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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 Transport of Dangerous Goods

REPORT OF THE SUB-COMMITTEE OF EXPERTS ON ITS TWENTIETH SESSION

(Geneva, 3-11 December 2001)

Addendum 2

Annex 2

<u>Draft amendments to the Model Regulations annexed to the twelfth revised edition of the Recommendations on the Transport of Dangerous Goods (ST/SG/AC.10/1/Rev.12)</u>

United Nations Recommendations on the Transport of Dangerous Goods

Amend paragraph 10 (page 2 of the English text) to read:

"10. Many of the substances listed in Classes 1 to 9 are deemed as being dangerous to the environment. Additional labelling is not always specified except for transport by sea. Criteria for substances and mixtures dangerous to the aquatic environment are given in Chapter 2.9 of the Model Regulations."

Part 1

1.2.1 Insert a new entry to read as follows:

"[GHS means the Globally Harmonized System for Hazard Classification and Communication, published by the United Nations as document (symbol to be inserted)].".

Part 2

Chapter 2.3

2.3.1.4 Add UN 3379 to the list of UN numbers.

Chapter 2.4

2.4.2.4.1 Add UN 3380 to the list of UN numbers.

Chapter 2.9

2.9.2 Add the following section:

"2.9.2 Classification of substances and mixtures hazardous to the environment by reason of aquatic pollution

2.9.2.1 Purpose, basis and applicability

2.9.2.1.1 The scheme for classifying substances and mixtures for the hazards they present to the aquatic environment is in accordance with [the criteria elaborated by the OECD, and contained in Chapter 3.10 of] the GHS [see Chapter 3.10 of the GHS]. 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. The basis, therefore, of the identification of hazard is the aquatic toxicity of the substance or mixture, although this may be modified by further information on the degradation and bioaccumulation behaviour.

2.9.2.1.2 While the scheme is intended to apply to all substances and mixtures, it is recognised that in some cases, e.g. metals or poorly soluble inorganic compounds, special guidance will be necessary².

This 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.

This can be found in Annexes [9] and [10] of the GHS.

2.9.2.2 Definitions and data requirements

2.9.2.2.1 The basic elements of the scheme are:

acute aquatic toxicity; potential for or actual bioaccumulation; degradation (biotic or abiotic) for organic chemicals; and chronic aquatic toxicity.

- 2.9.2.2.2 While data from internationally harmonised 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 practice (GLP). Where such data are not available, classification shall be based on the best available data.
- 2.9.2.2.3 Acute aquatic toxicity shall normally be determined using a fish 96 hour LC₅₀ (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC₅₀ (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC₅₀ (OECD Test Guideline 201 or equivalent). These species are considered as surrogates for all aquatic organisms. Data on other species such as Lemna may also be considered if the test methodology is suitable.
- 2.9.2.2.4 *The potential for bioaccumulation* shall normally be determined by using the octanol/water partition coefficient, usually reported as a log Kow determined according to OECD Test Guideline 107 or 117. While this represents a potential to bioaccumulate, an experimentally determined Bioconcentration Factor (BCF) provides a better measure and shall be used in preference when available. A BCF shall be determined according to OECD Test Guideline 305.
- 2.9.2.2.5 Environmental degradation for organic chemicals may be biotic or abiotic (eg. hydrolysis) and the criteria used reflect this fact (see 2.9.2.5). Ready biodegradation is most easily defined using the OECD biodegradability tests (OECD Test Guideline 301 (A F)). A pass level in these tests may be considered as indicative of rapid degradation in most aquatic environments. As these are freshwater tests, use of results from OECD Test Guideline 306, which is more suitable for the marine environment, is also included. Where such data are not available, a BOD(5 days)/COD ratio >0.5 is considered as indicative of rapid degradation. 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 degradability³.
- 2.9.2.2.6 Chronic aquatic toxicity data are less available than acute data and the range of testing procedures less standardised. Data generated according to the OECD Test Guidelines 210 (Fish Early Life Stage), 202 Part 2 or 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) may be accepted. Other validated and internationally accepted tests may also be used. The "No Observed Effect Concentrations" (NOECs) or other equivalent L(E)Cx shall be used.

2.9.2.3 Substance classification categories and criteria

2.9.2.3.1 Substances meeting the following criteria shall be categorised as 'hazardous to the aquatic environment' for transport purposes, if they satisfy the criteria for <u>Acute I</u>, <u>Chronic I</u> or

³ Special guidance on data interpretation is provided in the Annex [9] of the GHS.

<u>Chronic II.</u> These criteria describe in detail the classification categories set out diagrammatically in 2.9.2.7.

Acute toxicity

Category: Acute IAcute toxicity:96 hr LC_{50} (for fish) $\leq 1 \text{ mg/L}$ and/or48 hr EC_{50} (for crustacea) $\leq 1 \text{ mg/L}$ and/or72 or 96hr ErC_{50} (for algae or other aquatic plants) $\leq 1 \text{ mg/L}$.

Category: Acute I may be subdivided for some regulatory systems to include a lower band at LC_{50} or $EC_{50} \le 0.1$ mg/L.

Chronic toxicity

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\begin{tabular}{lll} \hline \textbf{Category: Chronic I} \\ \hline \textbf{Acute toxicity:} \\ & 96 \text{ hr LC}_{50} \text{ (for fish)} & \leq 1 \text{ mg/L and/or} \\ & 48 \text{ hr EC}_{50} \text{ (for crustacea)} & \leq 1 \text{ mg/L and/or} \\ & 72 \text{ or } 96 \text{hr ErC}_{50} \text{ (for algae or other aquatic plants)} & \leq 1 \text{ mg/L} \\ & \text{and the substance is not rapidly degradable and/or the log Kow} & 4 \text{ (unless the experimentally determined BCF} < 500). \\ \hline \end{tabular}
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Category: Chronic II

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Acute toxicity 96 hr LC_{50} (for fish) >1 to \leq 10 mg/L and/or 48 hr EC_{50} (for crustacea) >1 to \leq 10 mg/L and/or 72 or 96hr ErC_{50} (for algae or other aquatic plants) >1 to \leq 10 mg/L and the substance is not rapidly degradable and/or the log Kow \geq 4 (unless the experimentally determined BCF \leq 500), unless the chronic toxicity NOECs are \geq 1 mg/L.
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NOTES: Rationale for the scheme

NOTE 1: The classification scheme recognises that the core intrinsic hazard to aquatic organisms is represented by both the acute and chronic toxicity of a substance. Distinction is made between the acute hazard and the 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 shall be used to define the appropriate hazard category(s). 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 standardised. For that reason, these data form the core of the classification scheme.

NOTE 2: 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. Hazard categories up to LC_{50} or EC_{50} values of 100 mg/L are thus defined,

although categories up to 1000 mg/L may be used in certain regulatory frameworks. The Acute category I may be further sub-divided to include an additional category for acute toxicity LC_{50} or $EC_{50} \le 0.1$ mg/L in certain regulatory systems such as that defined by MARPOL 73/78 Annex II concerning bulk transport by sea.

- **NOTE 3:** For packaged substances it is considered that the principal hazard is defined by chronic toxicity, although acute toxicity at LC_{50} or EC_{50} levels $\leq I$ mg/L is also considered hazardous. Levels of substances up to 1 mg/L are considered to be possible in the aquatic environment following normal use and disposal. At toxicity levels above this, the short-term 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 and 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 chronic hazard category. Chronic toxicity showing NOECs >1 mg/L indicates that there is no chronic hazard category classification.
- **NOTE 4:** While the current scheme uses acute toxicity data in combination with a lack of rapid degradation and/or a potential to bioaccumulate as the basis for classification for assigning a chronic hazard category, actual chronic toxicity data form a better basis for classification where these data are available. It is thus the intention that the scheme should be further developed to accommodate such data. It is anticipated that in such a further development, the available chronic toxicity data would be used to classify in the chronic hazard in preference to that derived from their acute toxicity in combination with a lack of rapid degradation and/or a potential to bioaccumulate.
- **NOTE 5:** Recognition is given to the classification goals of MARPOL 73/78 Annex II that covers the transport of bulk quantities in ships' tanks, which are aimed at regulating operational discharges from ships and the assigning of suitable ship types. They go beyond 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.
- **NOTE 6:** 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 standardised. Data on other organisms may also be considered, 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} is normally 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.
- **NOTE 7:** 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 special guidance to be contained in Annexes [9] and [10] of the GHS will be developed on data interpretation for these substances and how the data should be used when applying the classification criteria.]
- **NOTE 8:** 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 Kow (log P(o/w)) ≥ 4 is intended to identify only those substances with a real potential to bioconcentrate. In recognition that the log Kow is only an imperfect surrogate for a measured BCF, such a measured value shall always take precedence. A BCF in fish of <500 indicates a low level of bioconcentration.

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 localised 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 long period and a wide area. One way of demonstrating rapid degradation utilises 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 failure in the screening test does not necessarily mean that the substance will not degrade rapidly in the environment. Thus a further criterion allows 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 is demonstrated under environmentally realistic conditions, then the definition of 'rapid degradability' is met. Many degradation data are available in the form of degradation halflives and these may also be used in defining rapid degradation. Details regarding the interpretation of these data are further elaborated in the Annex [9] of the GHS. Some tests measure the ultimate biodegradation of the substance, i.e. full mineralisation is achieved. Primary biodegradation shall not normally qualify in the assessment of rapid degradability unless it can be demonstrated that the degradation products do not fulfil the criteria for classification as dangerous to the aquatic environment.

NOTE 10: The criteria used reflect the fact that environmental degradation may be biotic or abiotic (e.g. hydrolysis). Equally, 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 shall be considered as rapidly degradable. Hydrolysis may be considered if the hydrolysis products do not fulfil the criteria for classification as dangerous to the aquatic environment. A specific definition of rapid degradability is included at 2.9.2.5. Other evidence of rapid degradation in the aquatic environment may also be considered and may be of particular importance where the substances inhibit microbial activity at the concentration levels used in standard testing. The range of available data and guidance on its interpretation are provided in the Annex [9] of the GHS.

NOTE 11: 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 either to increase or to decrease the bioavailability of the toxic species. Equally the use of bioaccumulation data shall be treated with care. Specific guidance is contained in Annex [10] of the GHS on how these data for such substances may be used in meeting classification criteria requirements.

NOTE 12: 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 substances is being developed and will be covered further in the Annex [10] of the GHS].

NOTE 13: While experimentally derived test data are preferred, where no experimental data are available, validated Quantitative Structure Activity Relationships (QSARs) for aquatic toxicity and log Kow 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 characterised. [Validity may be judged according to the criteria established within the US-EPA/EU/Japan Collaborative Project]*. QSARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation.

2.9.2.4 Mixtures classification categories and criteria

2.9.2.4.1 The classification scheme for mixtures covers the classification categories which are used for substances meaning acute category I and chronic categories I and II. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following assumption is made and is applied where appropriate.

The "relevant components" of a mixture are those which are present in a concentration of 1% (w/w) or greater, unless there is a presumption (e.g. in the case of highly toxic components) that a component present at less than 1% can still be relevant for classifying the mixture for aquatic environmental hazards.

- 2.9.2.4.1.1 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 components. Elements of the tiered approach include:
 - i) classification based on tested mixtures;
 - ii) classification based on bridging principles;
 - iii) the use of "summation of classified components" and /or an "additivity formula".

Figure 2.9.1 below outlines the process to be followed.

^{*} Note by the secretariat: A reference should be provided if this is publicly available. Otherwise this sentence should be deleted.

Aquatic toxicity test data available on the mixture as a whole **CLASSIFY** for Yes acute/chronic toxicity (2.9.2.4.2.1 and 2.9.2.4.2.2) Sufficient data **CLASSIFY** available on similar Apply bridging principles Yes For acute/ chronic mixtures to estimate (2.9.2.4.3.1 to 2.9.2.4.3.7) toxicity hazards Apply Summation Method (2.9.2.4.5.1 to 2.9.2.4.5.9) using: • Percentage of all components classified as "Chronic" Either aquatic toxicity or Percentage of components **CLASSIFY** classification data Yes classified as "Acute" For acute/chronic available for all toxicity Percentage of components with relevant components acute toxicity data: apply Additivity Formula (2.9.2.4.4.2) and convert the derived L(E)C₅₀ to the appropriate "Acute" Category Apply Summation Method and CLASSIFY Use available hazard data of known Additivity Formula, 2.9.2.4.4.1 to For acute /chronic components 2.9.2.4.5.9 and apply 2.9.2.4.5.10 toxicity

Figure 2.9.1: Tiered approach to classification of mixtures for acute and chronic aquatic environmental hazards

2.9.2.4.2 Classification of mixtures when data is available for complete mixture

2.9.2.4.2.1 When the mixture as a whole has been tested to determine its aquatic toxicity, it shall be classified according to the criteria that have been agreed for substances in 2.9.2.3, but only for acute toxicity. The classification is based on the data for: fish, crustacea and algae/plants. Classification of mixtures by using LC_{50} or EC_{50} data for the mixture as a whole is not possible for chronic categories since both toxicity data and environmental fate data are needed, and there are no degradability and bioaccumulation data for mixtures as a whole. It is not possible to apply the criteria for chronic classification because the data from degradability and bio-accumulation tests of mixtures cannot be interpreted; they are meaningful only for single substances.

2.9.2.4.2.2 When there is acute toxicity test data (LC₅₀ or EC₅₀) available for the mixture as a whole, this data as well as information with respect to the classification of components for chronic toxicity shall be used to complete the classification for tested mixtures as follows. When chronic (long term) toxicity data (NOEC) is also available, this shall be used in addition.

- (a) $L(E)C_{50}$ (LC_{50} or EC_{50}) of the tested mixture $\leq 1 \text{mg/L}$ and NOEC of the tested mixture $\leq 1.0 \text{ mg/L}$ or unknown:
 - (i) Classify mixture as Category Acute I
 - (ii) Apply Summation of Classified Components approach (see 2.9.2.4.5.6 to 2.9.2.4.5.9) for chronic classification (Chronic I, II, or no need of chronic classification).
- (b) $L(E)C_{50}$ of the tested mixture $\leq 1 \text{mg/L}$ and NOEC of the tested mixture > 1.0 mg/L:
 - (i) Classify mixture as Category Acute I
 - (ii) Apply Summation of Classified Components approach (see 2.9.2.4.5.6 to 2.9.2.4.5.9) for classification as Category Chronic I. If the mixture is not classified as Category Chronic I, then there is no need for chronic classification.
- (c) $L(E)C_{50}$ of the tested mixture >1mg/L, or above the water solubility, and NOEC of the tested mixture ≤ 1.0 mg/L or unknown:
 - (i) No need to classify for acute toxicity
 - (ii) Apply Summation of Classified Components approach (see 2.9.2.4.5.6 to 2.9.2.4.5.9) for Chronic classification or no need for chronic classification.
- (d) $L(E)C_{50}$ of the tested mixture >1mg/L, or above the water solubility, and NOEC of the tested mixture > 1.0 mg/L:
 - (i) No need to classify for acute or chronic toxicity
- 2.9.2.4.3 Classification of mixtures when data is not available for complete mixture.

Bridging Principles

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

Dilution

2.9.2.4.3.2 If a mixture is formed by diluting another classified mixture or a substance with a diluent which has an equivalent or lower aquatic hazard classification than the least toxic original component and which is not expected to affect the aquatic hazards of other components, then the mixture shall be classified as equivalent to the original mixture or substance.

2.9.2.4.3.3 If a mixture is formed by diluting another classified mixture or a substance with water or other totally non-toxic material, the toxicity of the mixture shall be calculated from the original mixture or substance.

Batching

2.9.2.4.3.4 The aquatic hazard classification of one production batch of a complex mixture shall be assumed to be substantially equivalent to that of another production batch of the same commercial product and 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 batch has changed. If the latter occurs, new classification is necessary.

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

2.9.2.4.3.5 If a mixture is classified as Chronic I and/or Acute I, and components of the mixture which are classified as Chronic I and/or Acute I are further concentrated, the more concentrated mixture shall be classified with the same classification category as the original mixture without additional testing.

Interpolation within one toxicity category

2.9.2.4.3.6 If mixtures A and B are in the same classification category and mixture C is made in which the toxicologically active components have concentrations intermediate to those in mixtures A and B, then mixture C shall be in the same category as A and B. Note that the identity of the components is the same in all three mixtures.

Substantially similar mixtures

2.9.2.4.3.7 Given the following:

- (a) Two mixtures: i) A + Bii) C + B
- (b) The concentration of component B is the same in both mixtures.
- (c) The concentration of component A in mixture (i) equals that of component C in mixture (ii).
- (d) Classification for A and C are available and are the same, i.e. they are in the same hazard category and are not expected to affect the aquatic toxicity of B,

then there shall be no need to test mixture (ii) if mixture (i) is already characterised by testing and both mixtures are classified in the same category.

- 2.9.2.4.4 Classification of mixtures when data are available for all components or only for some components of the mixture.
- 2.9.2.4.4.1 The classification of a mixture shall be based on summation of the classification of its components. The percentage of components classified as "Acute" or "Chronic" will feed straight into the summation method. Details of the summation method are described in 2.9.2.4.5.1 to 2.9.2.4.5.9.

2.9.2.4.4.2 Mixtures are often made of a combination of both components that are classified (as Acute I and/or Chronic I, II) and those for which adequate test data is available. When adequate toxicity data is available for more than one component in the mixture, the combined toxicity of those components shall be calculated using the following additivity formula, and the calculated toxicity shall be used to assign that portion of the mixture an acute toxicity category which is then subsequently used in applying the summation method.

$$\frac{\sum Ci}{L(E)C_{50m}} = \sum_{\eta} \frac{Ci}{L(E)C_{50i}}$$

where:

 $\begin{array}{l} C_i \\ L(E)C_{50i} \\ \eta \\ L(E)C_m \end{array}$ concentration of component i (weight percentage)

(mg/L) LC₅₀ or EC₅₀ for component i

number of components

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

2.9.2.4.4.3 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 substance toxicity values that relate to the same species (i.e.; fish, daphnia or algae) and then to use the highest toxicity (lowest value) obtained (viz., use the most sensitive of the three species). However, when toxicity data for each component are not available in the same species, the toxicity value of each component shall 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 toxicity shall then be used to classify this part of the mixture as Acute I, if appropriate, using the same criteria described for substances in 2.9.2.3.

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

2.9.2.4.5 Summation method

Rationale

In case of the substance classification categories Chronic I and Chronic II, the underlying toxicity criteria differ by a factor of 10 in moving from one category to the other. Substances with a classification in the 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 substances classified Acute I/Chronic I to Acute I/Chronic II together.

When a mixture contains components classified as Acute Category I, attention shall be paid to the fact that such components, when their acute toxicity is well below 1 mg/L [(See the GHS, Chapter 1.2, paragraph 28, Classification of Hazardous substances and Mixtures)], contribute to the toxicity of the mixture even at a low concentration. Active ingredients in pesticides often possess such high aquatic toxicity as do some other substances like organometallic compounds. Under these circumstances the application of the normal cutoff values/concentration limits may lead to an "underclassification" of the mixture. Therefore, multiplying factors shall be applied to account for highly toxic components, as described in 2.9.2.4.5.9.

Classification procedure

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

Classification for the Acute Category I

- 2.9.2.4.5.4 All components classified as Acute I shall be considered. If the sum of these components is greater than 25% the whole mixture shall be classified as Category Acute I.
- 2.9.2.4.5.5 The classification of mixtures for acute hazards based on this summation of classified components, is summarised in the Table below.

Table 2.9.2.4.5.5: Classification of a mixture for acute hazards, based on summation of classified components.

Sum of components classified a	s:	Mixture is classified as:		
Acute $I \times M^{a)}$	>25%	Acute I		

a) For explanation of the M factor, see 2.9.2.4.5.9.

Classification for the chronic categories I, II

- 2.9.2.4.5.6 First all components classified as Chronic I are considered. If the sum of these components is greater than 25% the mixture shall be classified as Category Chronic I. If the result of the calculation is a classification of the mixture as Category Chronic I the classification procedure is completed.
- 2.9.2.4.5.7 In cases where the mixture is not classified as Chronic I, classification of the mixture as Chronic II is considered. A mixture shall be classified as Chronic II if 10 times the sum of all components classified as Chronic I plus the sum of all components classified as Chronic II is greater than 25%. If the result of the calculation is classification of the mixture as Chronic II, the classification process is completed.
- 2.9.2.4.5.8 The classification of mixtures for chronic hazards, based on this summation of classified components, is summarised in the Table below.

Table 2.9.2.4.5.8: Classification of a mixture for chronic hazards, based on summation of classified components

Sum of components classified as:		Mixture is classified as:	
Chronic $I \times M^{a}$	>25%	Chronic I	
(M × 10 × Chronic I)+Chronic II	>25%	Chronic II	

Mixtures with highly toxic components

2.9.2.4.5.9 Acute Category 1 components with toxicities well below 1 mg/L may influence the toxicity of the mixture and are given increased weight in applying the summation of classification approach. When a mixture contains components classified as Acute or Chronic Category I, the tiered approach described in 2.9.2.4.5.4 to 2.9.2.4.5.8 shall be applied using a weighted sum by multiplying the concentrations of Acute Category 1 components by a factor, instead of merely adding up the percentages. This means that the concentration of "Acute I" in the left column of Table 2.9.2.4.5.5 and the concentration of "Chronic I" in the left column of Table 2.9.2.4.5.8 are multiplied by the appropriate multiplying factor. The multiplying factors to be applied to these components are defined using the toxicity value, as summarised in Table 2.9.2.4.5.9 below. Therefore, in order to classify a mixture containing Acute I and/or Chronic I components, the classifier needs to be informed of the value of the M factor in order to apply the summation method. Alternatively, the additivity formula (2.9.2.4.4.2) may be used when toxicity data are available for all highly toxic components in the mixture and there is convincing evidence that all other components, including those for which specific acute toxicity data are not available, are of low or no toxicity and do not significantly contribute to the environmental hazard of the mixture.

Table 2.9.2.4.5.9: Multiplying factors for highly toxic components of mixtures

L(E)C ₅₀ value	Multiplying factor (M)
$0.1 < L(E)C_{50} \le 1$	1
$0.01 < L(E)C_{50} \le 0.1$	10
$0.001 < L(E)C_{50} \le 0.01$	100
$0.0001 < L(E)C_{50} \le 0.001$	1000
$0.00001 < L(E)C_{50} \le 0.0001$	10000
(continue in factor 10 intervals)	

Classification of mixtures with components without any useable information

2.9.2.4.5.10 In the event that no useable information on acute and/or chronic aquatic toxicity is available for one or more relevant components, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture shall be classified based on the known components only.

2.9.2.5 Rapid degradability

- 2.9.2.5.1 Substances are considered rapidly degradable in the aquatic environment if the following criteria are met:
 - (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 shall 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, or

- (b) if, in those cases where only BOD and COD data are available, when the ratio of BOD5/COD is \geq 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.

2.9.2.6 Classification scheme for substances dangerous in transport to the aquatic environment⁴

Тох	xicity	Degradability	Bioaccumulation	Classification		
Acute (note 1)	Chronic (note 2)	(note 3)	(note 4)	Acute	Chronic	
Box 1 value ≤1.00		Box 5	Box 6	Acute I Box 1	Chronic I Boxes 1+5+6 Boxes 1+5 Boxes 1+6	
Box 2 1.0 < value ≤ 10.0	Box 7 value > 1.00	lack of rapid degradability	BCF \geq 500 or, if absent log Kow \geq 4		Chronic II Boxes 2+5+6 Boxes 2+5 Boxes 2+6 Unless Box 7	

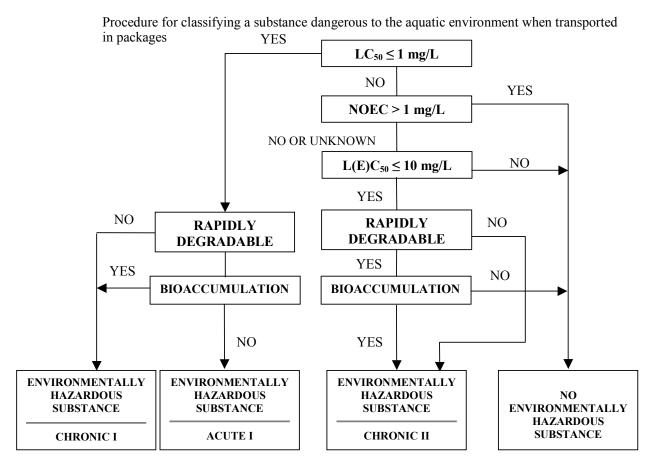
Notes to the table:

NOTE 1: Acute toxicity band based on LC_{50} or EC_{50} values in mg/L for fish, crustacea and/or algae or other aquatic plants (or QSAR estimation if no experimental data). 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 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 judgement may be used in deciding if classification shall be applied. Classification shall 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 shall be based on the lowest EC_{50} available.

Abridged OECD table.

- **NOTE 2:** Chronic toxicity band based on NOEC values in mg/L for fish or crustacea or other recognised measures for long-term toxicity⁵.
- **NOTE 3:** Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation.
- **NOTE 4:** Potential to bioaccumulate, based on an experimentally derived $BCF \ge 500$ or, if absent, a log $Kow \ge 4$ provided log Kow is an appropriate descriptor for the bioaccumulation potential of the substance. Measured log Kow values take precedence over estimated values and measured BCF values take precedence over log Kow values.

2.9.2.7 Classification flow chart



^[5] It is intended to develop the system further to include chronic toxicity data.]

2.9.2.8 Substances or mixtures dangerous to the aquatic environment not otherwise classified under these Regulations shall be designated:

UN 3077 [ENVIRONMENTALLY HAZARDOUS SUBSTANCE] SOLID, N.O.S. or

UN 3082 [ENVIRONMENTALLY HAZARDOUS SUBSTANCE] LIQUID, N.O.S.

PART 3

Dangerous Goods List

UN No. 2813 Add "PP83" in column (9).

UN No. 2956 Delete "181" in column (6).

UN No. 3166 Add "312" in column (6).

Add the following new entries:

UN	Name and Description	Class	Subsid-	UN	Special	Limited	Packagings	and IBCs	Portab	le tanks
No.		or division	iary Risks	packing group	provi- sions	quantities	Packing instruction	Special provi- sions	Portable tank instruction	Portable tank special provisions
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
3377	SODIUM PERBORATE MONOHYDRATE	5.1		III		5 kg	P002 IBC08 LP02	PP84 B3, B13	T1	
3378	SODIUM CARBONATE PEROXYHYDRATE	5.1		II		1 kg	P002 IBC08	PP84 B2, B4, B13	T1	
		5.1		III		5 kg	P002 IBC08 LP02	PP84 B3, B13	T1	
3379	DESENSITIZED EXPLOSIVE, LIQUID, N.O.S.	3		Ι	274 311	NONE	P099			
3380	DESENSITIZED EXPLOSIVE, SOLID, N.O.S.	4.1		I	274 311	NONE	P099			

Chapter 3.3

SP 133 Amend the existing special provision to read:

"If over-confined in packagings, this substance may exhibit explosive behaviour. Packagings authorized under packing instruction P409 are intended to prevent over-confinement. When a packaging other than those prescribed under packing instruction P409 is authorized by the competent authority of the country of origin in accordance with 4.1.3.7, the package shall bear an "EXPLOSIVE" subsidiary risk label unless the competent authority of the country of origin has permitted this label to be dispensed with for the specific packaging employed because test data have proved that the substance in this packaging does not exhibit explosive behaviour (see 5.4.1.5.5.1). The provisions of 7.1.3.1 shall also be then considered.".

SP 179 Amend special provision 179 to read:

"This designation shall be used for substances and mixtures which are dangerous to the aquatic environment or which are marine pollutants that do not meet the classification criteria of any other class or another substance within Class 9. This designation may also be used for wastes not otherwise subject to these Regulations but which are covered under the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal."

SP240 Add the following at the end of the existing special provision 240:

"Hybrid electric vehicles powered by both an internal combustion engine and wet batteries, sodium batteries or lithium batteries, transported with the battery(ies) installed shall be consigned under the entries UN 3166 "Vehicle, flammable gas powered" or UN 3166 "Vehicle, flammable liquid powered, as appropriate."

SP311 Add a new special provision to read as follows:

"311 Substances shall not be transported under this entry unless approved by the competent authority on the basis of the results of appropriate tests according to Part I of the Manual of Tests and Criteria. Packaging shall ensure that the percentage of diluent does not fall below that stated in the competent authority approval at any time during transport."

SP312 Add a new special provision 312 to read as follows:

"312 Vehicles that contain an internal combustion engine shall be consigned under the entries "Vehicle, flammable gas powered" or "Vehicle, flammable liquid powered", as appropriate. These entries include hybrid electric vehicles powered by both an internal combustion engine and wet batteries, sodium batteries or lithium batteries, transported with the battery(ies) installed."

PART 4

Chapter 4.1

4.1.1.15 Add a new paragraph 4.1.1.15 as follows:

"4.1.1.15 For plastics drums and jerricans, rigid plastics IBCs and composite IBCs with plastics inner receptacles, unless otherwise approved by the competent authority, the period of use permitted for the transport of dangerous substances shall be five years from the date of manufacture of the receptacles, except where a shorter period of use is prescribed because of the nature of the substance to be transported".

Renumber existing 4.1.1.15 and 4.1.1.16 as 4.1.1.16 and 4.1.1.17.

- 4.1.2.3 Delete this paragraph and renumber the remaining paragraphs accordingly.
- 4.1.4.1 **P002** Add a new special packing provision PP83 to read as follows:
 - "PP84 For UN 3377 and 3378, metal and rigid plastics packagings shall be vented.".
 - **P403** Add a new special packing provision PP83 to read as follows:
 - "PP83 For UN No. 2813, packing group I, waterproof bags containing not more than 20 g of substance for the purposes of heat formation may be packaged for transport. Each waterproof bag shall be sealed in a plastics bag and placed within a further plastics bag. No outer packaging shall contain more than 400 g of substance. Water or liquid that may react with the substance shall not be included in the packaging."
 - **P407** In the text before "Additional requirements", amend the beginning of the second sentence to read "The maximum gross mass of the package shall not exceed...".
 - **P903** Add the following paragraph after the sentence "Packaging conforming to the packing group II performance level.":

"In addition, batteries employing a strong, impact resistant outer casing of a gross mass of 12 kg or more, and assemblies of such batteries, may be packed in strong outer packagings, in protective enclosures (e.g., in fully enclosed or wooden slatted crates) unpackaged or on pallets. Batteries shall be secured to prevent inadvertent movement, and the terminals shall not support the weight of other superimposed elements.".

4.1.4.2 **IBC08** Add a new special packaging provision B13 to read:

"B13 For UN 3377 and 3378, metal and rigid plastics IBCs shall be vented.".

PART 5

Chapter 5.5

5.5.1.2 Delete the whole paragraph.

PART 6

Chapter 6.1

6.1.3.6.1 Insert the following new paragraph 6.1.3.6.1 between the first and the second paragraph of the existing 6.1.3.6:

"6.1.3.6.1 Packagings manufactured with recycled plastics material as defined in 1.2.1 shall be marked "REC". This mark shall be placed near the mark prescribed in 6.1.3.1."

The second paragraph of 6.1.3.6 becomes new 6.1.3.6.2*.

^{*} Note by the secretariat: As 6.1.3.6.1 and 6.1.3.6.2 do not address the same subject, it would seem preferable to insert the new paragraph as 6.1.3.6 and to renumber the existing 6.1.3.6 to 6.1.3.11 accordingly.

6.1.3.9 In the examples, replace:

"4G/Y145/S/83"	with	"4G/Y145/S/02"
"lAl/Y1.4/150/83"	with	"lAl/Y1.4/150/98"
"1A2/Y150/S/83"	with	"1A2/Y150/S/01"
"4HW/Y136/S/83"	with	"4HW/Y136/S/98"
"1A2/Y/100/91"	with	"1A2/Y/100/01"

6.1.3.10 In the examples, replace:

"1A1/Y1.4/150/83	with	"1A1/Y1.4/150/97
NL/RB/85 RL"		NL/RB/01 RL"
"1A2/Y150/S/83	with	"1A2/Y150/S/99
USA/RB/85 R"		USA/RB/00 R"

6.1.3.11 In the example, replace:

"1A2T/Y300/S/94" with "1A2T/Y300/S/01"

6.1.4.1.1 Add a Note to read as follows:

"NOTE: In the case of carbon steel drums, "suitable" steels are identified in ISO 3573:1999 "Hot rolled carbon steel sheet of commercial and drawing qualities" and ISO 3574:1999 "Cold-reduced carbon steel sheet of commercial and drawing qualities". For carbon steel drums below 100 litres "suitable" steels in addition to the above standards are also identified in ISO 11949:1995 "Cold-reduced electrolytic tinplate", ISO 11950:1995 "Cold-reduced electrolytic chromium/chromium oxide-coated steel" and ISO 11951:1995 "Cold-reduced blackplate in coil form for the production of tinplate or electrolytic chromium/chromium-oxide coated steel.".

(This text replaces the text proposed in document ST/SG/AC.10/C.3/38/Add.1 for the same paragraph).

6.1.4.8.2 Delete this paragraph and renumber the remaining paragraphs accordingly.

Chapter 6.3

6.3.1.2 In the example, replace:

"4G/CLASS 6.2/92" with "4G/CLASS 6.2/01"

Chapter 6.5

Assign paragraph number "6.5.2.1.2" to the list of examples under the heading "Examples of markings for various types of IBC in accordance with (a) to (h) above:" and in the examples, replace:

"11A/Y/02 89"	with	"11A/Y/02 99"
"13H3/Z/03 89"	with	"13H3/Z/03 01"
"31H1/Y/04 89"	with	"31H1/Y/04 99"
"31HA1/Y/05 19"	with	"31HA1/Y/05 01"
"11C/X/01 93"	with	"11C/X/01 02"

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Renumber subsequent paragraphs accordingly.

Chapter 6.6

6.6.3.2 In the examples, replace:

"96/N/PQRS" with "01/N/PQRS" "95/D/ABCD 987" with "02/D/ABCD 987" "06 97/S/1999" with "06 01/S/1999"

APPENDIX A and APLHABETICAL INDEX

Amend Appendix A and the alphabetical index in accordance with the amendments adopted for Chapter 3.2.
