**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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ENVIRONMENTAL HAZARDS

Classification criteria for the terrestrial environment

Transmitted by the expert from Spain on behalf of the group on terrestrial hazards

During the last biennium, the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS) decided that the work on developing classification and labelling criteria for terrestrial environmental hazards should stay on its work programme for the biennium 2005-2006 but would not be addressed to the OECD. The Sub-committee encouraged Spain to create a small informal intersessional working group with experts from the interested countries for continuing the work and submitting the results at the end of the current biennium.

Spain prepared an initial proposal for the development of terrestrial environment classification criteria, based on the combination of exposure routes and taxonomic groups as suggested by the OECD expert group. The proposal covered the relevant terrestrial trophic levels and included two acute categories and two chronic categories.

The proposal was submitted for comments to the expert group, constituted by Austria, Brazil, France, Japan, Slovenia, USA and Spain.

The Brazilian experts suggested the possibility of including Acute Category 3 and Chronic Categories 3 and 4, and thereby the harmonization with the aquatic environment classification and labelling. This suggestion has been taken into account and now the proposal presents three acute categories and four chronic categories.

The expert from France sent his comments to this proposal, presenting a draft of a "surrogate system" for the terrestrial environment analogous to the aquatic environment. The proposal is included in the comments' document for further discussion. It was also indicated that the toxicity tests on micro-organisms should be considered for the chronic categories, instead that for the acute categories. This proposal has been incorporated in the draft.

The result of the work of the group during the biennium 2005-2006 is contained in the annexes to this document. Annex 1 contains the comments on the initial proposal received from the members of the group and Annex 2 contains the final draft proposal for the classification criteria for the terrestrial environment.

The proposal in Annex 2 has been drafted following the structure of existing GHS chapters to facilitate its possible incorporation as a new chapter of Part 4 in the future.

The Sub-Committee is invited to study the proposal and to consider the need of including this item in the work programme of the OECD for the next biennium for further development.

Annex 1: Comments to the proposal for the classification of terrestrial hazards

Comments from	Date	Comment	Response from the writing party
Pedro Zagatto (Brazil)	May 31, 2006	This proposal was very well prepared and I can see that it was applied a good knowledge about the effects to terrestrial organisms. The most important toxicity tests and criteria for classification were perfectly established. Nevertheless, my unique recommendation is to study the possibility to increase the third and/or fourth categories to classify the chemical products and establish the risk statements for these categories. Cut-off values for category 3 and 4 could be 1/1000 and >1/1000, respectively. These different categories could be harmonized as the same classification as to the aquatic environment chapter, including the same risk statement, advertising words and signs.	
Matthieu Lassus (France)	Sept 20, 2006	The proposal for a terrestrial classification is very interesting and, like I said in the last UN-SCGHS, we welcome such an approach. Nevertheless, I think that, taking into account the political context and the hardness of the negotiations, the proposal should be more flexible in the aim of being accepted by the SCGHS. To do so, I propose an analogy with the "surrogate system" for aqua. tox., and reference with REACH developments in its technical Implementation Projects (RIPs) (this last point is very useful for 2 reasons : RIPs are based on compatible methodologies with GHS ; the bond will be made next step, between the two regulations for our European aspects)	
Matthieu Lassus (France)	Sept 28, 2006	After discussions with our expert in INERIS (Pascal Pandard if you know him), I give you, in a telegraphic style, more details about our point of view of the terrestrial classification proposal: a) the proposal is too complex in term of considered organisms categories vis-à-vis of the aquatic environment ; simplification is needed for the proposal to be agreed by the GHS committee. b) taking into account the effects on birds or mammals is not really appropriate, more especially for effects on mammals which are covered by toxicological tests on rodents. c) tests on micro-organisms are not for acute category but chronic one, because of there life cycles and the duration of the tests (LD 216 & 217) d) there is no information about the scientific background which allow to determine the cut-off limits for foliar exposures ; also, the cut-offs do not seem comparable with other selected categories. I send one more time my proposal for a terrestrial "surrogate system". As a said in my previous mail, the proposal should be more flexible in the aim of being accepted by the SCGHS. And to do so, I propose an analogy with the "surrogate system" for aqua. tox. (See below)	c. These tests are now used to determine chronic toxicity in micro-organism

Proposal from the expert from France on a terrestrial "surrogate system"

The logic to take into account terrestrial tests = a minimum test choice:

- If aqua. toxicity data are relevant with phys.-chem. proprieties, a simple conversion with terrestrial classification is needed→ the substance is classified for the Environment), If not terrestrial test are required to prove the only aquatic toxicity.
- If P-C properties and/or aqua. tox. tests presuppose a little aquatic toxicity → terrestrial tests should be envisaged

Table reading:

P-C criteria, Short-Term cat. (S-T), and Long-Term cat. (L-T) are taken independently; respectively aqua/terr C-T, and aqua/terr L-T cat. are related only.

Other end-points to develop:

Research of equivalence between end-points already performed → inhalation tox. for Air aspects,...
Think to sedimentary marine species → Molluscs cumulate aqua. & terr. end-points

P-C properties							Most considered compartment	Aqua.C.		Terr. C.		Label.	
Kow	Koc	Solubility	Degradation	Bioaccumulation	PH (condition of salting out ?)	Volatility		S-T	L-T *	S-T	L-T	NO terr.C.	Terr. C.
<4		High	High	<500			Water	CAT.3	CAT.3	CAT.2	CAT.2		ENV
<4		medium/high	medium/high	<500				CAT.4	CAT.4	CAT.2/NO	CAT.2/NO	AQUA	ENV
<4		medium/high	medium/high	<500				NO	NO	NO	NO	NO ENV	TERR
							Water + food + soil	CAT.1	CAT.1	CAT.1	CAT.1		ENV
								CAT.2	CAT.2	CAT.1	CAT.1		ENV
>4	>4	medium/low	medium/low	Testing with a terrestrian sp. and/or in function to the Koc (RIP 3.3) ; utilisation of the BSAF			Food + soil	CAT.3	CAT.3	CAT.1 (2 if BCF <500)	CAT.1	AQUA	ENV
>4	>4	Low	Low	Testing with a terrestrian sp. and/or in function to the Koc (RIP 3.3) ; utilisation of the BSAF				CAT.4	CAT.4	CAT.2 (NO if BCF <500)	CAT.2	AQUA	ENV
>4	>4	Low	Low	Testing with a terrestrian sp. and/or in function to the Koc (RIP 3.3) ; utilisation of the BSAF				NO	NO	Testing	Testing	NO ENV	TERR
						Gas at +50% in atmosphere at standard Temperature/ Pressure (other more precise arbitrary criteria ?)	Air			Testing	Testing	AQUA/NO ENV	ENV/TERR

* According to tests, if not, take NO-->4 and 4-->3

Annex 2

"CHAPTER 4.X

HAZARDOUS TO THE TERRESTRIAL ENVIRONMENT

4.x.1 **Definitions and general considerations**

4.x.1.1 *Definitions*

For the purposes of this chapter,

Acute toxicity means the intrinsic property of a substance to be injurious to an organism in a short-term exposure to that substance.

Acute (short-term) hazard is the hazard of a chemical caused by its intrinsic potential to be injurious to an organism during short-term exposure to that chemical.

Availability of a substance means the extent to which this substance becomes a soluble or disaggregate species. For metal availability, the extent to which the metal ion portion of a metal (M°) compound can disaggregate from the rest of the compound (molecule).

Bioavailability (or biological availability) means the extent to which a substance is taken up by an organism, and distributed to an area within the organism. It is dependent upon physico-chemical properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. Availability is not a prerequisite for bioavailability.

Bioaccumulation means net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (i.e. air, water, sediment/soil and food).

Bioconcentration means net result of uptake, transformation and elimination of a substance in an organism due to exposure.

Chronic toxicity means the intrinsic property of a substance to cause adverse effects to organisms during exposures which are determined in relation to the life-cycle of the organism.

Complex mixtures or multi-component substances or complex substances means mixtures comprising a complex mix of individual substances with different solubilities and physico-chemical properties. In most cases, they can be characterized as a homologous series of substances with a certain range of carbon chain length/number of degree of substitution.

Degradation means the decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water and salts.

EC_x is the concentration associated with $\times$ % response. The value of "$\times$", the percent effect, may be specified in advance, based on biological (or regulatory) considerations.

ER_{50} is the rate associated with 50 % response. The percent effect may be specified in advance, based on biological (or regulatory) considerations.

LC$_{50}$ is the median lethal concentration, i.e. that concentration of the test substance which causes the death to 50 % of the test animals within the test period.

LD$_{50}$ is a statistically derived single dose of a substance that can cause death in 50 % of animals when administered by the oral route.

LOAEL is the lowest concentration or amount of a substance, found by experiment or observation, which causes an adverse alteration of morphology, functional capacity, growth, development, or life span of a target organism distinguishable from normal (control) organisms of the same species and strain under defined conditions of exposure.

Long-term hazard is the hazard of a chemical caused by its chronic toxicity following long-term exposure levels in the terrestrial environment.

NOAEL is the highest level of continual exposure to a chemical which causes no significant adverse effect on morphology, biochemistry, functional capacity, growth, development or life span of individuals of the target species.

NOEC is the test concentration below the lowest concentration that did result in a statistically significant effect in the specific experiment.

4.x.1.2 *Basic elements*

4.x.1.2.1 The basic elements for use within the harmonized system are:

(a) acute toxicity;
(b) chronic toxicity

4.x.1.2.2 While data from internationally harmonized test methods, such as the OECD Test Guidelines, are preferred, in practice, data from national methods may also be used where they are considered as equivalent.

4.x.1.3 *Acute terrestrial toxicity*

Acute toxicity data for the different terrestrial organisms would normally be determined using an EC$_{50}$ or LC$_{50}$ for soil dwelling macro-organisms, such as invertebrates and plants (OECD Test Guidelines 207, 208, and 217 or equivalent), a LC50 for foliar invertebrates and/or pollinators (OECD Test Guidelines 213 and 214 or equivalent), and/or LD50 for vertebrates, such as birds and mammals (OECD Test Guidelines 223, 401, 420, 423, and 425 or equivalent).

4.x.1.4 *Chronic terrestrial toxicity*

Chronic toxicity data are less available than acute data and the range of testing procedures less standardized. For micro-organisms an EC$_{50}$ (OECD Test Guidelines 216 and 217 or equivalent) may be applied. Data generated (NOEC) according to the OECD Test Guidelines 220 and 222 can be accepted for soil dwelling vertebrates. Chronic toxicity data (NOAEL) for vertebrates could be obtained from bird and mammal tests used in risk assessment (OECD Test Guidelines 206, 407-409, 414 -417, 421, 422, 452, and 453). Other validated and internationally accepted tests could also be used.

4.x.1.5 *Other considerations*

While the scheme is intended to apply to all substances and mixtures, it is recognized that for some substances, e.g. metals, poorly soluble substances, etc., special guidance will be necessary. For instance, application of the criteria to metals and metal compounds is contingent on completion of an appropriate validation exercise, as provided in OECD series on Testing and Assessment No 29.

4.x.2   **Classification criteria for substances**

4.x.2.1   The harmonized classification system for substances consists of three acute classification categories and four chronic classification categories. The acute and the chronic classification categories are applied independently. The criteria for classification of a substance in Acute Categories 1 to 3 are defined on the basis of the acute toxicity data (EC_{50}, LD_{50}, or LC_{50}). The criteria for classification of a substance into chronic categories are defined on the basis of chronic toxicity data (NOEC or NOAEL).

4.x.2.2   The key ecological receptors for the terrestrial environment are terrestrial vertebrates, terrestrial plants, soil-ground-foliar dwelling invertebrates and soil micro-organisms. These terrestrial organisms can be exposed through several environmental compartments (soil, air, water and food). Hazard identification must consider the key combinations of receptor-exposure routes. Therefore, five different combinations of taxonomic-group/exposure-route: micro-organisms, soil-dwelling macro-organisms (invertebrates and plants), terrestrial plants considering foliar exposure, foliar invertebrates/pollinators (focusing on bees) and terrestrial vertebrates (birds and mammals) have been established (see Tables 4.x.1 to 4.x.5 below).

4.x.2.3   The system for classification recognizes that the core intrinsic hazard to terrestrial organisms is represented by both the acute and chronic toxicity of a substance, the relative importance of which is determined by the specific regulatory system in operation. Distinction can be 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 will normally be used to define the appropriate hazard category(ies). 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 standardized.

Table 4.x.1: Classification criteria for substances hazardous to micro-organisms

Chronic toxicity

Category: Chronic 1
$EC_{50} \leq 1$ mg/kg;   and/or
≥ 50 % of adverse effects on soil micro-organisms at a concentration ≤ 1 mg/kg dw
Category: Chronic 2
$EC_{50} > 1$ but ≤ 10 mg/kg; and/or
≥ 25 but < 50% of adverse effects on soil micro-organisms at a concentration ≤ 1 mg/kg dw
Category: Chronic 3
$EC_{50} > 10$ but ≤ 100 mg/kg; and/or
< 25% of adverse effects on soil micro-organisms at a concentration ≤ 1 mg/kg dw
Category: Chronic 4
Substances that are persistent and/or bioaccumulate (or not rapidly degradable) will be considered as a possible hazard to the terrestrial environment and will be classified in this category unless other scientific evidence exist showing classification to be unnecessary (e.g. $EC_x > 100$ mg/kg).

Table 4.x.2: Classification criteria for substances hazardous to soil dwelling macro-organisms: invertebrates and plants (soil exposure)

Acute toxicity	Chronic toxicity
Category: Acute 1 $EC_{50}/ LC_{50}/ER_{50}$ ≤ 10 mg/kg/dw	**Category: Chronic 1** NOEC ≤ 1 mg/kg
Category: Acute 2 $EC_{50}/ LC_{50}/ER_{50}$ > 10 but ≤ 100 mg/kg/dw	**Category: Chronic 2** NOEC > 1 but ≤ 10 mg/kg
Category: Acute 3 $EC_{50}/ LC_{50}/ER_{50}$ > 100 but ≤ 1000 mg/kg/dw	**Category: Chronic 3** NOEC > 10 but ≤ 100 mg/kg
	Category: Chronic 4
	Substances which are persistent and/or bioaccumulate (or not rapidly degradable) will be considered as a possible hazard to the terrestrial environment and will be classified in this category unless other scientific evidence exist showing classification to be unnecessary (e.g. $EC_x > 100$ mg/kg).

Table 4.x.3: Classification criteria for substances hazardous to terrestrial plants (foliar exposure)

Acute toxicity

Category: Acute 1 EC_{50}/ER_{50} ≤ 10 kg/ha
Category: Acute 2 EC_{50}/ER_{50} > 10 but ≤ 100 kg/ha
Category: Acute 3 EC_{50}/ER_{50} > 100 but ≤ 1000 kg/ha

Table 4.x.4: Classification criteria for substances hazardous to foliar invertebrates and pollinators (bees)

Acute toxicity

Category: Acute 1 LC_{50} ≤ 1 µg/bee
Category: Acute 2 LC_{50} > 1 but ≤ 10 µg/bee
Category: Acute 3 LC_{50} > 10 but ≤ 100 µg/bee

Table 4.x.5: Categories for substances hazardous to vertebrates: birds and mammals

Acute toxicity	Chronic toxicity
Category: Acute 1 $LD_{50} \leq 5$ mg/kg bw	**Category: Chronic 1** NOAEL ≤ 0.5 mg/kg bw
Category: Acute 2 $LD_{50} > 5$ but ≤ 50 mg/kg bw	**Category: Chronic 2** NOAEL $> 0.5 – 5$ mg/kg bw
Category: Acute 3 $LD_{50} > 50$ but ≤ 500 mg/kg bw	**Category: Chronic 3** NOAEL > 5 but ≤ 50 mg/kg bw
	Category: Chronic 4
	Substances which are persistent and/or bioaccumulate (or not rapidly degradable) will be considered as a possible hazard to the terrestrial environment and will be classified in this category unless other scientific evidence exist showing classification to be unnecessary (e.g. $EC_x > 100$ mg/kg).

4.x.2.4 *Category Chronic 4*

The system also introduces as "safety net" classification (Category: Chronic 4) for use when data available do not allow classification under formal criteria but there are nevertheless some grounds of concern. In case it is proven that there is a rapid degradation and a lack of bioaccumulation of the test substance, it would not be necessary to apply this chronic category of the terrestrial hazard classification.

4.x.2.5 *Use of QSARs*

While experimentally derived test data are preferred, where no experimental data are available, validated Quantitative Structure Activity Relationships (QSARs) for aquatic toxicity and log K_{ow} may be used in the classification process. Such validated QSARs may be used without modification to the agreed criteria, if restricted to chemicals for which their mode of action and applicability are well characterized. Reliable calculated toxicity and log K_{ow} values should be valuable in the safety net context. QSARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation.

4.x.2.6 *Integration of classification criteria*

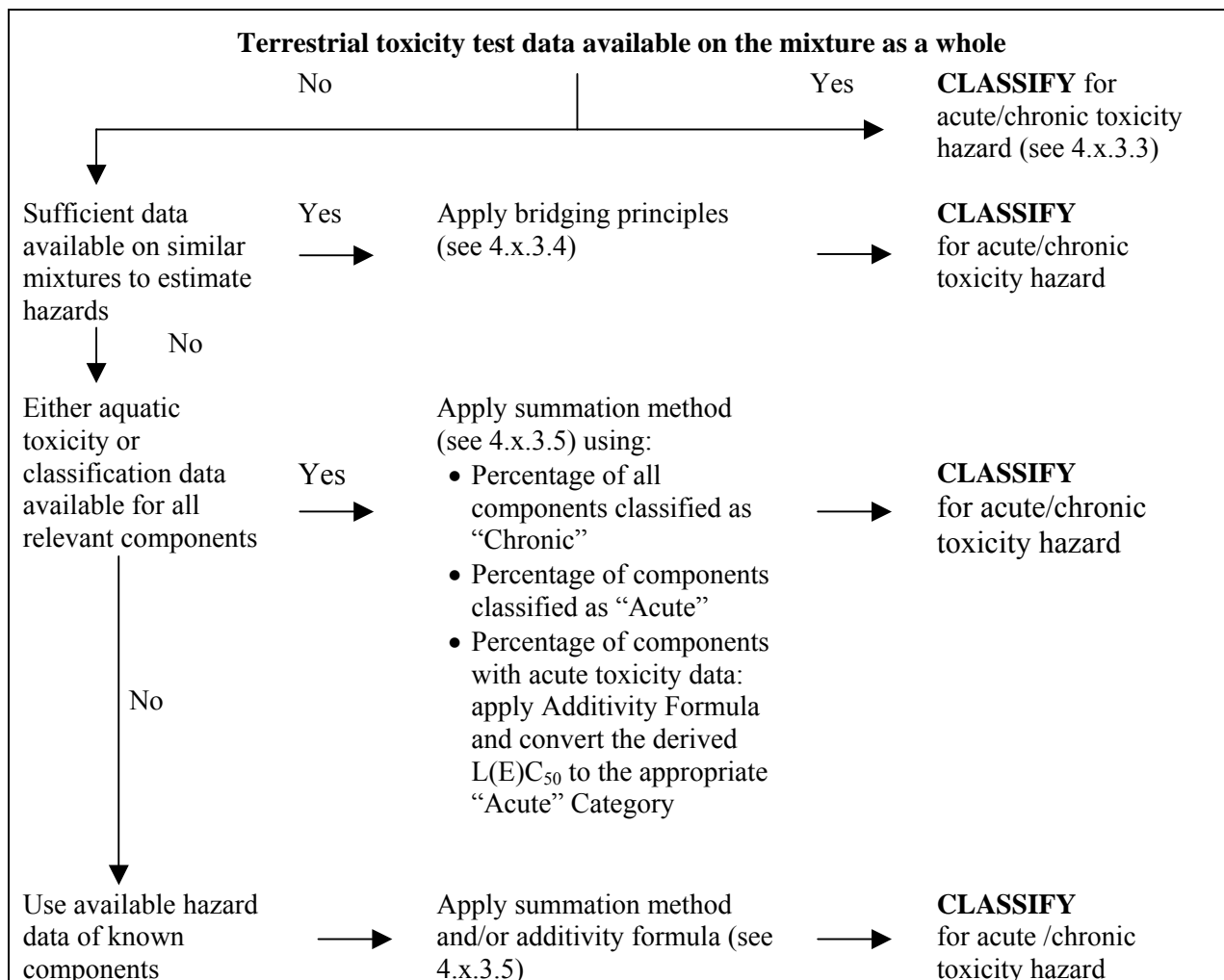| Categories	Criteria
ACUTE 1	The substance is classified as Acute 1 if at least one of the different taxonomic group/exposure route combinations fulfils the criteria for Acute 1 classification.
ACUTE 2	The substance is classified as Acute 2 if at least one of the different taxonomic group/exposure route combinations fulfils the criteria for Acute 2 classification and it is not classified as Acute 1.
ACUTE 3	The substance is classified as Acute 3 if at least one of the different taxonomic group/exposure route combinations fulfils the criteria for Acute 3 classification and it is not classified as Acute 1 or 2.
CHRONIC 1	The substance is classified as Chronic 1 if at least one of the different taxonomic group/exposure route combinations fulfils the criteria for Chronic 1 classification.
CHRONIC 2	The substance is classified as Chronic 2 if at least one of the different taxonomic group/exposure route combinations fulfils the criteria for Chronic 2 classification and it is not classified as Chronic 1.
CHRONIC 3	The substance is classified as Chronic 3 if at least one of the different taxonomic group/exposure route combinations fulfils the criteria for Chronic 3 classification and it is not classified as Chronic 1 or 2.
CHRONIC 4	The substance is classified as Chronic 4 if at least one of the different taxonomic group/exposure route combinations fulfils the criteria for Chronic 4 classification and it is not classified as Chronic 1, 2 or 3.

4.x.3 **Classification criteria for mixtures**

4.x.3.1 The classification system for mixtures covers all classification categories which are used for substances, meaning Acute Categories 1 to 3 and Chronic Categories 1 to 4. In order to make use of all available data for purposes of classifying the terrestrial environmental hazards of the mixture, the following assumption has been 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 terrestrial environmental hazards.

4.x.3.2 The approach for classification of terrestrial 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: (a) classification based on tested mixtures; (b) classification based on bridging principles, the use of "summation of classified components" and /or an "additivity formula". Figure 4.x.1 outlines the process to be followed.

Figure 4.x.1: Tiered approach to classification of mixtures for acute and chronic terrestrial environmental hazards

4.x.3.3 *Classification of mixtures when data are available for the complete mixture*

When the mixture as a whole has been tested to determine its toxicity, it can be classified to the criteria that have been agreed for substances, for both acute and chronic toxicity. The use of LD_{50}, EC_{50} or LC_{50} data for the mixture as a whole allows its classification in the acute categories. For chronic categories, the mixture will be classified applying data such as NOEC or NOAEL for the mixture as a whole when available.

4.x.3.4 *Classification of mixtures when data are not available for the complete mixture: Bridging principles*

4.x.3.4.1   Where the mixture itself has not been tested to determine its terrestrial environmental hazard, but there are sufficient data on the individual components and similar tested mixtures to adequately characterize the hazards of the mixture, this data will 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 characterizing the hazards of the mixture without the necessity for additional testing in animals.

4.x.3.4.2   *Dilution*

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 terrestrial hazards of other components, then the mixture may be classified as equivalent to the original mixture or substance.

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 can be calculated from the original mixture or substance.

4.x.3.4.3   *Batching*

The terrestrial hazard classification of one production batch of a complex mixture can 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 terrestrial hazard classification of the batch has changed. If the latter occurs, new classification is necessary.

4.x.3.4.4   *Concentration of mixtures which are classified with the most severe classification categories (Chronic 1 and Acute 1)*

If a mixture is classified as Chronic 1 and/or Acute 1, and components of the mixture which are classified as Chronic 1 and/or Acute 1 are further concentrated, the more concentrated mixture should be classified with the same classification category as the original mixture without additional testing.

4.x.3.4.5   *Interpolation within one toxicity category*

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 is assumed to be in the same category as A and B. Note that the identity of the components is the same in all three mixtures.

4.x.3.4.6   Substantially similar mixtures

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 toxicity of B.

Then there is no need to test mixture (ii) if mixture (i) is already characterized by testing and both mixtures would be classified in the same category.

4.x.3.5 *Classification of mixtures when data are available for all components or only for some components of the mixture*

[to be developed]

4.x.3.6 *Classification of mixtures with components without any useable information*

[to be developed]

4.x.4 **Hazard communication**

General and specific considerations concerning labelling requirements are provided in Hazard communication: Labelling (Chapter 1.4). Annex 2 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

Table 4.x.6: Label elements for hazardous to the terrestrial environment

ACUTE

	Category 1	**Category 2**	**Category 3**
Symbol	Environment	*No symbol*	*No symbol*
Signal word	Warning	*No signal word*	*No signal word*
Hazard statement	Very toxic to terrestrial life	Toxic to terrestrial life	Harmful to terrestrial life

CHRONIC

	Category 1	**Category 2**	**Category 3**	**Category 4**
Symbol	Environment	Environment	*No symbol*	*No symbol*
Signal word	Warning	*No signal word*	*No signal word*	*No signal word*
Hazard statement	Very toxic to terrestrial life with long lasting effects	Toxic to terrestrial life with long lasting effects	Harmful to terrestrial life with long lasting effects	May cause long lasting harmful effects to terrestrial life

4.x.5 **Decision logic for substances and mixtures hazardous to the terrestrial environment**

The decision logic which follows is not part of the harmonized classification system but is provided here as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of the decision logic.

[decision logics for substances and mixtures: to be developed]"

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