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**COMMITTEE OF EXPERTS ON THE TRANSPORT OF
DANGEROUS GOODS AND ON THE GLOBALLY
HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS**

**Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals**

**(First session, 9-11 July 2001,
agenda item 5)**

**GLOBALY HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS (GHS)**

Classification criteria for health hazards and hazards to the environment

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

INTRODUCTION

1. In November 1994, the OECD 22nd Joint Meeting agreed to establish the Advisory Group on Harmonisation of Classification and Labelling (AG-HCL) and created the Programme on Harmonisation of Classification and Labelling (HCL) to finalise the work started in 1991 as a Clearing House activity. The objectives of the new Programme on HCL were to develop a harmonised classification system for chemical substances covering the following nine hazard endpoints considered in existing classification systems: hazards to the aquatic environment, acute toxicity, skin irritation/corrosion, eye irritation/corrosion, sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, and target organ toxicity. In addition, the harmonised classification system for substances should also include the following hazards, not yet covered by existing systems: neurotoxic effects, immunotoxic effects and effects hazardous to the terrestrial environment. The Programme's objectives also included the development of a harmonised hazard classification system for chemical mixtures, based on the same endpoints as considered for substances. The target for finalising the work was set at the end of the year 2000, which was in agreement with the recommendations from UNCED in 1992.

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2. As the work progressed, Step 1 Detailed Review Documents (DRD's) were considered necessary for: germ cell mutagenicity, sensitisation, eye irritation/corrosion, skin irritation/corrosion, reproductive toxicity, target organ toxicity and chemical mixtures. These DRD's were subsequently drafted, discussed and agreed upon by *ad hoc* Expert Groups, endorsed by the Task Force on HCL, and submitted to the Joint Meeting for formal derestriction. They were used as the basis for consensus building on the Step 2 proposals for harmonised classification systems. The various Step 1 DRD's are available as EHS Monographs in the Series on Testing and Assessment as follows:

- No.12: Detailed Review Document on Classification Systems for Germ Cell Mutagenicity in OECD Member Countries [<http://www.oecd.org/ehs/test/monos>]
- No 13: Detailed Review Document on Classification Systems for Sensitizing Substances in OECD Member Countries [<http://www.oecd.org/ehs/test/monos>]
- No.14: Detailed Review Document on Classification Systems for Eye Irritation/Corrosion in OECD Member Countries [<http://www.oecd.org/ehs/test/monos>]
- No.15: Detailed Review Document on Classification Systems for Reproductive Toxicity in OECD Member Countries [<http://www.oecd.org/ehs/test/monos>]
- No.16: Detailed Review Document on Classification Systems for Skin Irritation/Corrosion in OECD Member Countries [<http://www.oecd.org/ehs/test/monos>]
- No. 25: Detailed Review Document Hazard Classification Systems for Specific Target Organ/Systemic Toxicity Following Repeated Exposure in OECD Member Countries [<http://www.oecd.org/ehs/test/monos>]
- No.30 Detailed Review Document on Hazard Classification Systems for Mixtures [<http://www.oecd.org/ehs/test/monos>]

ACHIEVEMENTS

Harmonised Classification Systems for Substances

3. In November 1998, the 28th Joint Meeting recognised the achievements made in the area of classification of substances and approved the concept of the "Integrated Document", bringing together the harmonised classification systems for each of the nine recognised hazard categories.

The 28th Joint Meeting further approved the content of Part 1 of the Integrated Document (General Introduction to the Harmonised Integrated Hazard Classification System) and all but one chapter of its Part 2 (which comprises the respective harmonised classification systems). In November 2000, the 31st Joint Meeting approved the one remaining chapter (on specific target organ systemic toxicity). The completed Part 2 of the Integrated Document comprises the following harmonised systems for the classification of chemical substances, which cause:

- Acute Toxicity;
- Skin Irritation/Corrosion;
- Eye Irritation/Corrosion;
- Respiratory or Skin Sensitisation;
- Mutations in Germ Cells;

- Cancer;
- Reproductive Toxicity;
- Specific Target Organ Oriented Systemic Toxicity Following Single Exposure;
- Specific Target Organ Oriented Systemic Toxicity Following Repeated Exposure;
- Hazards to the Aquatic Environment.

4. In January 1999 a Drafting Group of the Expert Group on Aquatic Environmental Hazards started work on a Guidance Documents to complement the technical complicated harmonised classification system for substances hazardous to the aquatic environment. Major parts of the Guidance Document were finalised in autumn 2000. Outstanding issues included Chapter 7 on the classification of metals and metal compounds and the details of a transformation/dissolution protocol. These activities were finalised in March/April 2001. Currently, the technical agreements are in the process of approval under written procedure by the Task Force on HCL and the Joint Meeting.

Harmonised Classification Criteria for Chemical Mixtures

5. The work on a harmonised classification system for mixtures comprised the same endpoints as considered for substances with the following two exceptions: i) skin and eye irritation/corrosion are combined into a common classification system; and ii) for specific target organ systemic toxicity the single and repeated exposure are combined into a single classification system but with certain distinctions between the two exposure scenarios.

6. In November 2000 the 31st Joint Meeting approved the classification systems for all but two hazard categories: the "skin and eye irritation/corrosion" and the "hazards to the aquatic environment". These two systems needed further work by the respective Drafting Groups assigned for this task. The Drafting Group on "skin and eye irritation/corrosion" finished the work in mid March 2001 by reaching full consensus on the classification criteria for the skin and eye hazards of mixtures. The Drafting Group on "hazards to the aquatic environment" needed more time for discussion and, unfortunately, could only come very close to an agreement. When it appeared that arguments were being recycled and no new discussion elements could be found, the Secretariat decided to forward the issue for resolution by the Task Force.

FOLLOW UP

7. All harmonised classification systems for human health and the environment, both those for substances and for mixtures have been integrated in the revised version of the "Integrated Document". The new document, titled: "Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures" also includes the Guidance Documents on the Classification of Substances Hazardous to the Aquatic Environment, and the Transformation/Dissolution Protocol, respectively. The revised and updated version of the integrated document comprises three distinct Parts and three Annexes as follows:

HARMONISED INTEGRATED CLASSIFICATION SYSTEM FOR HUMAN HEALTH AND ENVIRONMENTAL HAZARDS OF CHEMICAL SUBSTANCES AND MIXTURES**PART 1: GENERAL INTRODUCTION TO THE HARMONISED INTEGRATED HAZARD CLASSIFICATION SYSTEM**

- Chapter 1.1** Introduction
Chapter 1.2 Organisational Context for the Development of GHS
Chapter 1.3 General Consideration
Chapter 1.4 Building Block Approach

PART 2: HARMONISED HAZARD CLASSIFICATION SYSTEM FOR CHEMICAL SUBSTANCES

- Chapter 2.1** Harmonised System for the Classification of Chemicals Which Cause Acute Toxicity
Chapter 2.2 Harmonised System for the Classification of Chemicals Which Cause Skin Irritation/Corrosion
Chapter 2.3 Harmonised System for the Classification of Chemicals Which Cause Eye Irritation/Corrosion
Chapter 2.4 Harmonised System for the Classification of Chemicals Which Cause Respiratory or Skin Sensitisation
Chapter 2.5 Harmonised System for the Classification of Chemicals Which Cause Mutations In Germ Cells
Chapter 2.6 Harmonised System for the Classification of Chemicals Which Cause Cancer
Chapter 2.7 Harmonised System for the Classification of Chemicals Which Cause Reproductive Toxicity
Chapter 2.8 Harmonised System for the Classification of Chemicals Which Cause Specific Target Organ Oriented Systemic Toxicity Following Single Exposure
Chapter 2.9 Harmonised System for the Classification of Chemicals Which Cause Specific Target Organ Oriented Systemic Toxicity Following Repeated Exposure
Chapter 2.10 Harmonised System for the Classification Of Chemicals Which are Hazardous for the Aquatic Environment

PART 3: HARMONISED HAZARD CLASSIFICATION CRITERIA FOR MIXTURES

- Chapter 3.1** General Introduction and Considerations
Chapter 3.2 Harmonised System for the Classification of Chemical Mixtures Which Cause Acute Toxicity
Chapter 3.3 Harmonised System for the Classification of Chemical Mixtures Which Cause Skin And Eye Corrosion/ Irritation
Chapter 3.4 Harmonised System for the Classification of Chemical Mixtures Which Cause Respiratory Or Skin Sensitisation
Chapter 3.5 Harmonised System for the Classification of Chemical Mixtures Which Cause Germ Cell Mutagenicity
Chapter 3.6 Harmonised System for the Classification of Chemical Mixtures Which Cause Carcinogenicity
Chapter 3.7 Harmonised System for the Classification of Chemical Mixtures Which Cause Reproductive Toxicity
Chapter 3.8 Harmonised System for the Classification of Chemical Mixtures Which Cause Specific Target Organ Systemic Toxicity

ANNEX 1: Schematic Presentation Of The Harmonised Hazard Classification System For Chemical Substances

ANNEX 2: Guidance Document Nr.27: Guidance Document On The Use Of The Harmonised System For The Classification Of Chemicals Which Are Hazardous For The Aquatic Environment

ANNEX 3: Guidance Document Nr.29: Guidance Document On Transformation / Dissolution Of Metals And Metal Compounds In Aqueous Media

8. This new document has been submitted to the Task Force on HCL in April 2001 with a deadline of 14th May 2001 to: i) come to a resolution on the one remaining issue (on classification of mixtures hazardous the aquatic environment) and, ii) endorse the other hazard categories not yet approved by the Joint Meeting (see paragraphs 4 and 6). If final consensus will be reached on the outstanding categories, the document will be submitted, in written procedure, to the Joint Meeting on 18th May 2001 for final and overall approval and document declassification by 2nd July.

9. However, if the Task Force appears to be unable to reach consensus, they may refer any unresolved issue back to the Extended Expert Group on Aquatic Environmental Hazard or decide to establish a new, dedicated group of well respected experts prone to find solutions to resolve the remaining issue.
