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Item 4 (c) of the provisional agenda

PROPOSALS FOR AMENDMENTS TO THE REGULATIONS ANNEXED TO ADN

Substances hazardous for the aquatic environment

Note by the secretariat^{1,2}

Introduction

The UNECE secretariat has prepared a draft proposal of amendments to ADN chapter 2.4 concerning substances hazardous for the aquatic environment on the basis of the decisions taken by the UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals at its December 2008 session.

¹ Distributed in German by the Central Commission for the Navigation of the Rhine (CCNR) under the symbol CCNR/ZKR/ADN/WP.15/AC.2/2009/20.

² In accordance with the programme of work of the Inland Transport Committee for 2006-2010 (ECE/TRANS/166/Add.1, programme activity 02.7 (b)).

The reference documents are ST/SG/AC.10/36/Add.1 and Add.3. Text to be deleted is shown as struck through and new text is underlined.

[ST/SG/AC.10/36/Add.1]

~~2.9.3.1.4~~2.4.1.4 The two first amendments do not apply to the English text. (Dans la définition de "CE₅₀", remplacer "un produit chimique" par "une substance". Dans la définition de "CL₅₀", remplacer "matière" par "substance".)

Amend the definition of "NOEC" to read as follows:

"- NOEC (No Observed Effect Concentration): the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has not statistically significant adverse effect compared to the control;"

The fourth amendment does not apply to the English text. (Dans la définition de "Lignes directrices de l'OCDE", insérer "pour les essais" avant "publiées" et "(OCDE)" après "économiques".)

After the definition of "GLP", add the following new definition:

"- EC_x: the concentration associated with x% response;"

~~2.9.3.2.1~~2.4.2.1 Rearrange the indents 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."

~~2.9.3.2.3~~2.4.2.3 At the beginning, add the following two new paragraphs:

"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.

Acute (short-term) 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."

The existing text becomes the new third paragraph.

~~2.9.3.2.4~~2.4.2.4 Text of existing ~~2.9.3.2.6~~2.4.2.6, with the following modifications:

At the beginning, add the following two new paragraphs:

"*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.

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

The existing text becomes the new third paragraph. Amend the last sentence to read as follows: "The NOECs or other equivalent EC_x shall be used."

~~2.9.3.2.5~~2.4.2.5 *Text of existing ~~2.9.3.2.4~~2.4.2.4. The modifications do not apply to the English text.*

~~2.9.3.2.6~~2.4.2.6 *Text of existing ~~2.9.3.2.5~~2.4.2.5, with the following modifications:*

At the beginning, add the following new paragraph:

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

In the second sentence of the new second paragraph, replace "OECD biodegradability tests (OECD Test Guideline 301 (A - F))" with "biodegradability tests (A-F) of OECD Test Guideline 301". The amendments to the fourth and last sentences do not apply to the English text.

In sub-paragraph (a), at the end, after "has been degraded", insert the following text: ", 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 days⁴".

~~2.9.3.3~~2.4.3 Amend title to read as follows:

~~2.9.3.3~~2.4.3 *Substance classification categories and criteria*

~~2.9.3.3.1~~ Substances shall be classified as "environmentally hazardous substances (aquatic environment)", if they satisfy the criteria for Acute 1, Chronic 1, or Chronic 2, according to Table 2.9.1. These criteria describe in detail the classification categories. They are diagrammatically summarized in Table 2.9.2.

[Table and NOTES from ST/SG/AC.10/36/Add.3]

~~2.4.3.1~~ In subparagraphs (a) and (b), replace "the tables" with "table 2.4.3.1".
Replace the tables with the following table:

⁴ See Chapter 4.1 and Annex 9, paragraph A9.4.2.2.3 of the GHS.

Table 4.1.12.4.3.1: Categories for substances hazardous to the aquatic environment (*see Note 1*)

(a) Acute (short-term) aquatic hazard	
Category Acute 1: (<i>Note 2</i>)	
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 (<i>see Note 3</i>)
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 (<i>see Note 3</i>)
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 (<i>see Note 3</i>)
Some regulatory systems may extend this range beyond an L(E)C ₅₀ of 100mg/l through the introduction of another category.	
(b) Long-term aquatic hazard (<i>see also figure 4.1.12.4.3.1</i>)	
(i) Non-rapidly degradable substances (<i>see Note 4</i>) for which there are adequate chronic toxicity data available	
Category Chronic 1: (<i>see Note 2</i>)	
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: (<i>see Note 2</i>)	
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: (*see 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 (<i>see Note 3</i>)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (<i>see Notes 4 and 5</i>)	

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 (<i>see Note 3</i>)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (<i>see Notes 4 and 5</i>)	

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 (<i>see Note 3</i>)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (<i>see Notes 4 and 5</i>).	

(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} ≥ 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.

Substances which come under Category Chronic 4 alone are not considered to be environmentally hazardous in the sense of ADN.

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 4.1.3.5.52.4.4.6.4) to apply the summation method.*

NOTE 3: *Where the algal toxicity ErC₅₀ (= EC₅₀ (growth rate)) falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration shall 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 shall be used in deciding if classification shall be applied. Classification shall be based on the ErC₅₀. In circumstances where the basis of the EC₅₀ is not specified and no ErC₅₀ is recorded, classification shall be based on the lowest EC₅₀ available.*

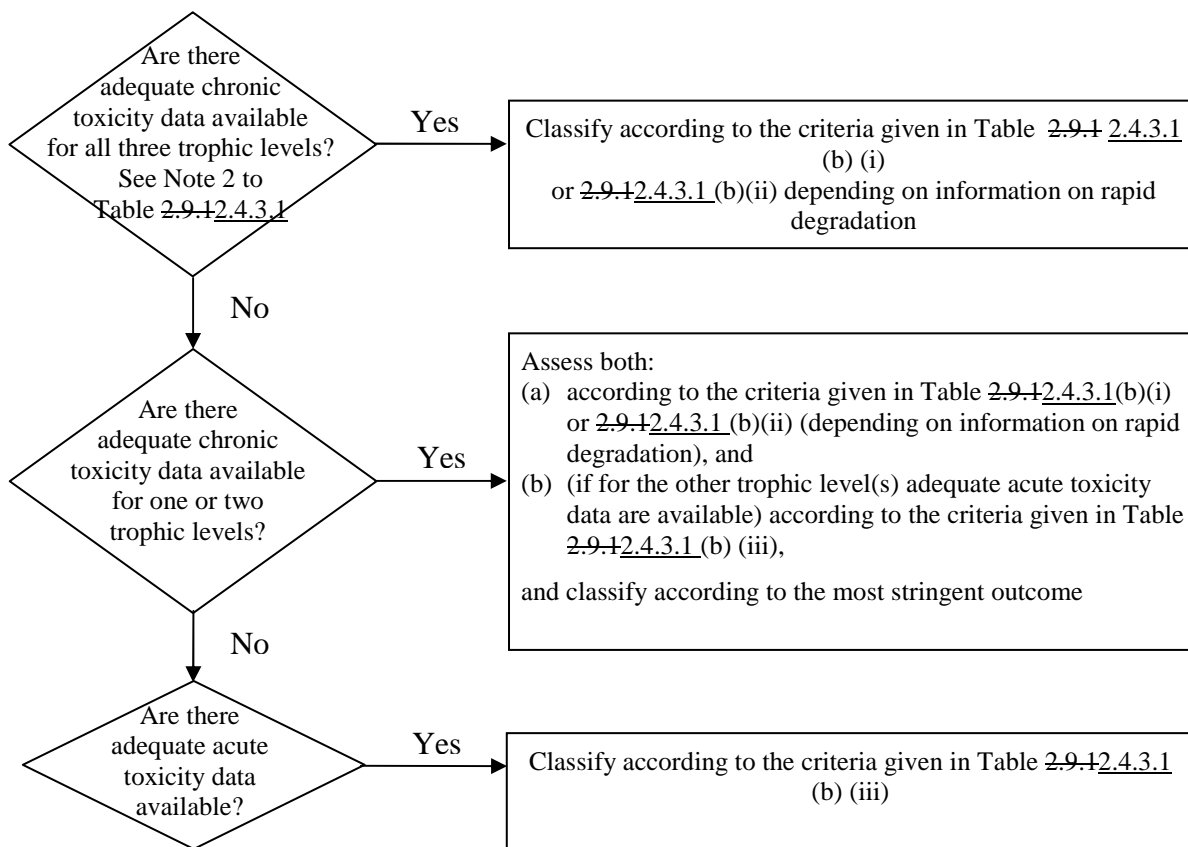
NOTE 4: Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation. When no useful data on degradability are available, either experimentally determined or estimated data, the substance shall be regarded as not rapidly degradable.

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.

[ST/SG/AC.10/36/Add.1]

2.4.3.1 Add the following figure:

Figure 2.9.12.4.3.1: Categories for substances long-term hazardous to the aquatic environment



2.9.3.3.2.4.3.2 The classification scheme in Table 2.9.22.4.3.2 below summarizes the classification criteria for substances.

[Table and NOTES from ST/SG/AC.10/36/Add.3]

2.4.3.2 Add the following table:

Table 4.1.22.4.3.2: 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 Quantitative Structure Activity Relationships (QSAR) estimation if no experimental data⁵).

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).

⁵ Special guidance is provided in Chapter 4.1, paragraph 4.1.2.13 and Annex 9, Section A9.6 of the GHS.

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 hazards.”.*

[ST/SG/AC.10/36/Add.1]

~~2.9.3.4.1~~2.4.4.1 In the first sentence, replace "meaning Aacute Categoriesy 1 to 3 and Chronic Categoriesy 1 and 2to 4" with ", meaning categories Acute 1 to 3 and Chronic 1 and 2to 4" The second amendment does not apply to the English text. (Dans la deuxième phrase, insérer "des dangers" après "classification".)

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

~~2.9.3.4.2~~2.4.4.2 Replace “Figure 2.9.1” with “Figure 2.9.2 (twice). In the heading of the figure, replace "chronic" with "long-term".

In the figure, in the middle column, modify the three bullet points to read them as sub-paragraphs (a), (b) and (c). In the new sub-paragraph (c), replace "formula" with "formulas" and insert "or EqNOECm" after "L(E)C₅₀" and "or “Chronic”" after "“Acute”". In the right column, replace "chronic toxicity" with "long-term" (four times).

~~2.9.3.4.3~~2.4.4.3 Amend to read as follows:

~~2.9.3.4.3~~2.4.4.3 ***Classification of mixtures when toxicity data are available for the complete mixture***

~~2.9.3.4.3~~2.4.4.3.1 When the mixture as a whole has been tested to determine its aquatic toxicity, this information shall be used for classifying the mixture according to the criteria that have been agreed for substances. The classification is normally based on the data for fish, crustacea and algae/plants (see ~~2.9.3.2.3~~2.4.2.3 and ~~2.9.3.2.4~~2.4.2.4). When adequate acute or

chronic data for the mixture as a whole are lacking, "bridging principles" or "summation method" shall be applied (see ~~2.9.3.4.4.2.4.4.4~~ and ~~2.9.3.4.5.2.4.4.5~~).

~~2.9.3.4.3.2.4.4.3.2~~ 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.

~~2.9.3.4.3.3.2.4.4.3.3~~ 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 $L(E)C_{50} \leq 1$ mg/l:

Classify the mixture as Acute 1, 2 or 3 in accordance with Table ~~2.9.12.4.3.1~~ (a);

- (b) When there are acute toxicity test data ($LC_{50}(s)$ or $EC_{50}(s)$) available for the mixture as a whole showing $L(E)C_{50}(s) > 1$ mg/l, or above the water solubility:

No need to classify for acute hazard under ADN these Regulations.

~~2.9.3.4.3.4.2.4.4.3.4~~ Classification for categories Chronic 1, ~~and 2~~, 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, ~~or 2~~, 2 or 3 in accordance with Table ~~2.9.12.4.3.1~~ (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, ~~or 2~~, 2 or 3 in all other cases in accordance with Table ~~2.9.12.4.3.1~~ (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 under ADN. these Regulations.

[ST/SG/AC.10/36/Add.3]

~~4.1.3.3.5~~2.4.4.3.5 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~~2.4.3.1 (c)".

[ST/SG/AC.10/36/Add.1]

~~2.9.3.4.4.2~~2.4.4.4 Amend the heading to read as follows: "***Classification of mixtures when toxicity data are not available for the complete mixture: bridging principles***".

~~2.9.3.4.4.2~~2.4.4.4.2 Amend to read as follows:

~~"2.9.3.4.4.2~~2.4.4.4.2 Dilution

~~2.9.3.4.4.2.1~~2.4.4.4.2.1 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 shall be classified as equivalent to the original tested mixture or substance. Alternatively, the method explained in ~~2.9.3.4.5~~2.4.4.5 may be applied."

~~2.9.3.4.4.3.1~~2.4.4.4.3 At the beginning, replace "one production batch of a complex mixture" with "a tested production batch of a mixture". Insert "untested" after "another" and replace "and produced" with "when produced". At the end of the first sentence, insert "untested" before "batch".

~~2.9.3.4.4.4.2~~2.4.4.4.4 The amendment does not apply to the English text.

~~2.9.3.4.4.4.1~~2.4.4.4.4 At the beginning, replace "If a mixture" with "If a tested mixture" and insert "the" before "ingredients". Insert "untested" after "concentrated" and "tested" after "original".

~~2.9.3.4.4.5.1~~2.4.4.4.5 Amend to read as follows:

~~"2.9.3.4.4.5.1~~ For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity 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 category as A and B."

~~2.9.3.4.4.6.1~~2.4.4.4.6 In sub-paragraph (b), insert "essentially" before "the same". In sub-paragraph (d), replace "Classifications" with "Data on aquatic hazards" and "the same" with "substantially equivalent". Amend the text after sub-paragraph (d) to read as follows:

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

~~2.9.3.4.5~~2.4.4.5 In the heading, insert "toxicity" before "data".

~~2.9.3.4.5.2~~2.4.4.5.2 Amend to read as follows:

~~2.9.3.4.5.2~~2.4.4.5.2 Mixtures may be made of a combination of both ingredients that are classified (as Acute 1 to 3 and/or Chronic 1, 2 to 4) and those for which adequate toxicity test data are available. When adequate toxicity data are available for more than one ingredient in the mixture, the combined toxicity of those ingredients shall be calculated using the following additivity formulas (a) or (b), depending on the nature of the toxicity data:

(a) Based on acute aquatic toxicity:

$$\frac{\sum C_i}{L(E)C_{50m}} = \sum_n \frac{C_i}{L(E)C_{50i}}$$

where:

C_i = concentration of ingredient i (mass percentage);
 $L(E)C_{50i}$ = LC_{50} or EC_{50} for ingredient i (mg/l);
 n = number of ingredients, and i is running from 1 to n;
 $L(E)C_{50m}$ = $L(E)C_{50}$ of the part of the mixture with test data

The calculated toxicity shall 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 (mass percentage) covering the rapidly degradable ingredients;
C_j	= concentration of ingredient j (mass 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;
$NOEC_j$	= 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 shall be used to assign that portion of the mixture a long-term hazard category, in accordance with the criteria for rapidly degradable substances (Table ~~2.9.4.3.1~~ (b) (ii)), which is then subsequently used in applying the summation method."

~~2.9.3.4.5.3~~ 2.4.4.5.3 In the first sentence, replace "each substance" with "each ingredient", "same species" with "same taxonomic group", "daphnia" with "crustacea" and "three species" with "three groups". In the second sentence, replace "species" with "taxonomic group". In the last sentence, insert "and chronic" before "toxicity" and "and/or Chronic 1 ~~or 2, 2 or 3~~" after "Acute 1, 2 or 3".

~~2.9.3.4.6.1.1~~ 2.4.4.6.1 The amendment does not apply to the English text. (Supprimer "de toxicité" (deux fois).)

~~2.9.3.4.6.2.1~~ 2.4.4.6.2 Amend the heading to read "*Classification for category Acute 1, 2 and 3*".

~~2.9.3.4.6.2.1~~ 2.4.4.6.2.1 In the first sentence, replace "All" with "First, all" and "shall be" with "are". In the second sentence, insert "the concentrations (in %) of" before "these ingredients". Delete "category" (twice).

~~2.9.3.4.6.2.2~~ Amend to read as follows:

~~"2.9.3.4.6.2.2 The classification of mixtures for acute hazards based on this summation of the concentrations of the classified ingredients is summarized in Table 2.9.3 below~~

Table ~~2.9.3.2.4.4.6.2.4~~: Amend title and column headings as follows:

Table 2.4.4.6.2.4 Classification of a mixture for acute hazards based on summation of the concentrations of classified ingredients

Sum <u>of the concentrations (in %)</u> of ingredients classified as:	Mixture is classified as:
Acute 1 x M ^a ≥ 25%	Acute 1

^a For explanation of the M factor, see 2.4.4.6.4

~~2.9.3.4.6.3.1~~2.4.4.6.3.1 The first amendment does not apply to the English text. (Dans la première phrase, supprimer "de toxicité".) In the second sentence, insert "the concentrations (in %) of" before "these ingredients". ~~Delete "category" (twice).~~

~~2.9.3.4.6.3.2~~2.4.4.6.3.2 Insert "the concentrations (in %) of" after "the sum of" (twice).

~~2.9.3.4.6.3.3~~2.4.4.6.3.5 Amend to read as follows:

~~"2.9.3.4.6.3.3~~2.4.4.6.3.5 The classification of mixtures for long-term hazards based on this summation of the concentrations of classified ingredients is summarized in Table ~~2.9.4~~2.4.4.6.3.5 below.

Table ~~2.9.4.2.4.4.6.3.5~~: Amend title and column headings as follows:

Table 2.4.4.6.3.5 Classification of a mixture for long-term hazards based on summation of the concentrations of classified ingredients

Sum <u>of the concentrations (in %)</u> of ingredients classified as:	Mixture is classified as:
Chronic 1 x M ^a ≥ 25%	Chronic 1
(M x 10 x Chronic 1) + Chronic 2 ≥ 25%	Chronic 2

^a ~~For explanation of the M factor, see 2.9.3.4.6.4".~~

~~2.9.3.4.6.4.1~~2.4.4.6.4 In the first sentence, replace "Category acute 1 ingredients with toxicities well below 1 mg/l may influence" with "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".

In the second sentence, insert "and Chronic 1" after "the concentrations of Acute 1". ~~In the third sentence, replace "Table 2.9.1" with "Table 2.9.3" and "Table 2.9.2" with "Table 2.9.4". In the fourth sentence, replace "summarised in Table 2.9.3" with "summarised in Table 2.9.5".~~ In the last sentence, insert "and/or chronic" after "specific acute".

Table ~~2.9.32.4.4.6.4~~ Replace with the following table:

"Table ~~2.9.52.4.4.6.4~~: Multiplying factors for highly toxic ingredients of mixtures

Acute toxicity L(E)C ₅₀ value	M factor	Chronic toxicity NOEC value	M factor	
			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	1 000	0.00001 < NOEC ≤ 0.0001	1 000	100
0.00001 < L(E)C ₅₀ ≤ 0.0001	10 000	0.000001 < NOEC ≤ 0.000 01	10 000	1 000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

^a *Non-rapidly degradable.*

^b *Rapidly degradable.*

~~2.9.3.4.6.5.1~~2.4.4.6.5 In the first sentence, replace "aquatic hazard" with "aquatic toxicity".

~~2.9.3.5~~ — Delete.
