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Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

OLIS : 20-May-1999
Dist. : 21-May-1999

English text only

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS

ENV/JM/HCL/M(99)2
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Task Force on Harmonisation of Classification and Labelling

Expert Group on Classification Criteria for Mixtures of the Task Force on Harmonisation of Classification and Labelling

DRAFT SUMMARY REPORT OF THE WORKSHOP ON FAMILIARISATION WITH EXISTING CLASSIFICATION SYSTEMS FOR MIXTURES

4th Meeting of the OECD Expert Group on Classification Criteria for Chemical Mixtures, 28th - 29th June 1999, Dublin, Ireland, beginning on 28th June at 9.30 a.m.

English text only

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DRAFT SUMMARY REPORT

Introduction

1. A one-day Workshop preceding the 3rd Meeting of the Expert Group on Classification Criteria for Mixtures was convened to familiarise delegates with the major existing classification systems for mixtures. The Workshop was structured around a series of chemical mixtures selected to illustrate conceptual, technical and practical differences between existing systems and, more importantly, to identify commonalities. The list of Workshop participants is added to this summary report as Annex 1.

2. The chemical mixtures were selected to cover the following categories: Industrial Products, Metal Alloys, Consumer Products and Pesticides. The major systems covered were : the EU Dangerous Preparations Directive (covering all preparations, irespective of their use), the US Hazard Communications Standard, Canadian WHMIS, US FIFRA, US CPSC and the Canadian CCCR. Unfortunately, the UN Transport system was not included in the excercise but will be added to the written material.

3. The material used at the Workshop to illustrate similarities and differences between the various systems contained in Annexes 2-5, for the industrial product examples, the stainless steel example, the consumer product examples and the pesticide comparison respectively.

Industrial Products

Dilution Principle

4. The EU conventional method incorporates the concept of dilution which results in classifying a mixture into step-wise levels of severity for some endpoints. For example, Very Toxic, Toxic and Harmful for acute oral toxicity. The US and Canadian systems assume the mixture has the hazard of the ingredient.

Hazard Identification vs. Classification

5. The US and Canadian systems identify the potential hazards of the mixture while the EU system classifies the mixture into the existing EU hazard categories.

"Additive" approach

6. For Acute Lethal Toxicity, the EU system adds the effects for all routes of exposure (oral, dermal, inhalation) to determine if the mixture is classified. The US and Canadian systems consider each route of exposure separately and do not add multiple component effects.

Professional Judgment

7. The US and Canadian systems allow for the use of professional judgment/bridging data to read across results of testing to similar products. These practices are based on sound scientific principles. Currently, the EU allows this but very narrowly defines a "similar product." In the coming EU Directive bridging data will be possible based on scientific data and will become similar to the US and Canadian system.

Metallic Alloys

8. Metallic alloys have specific physical, chemical and toxicological properties distinct from their elemental constituents and as such do not fit easily into either the existing EU or North American Classification Systems. In the European Union system for example, stainless steel alloys containing 1% or

more of nickel are classified as carcinogenic and the use of CMR test data is not allowed. In the North American system, alloys containing 0.1% or more of nickel are likewise classified as carcinogenic. However, the use of test results and bridging data are allowed.

9. In both jurisdictions, the use of test data for other endpoints such as dermal sensitization are allowed.

Consumer Products

10. The consumer products examples illustrated differences in approach among the existing systems which apply to chemical products in the consumer use setting.

- The EU applies the same system consumer products as for industrial chemicals in terms of classification. Thus, these products are subject to the same rules regarding the type of data used to classify chemicals, and the conventional method is applied in the absence of data on the mixture as a whole.

- The Canadian consumer product system differs from the WHMIS Workplace Approach. It is currently based on a list of covered products but is being revised to be criteria-based.

- The US system also differentiates between products in the workplace and in the consumer use setting. While the US workplace system uses a standardized system of concentration limits/cut-off percentages to assess the hazards of untested mixtures, the US Consumer Product Safety Commission (CPSC) does not use this approach to the classification of consumer products under the Federal Hazardous Substances Act (FHSA). The US approach to classification of consumer products is based on the need to communicate the "likelihood of harm" to consumer users of chemicals. To accomplish this, once a hazard is identified, there is a process to assess potential exposures and to determine the likelihood of harm (or risk) anticipated under expected conditions of consumer use or reasonably foreseeable misuse (including, for example, accidental ingestion by young children of chemicals used in the home). Thus, a consumer product label may not include all of the hazards included in the workplace label because of limited anticipated consumer exposure. This is particularly true in the case of chronic effects such as reproductive hazards, as illustrated in Example 2.

<u>Data Used for Classification</u>

11. With regard to the data used for classification, the US consumer product system expresses a preference for human data and experience. A wider range of test data is permitted to be used as long as the methods are scientifically valid. Bridging data and professional judgement may be used, and may lead to a reduced need for animal testing. The EU system takes a more limited approach to data acceptance, particularly with respect to human experience. However, positive human evidence will override negative animal test results in both systems.

Pesticides

12. For pesticides normally test data on the formulation are required for the acute lethal effect (all three routes of application), skin and eye irritation/corrosion, and sensitization to achieve a registration. Bridging of data is normally accepted in the US and in the EU.

13. Although chronic effects are assessed, they are not normally labelled in the US system.

Annex 1

List of Participants to the Workshop on Familiarisation with Existing Classification Systems for Mixtures

Paris, 1st February 1999

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Annexes 2-5

ANNEX 2 "The Industrial Products Examples"

ANNEX 3 "The Stainless Steel Example

ANNEX 4 "The Consumer Product Example"

ANNEX 5 "Pesticide Comparisons"

These documents are <u>not</u> available electronically, please contact the OECD Secretariat for copies.