

**Committee of Experts
on the Transport of Dangerous Goods
(Twentieth session, 7-16 December 1998)**

ENVIRONMENTALLY HAZARDOUS SUBSTANCES

Transmitted by the Expert from the United Kingdom

Introduction

1. In document ST/SG/AC.10/C.3/R.664 dated 22 September 1995, the expert from the United Kingdom made proposals for the inclusion in the UN Recommendations of provisions for the transport of packaged environmentally hazardous substances, ie water pollutants. These proposals followed from an informal working group of the Committee of Experts held at the International Maritime Organization from 2-4 May 1995 (report in document ST/SG/AC.10/C.3/R.635).
2. After considering the proposals, the Committee preferred to await decisions in the context of the development of the globally harmonized system (GHS) of chemicals under UNCED Agenda 21, Chapter 19. The United Kingdom proposals have since remained in the agendas of the Sub-Committee and Committee.
3. The development of harmonized criteria for the classification of aquatic pollutants has been co-ordinated by the Organization for Economic Co-operation and Development (OECD). The seventh meeting of its Advisory Group on Harmonization of Classification and Labelling Systems met in Paris from 1-2 September 1998 and the eighth high level meeting of the Advisory Group was held from 3-4 September 1998. During those meetings, agreement was reached on the criteria to be used to define a number of biological parameters, including hazardous to the aquatic environment. It now has to be decided how far the OECD scheme is relevant to the transport of dangerous goods and how that should be included in the Model Regulations.
4. The expert from the United Kingdom therefore proposes that this subject should be included as a major new agenda item in the future work programme of the Committee for the biennium 1999-2000.
5. This paper replaces document ST/SG/AC.10/C.3/R.664. It contains a first draft of a new Chapter 2.9 and notes of many points that will need to be taken into account. The GHS scheme for this subject includes much explanatory text that will be inappropriate in Model Regulations but will have to be included, probably by means of Notes and Footnotes or, possibly, in the Manual of Tests and Criteria. The expert from the United Kingdom intends to develop these proposals in a new formal document to be submitted for discussion by the Sub-Committee in July 1999. All comments made in time to the Department of the Environment, Transport and the Regions (RH2) in London will be welcome.
6. The following points should be noted, in particular:
 - (a) The text has been kept as close as possible to the agreed text for the GHS. This will facilitate updating and adaptation to technical progress of the transport scheme as the GHS is developed.

- (b) There are references in the text to a Guidance Document which is currently being developed under the GHS. The timetable for and the status of this Document will have to be considered.
- (c) The proposals at this stage are applicable only to substances and will require amending/updating when the criteria applicable to mixtures/preparations under discussion by the ILO working group are agreed for inclusion in the GHS.
- (d) Consideration has been given to existing classification systems in current regulations, including the EU 'Supply and Use' scheme, the revised GESAMP hazard evaluation procedure, the IMO scheme for Marine Pollutants, the European Road and Rail Transport rules (RID/ADR), the Canadian and US pesticides systems and the US land transport requirements. The proposed system is for use for packaged dangerous goods in multimodal transport; elements of it may be used for 'bulk' land transport and for bulk marine transport under MARPOL 73/78 Annex II insofar as this uses aquatic toxicity.

7. Particular attention will have to be paid to developments in the context of the GHS, by the GESAMP and IMO in relation to MARPOL 73/78, Annexes II and III and the IBC Code.

8. It is for consideration whether the proper shipping names for UN 3077 and UN 3082 should be made specific to the aquatic environment, with Basel Convention wastes not otherwise dangerous in transport dealt with differently.

Draft Proposal

CHAPTER 2.9

2.9.2 CLASSIFICATION OF SUBSTANCES DANGEROUS 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 for the hazards they present to the aquatic environment is based on [the globally harmonised system]. 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. [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.

2.9.2.1.2. This scheme is intended specifically for use with chemical substances [and will be extended at a later stage to cover preparations or other mixtures such as formulated pesticides]. 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. [The Guidance Document prepared [under the globally harmonised system] covers issues such as data interpretation and the application of the criteria defined below to such substances. Considering the complexity of this endpoint and the breadth of the application of the scheme, the Guidance Document is an important element in the operation of the [harmonised] system].

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 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.

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 crustacean 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 or actual bioaccumulation** shall normally be determined by using the octanol/water partition coefficient, usually reported as a log K_{ow} 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 **Degradation** for organic chemicals may be biotic or abiotic (eg. hydrolysis) and the criteria used reflect this fact (see 2.9.2.6). 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. [Special guidance on data interpretation is provided in the Guidance Document].

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 CLASSIFICATION CATEGORIES AND CRITERIA

2.9.2.3.1 Substances meeting the following criteria shall be categorised as 'dangerous to the aquatic environment' for transport purposes, if they satisfy the criteria for Acute I (and Chronic I by default) or Chronic II. These criteria describe in detail the classification categories set out diagrammatically in 2.9.2.8.

Acute toxicity

Category: Acute I

Acute toxicity:

96 hr LC₅₀ (for fish) ≤1 mg/L and/or

48 hr EC₅₀ (for crustacea) ≤1 mg/L and/or

72 or 96hr ErC₅₀ (for algae or other aquatic plants) ≤1 mg/L.

Category: Acute I may be subdivided for some regulatory systems to include a lower band at LC₅₀ or EC₅₀ ≤0.1 mg/L.

Chronic toxicity

Category: Chronic I

Acute toxicity:

96 hr LC₅₀ (for fish) ≤1 mg/L and/or

48 hr EC₅₀ (for crustacea) ≤1 mg/L and/or

72 or 96hr ErC₅₀ (for algae or other aquatic plants) ≤1 mg/L

and the substance is not rapidly degradable and/or the log Kow ≥4 (unless the experimentally determined BCF <500).

Category: Chronic II

Acute toxicity

96 hr LC₅₀ (for fish) >1 to ≤10 mg/L and/or

48 hr EC₅₀ (for crustacea) >1 to ≤10 mg/L and/or

72 or 96hr ErC₅₀ (for algae or other aquatic plants) >1 to ≤10 mg/L

and the substance is not rapidly degradable and/or the log Kow ≥4 (unless the experimentally determined BCF <500), unless the chronic toxicity NOECs are > 1 mg/L.

2.9.2.4 RATIONALE FOR THE SCHEME

2.9.2.4.1 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.

2.9.2.4.2. 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 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 subdivided to include an additional category for acute toxicity LC_{50} or $EC_{50} \leq 0.1$ mg/L in certain regulatory systems such as that defined by MARPOL 73/78 Annex II concerning bulk transport by sea].

2.9.2.4.3 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 ≤ 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.

2.9.2.4.4. 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].

[2.9.2.4.5 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.]

2.9.2.5 [EXPLANATORY NOTES]

2.9.2.5.1 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 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 EC₅₀ is treated as an acute value for classification purposes. This EC₅₀ is normally based on growth rate inhibition. If only the EC₅₀ based on reduction in biomass is available, or it is not indicated which EC₅₀ is reported, this value may be used in the same way.

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

2.9.2.5.3 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.

2.9.2.5.4 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 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.

2.9.2.5.5 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 2.9.2.6. 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 Guidance Document].

2.9.2.5.6 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].

2.9.2.5.7 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 Guidance Document].

2.9.2.5.8 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]. [Reliable calculated toxicity and log Kow values shall be valuable in a safety net context.] [QSARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation].

2.9.2.6 RAPID DEGRADABILITY

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%

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 ≥ 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.

2.9.2.7 **Classification Scheme for Substances Dangerous in Transport to the Aquatic Environment (abridged OECD Table)**

Toxicity		Degradability (note 3)	Bioaccumulation (note 4)	Classification	
Acute (note 1)	Chronic (note 2)			Acute	Chronic
Box 1 value ≤ 1.00		Box 5	Box 6	<u>Acute I</u> Box 1	<u>Chronic I</u> 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 ≥ 500 or, if absent log Kow ≥ 4		<u>Chronic II</u> Boxes 2+5+6 Boxes 2+5 Boxes 2+6 Unless Box 7

Notes to the table:

- Note 1. Acute toxicity band based on LC₅₀ or EC₅₀ 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 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 judgement may 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 2. Chronic toxicity band based on 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.]
- 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 ≥ 500 or, if absent, a log Kow ≥ 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.

2.9.2.8 PROCEDURE FOR CLASSIFYING A SUBSTANCE DANGEROUS TO THE AQUATIC ENVIRONMENT WHEN TRANSPORTED IN PACKAGES

1. Is the substance dangerous to the aquatic environment?

2. Acute aquatic toxicity value $\geq 10\text{mg/L}$ (Box 2)
(if value $> 1\text{ mg/L}$ go directly to 5.)

No

Yes

3. Potential to bioaccumulate
 $\log K_{ow} \geq 4$ (unless $BCF < 500$)(Box 6)

Yes

No

4. Not readily degradable (Box 5)

Yes

3b. $NOEC > 1\text{ mg/L}$ (Box 7)

Yes

No

5. Acute aquatic toxicity value $\leq 1\text{mg/L}$ (Box 1)

Yes

Classified as dangerous to the aquatic environment

Not classified as dangerous to the aquatic environment

2.9.2.9 Substances dangerous to the aquatic environment not otherwise classified under these Regulations should be designated:

UN3077 [ENVIRONMENTALLY HAZARDOUS SUBSTANCE] SOLID, N.O.S. or

UN3082 [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

Amend paragraph 10 to read:

"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 dangerous to the aquatic environment are given in Chapter 2.9 of the Model Regulations."

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."
