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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
(Twentieth session, 3-12 December 2001, agenda item 11 (b))

GLOBAL HARMONIZATION OF SYSTEMS OF CLASSIFICATION AND LABELLING OF CHEMICALS

Health hazards and hazards to the environment

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 Model Regulations of provisions for the transport of packaged environmentally hazardous substances, i.e. 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 classification under UNCED Agenda 21, Chapter 19. The United Kingdom proposals have since remained in the agendas of the Sub-Committee and Committee and have undergone development as the Globally Harmonized System (GHS) endpoint criteria has progressed.

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. These have been 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 Chemicals Committee and the Working Party on Chemicals in November 1998 and subsequently by other working parties. The OECD table for the Classification Scheme for substances hazardous to the aquatic environment is reproduced at Annex A for ease of reference.

4. The expert from the United Kingdom therefore submitted Paper INF.10 to the December 1998 Committee of Experts meeting proposing 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. This was agreed by the Committee and the expert from the United Kingdom invited written comments on the draft proposal.

5. Paper ST/SG/AC.10/C.3/1999/27 replaced document ST/SG/AC.10/C.3/R.664 and took account of the few comments received. It contained a first draft of a new Chapter 2.9 and notes of many points that would need to be taken into account in future *(shown in italics)*. 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.

6. The following points were noted, in particular:

(a) The text had 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) Consideration had 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 was 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;

Particular attention has been paid to developments in the context of the GHS in other fora.

7. 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. Conversely, it should also be considered whether the aquatic environment be deemed the most sensitive and that these proposals automatically read across to substances presenting a hazard to the environment generally.

8. Document ST/SG/AC.10/C.3/1999/27 was considered by the Sub-Committee at its sixteenth and seventeenth sessions. At the seventeenth session it was concluded that text based on the United Kingdom proposal be adopted placing the flow chart in square brackets and taking account of editorial comments from the expert from Belgium in paper ST/SG/AC.10/C.3/1999/77. At the July 2000 meeting the United

Kingdom subsequently produced INF.8 which took account of the comments from the expert of Belgium in ST/SG/AC.10/C.3/1999/77 with text, which in the opinion of the expert from the United Kingdom was ready for incorporation in the Model Regulations. Experts however were not ready to adopt the suggested text but did agree that the Information Paper should remain on the table to allow other experts to make comments and undertake further work. At the December 2000 Committee meeting the United Kingdom produced INF.33, a revised version of the earlier INF.8, which took into account comments from the representative of the OECD. The Committee decided that a decision on this document should not be made until the next biennium and experts were invited in the meantime to send comments to the United Kingdom expert. Few comments were received and at the 19th session of the Sub-Committee in July 2001 the United Kingdom resubmitted its paper to the Sub-Committee as INF.7 to be considered in conjunction with the paper produced by the expert from Belgium, ST/SG/AC.10/C.3/2001/15, which attempted to incorporate criteria for mixtures. It was agreed at that meeting that it would be preferable that future work should be based on one document. The expert of the United Kingdom was invited to produce a revised paper based on INF.7 to include not only pure substances but also criteria for mixtures based on that recently produced by OECD.

The present paper ST/SG/AC.10/C.3/2001/39 which is being submitted by the expert from United Kingdom now includes criteria for mixtures based on OECD guidance. For ease of reference Annex B cross references the paragraphs of the United Kingdom proposal to those of Chapter 10 of the GHS Guidelines Document. The expert from the United Kingdom asks the Sub-Committee to agree to adopt the subsequent text in the Model Regulations.

Draft Proposal

CHAPTER 2.9

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 of the GHS Document. 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.[1] 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 necessary.[2]

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 LC_{50} (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC_{50} (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC_{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.

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,

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[1] *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.*

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

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.[3]

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 Acute I, Chronic I or Chronic II. These criteria describe in detail the classification categories set out diagrammatically in 2.9.2.7.

Acute toxicity

Category: Acute I

Acute toxicity:

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.

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

Chronic toxicity

Category: Chronic I

Acute toxicity:

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

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 LC_{50} (for fish)	>1 to ≤ 10 mg/L and/or
48 hr EC_{50} (for crustacea)	>1 to ≤ 10 mg/L and/or
72 or 96hr ErC_{50} (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.

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

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 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 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.*

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 Document 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)) ³ 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 9. *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 Annex 9 of the GHS 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 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 Document.*

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 Document 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 Document.*

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.

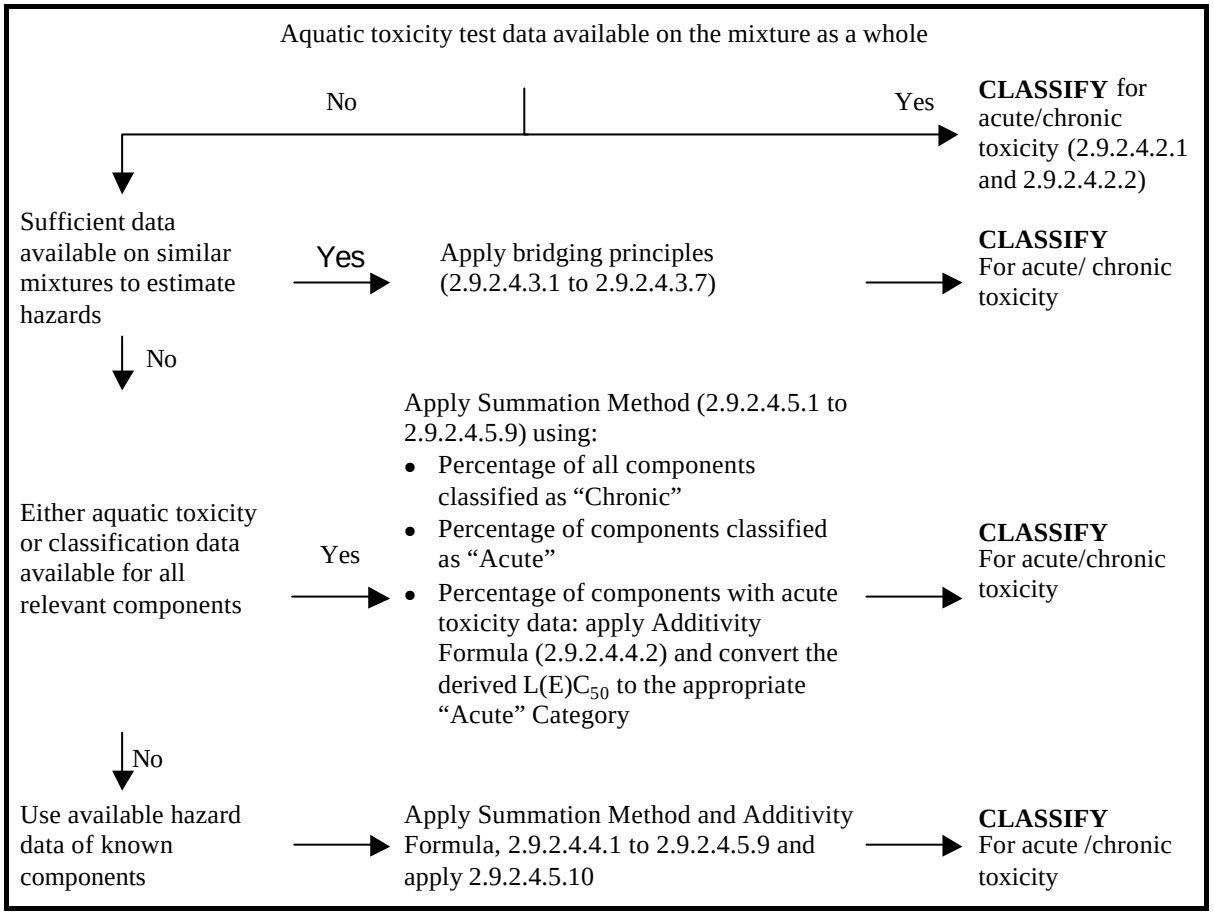
> The “relevant components” of a mixture are those which are present in a concentration of 1% (w/w) or greater, unless there is a presumption (e.g. in the case of highly toxic components) that a component present at less than 1% can still be relevant for classifying the mixture for aquatic environmental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

Figure 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 (LC_{50} or EC_{50}) 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.

- $L(E)C_{50}$ (LC_{50} or EC_{50}) of the tested mixture ≤ 1mg/L and NOEC of the tested mixture ≤ 1.0 mg/L or unknown:
  → Classify mixture as Category Acute I

→ 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).

- $L(E)C_{50}$ of the tested mixture ≤ 1mg/L and NOEC of the tested mixture > 1.0 mg/L:
  → Classify mixture as Category Acute I
  → 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.
- $L(E)C_{50}$ of the tested mixture >1mg/L, or above the water solubility, and NOEC of the tested mixture ≤ 1.0mg/L or unknown:
  → No need to classify for acute toxicity
  → 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.
- $L(E)C_{50}$ of the tested mixture >1mg/L, or above the water solubility, and NOEC of the tested mixture > 1.0 mg/L:
  → 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 + B
ii.) 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 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.

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

where:

C_i	=	concentration of component i (weight percentage)
$L(E)C_{50i}$	=	(mg/L) LC_{50} or EC_{50} for component i
η	=	number of components
$L(E)C_m$	=	$L(E)$-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

2.9.2.4.5.1 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.

2.9.2.4.5.2 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 Document Chapter 1.3 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 cut-off 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 Table 2 below.

Table 2: Classification of a mixture for acute hazards, based on summation of classified components.

Sum of components classified as:		Mixture is classified as:
Acute I × M[1)]	>25%	Acute I

1) 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 Table 3 below.

Table 3: Classification of a mixture for chronic hazards, based on summation of classified components

Sum of components classified as:		Mixture is classified as:
Chronic I × M[1)]	>25%	Chronic I
(M × 10 × Chronic I)+Chronic II	>25%	Chronic II

1) for explanation of the M factor, see 2.9.2.4.5.9

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 and the concentration of "Chronic I" in the left column of Table 3 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 4 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 4: Multiplying factors for highly toxic components of mixtures

L(E)C50 value	Multiplying factor (M)
$0.1 < L(E)C_{50}$ 1	1
$0.01 < L(E)C_{50} \leq 0.1$	10
$0.001 < L(E)C_{50} \leq 0.01$	100
$0.0001 < L(E)C_{50} \leq 0.001$	1000
$0.00001 < L(E)C_{50} \leq 0.0001$	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;

- 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 or mixture 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 ENVIRONMENT[4]

<table>
<tr><th colspan="2">Toxicity</th><th rowspan="2">Degradability (note 3)</th><th rowspan="2">Bioaccumulation (note 4)</th><th colspan="2">Classification</th></tr>
<tr><th>Acute (note 1)</th><th>Chronic (note 2)</th><th>Acute</th><th>Chronic</th></tr>
<tr><td>Box 1

value ≤1.00</td><td rowspan="2"></td><td rowspan="2">Box 5

lack of rapid degradability</td><td rowspan="2">Box 6

BCF ≥ 500 or, if absent log Kow ≥ 4</td><td><u>Acute I</u>

Box 1</td><td><u>Chronic I</u>

Boxes 1+5+6
Boxes 1+5
Boxes 1+6</td></tr>
<tr><td>Box 2

1.0 < value ≤ 10.0</td><td rowspan="2"></td><td rowspan="2"><u>Chronic II</u>

Boxes 2+5+6
Boxes 2+5
Boxes 2+6
Unless Box 7</td></tr>
<tr><td></td><td>Box 7

value > 1.00</td></tr>
</table>

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.

Note 2. Chronic toxicity band based on NOEC values in mg/L for fish or crustacea or other recognised measures for long-term toxicity[5].

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.

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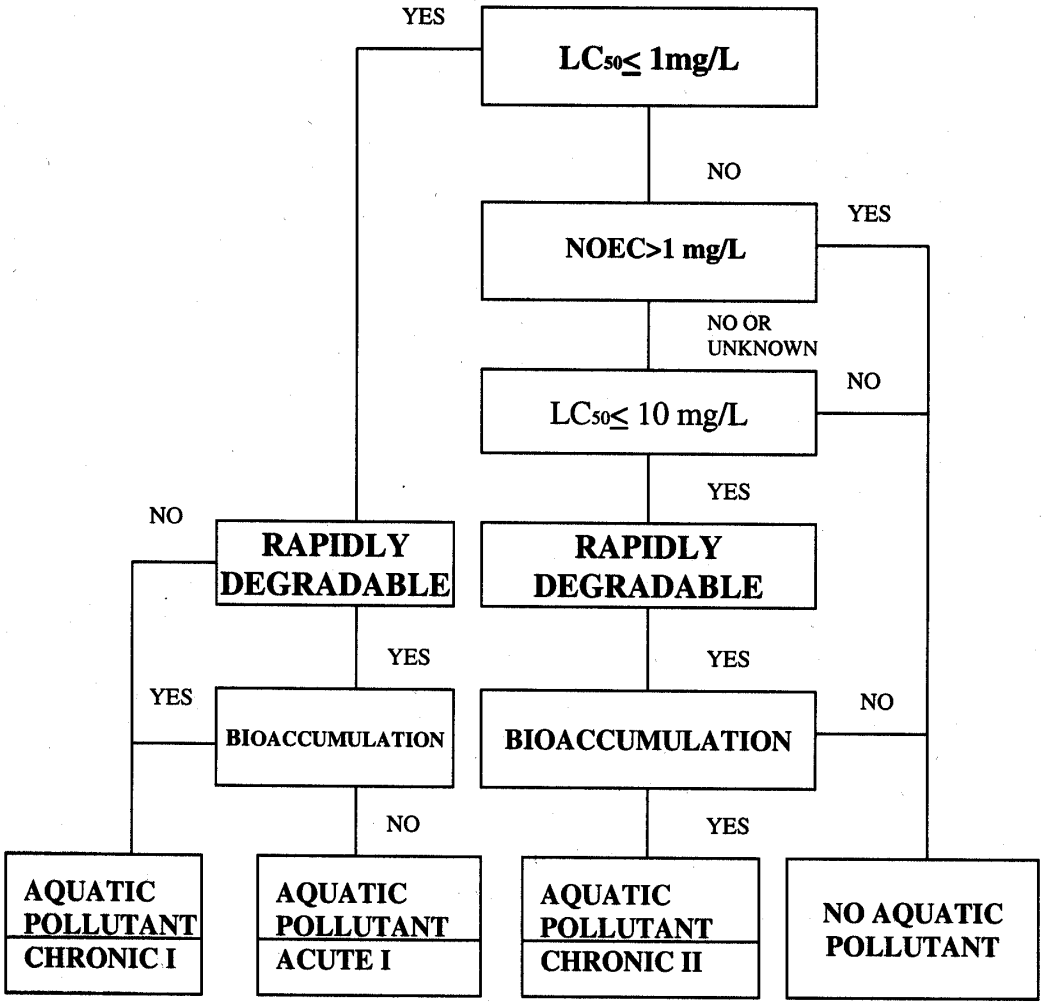
[4] *Abridged OECD table*

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

2.9.2.7 Classification Flow Chart



Procedure for classifying a substance dangerous to the aquatic environment when transported in packages

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.

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 and mixtures 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 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."

ANNEX A

Annex 2: Classification scheme for substances hazardous to the aquatic environment

Toxicity		Degradability (note 3)	Bioaccumulation (note 4)	Classification categories	
Acute (note 1)	**Chronic (note 2)**			**Acute**	**Chronic**
Box 1 value ≤ 1.00		Box 5	Box 6	Class: Acute I Box 1	Class: Chronic I Boxes 1+5+6 Boxes 1+5 Boxes 1+6
Box 2 1.00< value ≤ 10.0		Lack of rapid degradability	BCF ≥ 500 or, if absent log Kow ≥4	Class: Acute II Box 2	Class: Chronic II Boxes 2+5+6 Boxes 2+5 Boxes 2+6 Unless Box 7
Box 3 10.0< value ≤100				Class: Acute III Box 3	Class: Chronic III Boxes 3+5+6 Boxes 3+5 Boxes 3+6 Unless Box 7
Box 4 No acute toxicity (note 5)	Box 7 value>1.00				Class: Chronic IV Boxes 4+5+6 Unless Box 7

Notes to the table:

Note 1a. Acute toxicity band based on L(E)C-50 values in mg/L for fish, crustacea and/or algae or other aquatic plants (or QSAR estimation if no experimental data).

Note 1b Where the algal toxicity ErC-50 [= EC-50 (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgement should be used in deciding if classification should be applied. Classification should be based on the ErC-50. In circumstances where the basis of the EC-50 is not specified and no ErC-50 is recorded, classification should be based on the lowest EC-50 available.

Note 2a. Chronic toxicity band based on NOEC values in mg/L for fish or crustacea or other recognised measures for long-term toxicity.

Note 2b. It is the intention that the system be further developed 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.

Note 5. "No acute toxicity" is taken to mean that the L(E)C-50 is above the water solubility. Also for poorly soluble substances, (w.s. < 1.00 mg/L), where there is evidence that the acute test would not have provided a true measure of the intrinsic toxicity.

* * *

ANNEX B to ST/SG/AC.10/C.3/2001/39

Experts considering the proposals outlined in 2.9.2 onwards in ST/SG/AC.10/C.3/2001/39 should note that these correspond to text found in Chapter 10, Hazardous to the Aquatic Environment, in the GHS Document. In order to assist consideration of this proposal the expert from the United Kingdom, lists below in tabular form the cross references to the paragraphs in the UK's proposal and Chapter 10 of the GHS document.

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