

## GLOBAL HARMONISATION OF HAZARD COMMUNICATION

### INTRODUCTION

One of the topics addressed at the RIO Conference in 1992 on Environment and Development was the development and introduction of a globally harmonised hazard classification and compatible labelling system (GHS), including safety data sheets and easily understood symbols, to be introduced, if feasible, by the end of the year 2000. Harmonisation means establishing a common and coherent basis for chemical hazard classification and communication, from which appropriate elements relevant to means of transport, consumer, workers and environmental protection can be selected.

Amongst the **goals** listed for GHS were:

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

In order to achieve this, three main work areas were identified, namely

#### Classification of Substances

#### Classification of Mixtures

#### Hazard Communication (labels and safety data sheets)

A number of bodies are involved, e.g.

**OECD** (Organisation for Economic Co-operation and Development) have been involved in developing the harmonisation of classification criteria of substances and mixtures with regard to health and the environment.

**UNCETDG** (Committee of Experts on Transport of Dangerous Goods) have been involved in developing the harmonisation of classification criteria for physical/chemical properties.

**ILO** (International Labour Organisation) have been involved in developing the harmonisation of hazard communication.

### BACKGROUND

1. The involvement of international organizations in the field of classification and labelling of chemicals started in the early fifties. In 1952, the International Labour Organization (ILO) called on its Chemical Industries Committee to study the classification and labelling of dangerous substances. In 1953, the United Nations Economic and Social Council (ECOSOC) created within the Economic Council for Europe, the UN Committee of Experts on the Transport of Dangerous Goods (UN CETDG). This Committee elaborated the first internationally recognized classification and labelling system for the purpose of transporting dangerous goods. It was first published in 1956 as the UN Recommendations on the Transport of Dangerous Goods (UN RTDG). UN organizations such as the International Maritime Organization (IMO) and the International Civil Aviation Organization (ICAO) as well as other international and regional bodies covering all transport modes use the RTDG as a basis for classification and labelling of chemicals for the purpose of transport. The RTDG are now included in the transport legislation of most of the UN member States and are also used for labelling chemicals in the workplace in a large number of developing countries. A number of classification and labelling systems for chemicals have been elaborated by regional organizations such as the European Communities and by individual member States such as Australia, Canada, Japan and the USA, to cover consumers, workers and the environment.

2. The ILO adopted in 1989 a Resolution concerning the harmonization of systems of classification and labelling for the use of hazardous chemicals at work, and in 1990, a Convention (No.170) and a Recommendation (No.177) concerning safety in the use of chemicals at work. In response to the Resolution, the ILO evaluated the size of the task of harmonizing

classification systems and issued a report which was further reviewed at a consultation of experts (Geneva, 14-15 November 1991) and presented to the Director General of the ILO in December 1992 after appropriate updating to reflect recent developments.

3. The Joint Meeting of the Chemicals Group and Management Committee of the OECD endorsed on 20 November 1991 the participation of the OECD in international ongoing and future harmonization activities, particularly those initiated within the IPCS. A clearinghouse led by the CEC, Sweden and the USA was established to undertake harmonization of classification criteria for acute oral toxicity and hazard to the environment.

4. Proposals for the establishment, within the IPCS, of a Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS), were recommended at the ILO Consultation of Experts (Geneva, 14-15 November 1991) and elaborated between the ILO, the WHO, UNEP, the Secretariat of the UN Committee of Experts on Transport of Dangerous Goods (UN CETDG) and the OECD in the course of two meetings in Geneva (29 November 1991) and London (19 December 1991). The establishment of the Coordinating Group was endorsed by the IPCS Intersecretariat Coordinating Committee at its 29 January 1992 meeting in Geneva. At its second meeting (Geneva, 23 March 1992), the secretariat (ILO) of the Coordinating Group was asked to draft a Workplan for achieving harmonization within a reasonable period of time and to include in this workplan a set of general principles, the elements of the classification and hazard communication process for the purpose of prioritisation and, where possible, an assignment of priorities and tasks.

5. In its adopted Agenda 21, more particularly in Chapter 19 regarding the environmentally sound management of toxic chemicals, the United Nations Conference on Environment and Development (UNCED) (3-13 June 1992, Rio de Janeiro, Brazil), has identified harmonization of classification and labelling of chemicals by the year 2000 as being one of the six action programmes (see Annex 1), and has recommended that "...the International Programme on Chemical Safety (IPCS) should be the nucleus for international cooperation on environmentally sound management of toxic chemicals."

6. In April 1994, the International Conference on Chemical Safety (ICCS), held in Stockholm, Sweden, established an Intergovernmental Forum on Chemical Safety (IFCS) which adopted a resolution defining priorities for action to achieve environmentally sound management of chemicals worldwide. The priorities relevant to harmonization of chemical classification and labelling included recommended completion deadlines of 1997 for classification criteria and 2000 for completion of hazard communication elements. Another key priority was the consideration of an international framework to translate the technical work of harmonization into an instrument or recommendations applicable legally at the national level.

7. In November 1994, six intergovernmental organisations, namely the WHO, ILO, UNEP, FAO, UNIDO and the OECD have agreed to a Memorandum of Understanding establishing an Inter-Organisation Programme for the Sound Management of Chemicals (IOMC). The Memorandum came into force in March 1995 after its signature by the six participating organisation. This umbrella programme will coordinate the chemical safety activities of the six partners through an Inter-Organization Coordinating Committee (IOCC). The existing IPCS will remain as a joint technical programme of WHO, ILO and UNEP within the framework of the IOMC. At its first official meeting of the IOCC in Rome (June 1995) it was decided that the CG/HCCS would report to the IOCC rather than to the IPCS. Both the Secretariats of the Forum and the IOCC are located in WHO, Geneva.

8. The central role of the CG/HCCS in coordinating and overseeing the work of harmonizing existing systems of classification and labelling of chemicals was acknowledged by the UNCED, further reaffirmed by the ICCS in 1994. The Intersessional Group of the Forum, at its March 1995 1st meeting in Bruges, Belgium, requested the Group to elaborate a plan of action to translate the technical work of harmonization into an instrument or recommendation applicable at the national level.

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## PROGRESS TO DATE

The process of harmonisation has involved an enormous amount of work. At present, labels and material safety data sheets for the same product can differ throughout the world, the differences in some instances are more than merely significant, and could conceivably result in major health/safety incidents. There are a considerable number of problem areas still to be resolved, one of the major obstacles to be overcome are the differences between the European and American systems for the classification of mixtures. Other problems include the supply and inter-agency interface on transport issues, difficulties in obtaining a harmonised EU position, problems posed by various industrial sectors, etc.

## Classification of Substances

To illustrate the enormity of the problem, the following example is quoted for the differences in classification applied throughout the world for a substance with an oral toxicity (LD<sub>50</sub>) of 257mg/kg.

Transport	liquid: slightly toxic; solid: not classified
EU	Harmful
US	Toxic
CAN	Toxic
Australia	Harmful
India	Non-toxic
Japan	Toxic
Malaysia	Harmful
Thailand	Harmful
New Zealand	Hazardous
China	Not Dangerous
Korea	Toxic

Status - The classification of substances into general categories, started 1994, has now been largely completed. The classification of substances in the categories of acute toxicity, sensitisation, eye irritation, skin irritation, carcinogenicity, germ cell mutation, reproductive toxicity, aquatic toxicity and target organ toxicity, have all been agreed.

Many issues are still to be resolved and additional detail in some of the categories are given below as examples:

## Acute Toxicity

Class 5, where there may be a hazard to vulnerable populations

Vapours - ppm or mg/l?

Proportionality between the categories

Route to route extrapolation

Effect on the downstream consequences in the EU

## Respiratory and Skin Sensitisation

Use of two categories -

Class 1 - Strong sensitiser (high frequency of occurrence)

Class 2 - Sensitiser (low or moderate frequency of occurrence)

Animal studies to indicate potency have not been validated

Human testing is not widely accepted for dermal sensitisation

Insufficient weight given to an immunological mechanism in respiratory sensitisation

## Skin Irritation

Tiered approach using SAR and human experience prior to animal testing.

Corrosive - three classes. Irritation - two classes

Class 1A, 1B, 1C

Three classes for transport

Class 2 - Irritant

(1) mean value of >2.3 - <4.0 for erythema/eschar or for edema in 2/3 tested animals at 24, 48 and 72 hours on 3 consecutive days after the onset of dermal reactions, or

(2) inflammation that persists at the end of the observation period normally 14 days in at least 2 animals, or

(3) in some cases where there is a pronounced variability of response among

animals, with very definite positive effects related to chemical exposure in a single animal, but less than the criteria above

Class 3 - Mild Irritant optional for some use categories

mean value of >1.5 - <2.3 for erythema/eschar or for edema in 2/3 tested animals at 24, 48 and 72 hours or from grades on 3 consecutive days after the onset of dermal reactions

EU:

Significant inflammation of the skin which persists for at least 24 hours after an exposure period of up to 4 hours

(mean value of >2.0 for erythema/eschar or edema over 24, 48 and 72 hours)

## Heritable Mutations in Germ Cells

Class 1 (EU Cat 1 and 2)

Chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cell of humans

Class 1a - Chemicals known to induce heritable mutations in the germ cell of humans

Class 1b - Chemicals which should be regarded as if they induce heritable mutations in the germ cell of humans

Class 2 (EU Cat 3)

Chemicals which cause concern for man owing to the possibility that they may induce heritable mutations in the germ cells of humans

## Carcinogenicity

Class 1A - KNOWN to have carcinogenic potential for humans (largely based upon human epidemiological evidence)

Class 1B - PRESUMED to have carcinogenic potential for humans (largely based on animal evidence with strength of evidence together with additional considerations to establish a causal relationship between human exposure and cancer or from animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity - presumed human carcinogen)

Class 2 - Suspected human carcinogens

Based on human and/or animal studies, but which is not sufficiently convincing to place the chemical in Class 1 where there is limited evidence from human or animal studies together with strength of evidence and additional considerations

Other issues include:

Inclusion of Potency (to be developed in the future)

Lack of consideration of weight of evidence by some countries

Use of marker substances for complex substances (petroleum and coal distillates)

## Reproduction

Class 1 - Known or presumed human reproductive or development toxicant

Substances known to have produced an adverse effect in humans or for which there is evidence from animal studies possibly supplemented with other information to provide a strong presumption the substance has the capacity to interfere with reproduction in humans

Class 1A - KNOWN to have produced an adverse effect on reproductive ability or capacity or on development in humans. Largely based on evidence from humans.

Class 1B - PRESUMED to produce an adverse effect on reproductive ability or capacity or on development in humans. Largely based on evidence from experimental animals which provide clear evidence of specific reproductive toxicity in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effects for humans, classification in Class 2 may be more appropriate.

Class 2 - Suspected human reproductive or development toxicant. Some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of



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the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Class 1.

## Effects on lactation

Substance absorbed by women and shown to interfere with lactation or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breast-fed child.

Other issues include:

Maternal Toxicity

Single statistically significant study enough to classify

Weight of evidence not equally considered by all countries

Route of exposure irrelevant

Normal handling and use not considered

No classification cut-off limit

Relative potency not considered

Threshold effect not considered

Insufficient guidance to enable a harmonised approach

## Specific Target Organs/Systemic Toxicity

Divided into: Specific Target Organ/Systemic Toxicity following a Single Exposure

Specific Target Organ/Systemic Toxicity following a Repeated Exposure

Class 1 - Substances that have produced significant toxicity in humans, or which, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans following single/repeated exposures. Based on reliable and good quality evidence from human cases or epidemiological studies, or, observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations.

Class 2 - Substances which, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to be harmful to human health following single exposure. Based on observations from appropriate studies in experimental animals in which significant toxic effects of relevance to human health were produced at generally moderate exposure concentrations. In exceptional cases, human evidence can also be used to place a substance in Class 2.

A series of Exposure Guidance Values for both Single and Repeated Exposures has been drawn up but not yet finalised.

## Classification of Mixtures

All of the above applies to single substances. Where mixtures are concerned the general approach is:

Classifications may be based on mixtures if suitable data is available for that mixture (except perhaps CMR and environmental hazards - not agreed)

Bridging principles will be used if no such data is available

(Bridging data could include extrapolation between oral LD50, dermal LD50 and inhalation LC50 if appropriate pharmacodynamic and pharmacokinetic data is available. Evidence from human exposure that indicates toxic effects but does not provide lethal dose data can also be used, as can evidence from any other toxicity tests/assays).

Data from closely analogous substances using structure/activity relationships can also be used.

Specific methods for specific points will be used where neither of the above are available

Cut-off and concentration limits will be used, which will be uniform in all sectors.

The need to raise or lower limits if data available to reflect effects above or below the cut-off/concentration limits has been proposed, but not yet agreed.

The need to consider synergistic/antagonistic effects has been proposed, but not yet agreed.

## Hazard Communication (labels and safety data sheets)

The overall objectives are the development of a set of labels and material

safety data sheets that are consistent throughout the world.

So far, the working group, which is a tripartite group with representation or observers from governments, industry and employees drawn from the UK, Germany, Norway, Sweden, China, Brazil, USA, Canada, Finland, Australia and the Netherlands, have achieved the following:

Defined Terms of Reference

Carried out a comprehensive review of existing hazard communication systems

Prioritised the 'label elements' that will be harmonised

Developed an initial broad range of options for each element

Narrowed these options down

Developed options for harmonisation of safety sheets

Hazard statements and precautionary statements will be used which will be similar in concept to the present EU Risk and Safety phrases respectively. Since the standard 16 heading format will be used in Safety Data Sheets, in all probability there will be many similarities to the current EU sheets.

**Since the most rigid global hazard approaches are being adopted, classification systems will be more rigorous than those currently used in the EU, which will generally result in the labelling of more substances, although it is also possible that a few substances, currently labelled, will no longer need labelling. A reduced set of symbols will probably result, and there is little support for the continuation of the traditional St. Andrews Cross, which does not present a self-evident message.**

**Although a binding mechanism was considered for the need to implement GHS throughout the world, it was considered that this was impracticable at the moment, and that conformance to the requirements would need to be on a voluntary basis.**

## Future Plans and Implications

The GHS and TDG subcommittees will meet in July 2001, the GHS sub-committees will elect chair, vice-chair and agree terms of reference.

The workplan for 2001-2003 will be agreed in December 2001.

Guidance will be agreed and issued in July 2002.

In 2003, ECOSOC will formally adopt GHS.

The system will be fully operational by 2008.

It must be noted at this stage that GHS will not apply to areas such as waste, storage, etc. The subject of waste harmonisation will be addressed by other groups, and will not necessarily adopt the same system. It must be admitted at this stage that this is not an ideal situation, and is currently the subject of much controversy, but it must be appreciated that the classification and identification of waste is an enormously complex issue.

It is anticipated that all of the world's major economic countries will conform at an early stage, with the less well-developed areas, with current resource constraints, implementing the requirements at a later date. In time, the system could well become mandatory on a global basis following a suitable programme of appropriate capacity building to ensure that developing countries have adequate resources to implement the systems.

The many consequential changes in legislation will result in many changes in classification of chemicals, some being subject to increased restrictions or bans, whilst others may no longer be subject to restrictions or bans. All current Safety Data Sheets will need re-writing, and labels will need changing. However, the benefits will include

Only one system to learn

Only one system to apply

Reduced testing costs and time

Reduced development costs to produce regional variants of chemistry

No self-conflicting labelling on multi-lingual labels

Only one system to explain

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## Community Legislation referring to the Classification and Labelling System under Directive 67/548/EEC

### Substances Dangerous to Health and Environment

1. Council Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, and relevant amendments. Note: This has since been revoked and replaced by 1999/45/EC
2. Council Directive 83/265/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of paints, varnishes, printing inks, adhesives and similar products, and relevant amendments.
3. Commission Directive 90/35/EEC defining in accordance with Article 6 of Directive 88/379/EEC the categories of preparations the packaging of which must be fitted with child-resistant fastenings and/or carry a tactile warning of danger, and its amendments.
4. Commission Directive 91/155/EEC defining and laying down the detailed arrangements of the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC, and its amendments.
5. Commission Directive 91/442/EEC on dangerous preparations the packaging of which must be fitted with child-resistant fastenings, and its amendments.
6. Commission Directive 93/67/EEC laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC, and relevant amendments.
7. Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances, and relevant amendments.
8. Council Directive 76/769/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, and relevant amendments.
9. Council Regulation (EEC) No 2455/92 concerning the export and import of certain dangerous chemicals, and relevant amendments.
10. Council Directive 91/414/EEC concerning the placing of plant protection products on the market, and relevant amendments.
11. Council Directive 78/631/EEC on the approximation of the laws of the Member States relating to classification, packaging and labelling of dangerous preparations (pesticides), and relevant amendments.
12. Council Directive 98/8/EC concerning the placing of biocidal products on the market, and relevant amendments.

### Worker Health and Safety

13. Council Directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), and relevant amendments.
14. Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breast feeding, and relevant amendments.
15. Council Directive 90/394/EEC on the protection of workers from the risks related to exposures to carcinogens at work, and relevant amendments.
16. Council Directive 94/33/EC on the protection of young people at work, and relevant amendments.
17. Commission Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC, and relevant amendments. (safety data sheets)
18. Council Directive 92/58/EEC on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC), and relevant amendments.

### Major Industrial Accidents

19. Council Directive 96/82/EC on the control of major accident hazards involving dangerous substances (Seveso II), and relevant amendments.

### Consumer Products

20. Council Regulation EEC/880/92 on a Community eco-label award scheme, and relevant amendments.
21. 95/365/EC: Commission Decision of 25 July 1995 establishing the ecological criteria for the award of the Community eco-label to laundry detergents.
22. 99/10/EC: Commission Decision of 18 December 1998 establishing the ecological criteria for the award of the Community eco-label to paints and varnishes.
23. Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys, and relevant amendments.
24. Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosols dispensers, and relevant amendments.
25. Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, and relevant amendments.
26. Commission Directive 95/17/EC laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products, and relevant amendments.

### Waste

27. Council Directive 91/689/EEC on hazardous waste, and relevant amendments.

### Pollution

28. Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management, and relevant amendments.

### Testing Methods

29. Council Directive 87/18/EEC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, and relevant amendments.
30. Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition, and relevant amendments.

## REFERENCES

For those wishing to gain more information on the subject of GHS, or to keep updated with current developments, there are a number of useful website addresses.

OECD - <http://www.oecd.org/ehs/classify>

<http://www.oecd.org/ehs/class/index.htm>

ILO - <http://www.ilo.org/public/english/protection/safework/ghs>

IFCS (Forum) - <http://www.ifcs.ch>

UN - <http://www.unece.org/trans/danger/danger.htm>

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