UN/SCEGHS/15/INF.28

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

Fifteenth session,
Geneva, 9-11 July 2008
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

Progress report on terrestrial environmental hazards

Transmitted by the Organisation for Economic Co-operation and Development (OECD)

This document provides a progress report on the work on terrestrial environmental hazards following the mandate given by the Sub-Committee to the OECD (refer to the programme of work of the Sub-Committee for 2007-2008, approved by the Committee at its third session; documents ST/SG/AC.10/C.4/24, Annex 2 and ST/SG/AC.10/34, para.14).

A report on each item of the given mandate is included in Sections 2, 3, 4 and 5 of this document.

The detailed review of existing classification and labelling systems has been included in an annex to this document, which is circulated for the fifteenth session of the Sub-Committee as document UN/SCEGHS/15/INF.29.

1. Introduction

1. Two OECD documents related to terrestrial environmental hazards have been submitted to the UN Sub-Committee of Experts on the GHS (UN SCEGHS): document ST/SG/AC.10/C.4/2003/2 (Overview of historical and current work in OECD on Terrestrial Hazard Assessment) and document UN/SCEGHS/7/INF.15 (Issues to be addressed to develop the classification and labelling for terrestrial environmental hazards). In July 2006, Spain submitted document UN/SCEGHS/12/INF.5 (Classification criteria for the terrestrial environment). In December 2006, the UN SCEGHS requested that the OECD re-start working on hazards to the terrestrial environment, according to the following mandate:

(a) *To review existing systems (including those in place for pesticides in some countries) and evaluate the potential benefits of harmonizing classification*;

(b) *To consider hazard communication needs, options and alternatives for coverage of terrestrial hazards in the various sectors*;

(c) *To examine possibilities for the development of a generic scheme for the classification of substances as hazardous for the terrestrial environment under the GHS, taking into account the issues and options identified in previous documents, in particular, ENV/JM/HCL(2004)3 REV and UN/SCEGHS/12/INF.5, as well as other alternatives that may be presented to the expert group*;

(d) *To identify additional scientific issues that should be further investigated and to formulate specific questions for getting information on relevant gaps. The expert group may also identify relevant scientific bodies that could cooperate in addressing these specific questions.*

Discussion on numeric criteria and classification of mixtures will be postponed for the future.

2. The UN SCEGHS requested that the OECD provide a progress report on the work at the end of 2008. A report on each item of the above mandate is included in Sections 2, 3, 4 and 5 of this document. The Annex includes a detailed review of existing classification and labelling systems.

2. Review of existing systems and potential benefits of harmonising classification

2.1 *Review of existing systems*

3. As requested in part (a) of the mandate given by the UN SCEGHS for 2007-2008, a review of existing classification systems for hazards to the terrestrial environment was carried out.

4. There are hazard based systems for pesticides in North America and other countries, and a generic system for all chemicals in New Zealand (under revision at the moment of issuing this report).

5. The Annex presents a review document on the systems for classification of hazards to the terrestrial environment. The review is not exhaustive, as there are many other specific rules for the classification of pesticides, but considering the similarity among the systems, it was considered sufficient for presenting an international overview. Table 1.1 summarises the different classification systems.

6. This document will focus on hazard based classification. There is other information on classification and labelling in the Annex for some countries on specific taxonomic groups (e.g.: arthropods, micro-organisms or plants), but as it is not clear that it is hazard based, it is not included in Table 1.1.

Table 1.1:
Existing hazard based classification systems for hazards to the terrestrial environment

Geographic reference	Type of chemical		Classification groups	Implementation stage
Andean Community	Pesticides	Active ingredient	Birds Honey bees Earthworms	Implemented
		Formulated product		
Argentina	Phytosanitary products		Birds Honey bees Earthworms	Implemented
Canada	Pesticides		Honey bees Birds and mammals	Implemented
European Union	Chemicals		Fauna Flora Soil organisms	Non implemented[1]
New Zealand	Hazardous substances		Soil environment Terrestrial vertebrates (birds or mammals) Terrestrial invertebrates	Implemented (under revision)
USA	Pesticides		Birds and mammals Honeybees	Implemented
	Industrial chemicals		Birds and mammals Plants	Non implemented[2]

[1] *The EU system is not currently applied as the criteria for terrestrial hazards have not been developed yet. According to the currently available information, the proposed new EU Classification, Labelling and Packaging (CLP) Regulation will not include labelling elements concerning terrestrial hazards, as it is based on the current GHS.*

[2] *In addition to the system applied to pesticides; under the Toxic Substance Control Act (TSCA) hazard based labelling has been done case by case. Additional possibilities might be covered by the Consumer Labelling Initiative (CLI) and the Environmentally Preferable Purchasing (EPP).*

2.2 *Potential benefits of a globally harmonised classification and labelling system concerning chemicals hazardous to terrestrial organisms*

7. The benefits of the international harmonisation of toxic chemical control and environmental health and safety programs have been known for two to three decades as, for example: chemical safety, facilitation of trade, and reduction of cost to governments and industry. The benefits of harmonised classification and labelling systems were recognised in the Preamble of the Chapter of the 1992 Rio Conference dealing with toxic chemicals.

8. These benefits, including:

- enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication,
- facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis,
- provide a recognised framework for those countries without an existing system, and
- reduce the need for testing and evaluation of chemical,

formed the basis for the UN Decision to develop a Globally Harmonised System for the Classification and Labelling of the chemicals which pose a potential hazard to human health and the environment.

9. Subsequently, the OECD Task Force on Harmonisation of Classification and Labelling took on the task of overseeing the development of the GHS and set up, among others, an Expert Group on Classification of Environmental Hazards. It was tacitly agreed that the benefits from harmonization, listed above, applied to the environmental hazards, including to the aquatic and the terrestrial subdivisions.

10. Hazards for the aquatic environment were the first focus of the Expert Group because the aquatic hazard testing and hazard assessment was more advanced than with the terrestrial environment.

11. Industry states that the potential benefits of a GHS (harmonised) system for the classification of hazards for the terrestrial environment would be minimal, particularly in relation to the costs.

12. The following is a discussion of harmonisation in general and also more specifically on the need for and the benefits of the harmonisation of the classification of hazards for the terrestrial environment.

13. This text discusses harmonisation in a more principled and general manner. Several systems for hazard communication concerning effects on terrestrial organisms are, however, already in place around the world and this text is written based on the understanding that there is a need to communicate this hazard.

14. The text is largely based on existing text in GHS and also on a discussion paper regarding guidance for terrestrial effect assessment, prepared for OECD by the Danish Water Quality Institute (VKI) in December 1994 (Danish Discussion Paper Regarding Guidance for Terrestrial Effects Assessment. Danish Water Quality Institute (VKI) December 1994, OECD).

15. 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 has been recognised that an internationally-harmonised approach to classification and labelling will provide the foundation for such programs.

16. To these aims, a globally harmonised system of international criteria to classify and label substances and mixtures are as valid to chemicals hazardous for terrestrial ecosystems as to other hazard classes, already included in GHS.

Enhance the protection of human health and the environment

17. Availability of information about chemicals, their hazards, and ways to protect people and the environment, provide the foundation for national programmes for the safe management of chemicals. 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.

18. The GHS is not intended to harmonise risk assessment procedures or risk management decisions, which generally require some risk assessment in addition to hazard classification. GHS is a hazard based system and the degree for chemicals capacity to harm depends on their intrinsic properties. Obviously, chemical hazards are the same around the world; therefore a widespread management of chemicals in countries around the world will lead to safer conditions for the global population and the environment.

19. Classification normally aims at two principle objectives; to ensure that a user has sufficient information about the hazard so that risks can be avoided; and to ensure that a user can make an informed choice about purchase, i.e. opt to use less hazardous materials. Clearly, the latter works best where all substances have been evaluated for an endpoint and a hierarchy of hazard exists to distinguish them. It can be argued that the benefits of having more information on individual chemicals are therefore balanced by the potential for unjustifiably distorting the market with respect to the pursuit of a substitution policy. A scheme based on limited data availability would not be a significant benefit in this respect. Thus data availability is specifically discussed later within this document. Nevertheless, the issue of lack of data is also inherent to other GHS categories (no classification is not equivalent to no hazard).

20. It should be noted that the OECD mandate covers consideration of the benefits of harmonisation. However, some insights on potential benefits of a classification system are discussed below.

21. It can be argued that the level of benefit to be derived from a classification scheme is dependent on the level of available data and the extent to which these data identify substances not covered by the existing classification systems.

22. The first item has been specifically covered under point 4; fortunately regional regulations and efforts such as those developing in the EU and others have the potential for fulfilling the information gap on terrestrial hazards. Paragraph 29 evaluates the data availability issue. It is expected that for the most relevant groups of chemicals; information is or would become available within a short time period.

23. The second item cannot be addressed without a preliminary development of classification criteria; therefore the percentage of the total substances that will be classified solely for terrestrial hazards is unknown. However, data provided by Germany and the UK, although limited, indicate that depending on the criteria, terrestrial classification may address a relevant number of substances not covered by the aquatic system (e.g. in the analysis made available to the OECD by the UK, only 5 out of 16 substances with terrestrial toxicity <100 mg/kg were classified in the EU for aquatic hazards.

24. In addition, the regional implementation of the GHS may lead to additional benefits from an environmental classification system covering both aquatic and terrestrial compartments, even for substances requiring both classifications.

25. First, it should be noted that the terrestrial scheme may cover toxic but poorly soluble chemicals for which environmental hazard is not covered adequately by the aquatic classification scheme (see ENV/JM/HCL(2004)3 REV for additional information), and those particularly toxic to birds, plants and microorganisms.

26. Second, a harmonised terrestrial classification scheme would facilitate the implementation of measures for the protection of the (agricultural) environment from contamination, such those related to the agricultural use or valorisation of wastes and sludge as fertilisers or to wastewater reuse. The communication to the industrial user of the hazards of a substance for the terrestrial environment will allow the implementation of management measures for avoiding or controlling the presence of that substance in the valorised wastes and wastewaters. Voluntary agreements, downstream legislations and other initiatives, based on a proper identification and communication of the terrestrial hazards of a substance to industrial and downstream users, could be developed at the regional level. These initiatives would significantly improve the protection of the environment, e.g. through a careful use of the substances for avoiding the contamination of wastes/wastewaters to be valorised within the agricultural context, for setting priorities, or for establishing communication tools within the supply chain (e.g. to communicate that the waste for a particular industrial process may contain substances hazardous to the terrestrial environment and should not be reused or valorised as a fertiliser).

27. There are clear benefits for using a terrestrial environmental hazard classification scheme for pesticide actives, both plant protection products and biocides, but there are also some questions on the benefits of harmonisation for pesticides.

28. Industry considers that for pesticides, a harmonised hazard-based system may be of limited use given that risk-based procedures are implemented.

29. The review of existing systems indicates that both hazard-based and risk-based systems co-exist in many countries/regions.

Facilitate international trade

30. Chemicals are manufactured and traded globally, and a common system for classification and labelling will have benefits in terms of facilitating international trade, by promoting greater consistency in the national requirements for chemical hazard classification and communication that companies engaged in international trade must meet. While existing laws or regulations are similar in many respects, their differences, however, are significant enough to result in different labels or safety data sheets (SDS) for the same product in different countries. Decisions on when or how to communicate hazards on a label or SDS thus vary around the world, and companies wishing to be involved in international trade must have large staffs of experts who can follow the changes in these laws and regulations and prepare different labels and SDS.

Relevant group of chemicals

31. According to GHS there are four different target audiences: *workplaces, consumers, emergency responders* and *transport*. In addition, the classification regarding potential dangers for the environment is expected to allow for mitigation measures for non intended emissions of chemical substances into the environment. Pesticides can be used in consumer settings (e.g. lawn and garden products) and workplaces (e.g. pesticides used to treat seed in seed treatment plants) and thus does not constitute an additional target audience.

32. Due to the direct application of agricultural pesticides to terrestrial environments these chemicals are highly relevant when considering criteria for a classification and labelling system concerning chemicals hazardous to terrestrial organisms. Pesticides, however, constitute only a smaller part of chemical universe and in the development of a generic system other groups of chemicals need to be considered as well.

33. The identification of the type of chemicals for which terrestrial effects assessment could lead to national regulatory actions and to commence the identification of organisms of concern was discussed in an OECD discussion paper (Danish Discussion Paper Regarding Guidance for Terrestrial Effects Assessment. Danish Water Quality Institute (VKI) December 1994, OECD). The following text is based on what is presented in that paper.

34. The identification of the relevance of terrestrial effects assessment can be based on information concerning the routes of emission of different types of chemicals to the environment in combination with ecological considerations concerning types and compartments of ecosystems.

35. Chemicals may enter the terrestrial environment via a range of different emission routes (e.g. direct application, atmospheric deposition, or irrigation of cultivated areas). The chemicals can follow aerial, aquatic or solid phase routes to the ecosystems. Most chemicals will arrive through several routes. Based on the character of the emission, the chemicals can be divided into two groups:

(a) those that are produced to be deliberately applied to the environment (the agricultural chemicals and some biocides); and

(b) those that are not intended to reach the environment but are emitted as a consequence of different activities (the contaminants).

(From the point of view of source of emission, biocides that enter the environment as waste from industry or domestic use as well as spray drift or runoff from pesticides application on fields or forests are also considered contaminants.)

36. Differences in environmental and management conditions among regions may modify the relevance of specific routes. For example, irrigation with (treated) waste water is of particular relevance for Mediterranean and dry climates.

37. Chemicals that are used in high volumes (e.g. produced in or imported into a country at amounts exceeding 1 000 tons/year) may be emitted to the terrestrial environment in considerable amounts even though they belong to one of the groups for which release is expected to be of minor importance. Thus, for such "high production volume chemicals" terrestrial effects assessment has to be considered relevant.

38. The groups of chemicals for which terrestrial effects assessment is of primary relevance are:

- High production volume chemicals
- Pesticides and biocides applied to terrestrial environments
- Industrial chemicals (including most biocides) that are lipophilic, sorptive, non volatile, not rapidly degradable/persistent and toxic

39. A harmonised terrestrial effects classification and labelling system would produce particularly relevant benefits for these chemical groups.

Cost effective development and maintenance

40. Given the complexity of developing and maintaining a comprehensive system for classifying and labelling chemicals, many countries, however, have no system at all. For countries without an existing system it is very costly and time consuming to develop their own system. A task for the UNSCEGHS is

therefore to make GHS available for worldwide use and application. While governments, regional institutions and international organisations are the primary audiences, the GHS also contains sufficient context and guidance for those in industry who will ultimately be implementing the national requirements which are adopted.

41. There are concerns regarding costs, however costs cannot be quantified until the nature of the classification scheme is known.

42. The development of a viable classification system must take into account the utility or potential benefit of the scheme. Efforts must be made to keep the system simple so that data gathering and the classification process are not too costly in time and resources.

3. Hazard communication needs

43. Hazard communication would apply to all handling and use including any foreseeable accidental release and misuse. The aim of the symbol (to warn) would be similar for aquatic and terrestrial hazards.

44. Regarding pesticide uses, the hazard based classification is for the purpose of terrestrial hazards; some authorities or sectors already have independent provisions for communicating risks.

45. Current GHS elements are appropriate for communicating terrestrial hazards; the scheme should be developed to be compatible with the current aquatic hazards communication scheme:

- Symbol: a single symbol covering aquatic and terrestrial hazards is available (this symbol being already for environmental hazards in general terms) and could be used;

- Hazard statement: different options to be explored regarding the harmonisation with aquatic hazards. There are several possibilities for integrating/harmonizing the environmental hazards. The best way forward is to focus on the specific criteria for terrestrial hazards in a way that could be merged or not with the aquatic criteria at the end of the process. Options for communication include (i) a single hazard statement for the environment, with criteria combining aquatic and terrestrial hazard within the category, (ii) a combined hazard statement (e.g. very toxic to aquatic and terrestrial life) with parallel criteria combined at the end, and (iii) independent but parallel hazard statements.

46. The pros and cons as well as the difficulties will be better analysed once an agreed scheme could be available. It is also important to avoid overload the label.

4. Possibilities for the development of a generic scheme

47. As shown in document ST/SG/AC.10/C.4/2003/2 (ENV/JM(2003)19), there are a number of Test Guidelines available for the terrestrial compartment and more test methods are in development. Table 1 from UN/SCEGHS/7/INF.15 has been updated with the recent development of Test Guidelines. The updated table is shown below (Table 4.1).

Table 4.1:
Available OECD Test Guidelines for the terrestrial compartment (soil and above ground)

Test Method	OECD Test Guidelines
Avian Dietary Toxicity Test	TG 205
Avian Reproduction Test	TG 206
Earthworm, Acute Toxicity Tests	TG 207
Terrestrial Plants – Growth Test	TG 208 (revised)
Honeybees, Acute Oral Toxicity Test	TG 213
Honeybees, Acute Contact Toxicity Test	TG 214
Soil Microorganism: Nitrogen Transformation Test	TG 216
Soil Microorganism, Carbon Transformation Test	TG 217
Enchytraeid Reproduction Test	TG 220
Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)	TG 222
Terrestrial Plant Test: Vegetative Vigour Test	TG 227

48. Regarding data availability, the following issues are considered relevant:

- Current data availability is less extensive than for aquatic data
- Current data focuses on pesticides and “data rich” substances such as metals
- It is expected that REACH implementation will produce data or information for high production volume chemicals in a short period

49. Therefore, the availability of data and relevant information is not a problem for pesticides, biocides, and for some metals and other substances. For high production volume chemicals a large amount of information will be available in a few years time.

5. Additional scientific issues that should be further investigated

50. The updated document, UN/SCEGHS/7/INF.15, which was developed by the OECD in 2004, provides proposals for issues to be addressed to develop the classification and labeling for this hazard class and includes a list of Test Guidelines available or in development at that time (updated Table 4.1).

51. The following issues have been identified:

a) Need to revisit previous recommendations of the OECD regarding taxa and end-points according to current state of the art

b) Need for the selection of the most appropriate taxonomic groups

c) Need to consider the influence of soil type on hazard outcome, and if necessary and feasible to normalise test results

52. In reference to point b), the possibility of considering soil protozoa has been raised. This taxonomic group was not mentioned specifically in UN/SCEGHS/7/INF.15. The main reason why this essential taxonomic group was missing up to date is assumed to be explained by the low number of scientists in this specific area and the scientific discussion about reliable quantification methods. A specific document on relevance and possibilities for a short term assay on soil protozoa is available at: (http://www.umweltnet.at/article/articleview/66655/1/7033/).

Annex

CLASSIFICATION OF HAZARDS TO THE TERRESTRIAL ENVIRONMENT: A REVIEW

(see document UN/SCEGHS/15/INF.29)