UNITED NATIONS **ST**

Secretariat

Distr.
GENERAL

ST/SG/AC.10/C.4/2007/10
20 September 2007

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 Globally Harmonized System of Classification and Labelling of Chemicals

Fourteenth session,
Geneva, 12-14 December 2007
Item 2 (c) of the provisional agenda

UPDATING OF THE SECOND REVISED EDITION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Environmental hazards

Revision of Chapter 4.1: Consequential amendments to Annex 9 (sections A9.1 to A9.3) and Appendix VI

Transmitted by the Organization for Economic Co-operation and Development (OECD) [*/]

This document presents the proposal for revision of Annex 9 (Sections A9.1 to A9.3 and Appendix VI) as a consequence of proposed changes to Chapter 4.1 (circulated as documents ST/SG/AC.10/2007/8 and UN/SCEGHS/14/INF.2) in order to accommodate chronic toxicity to aquatic organisms for assigning a chronic hazard category.

Explanatory notes and the proposal showing the changes in visible mode are available as information documents UN/SCEGHS/14/INF.4 and UN/SCEGHS/14/INF.3 respectively.

[*/] In accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.4/24, Annex 2 and ST/SG/AC.10/34, para. 14) (Tasks assigned to OECD in relation to health hazards and hazards to the environment).

Note by the UNECE secretariat:

The OECD secretariat submitted a full revised text of sections A9.1 to A9.3 of Annex 9. However, due to the length of the text, and in accordance with the United Nations rules concerning the limitation of documentation, the secretariat reproduces only the paragraphs which include modifications.

This document has been divided into four parts, as follows:

- *Part 1: Amended paragraphs in Annex 9, section A9.1;*
- *Part 2: Amended paragraphs in Annex 9, section A9.2;*
- *Part 3: Amended paragraphs in Annex 9, section A9.3;*
- *Part 4: Proposed amendments to Annex 9, Appendix VI.*

PART 1:

AMENDED PARAGRAPHS IN ANNEX 9, SECTION A9.1

A9.1, A9.1.1 and A9.1.2 *(unchanged)*

A9.1.3 Although limited in scope, it is widely accepted that this compartment is both vulnerable, in that it is the final receiving environment for many harmful substances, and the organisms that live there are sensitive. It is also complex since any system that seeks to identify hazards to the environment must seek to define those effects in terms of wider effects on ecosystems rather than on individuals within a species or population. As will be described in detail in the subsequent sections, a limited set of specific properties of chemical substances have been selected through which the hazard can be best described: acute aquatic toxicity; chronic aquatic toxicity; lack of degradability; and potential or actual bioaccumulation. The rationale for the selection of these data as the means to define the aquatic hazard will be described in more detail in Section A9.2.

A9.1.4 This annex is limited, at this stage, to the application of the criteria to chemical substances. The term “substances” covers a wide range of chemicals, many of which pose difficult challenges to a classification system based on rigid criteria. The following sections will thus provide some guidance as to how these challenges can be dealt with based both on experience in use and clear scientific rationale. While the harmonized criteria apply most easily to the classification of individual substances of defined structure (see definition in Chapter 1.2), some materials that fall under this category are frequently referred to as “complex mixtures”. In most cases they can be characterized as a homologous series of substances with a certain range of carbon chain length/number or degree of substitution. Special methodologies have been developed for testing which provides data for evaluating the intrinsic hazard to aquatic organisms, bioaccumulation and degradation. More specific guidance is provided in the separate sections on these properties. For the purpose of this Guidance Document, these materials will be referred to as “complex substances” or “multi-component substances”.

A9.1.5 Each of these properties (i.e. acute aquatic toxicity, chronic aquatic toxicity, degradability, bioaccumulation) can present a complex interpretational problem, even for experts. While internationally agreed testing guidelines exist and should be used for any and all new data produced, many data usable in classification will not have been generated according to such standard tests. Even where standard tests have been used, some substances, such as complex substances, hydrolytically unstable substances, polymers etc, present difficult interpretational problems when the results have to be used within the classification scheme. Thus data are available for a wide variety of both standard and non-standard test organisms, both marine and freshwater, of varying duration and utilizing a variety of endpoints. Degradation data may be biotic or abiotic and can vary in environmental relevance. The potential to bioaccumulate can, for many organic chemicals, be indicated by the octanol-water partition coefficient. It can however be affected by many other factors and these will also need to be taken into account.

A9.1.6 and A9.1.7 *(unchanged)*

A9.1.8 Secondly, the guidance will provide detailed expert advice on the interpretation of data derived from the available databases, including how to use non-standard data, and specific quality criteria that may apply for individual properties. The problems of data interpretation for “difficult substances”, those substances for which standard testing methods either do not apply or give difficult interpretational problems, will be described and advice provided on suitable solutions. The emphasis will be on data interpretation rather than testing since the system will, as far as possible, rely on the best available existing data and data required for regulatory purposes. The four core properties, acute and chronic

aquatic toxicity (Section A9.3), degradability (Section A9.4) and bioaccumulation (Section A9.5) are treated separately.

A9.1.9 *(unchanged)*

A9.1.10 For many organic substances, the testing and interpretation of data present no problems when applying both the relevant OECD Guideline and the classification criteria. There are a number of typical interpretational problems, however, that can be characterized by the type of substance being studied. These are commonly called “difficult substances”:

(a) poorly soluble substances: these substances are difficult to test because they present problems in solution preparation, and in concentration maintenance and verification during aquatic toxicity testing. In addition, many available data for such substances have been produced using “solutions” in excess of the water solubility resulting in major interpretational problems in defining the true $L(E)C_{50}$ or NOEC for the purposes of classification. Interpretation of the partitioning behaviour can also be problematic where the poor solubility in water and octanol may be compounded by insufficient sensitivity in the analytical method. Water solubility may be difficult to determine and is frequently recorded as simply being less than the detection limit, creating problems in interpreting both aquatic toxicity and bioaccumulation studies. In biodegradation studies, poor solubility may result in low bioavailability and thus lower than expected biodegradation rates. The specific test method or the choice of procedures used can thus be of key importance;

(b) unstable substances: such substances that degrade (or react) rapidly in the test system present both testing and interpretational problems. It will be necessary to determine whether the correct methodology has been used, whether it is the substance or the degradation/reaction product that has been tested, and whether the data produced is relevant to the classification of the parent substance;

A9.1.10 (c) to (j) *(unchanged)*

A9.1.11 These represent some of the problems encountered in establishing the adequacy of data, interpreting the data and applying that data to the classification scheme. Detailed guidance on how to deal with these problems, as well as other issues related will be presented in the following sections. The interpretation of data on acute and on chronic aquatic toxicity will be covered in Section A9.3. This section will deal with the specific interpretational problems encountered for the above “difficult substances”, including providing some advice on when and how such data can be used within the classification scheme. Also covered will be a general description of the test data used and the testing methodologies suitable for producing such data.

A9.1.12 to A9.1.16 *(unchanged)*

PART 2:

AMENDED PARAGRAPHS IN ANNEX 9, SECTION A9.2

A9.2 The harmonized classification scheme

A9.2.1 ***Scope***

The criteria were developed taking into account existing systems for hazard classification, such as EU- Supply and Use System, the Canadian and US Pesticide systems, GESAMP hazard evaluation procedure, IMO Scheme for Marine Pollutant, the European Road and Rail Transport Scheme (RID/ADR), and the US Land Transport. These systems include supply and subsequent use of chemicals, the sea transport of chemical substances as well as transport of chemical substances by road and rail. The harmonized criteria are therefore intended to identify hazardous chemicals in a common way for use throughout all these systems. To address the needs for all different sectors (transport, supply and use) it was necessary to create two different sub-classes, one sub-class for acute aquatic hazards, consisting of three categories and one sub-class for long-term aquatic hazards, consisting of 4 categories. The Acute classification sub-class makes provision for two acute hazard categories (Acute 2 and 3) not normally used when considering packaged goods. For substances transported in bulk, there are a number of regulatory decisions that can uniquely arise because of the bulk quantities being considered. For these situations, for example where decisions are required on the ship type to be used, consideration of all acute hazard categories as well as the long-term hazard categories are considered important. The following paragraphs describe in detail the criteria to be used in defining each of these hazard categories.

A9.2.2 ***Classification categories and criteria***

The hazard categories for acute and chronic aquatic toxicity and their related criteria are set out in Chapter 4.1, section 4.1.2 and Table 4.1.1.

A9.2.3 ***Rationale***

A9.2.3.1 The harmonized system for classification recognizes that the intrinsic hazard to aquatic organisms is represented by both the acute and chronic or long-term toxicity of a substance, the relative importance of which is determined by the specific regulatory regimes in operation. Distinction can be made between the acute hazard and the chronic hazard and therefore hazard classes are defined for both properties representing a gradation in the level of hazard identified. Clearly the hazard identified by Chronic Category 1 is more severe than Chronic Category 2. Since the acute hazard and long-term hazard represent distinct types of hazard, they are not comparable in terms of their relative severity. Both hazard sub-classes should be applied independently for the classification of substances to establish a basis for all regulatory systems.

A9.2.3.2 The principal hazard classes defined by the criteria relate largely to the potential for chronic hazard. This reflects the overriding concern with respect to chemicals in the environment, namely that the effects caused are usually sub-lethal, e.g. effects on reproduction, and caused by longer-term exposure. While recognizing that the long-term hazard represents the principal concern, particularly for packaged goods where environmental release would be limited in scope, it must also be recognized that chronic toxicity data are expensive to generate and generally not readily available for most substances. On the other hand, acute toxicity data are frequently readily available, or can be generated to highly standardised protocols. It is this acute toxicity which has therefore been used as the core property in defining both the acute and the long-term hazard if no adequate chronic test data are available.

Nevertheless, it has been recognized that chronic toxicity data, if available, should be preferred in defining the long-term hazard category.

A9.2.3.3 The combination of chronic toxicity and intrinsic fate properties reflects the potential hazard of a chemical. Substances that do not rapidly degrade have a higher potential for longer term exposures and therefore should be classified in a more severe category than substances which are rapidly degradable (see A9.3.3.2.2).

A9.2.3.4 While recognizing that acute toxicity itself is not a sufficiently accurate predictor of chronic toxicity to be used solely and directly for establishing hazard, it is considered that, in combination with either a potential to bioaccumulate (i.e. a log Kow ≥ 4 unless BCF <500) or potential longer-term exposure (i.e. lack of rapid degradation) it can be used as a suitable surrogate for classification purposes. Substances that show acute toxicity and also bioaccumulate to a significant degree will normally show chronic toxicity at a significantly lower concentration. Equally substances that do not rapidly degrade have a higher potential for giving rise to longer term exposures which again may result in long-term toxicity being realized. Thus, for example, in absence of adequate chronic test data Category Chronic 1 should be assigned if either of the following criteria are met:

(a) $L(E)C_{50}$ for any appropriate aquatic species ≤1 mg/l and a potential to bioaccumulate (log K_{ow} ≥ 4 unless BCF <500);

(b) $L(E)C_{50}$ for any appropriate aquatic species ≤1 mg/l and a lack of rapid degradation.

A9.2.3.5 The precise definitions of the core elements of this system are described in detail in Sections A9.3, A9.4 and A9.5 respectively.

A9.2.3.6 *(New paragraph A9.2.3.6 is former paragraph A9.2.3.5.. The text remains unchanged)*

A9.2.3.7 In defining aquatic toxicity, it is not possible to test all species present in an aquatic ecosystem. Representative species are therefore chosen which cover a range of trophic levels and taxonomic groupings. The taxa chosen, fish, crustacea and aquatic plants that represent the “base-set” in most hazard profiles, represent a minimum data-set for a fully valid description of hazard. The lowest of the available toxicity values will normally be used to define the hazard category. Given the wide range of species in the environment, the three tested can only be a poor surrogate and the lowest value is therefore taken for cautious reasons to define the hazard category. In doing so, it is recognized that the distribution of species sensitivity can be several orders of magnitude wide and that there will thus be both more and less sensitive species in the environment. Thus, when data are limited, the use of the most sensitive species tested gives a cautious but acceptable definition of the hazard. There are some circumstances where it may not be appropriate to use the lowest toxicity value as the basis for classification. This will usually only arise where it is possible to define the sensitivity distribution with more accuracy than would normally be possible, such as when large data-sets are available. Such large data-sets should be evaluated with due caution.

A9.2.4 *Application*

A9.2.4.1 Generally speaking, in deciding whether a substance should be classified, a search of appropriate databases and other sources of data should be made for the following data elements:

(a) water solubility;
(b) acute aquatic toxicity (L(E)C50s);

(c) chronic aquatic toxicity (NOECs and/or equivalent ECx);
(d) available degradation (and specifically evidence of ready biodegradability);
(e) stability data, in water;
(f) fish bioconcentration factor (BCF);
(g) octanol/water partition coefficient (log Kow);

The water solubility and stability data, although not used directly in the criteria, are nevertheless important since they are a valuable help in the data interpretation of the other properties (see A9.1.10).

A9.2.4.2 To classify, a review should first be made of the available aquatic toxicity data. It will be necessary to consider all the available data and select those which meet the necessary quality criteria for classification. If there are no data available that meet the quality criteria required by the internationally standardized methods, it will be necessary to examine any available data to determine whether a classification can be made. If the data indicate that the acute aquatic toxicity $L(E)C_{50}$ >100 mg/l for soluble substances and the chronic aquatic toxicity > 1mg/l, then the substance is not classified as hazardous. There are a number of cases where no effects are observed in the test and the aquatic toxicity is thus recorded as a > water solubility value, i.e. there is no acute toxicity within the range of the water solubility in the test media. Where this is the case, and the water solubility in the test media is ≥1 mg/l, again, no classification need be applied.

A9.2.4.3 If chronic aquatic toxicity data are available cut-off values will depend on whether the chemical is rapidly degradable or not. Therefore, for non-rapidly degradable substances and those for which no information on degradation is available, the cut-off levels are higher than for those substances where rapid degradability can be confirmed (see Chapter 4.1, Tables 4.1.1 and 4.1.2).

A9.2.4.4 Where the lowest acute aquatic toxicity data are below 100 mg/l and no adequate chronic toxicity data are available, it is necessary to first decide which hazard category the toxicity falls in, and then to determine whether the chronic and/or the acute sub-class should be applied. This can simply be achieved by examining the available data on the partition coefficient, log K_{ow} and the available data on degradation. If either the log $K_{ow} \geq 4$ or the substance cannot be considered as rapidly degradable, then the appropriate long-term hazard category and the corresponding acute hazard category are applied independently. It should be noted that, although the log K_{ow} is the most readily available indication of a potential to bioaccumulate, an experimentally derived BCF is preferred. Where this is available, this should be used rather than the partition coefficient. In these circumstances, a BCF ≥500 would indicate bioaccumulation sufficient to classify in the appropriate long-term hazard class. If the substance is both rapidly degradable and has a low potential to bioaccumulate (BCF <500 or, if absent log K_{ow} <4) then it should not be assigned to a long-term hazard category, unless the chronic toxicity data indicate otherwise (A9.2.4.3).

A9.2.4.5 For poorly soluble substances, generally speaking, those with a water solubility in the test media of < 1 mg/l, for which no aquatic toxicity has been found, should be further examined to determine whether Chronic Category 4 needs to be applied. Thus, if the substance is both not rapidly degradable and has a potential to bioaccumulate (BCF ≥500 or, if absent log K_{ow} ≥4), the Chronic Category 4 should be applied.

A9.2.5, A9.2.6, A9.2.6.1 and A9.2.6.2 *(unchanged)*

A9.2.6.3 Normally, the identification of hazard, and hence the classification will be based on information directly obtained from testing of the substance being considered. There are occasions, however, where this can create difficulties in the testing or the outcomes do not conform to common

sense. For example, some chemicals, although stable in the bottle, will react rapidly (or slowly) in water giving rise to degradation products that may have different properties. Where such degradation is rapid, the available test data will frequently define the hazard of the degradation products since it will be these that have been tested. These data may be used to classify the parent substance in the normal way. However, where degradation is slower, it may be possible to test the parent substance and thus generate hazard data in the normal manner. The subsequent degradation may then be considered in determining whether an acute or long-term hazard class should apply. There may be occasions, however, when a substance so tested may degrade to give rise to a more hazardous product. In these circumstances, the classification of the parent should take due account of the hazard of the degradation product, and the rate at which it can be formed under normal environmental conditions.

PART 3:

AMENDED PARAGRAPHS IN ANNEX 9, SECTION A9.3

A9.3 *(unchanged)*

A9.3.1 Introduction

The basis for the identification of hazard to the aquatic environment for a substance is the aquatic toxicity of that substance. Classification is predicated on having toxicity data for fish, crustacea, and algae/aquatic plant available. These taxa are generally accepted as representative of aquatic fauna and flora for hazard identification. Data on these particular taxa are more likely to be found because of this general acceptance by regulatory authorities and the chemical industry. Other information on the degradation and bioaccumulation behaviour is used to better delineate the aquatic hazard. This section describes the appropriate tests for ecotoxicity, provides some basic concepts in evaluating the data and using combinations of testing results for classification, summarizes approaches for dealing with difficult substances, and includes a brief discussion on interpretation of data quality.

A9.3.2 and A9.3.2.1 *(unchanged)*

A9.3.2.2 The GHS criteria for determining health and environmental hazards should be test method neutral, allowing different approaches as long as they are scientifically sound and validated according to international procedures and criteria already referred to in existing systems for the endpoints of concern and produce mutually acceptable data. According to the proposed system (OECD 1998):

> *"Acute toxicity would normally be determined using a fish 96 hour LC50 (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC50 (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC50 (OECD Test Guideline 201 or equivalent). These species are considered as surrogate for all aquatic organisms and data on other species such as the duckweed Lemna may also be considered if the test methodology is suitable."*

Chronic testing generally involves an exposure that is lingering or continues for a longer time; the term can signify periods from days to a year, or more depending on the reproductive cycle of the aquatic organism. Chronic tests can be done to assess certain endpoints relating to growth, survival, reproduction and development.

> *"Chronic 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) can be accepted. Other validated and internationally accepted tests could also be used. The NOECs or other equivalent L(E)Cx should be used."*

An OECD document describes the main statistical methods for the analysis of data of standardized ecotoxicity tests (OECD 2006).

A9.3.2.3, A9.3.2.4, A9.3.2.5, A9.3.2.5.1, A9.3.2.5.2,
A9.3.2.6, A9.3.2.6.1, A9.3.2.6.2 and A9.3.2.7 *(unchanged)*

A9.3.2.7.1 Tests in algae

Algae are cultured and exposed to the test substance in a nutrient-enriched medium. Tests consistent with OECD Test Guideline 201 (Algal growth inhibition) should be used. Standard test methods employ a cell density in the inoculum in order to ensure exponential growth through the test, usually 3 to 4 days duration.

The algal test is a short-term test that_provides both acute and chronic endpoints,. The preferred observational endpoint in this study is algal growth rate inhibition because it is not dependent on the test design, whereas biomass depends both on growth rate of the test species as well as test duration and other elements of test design. If the endpoint is reported only as reduction in biomass or is not specified, then this value may be interpreted as an equivalent endpoint.

A9.3.2.7.2, A9.3.3, A9.3.3.1, A9.3.3.1.1, A9.3.3.1.2 and A9.3.3.2 *(unchanged)*

A9.3.3.2.1 Chronic toxicity, for purposes of classification, refers to the intrinsic property of a substance to cause adverse effects to aquatic organisms during exposures which are determined in relation to the life-cycle of the organism. Such chronic effects usually include a range of sublethal endpoints and are generally expressed in terms of a No Observable Effect Concentration (NOEC), or an equivalent ECx. Observable endpoints typically include survival, growth and/or reproduction. Chronic toxicity exposure durations can vary widely depending on test endpoint measured and test species used.

A.9.3.3.2.2 For the classification based on chronic toxicity a differentiation is made between rapidly degradable and non-rapidly degradable substances. Substances that do rapidly degrade are classified in Chronic Category 1 when a chronic toxicity determined to be ≤ 0.01 mg/l. Decimal bands are accepted for categorizing chronic toxicity above this category. Substances with a chronic toxicity measured from 0.01 to ≤ 0.1 mg/l are classified in Category 2 for chronic toxicity, from 0.1 to ≤ 1.0 mg/l are classified in Category 3 for chronic toxicity, and those over 1.0 mg/l are regarded as practically non-toxic. For substances that do not rapidly degrade or where no information on rapid degradation is available two Chronic Categories are used: Category 1 when a chronic toxicity determined to be ≤ 0.1 mg/l and Category 2 when chronic toxicity is measured from 0.1 to ≤ 1.0 mg/l.

A9.3.3.2.3 Since chronic toxicity data are less common in certain sectors than acute data, for classification schemes, the potential for chronic toxicity is, in absence of adequate chronic toxicity data, identified by appropriate combinations of acute toxicity, lack of degradability, and/or the potential or actual bioaccumulation. However, where adequate chronic toxicitydata exist, this shall be used in preference over the classification based on the combination of acute toxicity with degradability, and/or bioaccumulation. In this context, the following general approach should be used.

(a) If adequate chronic toxicity data are available for all three trophic levels this can be used directly to determine an appropriate chronic hazard category;

(b) If adequate chronic toxicity data are available for one or two trophic levels, it should be examined if acute toxicity data are available for the other trophic level(s). A potential classification is made for the trophic level(s) with chronic data and compared with that made using the acute toxicity data for the other trophic level(s). The final classification shall be made according to the most stringent outcome;

(c) In order to remove or lower a chronic classification using chronic toxicity data, it must be demonstrated that the NOEC(s) (or equivalent Ecx) used would be suitable

to remove or lower the concern for all taxa which resulted in classification based on acute data in combination with degradability, and/or bioaccumulation. This can often be achieved by using a long-term NOEC for the most sensitive species identified by the acute toxicity. Thus, if a classification has been applied based on a fish acute LC_{50}, it would generally not be possible to remove or lower this classification using a long-term NOEC from an invertebrate toxicity test. In this case, the NOEC would normally need to be derived from a long-term fish test of the same species or one of equivalent or greater sensitivity. Equally, if classification has resulted from the acute toxicity to more than one taxa, it is likely that NOECs from each taxa will be needed. In case of classification of a substance as Chronic Category 4, sufficient evidence should be provided that the NOEC or equivalent ECx for each taxa is greater than 1 mg/l or greater than the water solubility of the substances under consideration.

A9.3.3.2.4 Testing with algae/Lemna cannot be used for removing or lowering a classification because:

(a) the algae and Lemna tests are not long-term studies;

(b) the acute to chronic ratio is generally narrow; and

(c) the endpoints are more consistent with the acute endpoints for other organisms.

However where classification is applied solely due to the acute toxicity ($L(E)C_{50}$) observed in single algae/aquatic plant tests, but there is evidence from a range of other algae tests that the chronic toxicity (NOECs) for this taxonomic group is in the toxicity band corresponding to a less stringent classification category or above 1mg/l, this evidence could be used to consider removing or lowering a classification. At present this approach cannot be applied to aquatic plants since no standardized chronic toxicity tests have been developed.

A9.3.3.3 (*unchanged)*

A9.3.3.4 ***Test media for algae***

Algal tests are performed in nutrient-enriched media and the use of one common constituent, EDTA, or other chelators, should be considered carefully. When testing the toxicity of organic chemicals, trace amounts of a chelator like EDTA are needed to complex micronutrients in the culture medium; if omitted, algal growth can be significantly reduced and compromise test utility. However, chelators can reduce the observed toxicity of metal test substances. Therefore, for metal compounds, it is desirable that data from tests with high concentration of chelators and/or tests with stoichiometrical excess of chelator relative to iron should be critically evaluated. Free chelator may mask heavy metal toxicity considerably, in particular with strong chelators like EDTA. However, in the absence of available iron in the medium the growth of algae can become iron limited, and consequently data from tests with no or with reduced iron and EDTA should be treated with caution.

A9.3.3.5 and A9.3.4 (*unchanged)*

A9.3.4.1 The best quality data should be used as the fundamental basis for classification. Classification should preferably be based on primary data sources. It is essential that test conditions are clearly and completely articulated.

A9.3.4.2, A9.3.4.3, A9.3.5, A9.3.5.1, A9.3.5.2 (first paragraph) (*unchanged)*

A9.3.5.2 (a) Stability: If test chemical concentrations are expected to fall below 80% of nominal, testing, in order to be valid, may require exposure regimes which provide for renewal of the test material. Semi-static or flow-through conditions are preferred. Special problems arise, therefore, with respect to testing on algae, where the standard guidelines generally include static tests to be conducted. While alternative exposure regimes are possible for crustacea and fish, these tests are frequently conducted on static conditions as included in the internationally agreed guidelines. In these tests, a certain level of degradation as well as other relevant factors have to be tolerated and appropriate account must be taken in calculations of toxic concentrations. Some approaches on how this can be dealt with are covered in A9.3.5.6. Where degradation occurs, it is also important to consider the influence of the toxicity of the degradation products on the recorded toxicity in the test. Expert judgement will need to be exercised when deciding if the data can be used for classification;

A9.3.5.2 (b) to (e) (*unchanged)*

A9.3.5.3 (*unchanged)*

A9.3.5.4 In most difficult to test conditions, the actual test concentration is likely to be less than the nominal or expected test concentration. Where acute toxicities ($L(E)C_{50}$s) are estimated to be less than 1 mg/l for a difficult to test substance, one can be fairly confident the classification in the Acute Category 1 (and Chronic Category 1 if appropriate) is warranted. However, if the estimated acute toxicity is greater than 1 mg/l, the estimated toxicity is likely to under-represent the toxicity. In these circumstances, expert judgement is needed to determine the acceptability of a test with a difficult to test substance for use in classification. Where the nature of the testing difficulty is believed to have a significant influence on the actual test concentration when acute toxicity is estimated to be greater than 1 mg/l and the test concentration is not measured, then the test should be used with due caution in classification.

A9.3.5.5, A9.3.5.6, A9.3.5.6.1, A9.3.5.6.2, A9.3.5.7, A9.3.5.7.1 and
A9.3.5.7.2 (a), (b) and (c) (*unchanged)*

A9.3.5.7.2 (d) where chronic toxicity data are available, the same general rules should apply. Again, where these data cannot be validated by consideration of measured concentrations, the techniques used to achieve the maximum dissolved concentrations must be considered as appropriate.

A9.3.5.8 *Other factors contributing to concentration loss*

A number of other factors can also contribute to losses of concentration and, while some can be avoided by correct study design, interpretation of data where these factors have contributed may, from time to time, be necessary:

(a) sedimentation: this can occur during a test for a number of reasons. A common explanation is that the substance has not truly dissolved despite the apparent absence of particulates, and agglomeration occurs during the test leading to precipitation. In these circumstances, the $L(E)C_{50}$ or NOEC for classification purposes, may be considered to be based on the end of test concentrations. Equally, precipitation can occur through reaction with the media. This is considered under instability above;

(b) adsorption: this can occur for substances of high adsorption characteristics such as

high log Kow substances. Where this occurs, the loss of concentration is usually rapid and exposure may best be characterized by the end of test concentrations.

(c) bioaccumulation: losses may occur through the bioaccumulation of a substance into the test organisms. This may be particularly important where the water solubility is low and log K_{ow} correspondingly high. The $L(E)C_{50}$ or NOEC for classification purposes, may be calculated based on the geometric mean of the start and end of test concentrations.

A9.3.5.9, A9.3.5.9.1, A9.3.5.9.2,
A9.3.5.10, A9.3.5.10.1, A9.3.5.10.2,
Table A9.3.1,
A9.3.6, A9.3.6.1, A9.3.6.2, A9.3.6.2.1,
A9.3.6.2.2, A9.3.6.2.3 and A9.3.6.2.4 (*unchanged)*

PART 4:

PROPOSED AMENDMENTS TO ANNEX 9, APPENDIX VI

Add the following reference in section 1:

"OECD 2006. Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application, OECD Environment Health and Safety Publications, Series Testing and Assessment N) 54.
