.: ST/SG/AC.10/C.4/26, Annex 1)

2.6.4.2.5 Amend the introductory sentence before the list of standards to read as follows:

"The following methods for determining the flash point of flammable liquids should be used:".

Under “International Standards” insert "ISO 2719" and "ISO 13736" before "ISO 3679"

Under “National Standards”:

- Delete the references to the British Standards Institute standards (from "*British Standards Institute*" to "BS 2000 Part 170"); and
- In the list of *Deutsches Institut für Normung* standards, replace "*Burggraffenst 6*" with "*Burggrafenstr. 6*" in the address and delete the two last standards (DIN 51758 and DIN 53213).

(Ref. Doc.: ST/SG/AC.10/C.4/26, Annex 1)

2.6.4.2.6 Add a new 2.6.4.2.6 to read as follows:

“2.6.4.2.6 The following methods for determining the initial boiling point of flammable liquids should be used:

International standards

ISO 3924
ISO 4626
ISO 3405

National standards

American Society for Testing Materials International, 100 Barr Harbor Drive, PO Box C 700, West Conshohocken, Pennsylvania, USA 19428-2959:

ASTM D86-07a “Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure”

ASTM D1078-05 “Standard Test Method for Distillation Range of Volatile Organic Liquids”

Further acceptable methods

Method A.2 as described in sections 1.4.2 and 1.4.3 of Annex V to Directive 67/548/EEC⁵ as amended”

Add a new footnote 5 to read as follows:

“⁵ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended.”.

(Ref. Doc.: ST/SG/AC.10/C.4/26, Annex 1)

PART 3

Chapter 3.1

3.1.3.3 Add the following new sub-paragraph:

"(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category."

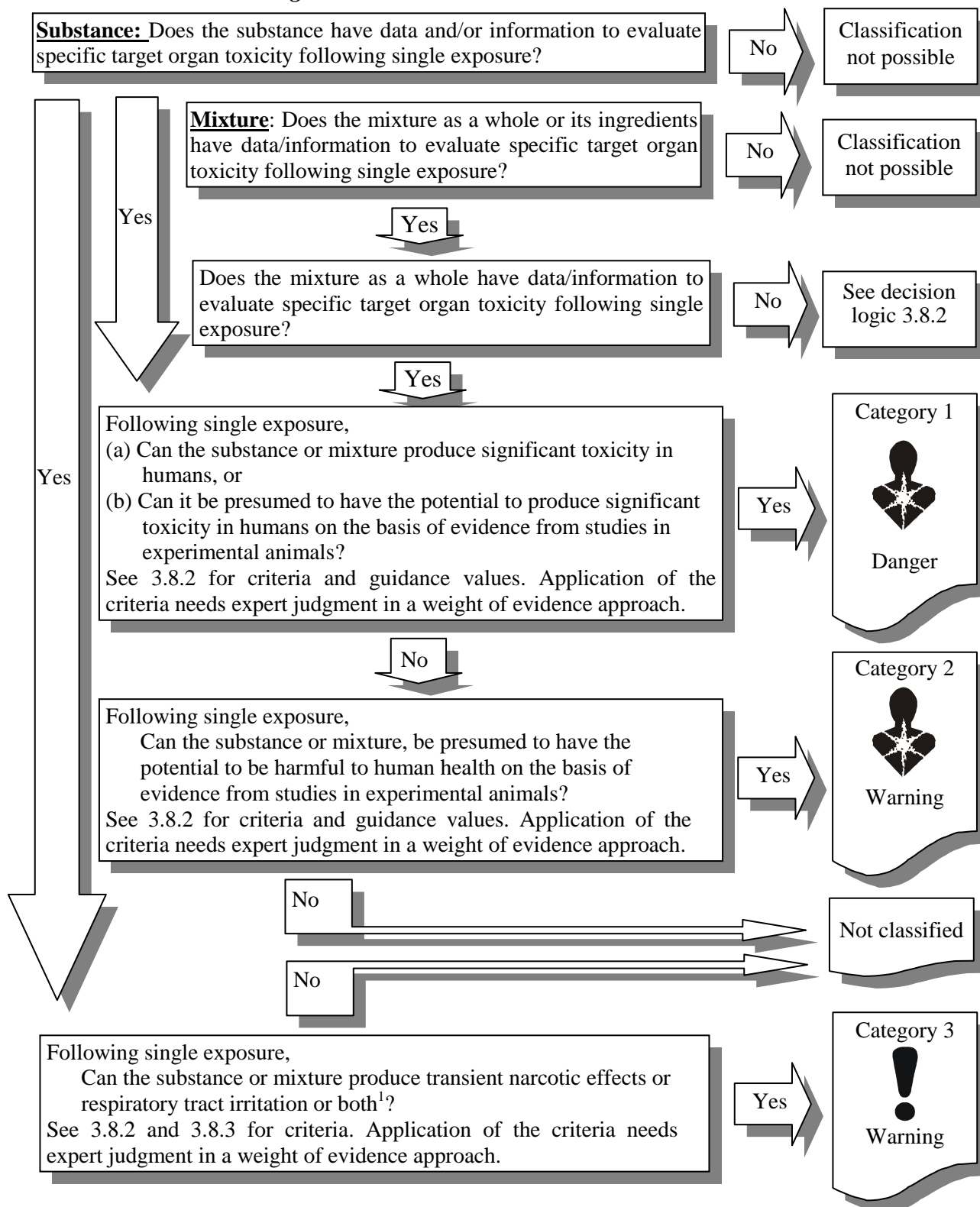
(Ref. Doc.: ST/SG/AC.10/C.4/30, Annex 1)

Chapter 3.8

Amend decision logics 3.8.1 and 3.8.2 in chapter 3.8 to read as follows (current introductory paragraph under 3.8.5 remains unchanged):

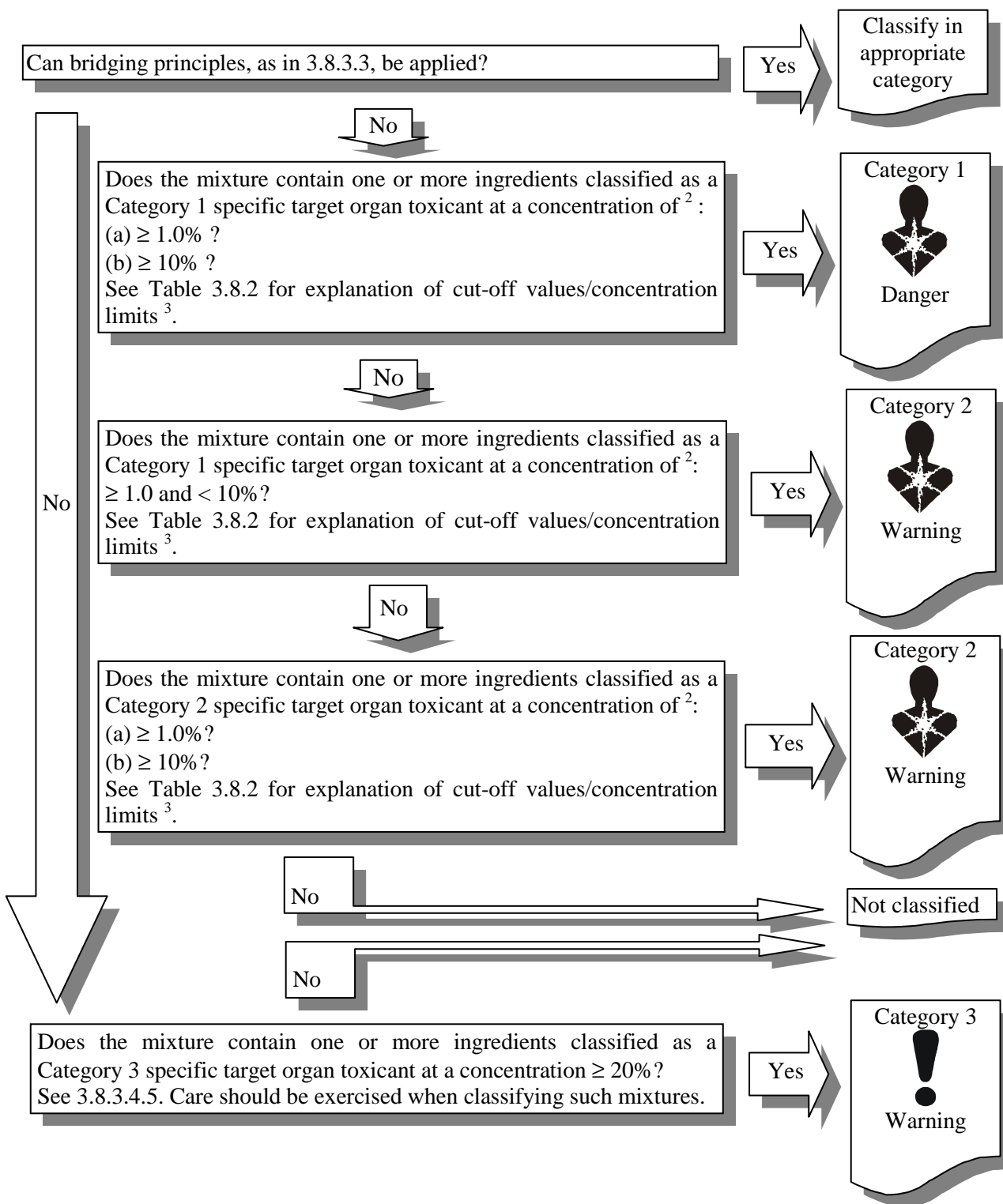
(Ref. Doc.: ST/SG/AC.10/C.4/30, Annex 1)

“3.8.5.1 Decision logic 3.8.1



¹ Classification in Category 3 would only occur when classification into Category 1 or Category 2 (based on more severe respiratory effects or narcotic effects that are not transient) is not warranted. See 3.8.2.2.1 (e) (respiratory effects) and 3.8.2.2.2 (b) (narcotic effects).

3.8.5.2 Decision logic 3.8.2



² See 3.8.2 of this Chapter and “The use of cut-off values/concentration limits” in Chapter 1.3, para. 1.3.3.2.

³ See 3.8.3.4 and Table 3.8.2 for explanation and guidance.

Chapter 3.10

3.10.1.6.4 Insert a new paragraph 3.10.1.6.4 to read as follows:

"3.10.1.6.4 Although the definition of aspiration in 3.10.1.2 includes the entry of solids into the respiratory system, classification according to (b) in table 3.10.1 for Category 1 or for Category 2 is intended to apply to liquid substances and mixtures only."

Current paragraph 3.10.1.6.4 becomes 3.10.1.6.5.

(Ref. Doc.: ST/SG/AC.10/C.4/30, Annex 1)

PART 4

Chapter 4.1

Amend Chapter 4.1 as follows:

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

4.1.1.1 In the definition of "*Acute aquatic toxicity*" insert "aquatic" before "exposure".

In the definition of "*Chronic aquatic toxicity*" replace "potential or actual properties" with "the intrinsic property" and insert "aquatic" before "exposures".

Insert the following definitions in alphabetical order:

"*EC_x* is defined as the concentration associated with $\times\%$ response.

For classification purposes, *Acute (short-term) hazard* is the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that chemical.

For classification purposes, *long-term hazard* is the hazard of a chemical caused by its chronic toxicity following long-term exposure in the aquatic environment.

NOEC (No Observed Effect Concentration) is defined as 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."

4.1.1.2.1 Rearrange current sub-paragraphs (a) to (d) to read as follows:

- "(a) acute aquatic toxicity;
- (b) chronic aquatic toxicity;
- (c) potential for or actual bioaccumulation; and
- (d) degradation (biotic or abiotic) for organic chemicals."

4.1.1.4 (new) Current paragraph 4.1.1.6 becomes new paragraph 4.1.1.4 with the following modification:

In the last sentence replace “L(E)Cx” with “ECx”.

4.1.1.5 (new) Current paragraph 4.1.1.4 becomes new paragraph 4.1.1.5.

4.1.1.6, 4.1.1.6.1 and 4.1.1.6.2 (new):

Current paragraphs 4.1.1.5, 4.1.1.5.1 and 4.1.1.5.2 become new paragraphs 4.1.1.6, 4.1.1.6.1 and 4.1.1.6.2, respectively.

In new paragraph 4.1.1.6.1, replace “(See 4.1.2.10.3)” with “(see 4.1.2.11.3).”

4.1.2.1 Amend to read as follows:

“4.1.2.1 Whilst the harmonized classification system for substances consists of three acute classification categories and four chronic classification categories, the core part of the harmonized classification system for substances consists of three acute classification categories and three chronic classification categories (see Table 4.1.1 (a) and (b)). The acute and the chronic classification categories are applied independently. The criteria for classification of a substance in categories Acute 1 to 3 are defined on the basis of the acute toxicity data only (EC₅₀ or LC₅₀). The criteria for classification of a substance into categories 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 (new) Current paragraph 4.1.2.12 becomes new paragraph 4.1.2.2, with the following modifications:

- Delete the title (“Category Chronic 4”);
- In the third sentence, replace “poorly water soluble organic substances” with “poorly water soluble substances”;
- Amend the last sentence to read as follows:
“The need for this classification can be negated by demonstrating that the substance does not require classification for aquatic long-term hazards.”.

4.1.2.3 (new) Insert a new paragraph to read as follows:

“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).”

Current paragraph 4.1.2.3 becomes new paragraph 4.1.2.5.

4.1.2.4 (new) Current paragraph 4.1.2.2 becomes new paragraph 4.1.2.4, with the following modifications:

- In the first sentence insert “(Table 4.1.1)” after “following criteria”; and
- in the last sentence replace “Table 4.1.1” with “Table 4.1.2”.

Figure 4.1.1 and Table 4.1.1: Replace with the following new table 4.1.1:

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

(a) Acute (short-term) aquatic hazard	
<u>Category Acute 1:</u> (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.	
<u>Category Acute 2:</u>	
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)
<u>Category Acute 3:</u>	
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 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 the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5)	
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 the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5)	
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 the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5).	

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

(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.

Amend Notes 1 to 5 to table 4.1.1 to read as follows:

“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.

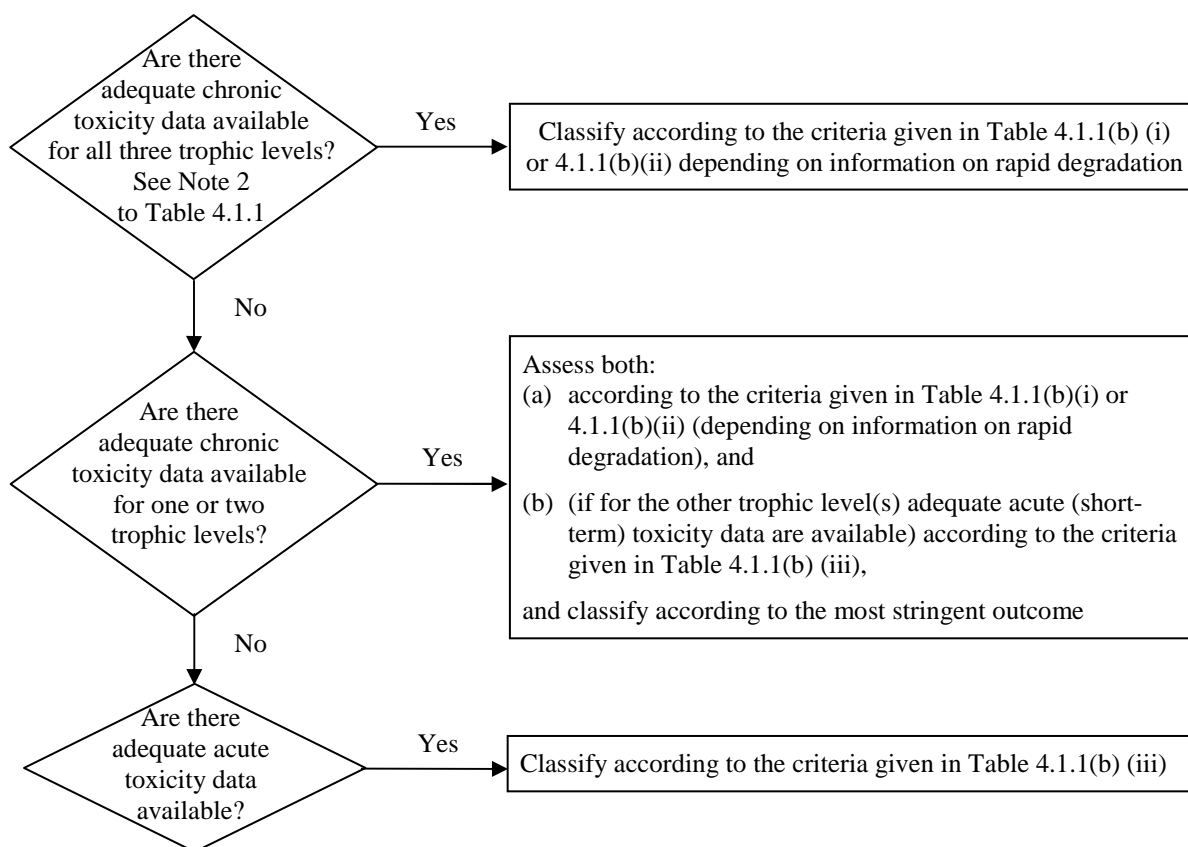
NOTE 3: Where the algal toxicity ErC_{50} [= EC_{50} (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. 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 $BCF \geq 500$ or, if absent, a $\log K_{ow} \geq 4$ 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: Insert a new figure 4.1.1 to read as follows:

“Figure 4.1.1: Categories for substances long-term hazardous to the aquatic environment



”

4.1.2.5 (new) Current paragraph 4.1.2.3 becomes new paragraph 4.1.2.5 with the following modifications:

- Amend the third sentence to read as follows:
“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).”
- Delete the last sentence (“For that reason...system”).

4.1.2.6 (new) Current paragraph 4.1.2.4 becomes new paragraph 4.1.2.6.

4.1.2.7 (new) Current paragraph 4.1.2.5 becomes new paragraph 4.1.2.7 with the following modifications:

- In the fifth sentence, insert “in those cases” before “it is necessary”.
- In the sixth sentence, replace “chronic” with “long-term”.

- Amend the seventh sentence to read as follows:

“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 hazard categories 1 to 3 would be necessary.”

4.1.2.6 Delete.

4.1.2.8 (new) Current paragraph 4.1.2.7 becomes new paragraph 4.1.2.8.

4.1.2.9, 4.1.2.9.1 and 4.1.2.9.2 (new):

Current paragraphs 4.1.2.8, 4.1.2.8.1 and 4.1.2.8.2, become new paragraphs 4.1.2.9, 4.1.2.9.1 and 4.1.2.9.2, respectively.

4.1.2.10 (new) Current paragraph 4.1.2.9 becomes new paragraph 4.1.2.10, with the following modification:

Add the following sentence at the end of the current text:

“Some relationships can be observed between chronic toxicity and bioaccumulation potential, as toxicity is related to the body burden.”.

4.1.2.11, 4.1.2.11.1, 4.1.2.11.2, 4.1.2.11.3, 4.1.2.12, 4.1.2.12.1 and 4.1.2.12.2 (new)

Current paragraphs 4.1.2.10, 4.1.2.10.1, 4.1.2.10.2, 4.1.2.10.3, 4.1.2.11, 4.1.2.11.1 and 4.1.2.11.2 become new paragraphs 4.1.2.11, 4.1.2.11.1, 4.1.2.11.2, 4.1.2.11.3, 4.1.2.12, 4.1.2.12.1 and 4.1.2.12.2, respectively.

4.1.2.14 Insert a new sub-section 4.1.2.14 to read as follows:

“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			
Acute hazard (Note 1)	Long-term 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	Category: Chronic 1	Category: Chronic 1	Category: Chronic 1
$L(E)C_{50} \leq 1.00$	$NOEC \text{ or } EC_x \leq 0.1$	$NOEC \text{ or } EC_x \leq 0.01$	$L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or $BCF \geq 500$ or, if absent $\log K_{ow} \geq 4$
Category: Acute 2	Category: Chronic 2	Category: Chronic 2	Category: Chronic 2
$1.00 < L(E)C_{50} \leq 10.0$	$0.1 < NOEC \text{ or } EC_x \leq 1$	$0.01 < NOEC \text{ or } EC_x \leq 0.1$	$1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or $BCF \geq 500$ or, if absent $\log K_{ow} \geq 4$
Category: Acute 3		Category: Chronic 3	Category: Chronic 3
$10.0 < L(E)C_{50} \leq 100$		$0.1 < NOEC \text{ or } EC_x \leq 1$	$10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or $BCF \geq 500$ 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 $BCF \geq 500$ or, if absent $\log K_{ow} \geq 4$, unless $NOECs > 1 \text{ mg/l}$		

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 long-term 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 long-term 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 hazards.*”.

4.1.3.1 Amend the second paragraph to read as follows:

“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.”.

Figure 4.1.2 In the title, replace “chronic” with “long-term”;

After “CLASSIFY” on the right hand side, replace (4 times) “chronic toxicity hazard” with “long-term hazard”.

Amend (c) to read as follows:

“Percentage of ingredients with acute toxicity data: apply additivity formulas (see 4.1.3.5.2) and convert the derived L(E)C₅₀ or EqNOEC_m to the appropriate “Acute” or “Chronic” category”.

4.1.3.3 Amend to read as follows:

”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 decision logic 4.1.5.2.2 and paragraphs 4.1.3.4 and 4.1.3.5).

4.1.3.3.2 The long-term 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 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 ≤ 1 mg/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 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)".

4.1.3.5.2 Amend to read as follows:

"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

test data are 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 aquatic toxicity:

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

where:

- C_i = concentration of ingredient i (weight percentage);
- $L(E)C_{50_i}$ = 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 an acute hazard category which is then subsequently used in applying the summation method;

(b) Based on chronic aquatic toxicity:

$$\frac{\sum C_i + \sum C_j}{EqNOEC_m} = \sum_n \frac{C_i}{NOEC_i} + \sum_n \frac{C_j}{0.1 \times NOEC_j}$$

where:

- C_i = concentration of ingredient i (weight percentage) covering the rapidly degradable ingredients;
- C_j = concentration of ingredient j (weight percentage) covering the non-rapidly degradable ingredients;
- $NOEC_i$ = NOEC (or other recognized measures for long-term toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/l;
- $NOEC_j$ = NOEC (or other recognized measures for long-term 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 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 In the first sentence, replace “to the same species (i.e. fish, daphnia or algae)” with “to the same taxonomic group (i.e. fish, crustacean or algae)” and “of the three species” with “of the three groups”.

In the last sentence, replace “The calculated acute toxicity” with “The calculated acute and chronic toxicity” and insert “and/or Chronic 1, 2 or 3” after “Acute 1, 2 or 3”.

- 4.1.3.5.5.1.2 Amend the first sentence to read as follows:

“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).”

- 4.1.3.5.5.3.4 Replace “Table 4.1.2” with “Table 4.1.3”.

Table 4.1.2 Renumber as “Table 4.1.3”

- 4.1.3.5.5.4.1 At the beginning of the second sentence replace “If the sum of these ingredients” with “If the sum of the concentrations (in %) of these ingredients”.

- 4.1.3.5.5.4.5 Replace “chronic” with “long-term” and “Table 4.1.3” with “Table 4.1.4”.

Table 4.1.3 Renumber as “Table 4.1.4” and replace, in the title, “chronic” with “long-term”.

- 4.1.3.5.5.5 Amend the first sentence to read as follows:

“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.”

In the second sentence replace “Acute 1 ingredients” with “Acute 1 and Chronic 1 ingredients”

In the fourth sentence, replace “Table 4.1.4” with “Table 4.1.5”

In the last sentence, replace “specific acute toxicity data” with “specific acute and/or chronic toxicity data”.

Table 4.1.4 Renumber as “Table 4.1.5” and amend to read as follows:

“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 ≤ 1	1	0.01 < NOEC ≤ 0.1	1	-
0.01 < L(E)C ₅₀ ≤ 0.1	10	0.001 < NOEC ≤ 0.01	10	1
0.001 < L(E)C ₅₀ ≤ 0.01	100	0.0001 < NOEC ≤ 0.001	100	10
0.0001 < L(E)C ₅₀ ≤ 0.001	1000	0.00001 < NOEC ≤ 0.0001	1000	100
0.00001 < L(E)C ₅₀ ≤ 0.0001	10000	0.000001 < NOEC ≤ 0.00001	10000	1000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

^a Non-rapidly degradable

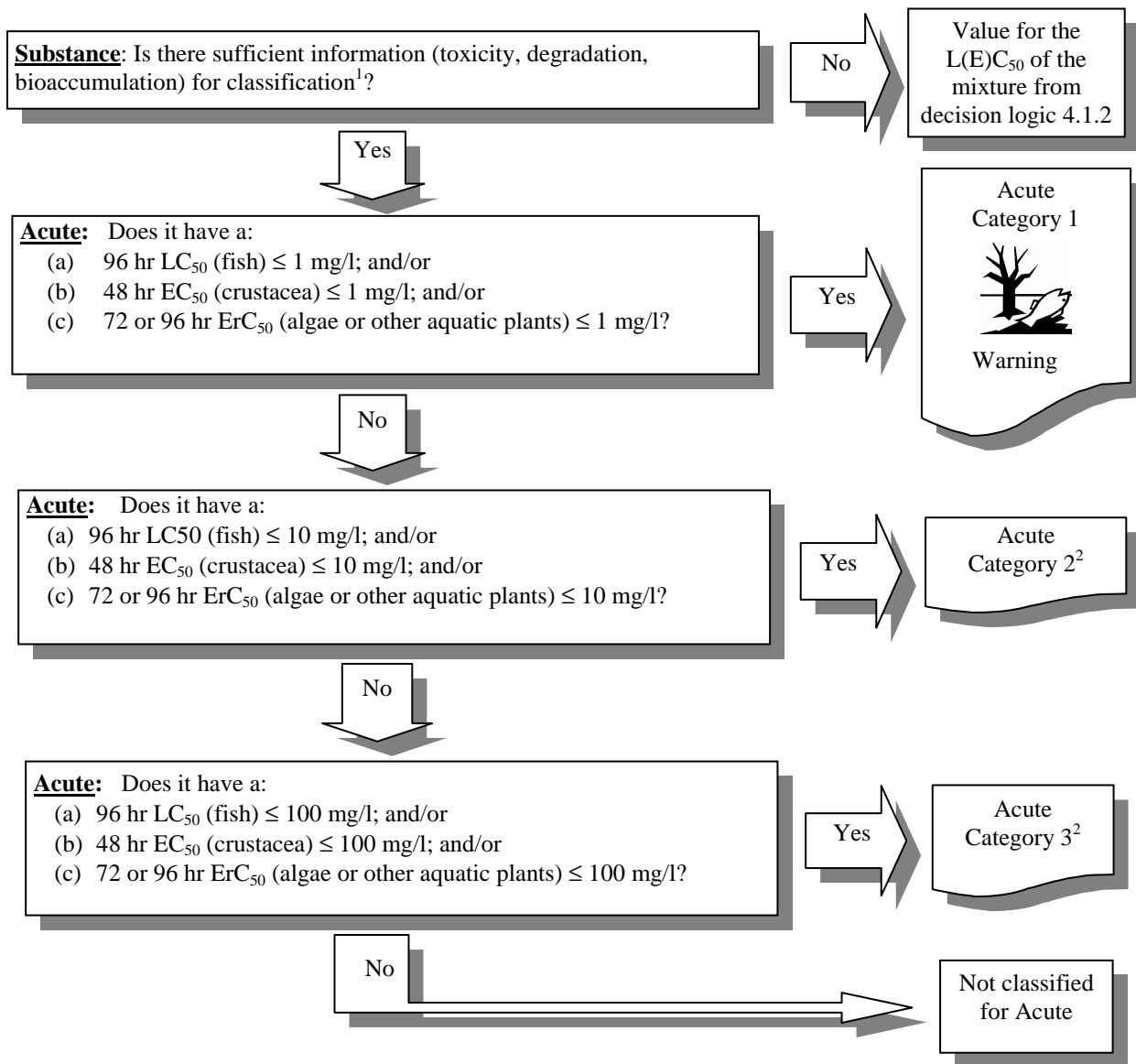
^b Rapidly degradable

Table 4.1.5 Renumber as “Table 4.1.6”

4.1.5.1 Replace current decision logics with the following:

“4.1.5.1 Acute (short-term) aquatic hazard classification

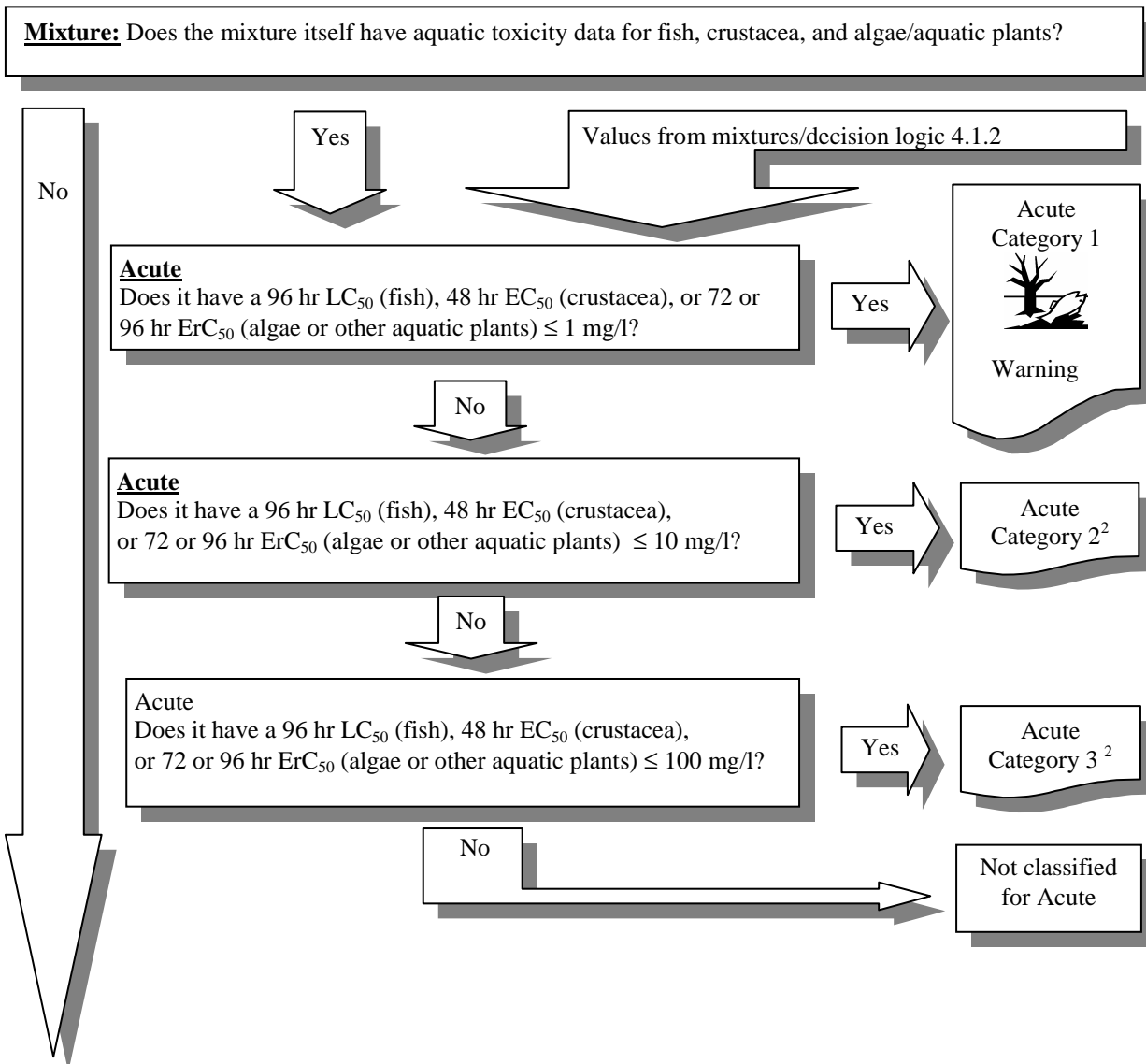
4.1.5.1.1 Decision logic 4.1.1 for substances and mixtures hazardous to the aquatic environment



(Cont'd on next page)

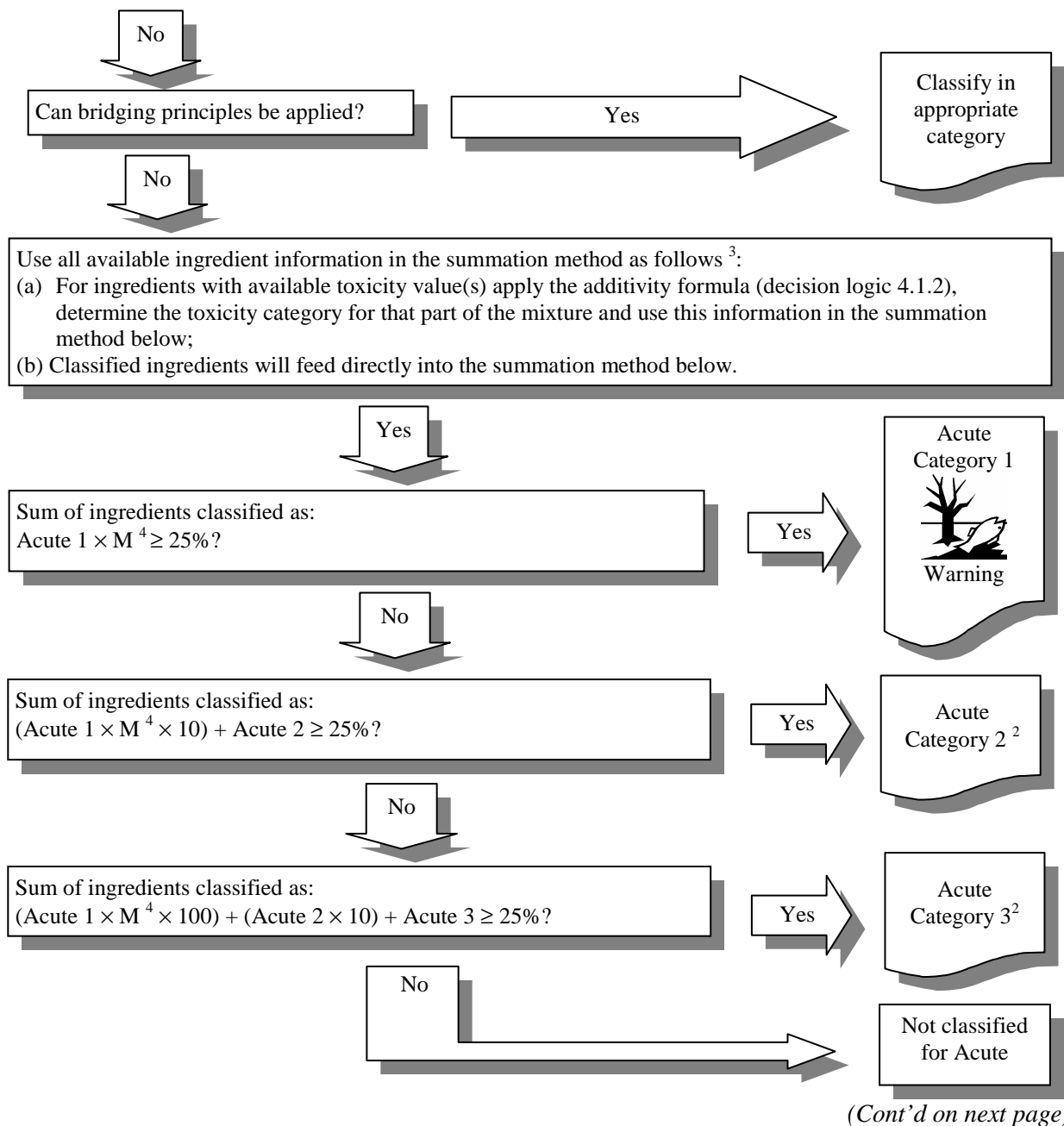
¹ Classification can be based on either measured data and/or calculated data (see 4.1.2.13 and Annex 9) and/or analogy decisions (see A9.6.4.5 in Annex 9).

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



(Cont'd on next page)

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. 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 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 Mixtures decision logic 4.1.2 (additivity formula)

Apply the additivity formula:

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

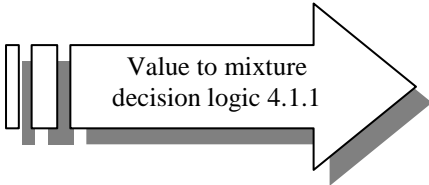
where:

C_i = concentration of ingredient i (weight percentage)

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

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

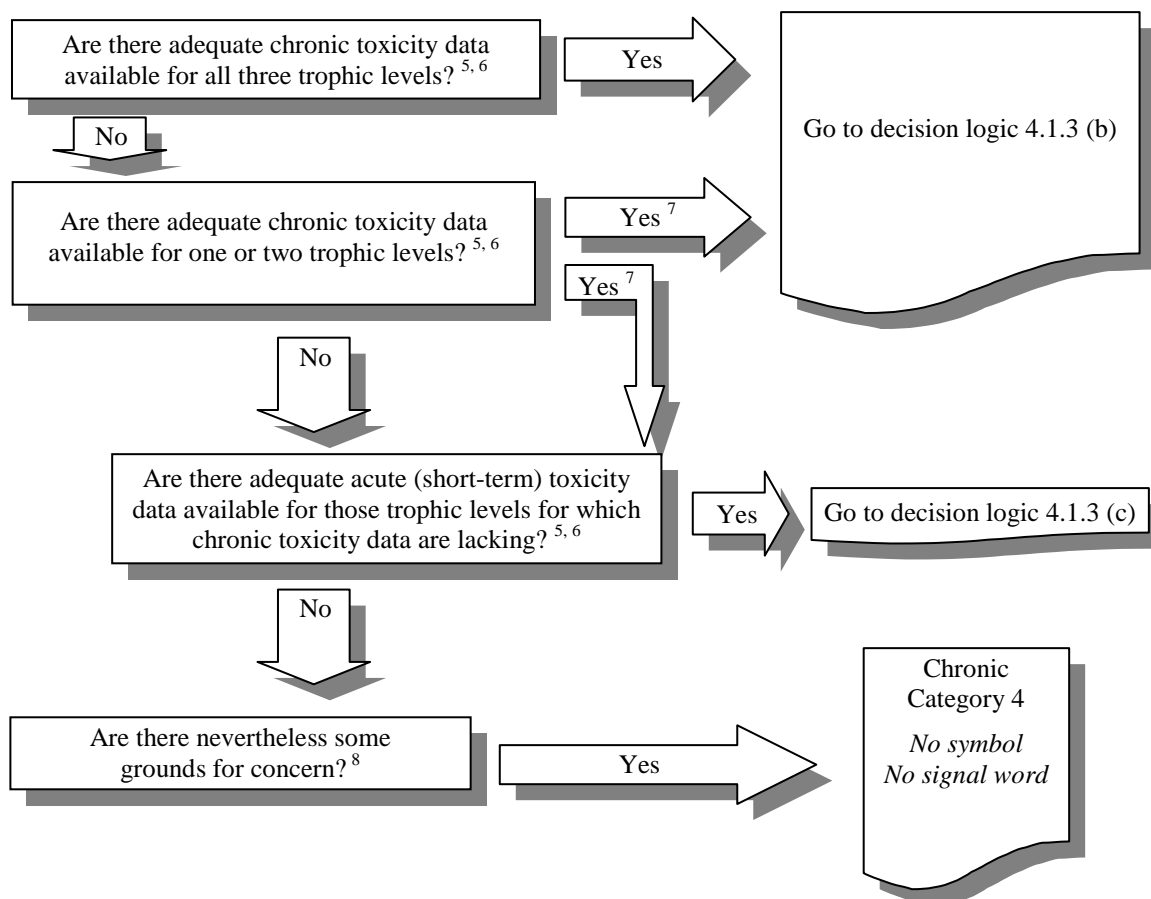
$L(E)C_{50_m}$ = $L(E)C_{50}$ of the part of the mixture with test data



Value to mixture
decision logic 4.1.1

4.1.5.2 Long-term aquatic classification

4.1.5.2.1 Mixtures decision logic 4.1.3 (a) for substances



(Cont'd on next page)

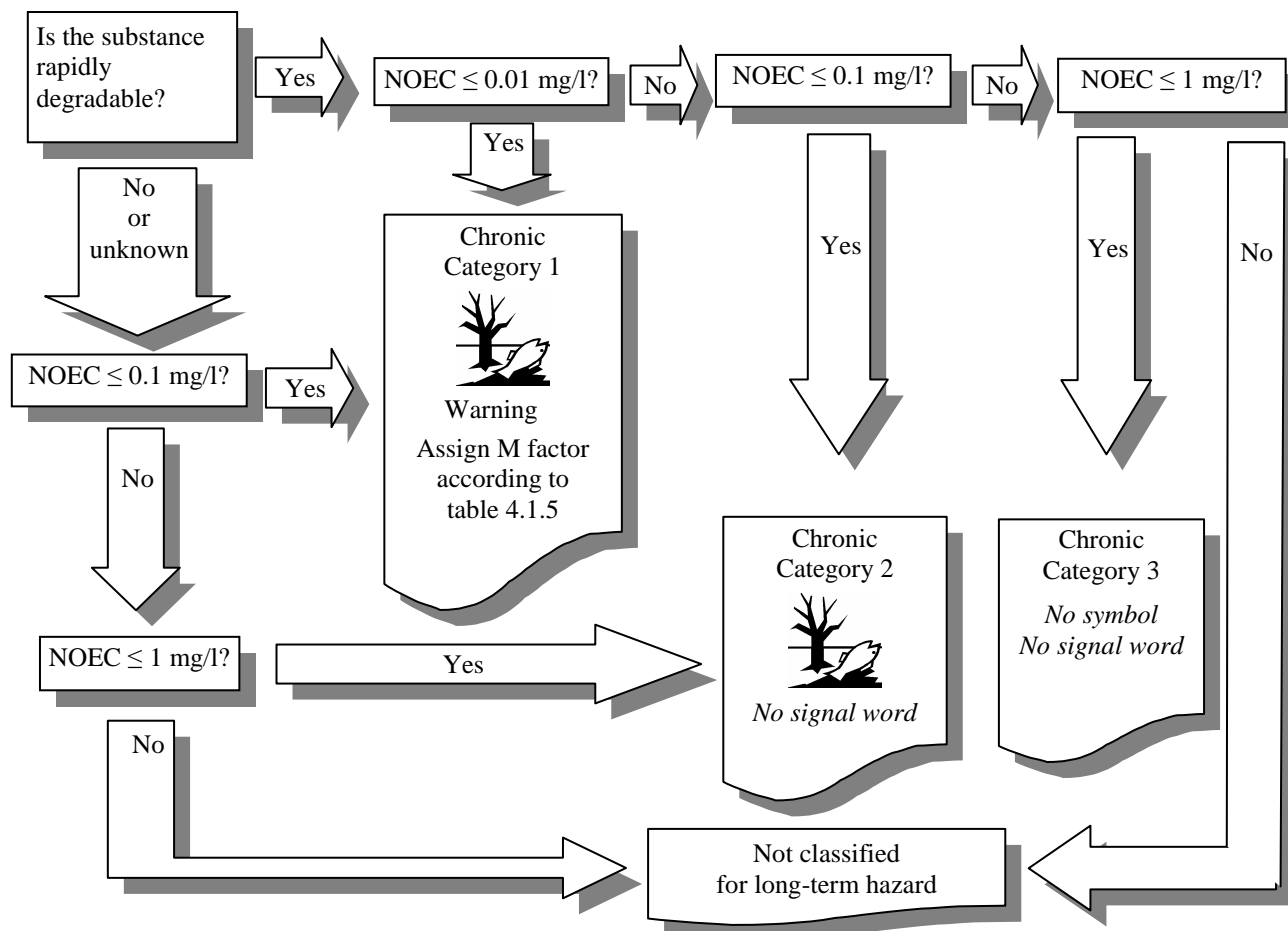
⁵ Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent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

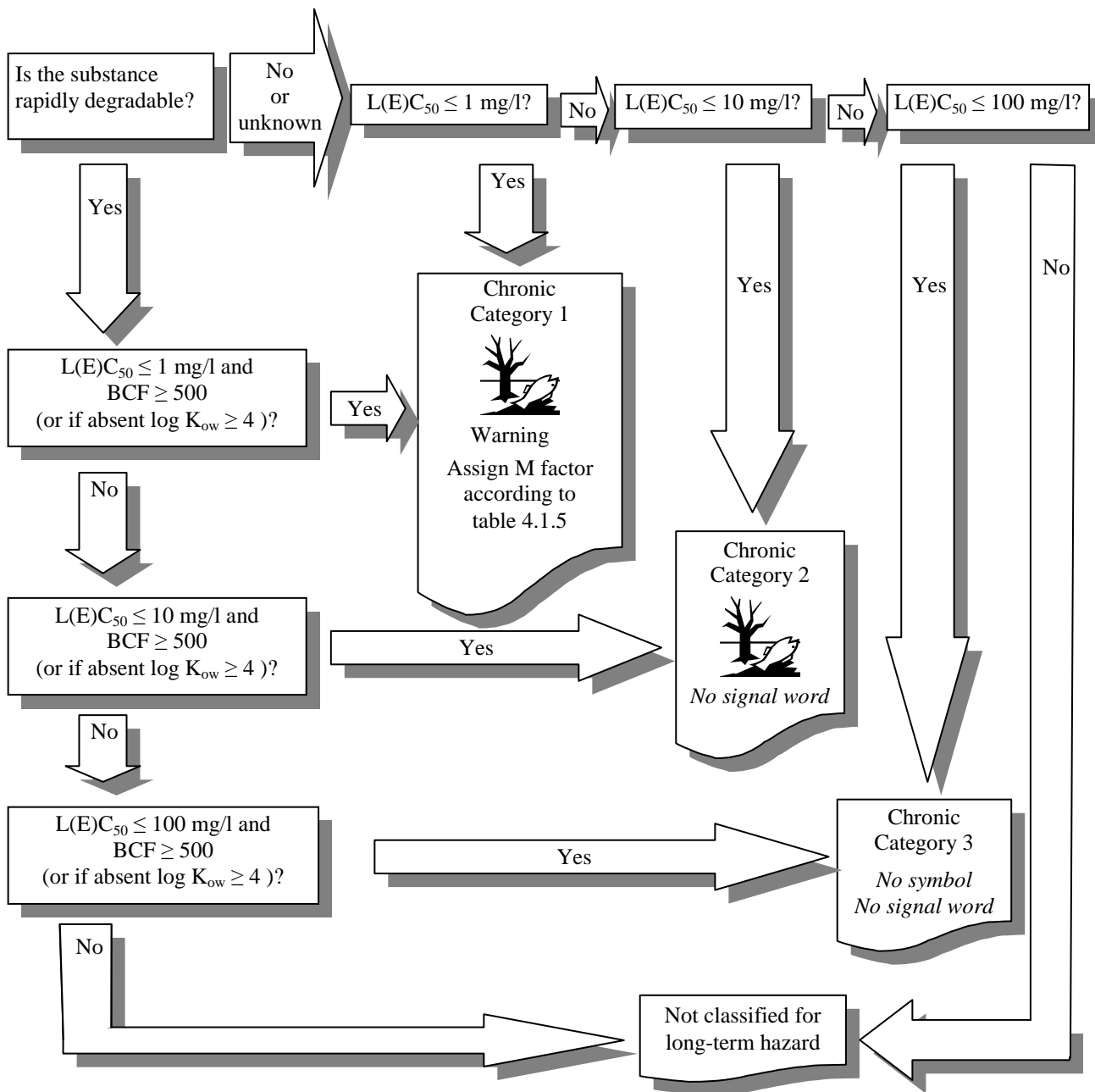
4.1.5.2.2 Decision logic 4.1.3 (b) for substances (when adequate chronic toxicity data are available for all three trophic levels)⁵



(Cont'd on next page)

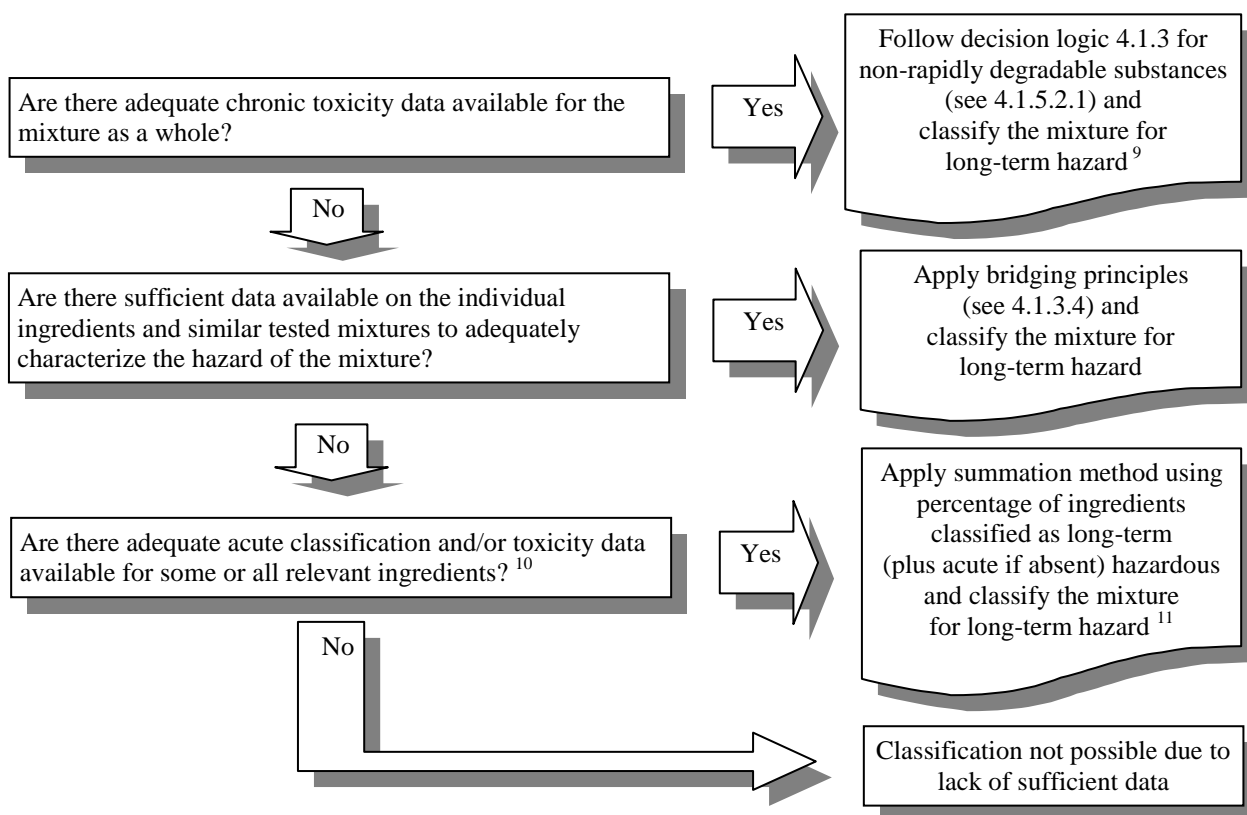
⁵ Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent (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 of 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 aquatic hazard is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed a definitive hazard category. 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”.*

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 formula in 4.1.3.5.2 (a). The calculated toxicity may be used to assign that portion of the mixture an acute 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 for each ingredient a toxicity value that relate to the same species-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 groups) (see 4.1.3.5.3)).*

Chapter 4.2

Add a new chapter 4.2 to read as follows:

(Ref. Doc.: ST/SG/AC.10/C.4/30, Annex 1)

**“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 adjusted and amended by the meetings of the Parties.

4.2.2 Classification criteria¹

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 of the Montreal Protocol; or Any mixture containing at least one ingredient classified as hazardous to the ozone layer, at a concentration $\geq 0.1\%$

4.2.3 Hazard communication

General and specific considerations concerning labelling requirements are provided in *Hazard Communication: Labelling* (Chapter 1.4). Annex 2 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.

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 does not apply to medical inhalers at the point of intentional intake.*

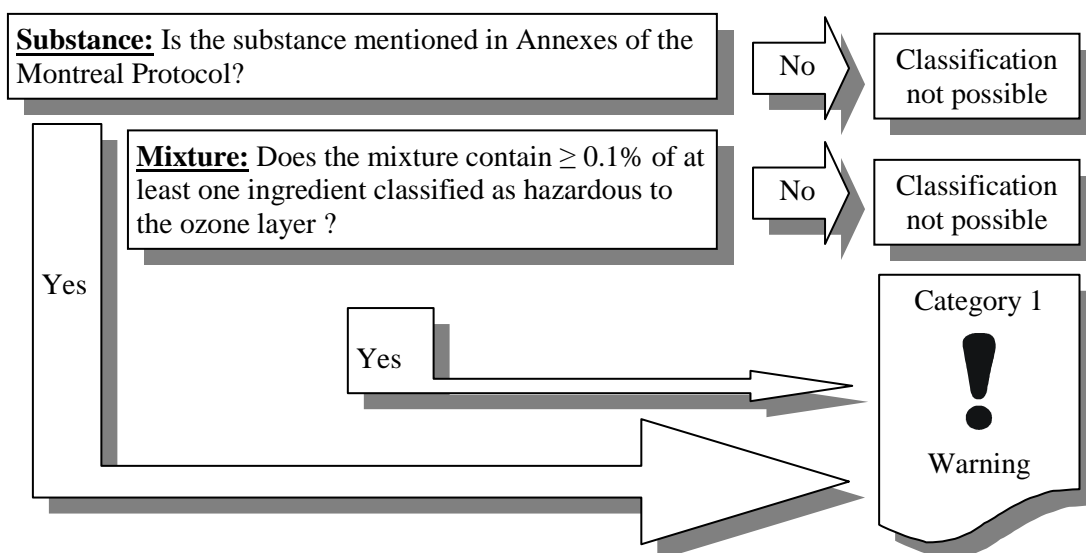
Table 4.2.2 Label elements for substances and mixtures hazardous to the ozone layer

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

4.2.4 Decision logic for ozone depleting substances and mixtures

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 4.1.1 for substances and mixtures




ANNEXES

Annex 1

In the headings of the tables for the allocation of label elements in page 259 of the English version, replace “AQUATIC TOXICITY (ACUTE)” and “AQUATIC TOXICITY (CHRONIC)” with “AQUATIC HAZARD (ACUTE)” and “AQUATIC HAZARD (LONG-TERM)”.

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

Insert the following table at the end of current text in Annex 1:

HAZARDOUS TO THE OZONE LAYER				
Category 1	-	-	-	-
 <p>Warning</p> <p>Harms public health and the environment by destroying ozone in the upper atmosphere</p>				
<p>Not required under the <i>UN Recommendations on the Transport of Dangerous Goods, Model Regulations.</i></p>				

(Ref. Doc.: ST/SG/AC.10/C.4/30, Annex 1)

Annex 2

A2.28 (b) In the title, replace “Chronic hazards” with “Long-term hazards”;

For Category 1:

replace paragraph 1 with the following text:

“1. *For substances rapidly degradable:*

- (a) $\text{NOEC} \leq 0.01 \text{ mg/l}$; or if absent
- (b) $\text{L(E)C}_{50} \leq 1 \text{ mg/l}$ and $\text{BCF} \geq 500$ (or if absent $\log K_{ow} \geq 4$)

2. *For substances non-rapidly degradable:*

- (a) $\text{NOEC} \leq 0.1 \text{ mg/l}$; or if absent
- (b) $\text{L(E)C}_{50} \leq 1 \text{ mg/l}$ ”

Renumber current paragraphs 2, 3 and 4 as 3, 4 and 5 respectively.

For Category 2:

replace paragraph 1 with the following text:

“1. *For substances rapidly degradable:*

- (a) $0.01 < \text{NOEC} \leq 0.1 \text{ mg/l}$ or if absent
- (b) $1 \text{ mg/l} < \text{L(E)C}_{50} \leq 10 \text{ mg/l}$ and $\text{BCF} \geq 500$ (or if absent $\log K_{ow} \geq 4$)

2. *For substances non-rapidly degradable:*

- (a) $0.1 < \text{NOEC} \leq 1 \text{ mg/l}$ or if absent
- (b) $1 \text{ mg/l} < \text{L(E)C}_{50} \leq 10 \text{ mg/l}$

Renumber current paragraphs 2, 3 and 4 as 3, 4 and 5 respectively.

For Category 3:

replace paragraph 1 with the following text:

“1. *For substances rapidly degradable:*

- (a) $0.1 < \text{NOEC} \leq 1 \text{ mg/l}$ or if absent
- (b) $10 \text{ mg/l} < \text{L(E)C}_{50} \leq 100 \text{ mg/l}$ and $\text{BCF} \geq 500$ (or if absent $\log K_{ow} \geq 4$)

2. *For substances non-rapidly degradable:*

$10 \text{ mg/l} < \text{L(E)C}_{50} \leq 100 \text{ mg/l}$ ”

Renumber current paragraphs 2, 3 and 4 as 3, 4 and 5 respectively.

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

A2.29 Insert the following new table at the end of current annex 2:

“A2.29 Hazard to the ozone layer

Hazard category	Criteria	Hazard communication elements	
		1	1. <i>For substances</i> Any of the controlled substances listed in Annexes of the Montreal Protocol 2. <i>For mixtures</i> Any mixture containing at least one ingredient classified as hazardous to the ozone layer, at a concentration $\geq 0.1\%$
Signal word	Warning		
Hazard Statement	Harms public health and the environment by destroying ozone in the upper atmosphere		

(Ref. Doc.: ST/SG/AC.10/C.4/30, Annex 1)

Annex 3

Section 1

In Table A3.1.3, column (3) (page 301 of the English version):

replace “acute toxicity (Chapter 4.1)” with “acute hazard (Chapter 4.1)” and “chronic toxicity (Chapter 4.1)” with “long-term hazard (Chapter 4.1)”;

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

Section 2

In Table A3.2.2 (for P273), Table A3.2.3 (for P391) and Table A3.2.5 (for P501):

replace, in column (3), “acute toxicity (Chapter 4.1)” with “acute hazard (Chapter 4.1)” and “chronic toxicity (Chapter 4.1)” with “long-term hazard (Chapter 4.1)”.

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

Section 3

A3.3.5 In the matrix of precautionary statements for hazardous to the aquatic environment (pages 393 and 394 of the English version) replace, in the title: “CHRONIC HAZARD” with “LONG-TERM HAZARD”.

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

Annex 9

(Ref. Doc.: ST/SG/AC.10/C.4/28, Annex 1)

A9.1.3 In the last but one sentence, replace “aquatic toxicity” with “acute aquatic toxicity; chronic aquatic toxicity;”

A9.1.4 Amend the first sentence to read as follows: “This annex is limited, at this stage, to the application of the criteria to chemical substances.”

A9.1.5 In the first sentence, replace “aquatic toxicity” with “acute aquatic toxicity; chronic aquatic toxicity;”.

A9.1.8 In the last sentence, replace “The three core properties, aquatic toxicity” with “The four core properties, acute and chronic aquatic toxicity”.

A9.1.10 In (a), insert “or NOEC” after “L(E)C₅₀”.
In (b), amend the first sentence to read as follows: “unstable substances: such substances that degrade (or react) rapidly in the test system present both testing and interpretational problems”.

A9.1.11 In the third sentence, replace “data on aquatic toxicity” with “data on acute and on chronic aquatic toxicity”

A9.2.1 In the fourth sentence, replace “one Acute sub-class, consisting of three categories and one sub-class, consisting of 4 categories” with “one sub-class for acute aquatic hazards, consisting of three categories and one sub-class for long-term aquatic hazards, consisting of four categories.”.

In the last but one sentence replace “chronic hazard categories” with “long-term hazard categories”.

A9.2.2 Replace “Figure” with “Table”.

A9.2.3.1 In the first sentence, replace “longer-term toxicity” with “long-term toxicity”.
In the last but one sentence, replace “chronic hazard” with “long-term hazard”.

A9.2.3.2 In the third sentence, replace “chronic hazard” with “long-term hazard”.

Amend the fifth and sixth sentences to read as follows:

“It is this acute toxicity which has therefore been used as the core property in defining both the acute and the long-term hazard if no adequate chronic test data are available. Nevertheless, it has been recognized that chronic toxicity data, if available, should be preferred in defining the long-term hazard category.”

Delete the last sentence (“The development...of the scheme”).

A9.2.3.3 Insert a new paragraph to read as follows:
“A9.2.3.3 The combination of chronic toxicity and intrinsic fate properties reflects the potential hazard of a chemical. Substances that do not rapidly degrade have a higher potential for longer term exposures and therefore should be classified in a more severe category than substances which are rapidly degradable (see A9.3.3.2.2).”

Current paragraphs A9.2.3.3 to A9.2.3.6 become A9.2.3.4 to A9.2.3.7.

A9.2.3.4 (former A9.2.3.3) Amend the second sentence to read as follows:
“Substances rapidly biodegrading that show acute toxicity with a significant degree of bioaccumulation will normally show chronic toxicity at a significantly lower concentration.”.

Delete the third sentence (“Precise acute generally precautionary”).

Amend the last sentence before (a) and (b), to read as follows:

“Thus, for example, in absence of adequate chronic test data, category Chronic 1 should be assigned if either of the following criteria are met:”

A9.2.3.5 (former A9.2.3.4) Amend to read as follows:

“A9.2.3.5 The precise definitions of the core elements of this system are described in detail in sections A9.3, A9.4 and A9.5 respectively.”

A9.2.3.7 (former A9.2.3.6) In the first sentence delete “acute”.

A9.2.4.1 Amend current sub-paragraphs (a) to (g) to read as follows:

- “(a) water solubility;
- (b) acute aquatic toxicity (L(E)C₅₀s);
- (c) chronic aquatic toxicity (NOECs and/or equivalent ECx);
- (d) available degradation (and specifically evidence of ready biodegradability);
- (e) stability data, in water;
- (f) fish bioconcentration factor (BCF);
- (g) octanol/water partition coefficient (log K_{ow});”

A9.2.4.2 In the fourth sentence, insert “and the chronic aquatic toxicity greater than 1mg/l,” after “soluble substances”

A9.2.4.3 Insert a new paragraph A9.2.4.3 to read as follows:

“A9.2.4.3 If chronic aquatic toxicity data are available cut-off values will depend on whether the chemical is rapidly degradable or not. Therefore, for non-rapidly degradable substances and those for which no information on degradation is available, the cut-off levels are higher than for those substances where rapid degradability can be confirmed (see Chapter 4.1, Tables 4.1.1 and 4.1.2).”.

Current paragraphs A9.2.4.3 and A9.2.4.4 become A9.2.4.4 and A9.2.4.5 respectively.

A9.2.4.4 (former A9.2.4.3) Amend the beginning of the first sentence to read as follows:

“Where the lowest acute aquatic toxicity data are below 100 mg/l and no adequate chronic toxicity data are available, it is necessary...”.

In the third and sixth sentences, replace “chronic hazard” with “long-term hazard”.

Amend the last sentence to read as follows:

“If the substance is both rapidly degradable and has a low potential to bioaccumulate (BCF < 500 or, if absent log K_{ow} < 4) then it should not be

assigned to a long-term hazard category, unless the chronic toxicity data indicate otherwise (A9.2.4.3).”.

A9.2.6.3 In the seventh sentence, replace “chronic hazard” with “long-term hazard”.

A9.3.2.2 In the paragraph starting with “Chronic testing” insert “generally” before “involves”.

Add the following paragraph at the end, after the second paragraph in italics:

“An OECD document describes the main statistical methods for the analysis of data of standardized ecotoxicity tests (OECD 2006).”

A9.3.2.7.1 Amend the first sentence of the second paragraph to read as follows:

“The algal test is a short-term test that provides both acute and chronic endpoints.”

A9.3.3.2.1 In the first sentence, replace “potential or actual properties” with “intrinsic property”.

A9.3.3.2.2 Insert a new paragraph A9.3.3.2.2 to read as follows:

“A9.3.3.2.2 For the classification based on chronic toxicity a differentiation is made between rapidly degradable and non-rapidly degradable substances. Substances that do rapidly degrade are classified in category Chronic 1 when a chronic toxicity determined to be ≤ 0.01 mg/l. Decimal bands are accepted for categorizing chronic toxicity above this category. Substances with a chronic toxicity measured from 0.01 to 0.1 mg/l are classified in category Chronic 2 for chronic toxicity, from 0.1 to 1.0 mg/l are classified in category Chronic 3 for chronic toxicity, and those over 1.0 mg/l are regarded as practically non-toxic. For substances that do not rapidly degrade or where no information on rapid degradation is available two chronic categories are used: Chronic 1 when a chronic toxicity determined to be ≤ 0.1 mg/l and Chronic 2 when chronic toxicity is measured from 0.1 to 1.0 mg/l.”

Current paragraphs A9.3.3.2.2 and A9.3.3.2.3 become new paragraphs A9.3.3.2.3 and A9.3.3.2.4, respectively.

A9.3.3.2.3 (former A9.3.3.2.2) Amend to read as follows:

“A9.3.3.2.3 Since chronic toxicity data are less common in certain sectors than acute data, for classification schemes, the potential for chronic toxicity is, in absence of adequate chronic toxicity data, identified by appropriate combinations of acute toxicity, lack of degradability, and/or the potential or actual bioaccumulation. However, where adequate chronic toxicity data exist, this shall be used in preference over the classification based on the combination of acute toxicity with degradability, and/or bioaccumulation. In this context, the following general approach should be used:

- (a) If adequate chronic toxicity data are available for all three trophic levels this can be used directly to determine an appropriate chronic hazard category;
- (b) If adequate chronic toxicity data are available for one or two trophic levels, it should be examined if acute toxicity data are available for the other trophic level(s). A potential classification is made for the trophic level(s) with chronic data and compared with that made using the acute toxicity data for the other trophic level(s). The final classification shall be made according to the most stringent outcome;
- (c) In order to remove or lower a chronic classification using chronic toxicity data, it must be demonstrated that the NOEC(s) (or equivalent ECx) used would be suitable to remove or lower the concern for all taxa which resulted in classification based on acute data in combination with degradability, and/or bioaccumulation. This can often be achieved by using a long-term NOEC for the most sensitive species identified by the acute toxicity. Thus, if a classification has been based on a fish acute LC₅₀, it would generally not be possible to remove or lower this classification using a long-term NOEC from an invertebrate toxicity test. In this case, the NOEC would normally need to be derived from a long-term fish test of the same species or one of equivalent or greater sensitivity. Equally, if classification has resulted from the acute toxicity to more than one taxa, it is likely that NOECs from each taxa will be needed. In case of classification of a substance as Chronic 4, sufficient evidence should be provided that the NOEC or equivalent ECx for each taxa is greater than 1 mg/l or greater than the water solubility of the substances under consideration.”

A9.3.3.2.4 (former A9.3.3.2.3) In the first paragraph:

- replace “de-classifying chemicals” with “removing or lowering a classification” and “(1)”, “(2)” and “(3)” with “(a)”, “(b)” and “(c)” respectively;
- insert “acute” before “endpoints” at the end.

In the second paragraph, insert “is in the toxicity band corresponding to a less stringent classification category or” before “above 1 mg/l” and replace “declassification” with “removing or lowering a classification”.

A9.3.3.2.4 Delete.

A9.3.5.4 In the second sentence, replace “Where toxicities” with “Where acute toxicities”; in the third sentence replace, “if the estimated toxicity is greater than” with “if the estimated acute toxicity is greater than” and in the fifth sentence, replace “when toxicity is estimated to be” with “when acute toxicity is estimated to be”.

A9.3.5.7.2 (d) Delete the second sentence (“In principle...be considered”).

A9.3.5.8 (a) and (c) Insert “or NOEC” after “L(E)C₅₀”.

Annex 9, Appendix VI

Add the following reference in section 1 “Aquatic toxicity” (page 535 of the English version):

“OECD 2006. “Current approaches in the statistical analysis of ecotoxicity data: A guidance to application”, OECD Environment Health and Safety Publications Series Testing and Assessment N.54.
