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

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OTHER IMPLEMENTATION ISSUES

Terminology issues: Use of the term "chemicals"
(refer to document ST/SG/AC.10/C.4/2008/22, paragraph 4.1, issue 1.2)

Note by the secretariat

Introduction

1. One of the terminology issues identified by the informal working group on implementation was the use of the term "chemical" in the GHS.

2. The informal group considered that "chemical" was used in the GHS to mean "substance(s)" or "mixture(s)" and suggested that a definition be included in Chapter 1.2, in order to avoid any ambiguity.

3. The group also discussed whether the term "chemical" should be revised to "substance(s)" or "mixture(s)", as appropriate, throughout the GHS, but there was not consensus on this issue, as not all members of the group considered that such changes were necessary.

4. Since the secretariat volunteered to study the issue and to identify any possible solutions, the informal working group concluded that the Sub-Committee would be invited to consider the proposal by the secretariat.

Proposal

5. Taking into account the interpretation given by the informal working group the following definition for "chemical" is proposed:

> "*Chemical* is a collective term used to designate substances and mixtures, as defined in the GHS, as well as chemical products."

The Sub-Committee may wish to consider adopting the proposed definition to be included in Chapter 1.2 of the GHS.

6. Extracts from the relevant paragraphs of the GHS text where "chemical" is used, together with the proposed changes, when applicable, are reproduced hereafter for consideration of the Sub-Committee.

7. The secretariat would like to note that in many cases, the proposed changes will contribute to the consistent use of the terminology within a given paragraph or section (e.g.: 3.9.2 and A9.3.5) irrespective of the Sub-Committee's decision regarding the proposed definition for "chemical".

Proposed amendments to the GHS text: *(New or amended text is shown in blue. Deleted text is crossed out.*

Chapter 1.1

1.1.1.1 The use of chemicals ~~[products]~~ to enhance and improve life is a widespread practice worldwide. But alongside the benefits of these products, there is also the potential for adverse effects to people or the environment. As a result, a number of countries or organizations have developed laws or regulations over the years that require information to be prepared and transmitted to those using chemicals, through labels or safety data sheets (SDS). Given the large number of chemicals ~~[products]~~ available, individual regulation of all of them is simply not possible for any entity. Provision of information gives those using chemicals the identities and hazards of these chemicals, and allows the appropriate protective measures to be implemented in the local use settings.

1.1.1.2 While these existing laws or regulations are similar in many respects, their differences are significant enough to result in different labels or SDS for the same ~~product~~ chemical in different countries. Through variations in definitions of hazards, a chemical may be considered flammable in one country, but not another. [….]. In addition, given the complexity of developing and maintaining a comprehensive system for classifying and labelling chemicals, many countries have no system at all.

1.1.1.3 Given the reality of the extensive global trade in chemicals, and the need to develop national programs to ensure their safe use, transport, and disposal, it was recognized that an internationally-harmonized approach to classification and labelling would provide the foundation for such programs. Once countries have consistent and appropriate information on the chemicals they import or produce in their own countries, the infrastructure to control chemical exposures and protect people and the environment can be established in a comprehensive manner.

1.1.1.4 (c) "Reduce the need for testing and evaluation of chemicals; and

(d) Facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis.

1.1.1.6 (b) The hazard classification process refers principally to the hazards arising from the intrinsic properties of chemicals ~~elements and compounds and mixtures thereof~~, whether natural or synthetic[1];

(d) The scope of harmonization includes both hazard classification criteria and hazard communication tools, e.g. labelling and ~~chemical~~ safety data sheets, taking into account especially the four existing systems identified in the ILO report[2];

(h) Validated data already generated for the classification of chemicals under the existing systems should be accepted when reclassifying these chemicals under the harmonized system;

(i) A new harmonized classification system may require adaptation of existing methods for testing of chemicals;

1.1.2.2 […]. In addition, decision logics for each hazard have been developed. Some examples of classification of chemicals in the text, as well as in Annex 8, illustrate how to apply the criteria. […].

1.1.2.5 In developing this clarification, the CG/HCCS carefully considered many different issues with regard to the possible application of the GHS. There were concerns raised about whether certain sectors or products should be exempted, for example, or about whether or not the system would be applied at all stages of the life cycle of a chemical. Three parameters were agreed in this discussion, and are critical to application of the system in a country or region. These are described below:

(a) Parameter 1:	The GHS covers all hazardous chemicals. The mode of application of the hazard communication elements of the GHS (e.g. labels, safety data sheets) may vary by product category or stage in the life cycle. Target audiences for the GHS include consumers, workers, transport workers, and emergency responders.

(i) Existing hazard classification and labelling systems address potential exposures to all potentially hazardous chemicals in all types of use situations, including production, storage, transport, workplace use, consumer use, and presence in the environment. They are intended to protect people, facilities, and the environment. The most widely applied requirements in terms of chemicals covered are generally found in the parts of existing systems that apply to the workplace or transport. It should be noted that the term chemical is used broadly in the UNCED agreements and subsequent documents to include substances, products, mixtures, preparations, or any other terms that may be used in existing systems to denote coverage.

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[1] *In some cases it is necessary also to take into account hazards arising from other properties, such as the physical state of the substance or mixture (e.g. pressure and temperature) or properties of substances produced by certain chemical reactions (e.g. flammability of gases produced by contact with water).*

[2] *1992 ILO Report on the size of the task of harmonizing existing systems of classification and labelling for hazardous chemicals.*

(ii) Since all chemicals ~~[and chemical products]~~ in commerce are made in a workplace (including consumer products), handled during shipment and transport by workers, and often used by workers, there are no complete exemptions from the scope of the GHS for any particular type of chemical ~~or product~~. […]

(iii) At other stages of the life cycle for these same ~~[products]~~chemicals, the GHS may not be applied at all. […].

(b) Parameter 2:	The mandate for development of a GHS does not include establishment of uniform test methods or promotion of further testing to address adverse health outcomes.

(i) […..]

(ii) The GHS is based on currently available data. Since the harmonized classification criteria are developed on the basis of existing data, compliance with these criteria will not require retesting of chemicals for which accepted test data already exists.

1.1.2.6.2.1 Each hazard classification and communication system (workplace, consumer, transport) begins coverage with an assessment of the hazards posed by the chemical ~~[or chemical product]~~ involved. […]

1.1.3.1.1 The goal of the GHS is to identify the intrinsic hazards found in ~~chemical~~ substances and mixtures and to convey hazard information about these hazards. [….]

1.1.3.1.5.1 […] For example, if a system covers the carcinogenicity of a chemical, it should follow the harmonized classification scheme and the harmonized label elements.

Chapter 1.2

Aspiration means the entry of a liquid or solid chemical ~~product~~ into the trachea and lower respiratory system directly through the oral or nasal cavity, or indirectly from vomiting;

Carcinogen means a chemical ~~substance or a mixture of chemical substances~~ which induce cancer or increase its incidence;

Chemical identity means a name that will uniquely identify a chemical. This can be a name that is in accordance with the nomenclature systems of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS), or a technical name;

LC_{50} (50% lethal concentration) means the concentration of a chemical in air or of a chemical in water which causes the death of 50% (one half) of a group of test animals;

LD_{50} means the amount of a chemical, given all at once, which causes the death of 50% (one half) of a group of test animals;

Chapter 1.3

1.3.2.1.1 The GHS applies to pure ~~chemical~~ substances, their dilute solutions and to mixtures ~~of chemical substances~~. […]

1.3.2.2.3 As noted in IOMC Description and further clarification of the anticipated application of the GHS in the *Purpose, scope and application* (Chapter 1.1, para. 1.1.2.4), it is recognized that once a chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting.

1.3.2.4.2 The classification of a ~~chemical~~ substance or mixture depends both on the criteria and on the reliability of the test methods underpinning the criteria. In some cases the classification is determined by a pass or fail of a specific test, (e.g. the ready biodegradation test for substances or ingredients of mixtures), while in other cases, interpretations are made from dose/response curves and observations during testing. In all cases, the test conditions need to be standardized so that the results are reproducible with a given ~~chemical~~ substance and the standardized test yields "valid" data for defining the hazard class of concern. In this context, validation is the process by which the reliability and the relevance of a procedure are established for a particular purpose.

1.3.2.4.4 *Previously classified chemicals*

One of the general principles established by the IOMC-CG-HCCS states that test data already generated for the classification of chemicals under the existing systems should be accepted when classifying these chemicals under the harmonized system thereby avoiding duplicative testing and the unnecessary use of test animals. This policy has important implications in those cases where the criteria in the GHS are different from those in an existing system. In some cases, it may be difficult to determine the quality of existing data from older studies. In such cases, expert judgement will be needed.

1.3.2.4.7 *Evidence from humans*

For classification purposes, reliable epidemiological data and experience on the effects of chemicals on humans (e.g. occupational data, data from accident databases) should be taken into account in the evaluation of human health hazards of a chemical. Testing on humans solely for hazard identification purposes is generally not acceptable.

Chapter 1.4

1.4.3.1 The needs of the target audiences that will be the primary end-users of the harmonized hazard communication scheme have been identified. Particular attention

was given to a discussion of the manner in which these target audiences will receive and use the information conveyed about hazardous chemicals. Factors discussed include the potential use of products, availability of information other than the label and the availability of training.

1.4.3.3 *Workplace*: Employers and workers need to know the hazards specific to the chemicals used and or handled in the workplace, as well as information about the specific protective measures required to avoid the adverse effects that might be caused by those hazards. In the case of storage of chemicals, potential hazards are minimized by the containment (packaging) of the chemical, but in the case of an accident, workers and emergency responders need to know what mitigation measures are appropriate. […]

1.4.7.2.1 Suppliers should respond to "new and significant" information they receive about a chemical hazard by updating the label and safety data sheet for that chemical. New and significant information is any information that changes the GHS classification of the substance or mixture and leads to a resulting change in the information provided on the label or any information concerning the chemical and appropriate control measures that may affect the SDS. […].

1.4.7.2.3 Suppliers should also periodically review the information on which the label and safety data sheet for a substance or mixture is based, even if no new and significant information has been provided to them in respect of that substance or mixture. This will require e.g. a search of chemical hazard databases for new information.[…].

1.4.8.2 (a) whether the inclusion of certain chemicals or classes of chemicals in the arrangements is appropriate to the needs of the system;

1.4.8.3 (a) For information otherwise required on labels or safety data sheets, CBI claims should be limited to the names of ~~chemicals~~ substances, and their concentrations in mixtures. All other information should be disclosed on the label and/or safety data sheet, as required;

[…]

(d) Where a medical professional determines that a medical emergency exists due to exposure to a hazardous ~~chemical~~ substance or ~~a chemical~~ mixture, mechanisms should be in place to ensure timely disclosure by the supplier or employer or competent authority of any specific confidential information necessary for treatment. The medical professional should maintain the confidentiality of the information;

1.4.9 Training

Training users of hazard information is an integral part of hazard communication. Systems should identify the appropriate education and training for GHS target audiences who are required to interpret label and/or SDS information and to take appropriate action in response to chemical hazards. […]. Others involved in the transport and supply of hazardous chemicals also require training to varying degrees.[…].

1.4.10.5.5.1 Workplace labelling

[…]

Alternative means of providing workers with the information contained in GHS labels are needed usually where hazardous chemicals are transferred from an original supplier container into a workplace container or system, or where chemicals are produced in a workplace but are not packaged in containers intended for sale or supply. Chemicals that are produced in a workplace may be contained or stored in many different ways such as: small samples collected for testing or analysis, piping systems including valves, process or reaction vessels, ore cars, conveyer systems or free-standing bulk storage of solids. In batch manufacturing processes, one mixing vessel may be used to contain a number of different ~~chemical~~ mixtures.

[…] Some examples of workplace situations where chemicals may be transferred from supplier containers include: containers for laboratory testing or analysis, storage vessels, piping or process reaction systems or temporary containers where the chemical will be used by one worker within a short timeframe. Decanted chemicals intended for immediate use could be labelled with the main components and directly refer the user to the supplier label information and SDS.

[…] Examples of alternative methods include: use of product identifiers together with GHS symbols and other pictograms to describe precautionary measures; use of process flow charts for complex systems to identify chemicals contained in pipes and vessels with links to the appropriate SDS; use of displays with GHS symbols, colour and signal words in piping systems and processing equipment; […].

Chapter 1.5

1.5.1.1 The SDS should provide comprehensive information about a ~~chemical~~ substance or mixture for use in workplace chemical control regulatory frameworks. […]. The information acts as a reference source for the management of hazardous chemicals in the workplace. […]

Table 1.5.2 : Item 1 (c): "(c) Recommended use of the chemical and restrictions on use;"
Item 5 (b): "(b) Specific hazards arising from the chemical (e.g. nature of any hazardous combustion products).

Chapter 3.1

"3.1.2 Classification criteria for substances

3.1.2.1 ~~Chemicals~~ Substances can be allocated to one of five toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in the table below. […]"

Note (d) to table 3.1.1:

(d) For some ~~chemicals~~ substances the test atmosphere will not just be a vapour but will consist of a mixture of liquid and vapour phases. For other ~~chemicals~~

substances the test atmosphere may consist of a vapour which is near the gaseous phase. In these latter cases, classification should be based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

3.1.2.5 Category 5 is for ~~chemicals~~ substances which are of relatively low acute toxicity but which, under certain circumstances, may pose a hazard to vulnerable populations. Criteria for identifying substances in Category 5 are provided in addition to the table. These substances are anticipated to have an oral or dermal LD_{50} value in the range 2000 - 5000 mg/kg bodyweight and equivalent doses for inhalation exposure […]

Chapter 3.2

3.2.2 Classification criteria for substances

3.2.2.2 Several factors should be considered in determining the corrosion and irritation potential of ~~chemicals~~ substances before testing is undertaken. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. […] It also stands to reason that if a ~~chemical~~ substance is highly toxic by the dermal route, a skin irritation/corrosion study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. […].

All the above information that is available on a ~~chemical~~ substance should be used in determining the need for *in vivo* skin irritation testing. […].

Chapter 3.3

3.3.2.4 Several factors should be considered in determining the serious eye damage or irritation potential of ~~chemicals~~ substances before testing is undertaken. […]

3.3.2.5 All the above information that is available on a ~~chemical~~ substance should be used in determining the need for *in vivo* eye irritation testing. ….]

NOTES to Figure 3.3.1:

Step 1a/b: […] Analysis of pre-existing experience with the ~~chemical~~ substance may identify serious eye damage, corrosion and irritation potential for both skin and eye effects:

(ii) Step 1b - evaluation of data on skin corrosivity - skin corrosive substances should not be instilled into the eyes of animals; such substances should be considered as leading to serious damage to the eyes as well (Category 1).

For those ~~chemicals~~ substances where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

Chapter 3.5

3.5.2 Classification criteria for substances

[…]

3.5.2.3 The system is hazard based, classifying ~~chemicals~~ substances on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of ~~chemical~~ substances.

CATEGORY 1: ~~Chemicals~~ Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans

Category 1A: Substances~~Chemicals~~ known to induce heritable mutations in germ cells of humans

Positive evidence from human epidemiological studies.

Category 1B: Substances~~Chemicals~~ which should be regarded as if they induce heritable mutations in the germ cells of humans

[…]

CATEGORY 2: Substances~~Chemicals~~ which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans

[…]

NOTE: Substances~~*Chemicals*~~ *which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.*

3.5.2.10 The classification of individual substances should be based on the total weight of evidence available, using expert judgement. In those instances where a single well-conducted test is used for classification, it should provide clear and unambiguously positive results. If new, well validated, tests arise these may also be used in the total weight of evidence to be considered. The relevance of the route of exposure used in the study of the ~~chemical~~ substance compared to the route of human exposure should also be taken into account.

Chapter 3.6

3.6.1 Definitions

The term *carcinogen* denotes a chemical ~~substance or a mixture of chemical substances~~ which induce cancer or increase its incidence. ~~Substances~~ Chemicals which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans.

Classification of a chemical as posing a carcinogenic hazard is based on ~~the~~ its inherent properties ~~of the substance~~ and does not provide information on the level of the human cancer risk which the use of the chemical may represent.

3.6.2 Classification criteria for substances

3.6.2.1 For the purpose of classification for carcinogenicity, ~~chemical~~ substances are allocated to one of two categories based on strength of evidence and additional considerations (weight of evidence). In certain instances, route specific classification may be warranted.

Figure 3.6.1: Hazard categories for carcinogens

CATEGORY 1:	Known or presumed human carcinogens
	The placing of a ~~chemical~~ substance in Category 1 is done on the basis of epidemiological and/or animal data. An individual ~~chemical~~ substance may be further distinguished:
Category 1A:	Known to have carcinogenic potential for humans; the placing of a ~~chemical~~ substance is largely based on human evidence.
Category 1B:	Presumed to have carcinogenic potential for humans; the placing of a ~~chemical~~ substance is largely based on animal evidence.
	Based on strength of evidence together with additional considerations, such evidence may be derived from human studies that establish a causal relationship between human exposure to a ~~chemical~~ substance and the development of cancer (known human carcinogen). […]
	Classification: Category 1 (A and B) Carcinogen
CATEGORY 2:	Suspected human carcinogens
	The placing of a ~~chemical~~ substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the ~~chemical~~ substance in Category 1. Based on strength of evidence together with additional considerations, such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.
	Classification: Category 2 Carcinogen

3.6.2.2 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for ~~chemicals~~ substances which have an intrinsic property to produce such toxic effects. […].

3.6.2.3 *Carcinogen classification* is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place ~~chemicals~~ substances with human cancer potential into hazard categories.

3.6.2.5.2 (g) Structural similarity or not to (a) ~~chemical~~substance(s) for which there is good evidence of carcinogenicity;

3.6.2.5.3 *Mutagenicity:* It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity *in vivo* may indicate that a ~~chemical~~ substance has a potential for carcinogenic effects.

3.6.2.5.4 The following additional considerations apply to classification of ~~chemicals~~ substances into either Category 1 or Category 2. A ~~chemical~~ substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1 or Category 2 based on tumour data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, e.g. for benzidine congener dyes.

3.6.2.5.5 The classification should also take into consideration whether or not the substance~~chemical~~ is absorbed by a given route(s); or whether there are only local tumours at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.

Chapter 3.7

3.7.2 Classification criteria for substances

3.7.2.1 *Hazard categories*

For the purpose of classification for reproductive toxicity, ~~chemical~~ substances are allocated to one of two categories. […]

3.8.2.1.6 In exceptional cases, based on expert judgement, it may be appropriate to place certain substances with human evidence of target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. […]. In other words, if there are also animal data available on the ~~chemical~~ substance that warrant Category 1 classification, the ~~chemical~~ substance should be classified as Category 1.

Chapter 3.8

3.8.2 Classification criteria for substances

3.8.2.1.10 *Other considerations*

3.8.2.1.10.1 When a ~~chemical~~ substance is characterized only by use of animal data (typical of new ~~chemicals~~substances, but also true for many existing ~~chemicals~~substances), the classification process would include reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

3.8.2.1.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to single exposure to a ~~chemical~~ substance, the substance may be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a ~~chemical~~ substance is unclassified because specific target organ toxicity observed was considered not relevant or significant to humans, if subsequent human incident data become available showing a specific target organ toxic effect, the substance should be classified.

3.8.2.1.10.3 A ~~chemical~~ substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from […]

Chapter 3.9

3.9.1 Definitions and general considerations

3.9.1.2 Classification identifies the chemical ~~substance~~ as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

3.9.2 Classification criteria for substances

3.9.2.6 In exceptional cases, based on expert judgement, it may be appropriate to place certain substances with human evidence of specific target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. […] In other words, if there are also animal data available on the ~~chemical~~ substance that warrant Category 1 classification, the ~~chemical~~ substance should be classified as Category 1.

3.9.2.10 *Other considerations*

3.9.2.10.1 When a ~~chemical~~ substance is characterized only by use of animal data (typical of new chemicals, but also true for many existing ~~chemicals~~substance), the classification process would include reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

3.9.2.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a ~~chemical~~ substance, the substance may be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a ~~chemical~~ substance is unclassified because no specific target organ toxicity was seen at or below the proposed dose/concentration guidance value for animal testing, if subsequent human incident data become available showing a specific target organ toxic effect, the substance should be classified.

3.9.2.10.3 A ~~chemical~~ substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from […].

Chapter 3.10

3.10.1 Definitions and general and specific considerations

3.10.1.2 *Aspiration* means the entry of a liquid or solid chemical ~~product~~ directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

Chapter 4.1

4.1.1.7.1 The harmonized system for classifying chemicals ~~substances~~ for the hazards they present to the aquatic environment is based on a consideration of existing systems listed in 4.1.1.7.4. 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. To that extent, the proposal 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 further information on the degradation and bioaccumulation behaviour.

4.1.2.13 *Use of QSARs*

[…] 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. […].

Annex 3

A3.3.1.2 The starting point for assigning precautionary statements is the hazard classification of the chemical ~~product~~. The system of classifying hazards in the GHS is based on the intrinsic properties of the chemicals involved (see 1.3.2.2.1). […].

A3.3.2.3 […] For some specific chemicals, supplementary first aid, treatment measures or specific antidotes or cleansing materials may be required. […].

A3.3.4.6 […] For example, if a chemical is carcinogenic and acutely toxic then the first aid measures for acute toxicity will take precedence over those for longer term effects. In addition, medical attention to delayed health effects may be required in cases of incidental exposure, even if not associated with immediate symptoms of intoxication.

Annex 4

A4.3.1.3 *Recommended use of the chemical and restrictions on use*

Provide the recommended or intended use of the substance or mixture, including a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc. Restrictions on use should, as far as possible, be stated including non-statutory recommendations by the supplier.

A4.3.5.2 *Specific hazards arising from the chemical*

Provide advice on specific hazards that may arise from the chemical, such as hazardous combustion products that form when the substance or mixture burns. […]

A4.3.10.1 *Reactivity*

A4.3.10.1.1 Describe the reactivity hazards of the substance or mixture in this section. Provide specific test data for the substance or mixture as a whole, where available. However, the information may also be based on general data for the class or family of chemical if such data adequately represent the anticipated hazard of the substance or mixture.

A4.3.10.5 *Incompatible materials*

List classes of chemicals or specific substances with which the substance or mixture could react to produce a hazardous situation (e.g. explosion, release of toxic or flammable materials, liberation of excessive heat).

Annex 5

A5.1.1 The Globally Harmonized System of Classification and Labelling of Chemicals is based on an assessment of the intrinsic hazardous properties of the chemicals involved.

A5.1.5 While intrinsic hazards of a chemical can be determined for all sectors, information about exposure, and thus risk, varies significantly among the sectors covered by the GHS. […]

A5.2 General principles

A5.2.1 While the specific risk assessment approach has not been addressed or harmonized in the GHS, certain general principles are as follows:

(a) All chemicals should be classified based on GHS classification criteria

(b) Risk-based labelling can only be applied by the competent authorities to the chronic health hazards of chemicals in the consumer product setting. […]

[…] The only chemicals it may be applied to are those in the consumer product setting where consumer exposures are generally limited in quantity and duration;

A5.2.2.1 In general, consumers rely on product labels for information about the effects of a chemical ~~product~~. Whereas other sectors have additional sources of information (e.g. safety data sheets, transport documents) to expand upon or refine product information and relate risk to the hazard information provided, the consumer sector generally does not.

A5.2.2.2 As noted above, the general rule for the GHS is that the label information will be based on intrinsic properties (hazards) of the chemical in all sectors. […]

A5.2.2.3 In particular, the principle of the user's "right-to-know" about the intrinsic hazards of the chemical is important and widely supported by many stakeholders. Hazard information is an incentive to choose less hazardous chemicals for use. […]

Table A6.1, module 3 (3rd column): Intention to use, store and dispose of the chemical.

Module 4: To test whether subjects' perception of the label will influence their reported intention to use, store or dispose of the chemical.

Module 9: To assess safety practices in relation to a simulated exercise in which a chemical is handled.

To identify whether past experience in relation to chemicals plays a significant role in both safety practices, and in the impact of signal words and symbols on safety practices.

Module 10: To ascertain past history of contact with chemicals and training.

Annex 6

A6.4.1 *Target populations*

A6.4.1.1 […]. These are largely adult working populations, typical of groups who use, distribute or manage chemicals, either directly or indirectly. […].

A6.5.8.3 To standardize opportunities for comprehension, the actual chemicals identified in the labels will be spurious chemicals, although made to look as if they could be genuine agents. This aims to retain context, while not disadvantaging those unfamiliar with a particular chemical.

Annex 9

A9.1.2 The hazard classification scheme has been developed with the object of identifying those ~~chemical~~ substances that present, through the intrinsic properties they possess, a danger to the aquatic environment. In this context, the aquatic environment is taken as the aquatic ecosystem in freshwater and marine, and the organisms that live in it. For most substances, the majority of data available addresses this environmental compartment. […].

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: aquatic toxicity; lack of degradability; and potential or actual bioaccumulation. […].

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A9.1.4 The application of the criteria is also limited, at this stage, 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. […].

A9.1.5 […] The potential to bioaccumulate can, for many organic chemicals, be indicated by the octanol-water partition coefficient. […].

A9.2.1 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 chemicals ~~substances~~ as well as transport of chemicals ~~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. […] For ~~substances~~ chemicals transported in bulk, there are a number of regulatory decisions that can uniquely arise because of the bulk quantities being considered. […].

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. […]

A9.2.6.2 […] For example, the test details and experimental design may be critical to the assessment of the usability of some data, such as that from hydrolytically unstable chemicals, while less so for other chemicals. Such difficulties are described further in Section A9.3.

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. […]

A9.3.5 *Difficult to test substances*

A9.3.5.1 Valid aquatic toxicity tests require the dissolution of the test substance in the water media under the test conditions recommended by the guideline. In addition, a bioavailable exposure concentration should be maintained for the duration of the test. Some ~~chemical~~ substances are difficult to test in aquatic systems and guidance has been developed to assist in testing these materials (DoE 1996; ECETOC 1996; and US EPA 1996). OECD is in the process of finalizing a Guidance Document on Aquatic Toxicity testing of Difficult Substances and Mixtures (OECD, 2000). This latter document is a good source of information on the types of substances that are difficult to test and the steps needed to ensure valid conclusions from tests with these materials.

A9.4.1.1 Degradability is one of the important intrinsic properties of ~~chemical~~ substances that determine their potential environmental hazard. Non-degradable substances will persist in the environment and may consequently have a potential for causing long-term adverse effects on biota. In contrast, degradable substances may be removed in the sewers, in sewage treatment plants or in the environment.

Classification of ~~chemical~~ substances is primarily based on their intrinsic properties. However, the degree of degradation depends not only on the intrinsic recalcitrance of the molecule, but also on the actual conditions in the receiving environmental compartment as e.g. redox potential, pH, presence of suitable micro-organisms, concentration of the substances and occurrence and concentration of other substrates. The interpretation of the degradation properties in an aquatic hazard classification context therefore requires detailed criteria that balance the intrinsic properties of the substance and the prevailing environmental conditions into a concluding statement on the potential for long-term adverse effects. The purpose of the present section is to present guidance for interpretation of data on degradability of organic substances. The guidance is based on an analysis of the above mentioned aspects regarding degradation in the aquatic environment. Based on the guidance a detailed decision scheme for use of existing degradation data for classification purposes is proposed. […]

A9.4.2.1 *Rapid degradability*

Aquatic hazard classification of ~~chemical~~ substances is normally based on existing data on their environmental properties.[…].

A9.4.3.2.2 The present standard methods for investigating degradability of ~~chemical~~ substances are developed for readily soluble test compounds. However, many organic substances are only slightly soluble in water. As the standard tests require 2-100 mg/l of the test substance, sufficient availability may not be reached for substances with a low water solubility. […]

A9.5.1.1 Bioaccumulation is one of the important intrinsic properties of ~~chemical~~ substances that determine the potential environmental hazard. Bioaccumulation of a substance into an organism is not a hazard in itself, but bioconcentration and bioaccumulation will result in a body burden, which may or may not lead to toxic effects. In the

harmonized integrated hazard classification system for human health and environmental effects of ~~chemical~~ substances (OECD, 1998), the wording "potential for bioaccumulation" is given. A distinction should, however, be drawn between bioconcentration and bioaccumulation. Here bioconcentration is defined as the net result of uptake, transformation, and elimination of a substance in an organism due to waterborne exposure, whereas bioaccumulation includes all routes of exposure (i.e. via air, water, sediment/soil, and food). Finally, biomagnification is defined as accumulation and transfer of substances via the food chain, resulting in an increase of internal concentrations in organisms on higher levels of the trophic chain (European Commission, 1996). For most organic chemicals uptake from water (bioconcentration) is believed to be the predominant route of uptake. Only for very hydrophobic substances does uptake from food become important. Also, the harmonized classification criteria use the bioconcentration factor (or the octanol/water partition coefficient) as the measure of the potential for bioaccumulation. For these reasons, the present guidance document only considers bioconcentration and does not discuss uptake via food or other routes.

A9.5.1.2 Classification of a ~~chemical~~ substance is primarily based on its intrinsic properties. However, the degree of bioconcentration also depends on factors such as the degree of bioavailability, the physiology of test organism, maintenance of constant exposure concentration, exposure duration, metabolism inside the body of the target organism and excretion from the body. The interpretation of the bioconcentration potential in a chemical classification context therefore requires an evaluation of the intrinsic properties of the substance, as well as of the experimental conditions under which bioconcentration factor (BCF) has been determined. […]

A9.5.2.1 Environmental hazard classification of a ~~chemical~~ substance is normally based on existing data on its environmental properties. Test data will only seldom be produced with the main purpose of facilitating a classification. Often a diverse range of test data is available which does not necessarily match the classification criteria. Consequently, guidance is needed on interpretation of existing test data in the context of hazard classification.

A9.5.3.2.1 Some ~~chemical~~ substances are difficult to test in aquatic systems and guidance has been developed to assist in testing these materials (DoE, 1996; ECETOC 1996; and US EPA 1996). OECD is in the process of finalizing a guidance document for the aquatic testing of difficult substances (OECD, 2000). This latter document is a good source of information, also for bioconcentration studies, on the types of substances that are difficult to test and the steps needed to ensure valid conclusions from tests with these substances. Difficult to test substances may be poorly soluble, volatile, or subject to rapid degradation due to such processes as phototransformation, hydrolysis, oxidation, or biotic degradation.

A9.7.1.1 The harmonized system for classifying ~~chemical~~ substances is a hazard-based system, and the basis of the identification of hazard is the aquatic toxicity of the substances, and information on the degradation and bioaccumulation behaviour (OECD 1998). Since this document deals only with the hazards associated with a given substance when the substance is dissolved in the water column, exposure from

this source is limited by the solubility of the substance in water and bioavailability of the substance in species in the aquatic environment. […]

Annex 9

APPENDIX I

3.7.1 Many ~~chemical~~ substances end up in the soil or sediment compartments and an assessment of their degradability in these environments may therefore be of importance. Among standard methods may be mentioned the OECD Test Guideline 304A test on inherent biodegradability in soil, which corresponds to the OPPTS 835.3300 test.

3.8.1 In recent years, possibilities for estimating environmental properties of ~~chemical~~ substances have been developed and, among these, also methods for predicting the biodegradability potential of organic substances (e.g. the Syracuse Research Corporation's Biodegradability Probability Program, BIOWIN). […]
