**UNITED NATIONS**

# ST

**Secretariat**

Distr.
GENERAL

ST/SG/AC.10/C.3/2001/15
12 April 2001

ORIGINAL : ENGLISH

**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**
**(Nineteenth session, 2-6 July 2001, agenda item 7 (c))**

## LISTING AND CLASSIFICATION

### Classification of substances hazardous for the aquatic environment

### Transmitted by the expert from Belgium

## 1. Background

- During the UN Committee meeting of December 2000, comments were asked on document UN/CETDG/21/INF.33, concerning the classification of substances hazardous to the environment by reason of aquatic pollution.

- After careful study of this document, Belgium decided to propose an alternative text for sub-chapter 2.9.2. Detailed comments would lead to a lengthy and complicated paper, whilst the proposed changes result in a much simpler text than the one contained in INF. 33.

## 2. Overview of the major changes with respect to UN/CETDG/21/INF.33

- The original proposal is limited to pure substances. Belgium is of the opinion that this limitation is not necessary and that it would diminish the utility of this chapter to such an extent that its introduction would hardly be worthwhile.

- Sub-paragraph 2.9.2.1.1 is purely informative and should therefore not be part of the model regulations themselves. In the Belgian document, this paragraph has been transformed into a note that precedes the already existing ones giving the rationale for the scheme.

- Each of the paragraphs 2.9.2.3, 2.9.2.5 and 2.9.2.6 tells us what substances shall be categorised as hazardous to the aquatic environment for transport purposes. Exactly the same information is presented three times, in a different manner. This is unnecessary and very confusing to the reader. To add to the confusion, another criterion (for rapid degradability) is interceded in 2.9.2.4. In the Belgian proposal, 2.9.2.4 RAPID DEGRADABILITY is transferred to the end of 2.9.2.2.5 (Environmental degradation) and paragraphs 2.9.2.3, 2.9.2.5 and 2.9.2.6 are combined.

- The subdivision in chronic I, chronic II and acute I is of no practical use for transport purposes. Therefore, the paragraph that combines 2.9.2.3, 2.9.2.5 and 2.9.2.6 is based on the first alternative of flow chart 2.9.2.6.

- In UN/CETDG/21/INF.33, the proposal for paragraph 10 is not very satisfactory. The phrase "Additional labelling is not always specified ... " lacks clarity and is contradictory to 5.2.2.1.2. The "hazardous to the aquatic environment" risk is to be treated in the same manner as the other risks.

- Annex A (the OECD classification model) contains parts that are not applicable in transport, and leads to confusion. It is better not to reproduce it in the modal regulations.

## 3. Proposal

Introduce the following sub-chapter 2.9.2 in the Modal regulations:

"**2.9.2 Classification of substances dangerous to the environment by reason of aquatic pollution**

### 2.9.2.1 Purpose, basis and applicability

The scheme for classifying substances for the hazards they present to the aquatic environment is intended specifically for use with chemical substances, including preparations or other mixtures. While the scheme is intended to apply to all substances, it is recognised that in some cases, e.g. metals or poorly soluble inorganic compounds, special guidance will be necessary [1].

### 2.9.2.2 Definitions and data requirements

2.9.2.2.1 The classification of substances hazardous to the environment by reason of aquatic pollution is based on their acute aquatic toxicity, their potential for or actual bioaccumulation, their degradability (biotic or abiotic) for organic chemicals and their chronic aquatic toxicity.
While data from internationally harmonized test methods are preferred, in practice data from national methods may also be used where they are considered as equivalent. In general, it has been agreed that freshwater and marine species toxicity data can be considered as equivalent data and are preferably to be derived using OECD Test Guidelines or equivalent according to the principles of good laboratory practice (GLP). Where such data are not available, classification shall be based on the best available data.

2.9.2.2.2 *Acute aquatic toxicity* shall normally be determined using a fish 96 hour $LC_{50}$ (OECD Test Guideline 203 or equivalent), a crustacean species 48 hour $EC_{50}$ (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour $ErC_{50}$ (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.

[1] *Special guidance on data interpretation is provided in the OECD Guidance Document.*

2.9.2.2.3 The *potential for or actual 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. This BCF shall be determined according to OECD Test Guideline 305.

2.9.2.2.4 *Environmental Degradation for organic chemicals* may be biotic or abiotic (e.g. hydrolysis) and the criteria used reflect this fact. 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 degradability [2].

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 :
- tests based on dissolved organic carbon : 70 % of theoretical maximum ;
- tests based on oxygen depletion or carbon dioxide generation: 60 % of theoretical maximum.

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 $ 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.

2.9.2.2.6 *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 Procedure for classifying a pure substance dangerous to the aquatic environment for transport purposes**

***Note 1:*** *The scheme for classifying substances for the hazards they present to the aquatic environment is in accordance with the criteria for the classification of substances hazardous to the aquatic environment presented in the OECD paper "Harmonised Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances" as endorsed by the 28th Joint meeting of the OECD Chemicals Committee and Working Party on Chemicals. The aquatic environment may be considered in*

[2] *Special guidance on data interpretation is provided in the OECD Guidance Document.*

*terms of the aquatic organisms and the aquatic ecosystem of which they are part (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.). The basis, therefore, of the identification of hazard is the aquatic toxicity of the substance, although this may be modified by taking account of the degradation and bioaccumulation behaviour.*

***Note 2:*** *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 3****: Acute toxicity represents a key property in defining the hazard where transport of large quantities of a substance may give rise to short-term dangers arising from accidents or major spillages. Hazards categories up to $LC_{50}$ or $EC_{50}$ values of 10 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 $EC_{50}$ # 0.1 mg/L in certain regulatory systems such as that defined by MARPOL 73/78 Annex II concerning bulk transport by sea.*

***Note 4:*** *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 # 1 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 5:*** *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 6:*** *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 7:*** *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 8:*** *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 will be developed on data interpretation for these substances and how the data should be used when applying the classification criteria.*

***Note 9:*** *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.*

***Note 10:*** *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 half-lives and these may also be used in defining rapid degradation. Details regarding the interpretation of these data are further elaborated in the OECD Guidance Document. 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.*

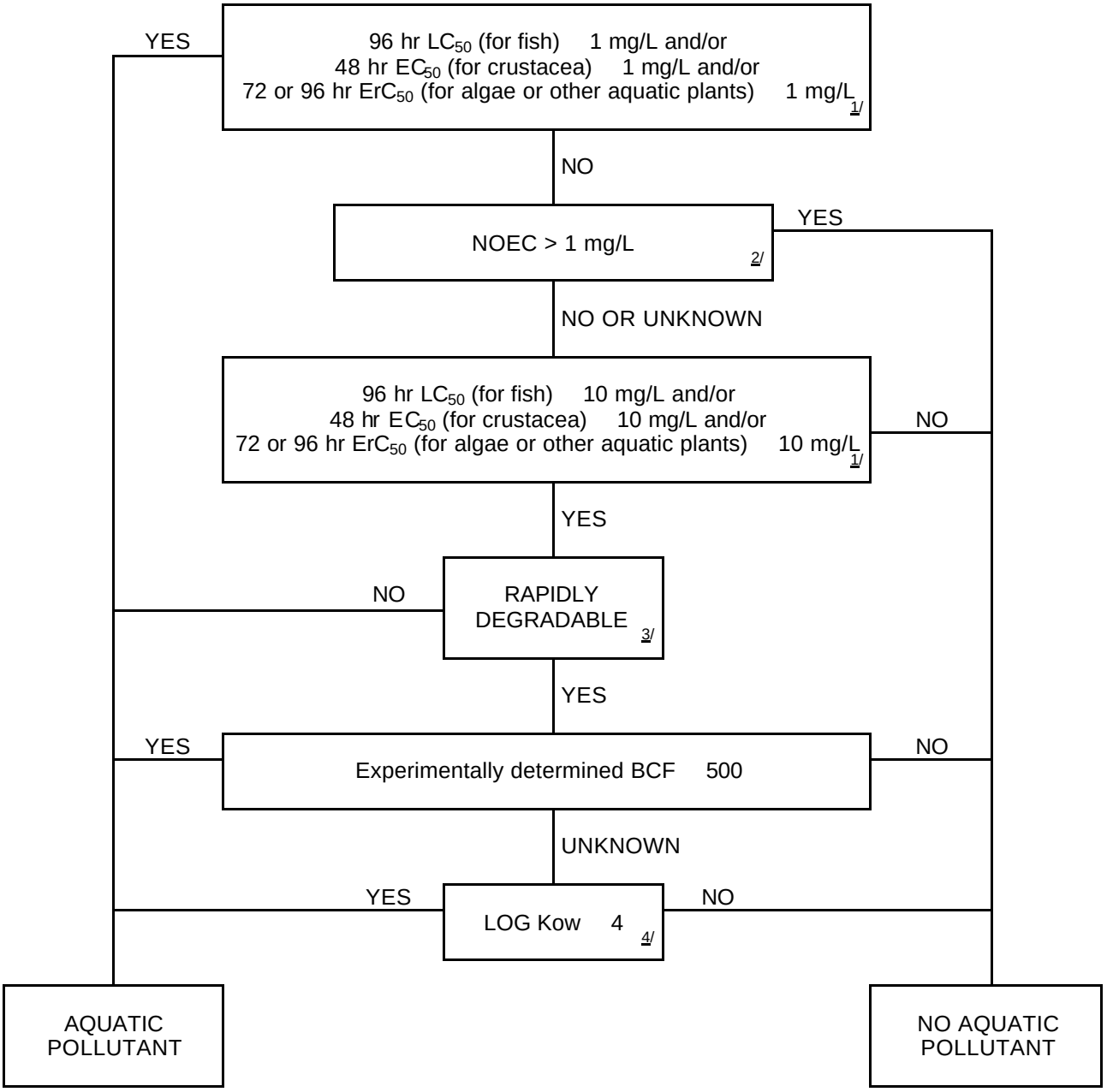
***Note 11:*** *The criteria used reflect the fact that environmental degradation may be biotic or abiotic (e.g. hydrolysis). Equally, failing the ready biodegradability criteria in the OECD tests does not mean that the substance will not be degraded rapidly in the real environment. Thus, where such 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 2.9.2.2.4. 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 OECD Guidance Document.*

***Note 12:*** *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 will be provided on how these data for such substances may be used in meeting classification criteria requirements.*

***Note 13****: 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 OECD Guidance Document.*

***Note 14:*** *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 characterized. 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.*

2.9.2.3.1 Substances shall be categorised as 'hazardous to the aquatic environment' for transport purposes, according to the following classification scheme:



[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.*

[2/] *NOEC values in mg/L for fish or crustacea or other recognised measures for long-term toxicity (it is intended to develop the system further to include chronic toxicity data).*

[3/] *Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation.*

[4/] *Provided log Kow is an appropriate descriptor for the bioaccumulation potential of the substance. Measured log Kow values take precedence over estimated values.*

### 2.9.2.4 Procedure for classifying preparations and mixtures dangerous to the aquatic environment for transport purposes

Preparations and mixtures shall be categorised as dangerous to the aquatic environment for tansport purposes in the same way as pure substances. If this determination is not possible without disproportionate cost or effort (as for some kind of wastes), the solutions or mixtures shall be categorised on the basis of the applicable classification criteria given in [ENV/JM/HCL(2000)9/REV9] of the OECD.

### 2.9.2.5 Proper shipping name and packing group

Substances, preparations and mixtures

- of which it is demonstrated according to the classification scheme of 2.9. that they are hazardous to the aquatic environment, and
- which are not otherwise classified under these Model Regulations, shall be designated :

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

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

They shall be assigned to packing Group III.

## CONSEQUENTIAL AMENDMENTS

United Nations Recommendations on the Transport of Dangerous Goods

**Chapter 1.2.1**

Add the definition : "*OECD Guidance Document* means [correct reference to be included].

**Chapter 3.2**

In the Dangerous Goods List, a code shall appear in column (4) to indicate which substances shall bear the new mark/label.

**Chapter 3.3**

Amend special provision 179 to read:

> "This designation shall be used for substances 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."

**Chapter 5**

The adopted mark/label of the ILO working group shall be added.

_____