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

PART 1

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PART 1

INTRODUCTION

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CHAPTER 1.1

PURPOSE, SCOPE AND APPLICATION OF THE GLOBALLY HARMONIZED SYSTEM FOR HAZARD CLASSIFICATION AND COMMUNICATION (GHS)

1.1.1 Purpose

~~1.~~1.1.1.1. The use of chemical products to enhance and improve life is a widespread practice worldwide. But alongside the benefits of these products, there is also the potential for adverse effects to occur in people or the environment. As a result, a number of countries or organizations have developed laws or regulations over the years that require information to be prepared and transmitted to those using chemicals, through labels or Safety Data Sheets (SDS). Given the large number of chemical products available, individual regulation of all of them is simply not possible for any entity. Provision of information gives those using chemicals the identities and hazards of these chemicals, and allows the appropriate protective measures to be implemented in the local use settings.

~~2.~~1.1.1.2 While these existing laws or regulations are similar in many respects, their differences are significant enough to result in different labels or ~~safety data sheets~~SDS for the same product in different countries. Through variations in definitions of hazards, a chemical may be considered flammable in one country, but not another. Or it may be considered to cause cancer in one country, but not another. Decisions on when and how to communicate 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 ~~safety data sheets~~SDS. In addition, given the complexity of developing and maintaining a comprehensive system for classifying and labelling chemicals, many countries have not been able to have such a system at all.

~~3.~~1.1.1.3 Given the reality of extensive global trade in chemicals, and the need to develop national programs to ensure their safe use, transport, and disposal, it was recognised that an internationally-harmonized approach to classification and labelling would provide the foundation for such programs. 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.

~~4.~~1.1.1.4 Thus the reasons for setting the objective of harmonisation were many. Benefits anticipated when the GHS is implemented include the following:

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

~~5.~~1.1.1.5 The work began with examination of existing systems, and determination of the scope of the work. While many countries had some requirements, the following systems were deemed to be the “major” existing systems and would be used for the elaboration of the GHS:~~, the requirements of which formed the primary basis for the work:~~

(a) Requirements of systems in the United States of America for the workplace, consumers and pesticides;

(b) Requirements of Canada for the workplace, consumers and pesticides;

(c) European Union directives for classification and labelling of substances and preparations;

(d) The United Nations Recommendations on the Transport of Dangerous Goods.

6.1.1.1.6 The requirements of other countries were also examined as the work developed, but the primary task was to find ways to adopt the best aspects of these existing systems and develop a harmonized approach. This work was done based on agreed principles of harmonisation that were adopted early in the process:

(a) the level of protection offered to workers, consumers, the general public and the environment should not be reduced as a result of harmonizing the classification and labelling systems;

(b) the hazard classification process refers only to the hazards arising from the intrinsic properties of chemical elements and compounds, and mixtures thereof, whether natural or synthetic;

(c) harmonisation means establishing a common and coherent basis for chemical hazard classification and communication, from which the appropriate elements relevant to means of transport, consumer, worker and environment protection can be selected;

(d) the scope of harmonisation includes both hazard classification criteria and hazard communication tools, e.g. labelling and chemical safety data sheets, taking into account especially the four existing systems identified in the ILO report[1];

(e) changes in all these systems will be required to achieve a single globally harmonized system; transitional measures should be included in the process of moving to the new system;

(f) the involvement of concerned international organizations of employers, workers, consumers, and other relevant organizations in the process of harmonisation should be ensured;

(g) the comprehension of chemical hazard information, by the target audience, e.g. workers, consumers and the general public should be addressed;

(h) validated data already generated for the classification of chemicals under the existing systems, should be accepted when reclassifying these chemicals under the harmonized system;

(i) a new harmonized classification system may require adaptation of existing methods for testing of chemicals;

(j) in relation to chemical hazard communication, the safety and health of workers, consumers and the public in general, as well as the protection of the environment, should be ensured while protecting confidential business information, as prescribed by the competent authorities.

[1] *1992 ILO Report on the Size of the Task of Harmonizing Existing Systems of Classification and Labelling for Hazardous Chemicals.*

1.1.2 Scope

~~7.~~1.1.2.1 The GHS includes the following elements:

(a) harmonized criteria for classifying substances and mixtures according to their health, environmental and physical hazards of substances and mixtures; and

(b) harmonized hazard communication elements, including requirements for labelling and safety data sheets.

~~8.~~1.1.2.2 This document describes the classification criteria and the hazard communication elements by type of hazard (e.g. acute toxicity; flammability). In addition, decision logics for each hazard have been developed, as well as examples of classification of chemicals to illustrate how to apply the criteria. There is also some discussion about issues that were raised during the development of the system where additional guidance was thought to be necessary to implement the system.

~~9.~~1.1.2.3 The scope of the GHS is based on the mandate from the 1992 United Nations Conference on Environment and Devleopment (UNCED)~~[2]~~ for development of such a system as stated in paragraphs 26 and 27 of the Agenda 21, Chapter 19, Programme Area B, reproduced below:

"*26. Globally harmonized hazard classification and labelling systems are not yet available to promote the safe use of chemicals, inter alia, at the workplace or in the home. Classification of chemicals can be made for different purposes and is a particularly important tool in establishing labelling systems. There is a need to develop harmonized hazard classification and labelling systems, building on ongoing work;*

27. A globally harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000."

~~10.~~1.1.2.4 This mandate was later analyzed and refined in the harmonisation process to identify the parameters of the GHS. As a result, the following clarification was adopted by the Interorganization Programme for the Sound Management of Chemicals (IOMC) Coordinating Group to ensure that participants were aware of the scope of the effort:

> "*The work on harmonisation of hazard classification and labelling focuses on a harmonized system for all chemicals, and mixtures of chemicals. The application of the components of the system may vary by type of product or stage of the life cycle. Once a chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting. Pharmaceuticals, food additives, cosmetics, and pesticide residues in food will not be covered by the GHS in terms of labelling at the point of intentional intake. However, these types of chemicals would be covered where workers may be exposed, and, in transport if potential exposure warrants. The Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS) recognizes that further discussion will be required to address specific application issues for some product use categories which may require the use of specialized expertise.*"[3]

~~[2] *United Nations Conference on Environment and Development (UNCED), Agenda 21, Chapter 19, Programme Area B.*~~

[3] *IOMC Description and Further Clarification of the Anticipated Application of the Globally Harmonized System (GHS), IFCS/ISG3/98.32B*

~~11.~~1.1.2.5 In developing this clarification, the CG/HCCS carefully considered many different issues with regard to the possible application of the GHS. There were arguments raised about certain sectors or products being exempted, for example, or about whether or not the system would be applied at all stages of the life cycle of a chemical. ~~The following~~Three parameters were agreed in this discussion, and are critical to application of the system in a country or region. They are described below:

~~**(i)The GHS covers all hazardous chemicals. The mode of application of the hazard communication components of the GHS (e.g. labels, safety data sheets) may vary by product category or stage in the life cycle. Target audiences for the GHS include consumers, workers, transport workers, and emergency responders.**~~

~~**(ii)The mandate for development of a GHS does not include establishment of uniform test methods or promotion of further testing to address adverse health outcomes.**~~

~~**(iii) In addition to animal data and valid in vitro testing, human experience, epidemiological data, and clinical testing provide important information that should be considered in application of the GHS.**~~

(a) Parameter ~~(i)~~1: The GHS covers all hazardous chemicals. The mode of application of the hazard communication components of the GHS (e.g. labels, material safety data sheets) may vary by product category or stage in the life cycle. Target audiences for the GHS include consumers, workers, transport workers, and emergency responders.

~~12.~~ (i) Existing hazard classification and labelling systems address potential exposures to all potentially hazardous chemicals in all types of use situations, including production, storage, transport, workplace use, consumer use, and presence in the environment. They are intended to protect people, facilities, and the environment. The most widely applied requirements in terms of chemicals covered are generally found in the parts of existing systems that apply to the workplace or transport. It should be noted that the term chemical is used broadly in the UNCED agreements and subsequent documents to include substances, products, mixtures, preparations, or any other terms that may be used in existing systems to denote coverage.

~~13.~~ (ii) Since all chemicals and chemical products in commerce are made in a workplace (including consumer products), handled during shipment and transport by workers, and often used by workers, there are no complete exemptions from the scope of the GHS for any particular type of chemical or product. In some countries, for example, pharmaceuticals are currently covered by workplace and transport requirements in the manufacturing, storage, and transport stages of the life cycle. Workplace requirements may also be applied to employees involved in the administration of some drugs, or clean-up of spills and other types of potential exposures in health care settings. SDSs and training must be available for these employees under some systems. It is anticipated that the GHS would be applied to pharmaceuticals in a similar fashion.

~~14.~~ (iii) At other stages of the life cycle for these same products, the GHS may not be applied at all. For example, at the point of intentional human intake or ingestion, or intentional application to animals, products such as human or veterinary pharmaceuticals are generally not subject to hazard labelling under existing systems. Such requirements would not normally be applied to these products as a result of the GHS. (It should be noted that the risks to subjects associated with the medical use of human or veterinary

pharmaceuticals are generally addressed in package inserts and are not part of this harmonisation process.) Similarly, products such as foods that may have trace amounts of food additives or pesticides in them are not currently labelled to indicate the presence or hazard of those materials. It is anticipated that application of the GHS would not require them to be labelled as such.

(b) Parameter ~~(ii)~~ 2: The mandate for development of a GHS does not include establishment of uniform test methods or promotion of further testing to address adverse health outcomes.

~~15.~~ (i) Tests that determine hazardous properties, which are conducted according to internationally, recognized scientific principles can be used for purposes of a hazard determination for health and environmental hazards. The GHS criteria for determining health and environmental hazards should be test method neutral, allowing different approaches as long as they are scientifically sound and validated according to international procedures and criteria already referred to in existing systems for the end point of concern and produce mutually acceptable data. While the OECD is the lead organization for development of harmonized health hazard criteria, the GHS is not tied to the OECD Test Guidelines Program. For example, drugs are tested according to agreed criteria developed under the auspices of the World Health Organization (WHO). Data generated in accordance with these tests would be acceptable under the GHS. Criteria for physical hazards under the UNSCETDG are linked to specific test methods for endpoints such as flammability and explosivity.

~~16.~~ (ii) The GHS is based on currently available data. Since the harmonized classification criteria are developed on the basis of existing data, compliance with these criteria will not require retesting of chemicals for which accepted test data already exists.

(c) Parameter ~~(iii)~~3: In addition to animal data and valid in vitro testing, human experience, epidemiological data, and clinical testing provide important information that should be considered in application of the GHS.

~~17.~~ (i) Most of the current systems acknowledge and make use of ethically obtained human data or available human experience. Application of the GHS should not prevent the use of such data, and the GHS should explicitly acknowledge the existence and use of all appropriate and relevant information concerning hazards or the likelihood of harmful effects (i.e. risk).

1.1.2.6 *Other scope limitations*

~~18.~~1.1.2.6.1 The GHS is not intended to harmonize risk assessment procedures or risk management decisions (such as establishment of a permissible exposure limit for employee exposure), which generally require some risk assessment in addition to hazard classification. In addition, application of the international agreement on the Rotterdam Convention on the Prior Informed Consent for Certain Hazardous Chemicals and Pesticides in International Trade (PIC), signed in September 1998, is not related to the GHS, and neither are chemical inventory requirements in various countries[4].

[4] *IOMC Description and Further Clarification of the Anticipated Application of the Globally Harmonized System (GHS), IFCS/ISG3/98.32B.*

~~**Hazard vs. Risk**~~

~~19.~~1.1.2.6.2 Hazard vs. Risk: Each hazard classification and communication system (workplace, consumer, transport) begins coverage with an assessment of the hazards posed by the chemical or chemical product involved. The degree of its capacity to harm depends on its intrinsic properties, i.e. its capacity to interfere with normal biological processes, and its capacity to burn, explode, corrode, etc. This is based primarily on a review of the scientific studies available. The concept of risk or the likelihood of harm occurring, and subsequently communication of that information, is introduced when exposure is considered in conjunction with the data regarding potential hazards. The basic approach to risk assessment is the simple formula:

Hazard × Exposure = Risk

~~20.~~1.1.2.6.3 Thus if you can minimize either hazard or exposure, you minimize the risk or likelihood of harm. Successful hazard communication alerts the user to the presence of a hazard and the need to minimize exposures and the resulting risks.

~~21.~~1.1.2.6.4 All of the systems for conveying information (workplace, consumer, transport) include both hazard and risk in some form. They vary in where and how they provide the information, and the level of detail they have regarding potential exposures. For example, exposure of the consumer to pharmaceuticals comprises a specific dose that is prescribed by the physician to address a certain condition. The exposure is intentional. Therefore, a determination has been made by a drug regulatory agency that for the consumer, an acceptable level of risk accompanies the specific dosage provided. Information that is provided to the person taking the pharmaceutical conveys the risks assessed by the drug regulatory agency rather than addressing the intrinsic hazards of the pharmaceutical or its components.

1.1.4 Application of the GHS

1.1.4.1 *Harmonisation of the application of the GHS*

~~22.~~1.1.4.1.1 The goal of the GHS is to identify the intrinsic hazards found in chemical substances and mixtures and to convey hazard information about these hazards. The criteria for hazard classification are harmonized. Hazard statements, symbols and signal words have been standardized and harmonized and now form an integrated hazard communication system. The GHS will allow the hazard communication elements of the existing systems to converge. Competent authorities will decide how to apply the various elements of the GHS based on the needs of the competent authority and the target audience. (See also *Hazard Communication: Labelling* (Chapter 1.~~3~~4, paragraph ~~5~~9~~1~~1.4.10.5.4.2) and *Consumer Product Labelling Based on the Likelihood of Injury*, Annex ~~5~~4.)

~~23.~~1.1.4.1.2 For transport, it is expected that application of the GHS will be similar to application of current transport requirements. Containers of dangerous goods will be marked with pictograms that address acute toxicity, physical hazards, and environmental hazards. As is true for workers in other sectors, workers in the transport sector will be trained. The elements of the GHS that address such elements as signal words and hazard statements are not expected to be adopted in the transport sector.

~~24.~~1.1.4.1.3 In the workplace, it is expected that all of the GHS elements will be adopted, including labels that have the harmonized core information under the GHS, and safety data sheets. It is also anticipated that this will be supplemented by employee training to help ensure effective communication.

~~25.~~1.1.4.1.4 For the consumer sector, it is expected that labels will be the primary focus of GHS application. These labels will include the core elements of the GHS, subject to some sector-specific

considerations in certain systems. (See also *Hazard Communication: Labelling* (Chapter 1.~~3~~4, paragraph ~~59~~1.4.10.5.4.2) and *Consumer Product Labelling Based on the Likelihood of Injury*, Annex ~~5~~4)

~~26.~~1.1.4.1.5 Consistent with the building block approach, countries are free to determine which of the *building blocks* will be applied in different parts of their systems. However, where a system covers something that is in the GHS, and implements the GHS, that coverage should be consistent. For example, if a system covers the carcinogenicity of a chemical, it must follow the harmonized classification scheme, and the harmonized label elements.

~~**Building block approach**~~
~~27.~~1.1.4.1.6 In examining the requirements of existing systems, it was noted that coverage of hazards may vary by the perceived needs of the target audience for information. In particular, the transport sector focuses on acute health effects and physical hazards, but has not to date covered chronic effects due to the types of exposures expected to be encountered in that setting. But there may be other differences as well, with countries choosing not to cover all of the effects addressed by the GHS in each use setting.

~~28.~~1.1.4.1.7 The harmonized elements of the GHS may thus be seen as a collection of building blocks from which to form a regulatory approach. While the full range is available to everyone, and should be used if a country or organization chooses to cover a certain effect when it adopts the GHS, the full range does not have to be adopted. While physical hazards are important in the workplace and transport sectors, consumers may not need to know some of the specific physical hazards in the type of use they have for a product. As long as the hazards covered by a sector or system are covered consistently with the GHS criteria and requirements, it will be considered appropriate implementation of the GHS.

1.1.4.2 ~~International body to implement, maintain, and update~~ *Implementation of the GHS*

~~29.~~1.1.4.2.1 For the purposes of implementing the GHS and keeping it up-to-date, t~~T~~he United Nations Economic and Social Council (ECOSOC), has reconfigured, by resolution 1999/65 of 26 October 1999, its Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCETDG/GHS), maintaining its Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) and creating a new subsidiary body the ~~has the international responsibility for implementation and oversight of the completed GHS. It has reconfigured an existing committee and subcommittee in its structure to form a new subcommittee on the GHS, and a new parent committee responsible for the GHS subcommittee as well as the existing subcommittee on the Transport of Dangerous Goods. The~~ Sub-Ccommittee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS) with ~~has~~ the following functions:

(a) To act as custodian of the GHS, managing and giving direction to the harmonisation process;

(b) To keep the GHS system up-to-date as necessary, considering the need to introduce changes, ensure its continued relevance and practical utility, and determining the need for and timing of the updating of technical criteria, working with existing bodies as appropriate;

(c) To promote understanding and use of the GHS and to encourage feedback;

(d) To make the GHS available for worldwide use and application;

(e) To make guidance available on the application of the GHS, and on the interpretation and use of technical criteria to support consistency of application; and

(f) To prepare work programmes and submit recommendations to the committee.

~~30.~~1.1.4.2.2 The ~~GHS Subcommittee and the Subcommittee of Experts on Transport of Dangerous Goods~~UNSCEGHS and the UNSCETDG, ~~will~~ both operate under the parent committee with responsibility for these two areas. The ~~UN~~ Committee ~~of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals~~ is responsible for strategic issues rather than technical issues. It is not envisaged that it would review, change or revisit technical recommendations of the sub-committees. Accordingly, its main functions are:

(a) To approve the work programmes for the sub-committees in the light of available resources;

(b) To coordinate strategic and policy directions in areas of shared interests and overlap;

(c) To give formal endorsement to the recommendations of the sub committees and provide the mechanism for channelling these to ECOSOC; and

(d) To facilitate and coordinate the smooth running of the sub-committees.

1.1.5 The GHS

~~31.~~1.1.5.1 ~~The GHS~~This document describes the GHS~~. It consolidates~~ and contains ~~the work of the technical focal points, and adds~~ guidance, examples, and descriptions to assist countries and organizations to develop tools to implement the system in their own requirements.

1.1.5.2 This document contains recommendations concerning the classification, labelling, and preparation of SDS with a national system that can be used by government or industry since the GHS is designed to permit self-classification. It presents a basic scheme of provisions that will allow uniform development of national and international regulations governing the GHS, while remaining flexible enough to accommodate any special requirements that might have to be met. It is expected that governments, intergovernmental organizations and other international organizations, when revising or developing regulations for which they are responsible, will conform to the principles laid down in this document, thus contributing to world-wide harmonization in this field. Furthermore, the new structure, format and contents should be followed to the greatest extent possible in order to create a more user-friendly approach, to facilitate the work of enforcement bodies and to reduce the administrative burden. **[former para 14 of part 4]**

~~32.~~1.1.5.3 While this document provides the primary basis for the description of the GHS, it is anticipated that technical assistance tools will be made available as well to assist and promote implementation.

CHAPTER 1.2

DEFINITIONS AND ABBREVIATIONS

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

ADR means the European Agreement concerning the International Carriage of Dangerous Goods by Road (United Nations publication ECE/TRANS/140 (Vol. I and II))[ECE/TRANS/160(Vol.I and Vol.II)].

Aerosols means any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state. Aerosol includes aerosol dispensers.

Alloy means is a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purpose of classification under the GHS.

ASTM means the "American Society of Testing and Materials".

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

BCF means "bioconcentration factor".

Bioavailability (or biological availability) means the extend 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 bio availability.

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

BOD/COD means "biochemical oxygen demand/chemical oxygen demand".

CA means "competent authority".

Carcinogen means a chemical substance or a mixture of chemical substances which induce cancer or increase its incidence.

CAS means "Chemical Abstract Service".

CBI means "confidential business information".

Chemical identity means a name that will uniquely identify a chemical. This can be a name that is in accordance with the nomenclature systems of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS), or a technical name.

Chronic toxicity means potential or actual properties of a substance to cause adverse effects to aquatic organisms during exposures which are determined in relation to the life-cycle of the organism.

Competent authority means the authority or authorities or any other body or bodies designated as such in each State and each specific case in accordance with domestic law.

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 characterised as a homologous series of substances with a certain range of carbon chain length/number of degree of substitution.

Compressed gas means a gas which when packaged under pressure is entirely gaseous at -50 °C; including all gases with a critical temperature ≤ -50 °C.

Contact sensitizer means a substance that will induce an allergic response following skin contact.

Corrosive to metal means a substance or a mixture which by chemical action will materially damage, or even destroy, metals.

Critical temperature means the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.

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

Dermal Corrosion means the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the epidermis, following the application of a test substance for up to 4 hours.

Dermal irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours.

DIN means “drug identification number”.

Dissolved gas **means a** gas which when packaged under pressure is dissolved in a liquid phase solvent.

EC_{50} means the effective concentration of drug [substance] that causes 50% of the maximum response.

ECOSOC means the Economic and Social Council of the United Nations.

EINECS means “European Inventory of Existing Commercial Chemical Substances”.

ErC_{50} means EC_{50} in terms of reduction of growth rate.

EU means “European Union”.

Explosive article **means a**n article containing one or more explosive substances.

Explosive substance **means a** solid or liquid substance (or mixture of substances) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic substances are included even when they do not evolve gases.

***Eye corrosion* means** the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

***Eye irritation* means** the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.

Flammable gas means a gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa.

Flammable liquid means a liquid having a flash point of not more than 93 °C.

***Flammable solid* means** a solid which is readily combustible, or may cause or contribute to fire through friction.

Flash point means the lowest temperature (corrected to a standard pressure of 101.3 kPa) at which the application of an ignition source causes the vapours of a liquid to ignite under specified test conditions.

Gas means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa; or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa.

GESAMP means "the Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection of IMO/FAO/UNESCO/WMO/WHO/IAEA/UN/UNEP.".

GHS means "the Globally Harmonized System ~~for Hazard~~ of Classification and ~~Communication~~Labelling of Chemicals".

Hazard category ~~This is the term used~~ in ~~the~~ this document ~~to describe~~ means the division of criteria within each hazard class, ~~i.e.~~e.g. oral acute toxicity ~~has~~ includes five hazard categories and flammable liquids ~~has~~includes four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally.

Hazard class ~~This is the term used~~ in this document ~~to describe~~means the nature of the physical, health or environmental hazard, ~~i.e~~e.g. flammable solid carcinogen, oral acute toxicity.

Hazard statement means a ~~phase~~ statement assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including, where appropriate, the degree of hazard.

IARC means the "International Agency for the Research on Cancer".

IMO means the "International Maritime Organization".

Initial boiling point means the temperature of a liquid at which its vapour pressure is equal to the standard pressure (101.3 kPa), i.e. the first gas bubble appears.

IOMC means the "Inter-organization Programme on the Sound Management of Chemicals"

IPCS means the "International Programme on Chemical Safety".

IUPAC means the "International Union of Pure and Applied Chemistry".

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous product, selected as relevant to the target sector (s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of ~~the~~ a hazardous product.

Label element means one type of information that has been harmonized for use in a label, e.g. pictogram, signal word.

***LC_{50}* (50% lethal concentration)** means the concentration of a material[substance] in air or of a chemical in water which causes the death of 50% (one half) of a group of test animals.

LD_{50} means the amount of a material[substance], given all at once, which causes the death of 50% (one half) of a group of test animals.

$L(E)C_{50}$ means LC_{50} or EC_{50}.

***Liquefied gas* means a** gas which when packaged under pressure, is partially liquid at temperatures above –50 °C. A distinction is made between:

(i) High pressure liquefied gas: a gas with a critical temperature between -50 °C and +65 °C; and
(ii) Low pressure liquefied gas: a gas with a critical temperature above +65 °C.

Liquid means a substance which at 50 °C has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. A viscous substance for which a specific melting point cannot be determined shall be subjected to the ASTM D 4359-90 test; or to the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)[5].

***Manual of Tests and Criteria* means** the third revised edition of the United Nations publication entitled "Recommendations on the Transport of Dangerous goods, Manual of Tests and Criteria" (ST/SG/AC.10/11/Rev.3).

MARPOL means the “International Convention for the Prevention of Pollution from Ships”.

***Mixture* means m**ixtures or solutions composed of two or more substances in which they do not react.

Mutagen means an agent giving rise to an increased occurrence of mutations in populations of cells and /or organisms.

Mutation means a permanent change in the amount or structure of the genetic material in a cell.

NGO means “non-governmental organization”.

NOEC means the “no observed effect concentration”.

OECD means “The Organization for Economic Cooperation and Development”.

OSHA means “The Occupational Safety and Health Administration”.

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[5] *United Nations publication: ECE/TRANS/140.*

***Organic peroxides* means** liquid or solid organic substances which contain the bivalent -0-0- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals.

***Oxidizing gas* means** any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

***Oxidizing liquid* means** a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

***Oxidizing solid* means** a solid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

QSAR means "quantitative structure-activity relationships".

PIC means "prior informed consent".

Pictogram means a composition that may include a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information.

Precautionary statement means a phrase (and/or pictogram) that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product.

Product identifier means the name or number used for a hazardous product on a label or in the SDS. It provides a unique means by which the product user can identify the substance or mixture within the particular use setting e.g. transport, consumer or workplace.

***Pyrophoric liquid*:** A pyrophoric liquid is a liquid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air.

***Pyrophoric solid* means** a solid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air.

***Pyrotechnic article* means a**n article containing one or more pyrotechnic substances.

***Pyrotechnic substance* means a** substance or mixture of substances designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

Readily combustible solid means powdered, granular, or pasty substance which is dangerous if it can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

***Refrigerated liquefied gas* means a** gas which when packaged is made partially liquid because of its low temperature.

***Respiratory sensitizer* means** a substance that induces hypersensitivity of the airways following inhalation of the substance.

RID means The Regulations concerning the International Carriage of Dangerous Goods by Rail [Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) (CIM) of COTIF (Convention concerning international carriage by rail)]

SAR means "Structure Activity Relationship".

SDS means "Safety Data Sheet".

Self-Accelerating Decomposition Temperature (SADT) means the lowest temperature at which self-accelerating decomposition may occur with substance as packaged.

Self-heating substance **means** a solid or liquid substance, other than a pyrophoric substance, which, by reaction with air and without energy supply, is liable to self-heat; this substance differs from a pyrophoric substance in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

Self-reactive substance **means** thermally unstable liquid or solid substances liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances or mixtures classified under the GHS as explosive, organic peroxides or as oxidizing. ***ignal word*** means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The GHS uses 'Danger' and 'Warning' as signal words.

Skin corrosion means the production of irreversible damage to the skin following the application of a test substance for up to 4 hours.

Skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours.

Skin sensitizer means a substance that induces an allergic response following skin contact.

Solids means substances which do not meet the definitions of liquids or gases.

SPR means "Structure Property Relationship".

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Substances which, in contact with water, emit flammable gases means solid or liquid substances which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

Supplemental label element means any additional non-harmonized type of information supplied on the container of a hazardous product that is not required or specified under the GHS. In some cases this information may be required by other competent authorities or it may be additional information provided at the discretion of the manufacturer/distributor.

Symbol means a graphical element intended to succinctly convey information.

***Technical name* means a** name that is generally used in commerce, regulations and codes to identify a substance or mixture, other than the IUPAC or CAS name, and that is recognized by the scientific community. Examples of technical names include those used for complex mixtures (e.g., petroleum fractions or natural products), pesticides (e.g., ISO or ANSI systems), dyestuffs (Colour Index system) and minerals.

UNCED means the “United Nations Conference on Environment and Development”.

UNCETDG/GHS means the "United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals".

UNITAR means United Nations Institute for Training and Research.

UN Model Regulations means the "Model Regulations" annexed to the [thirteenth] revised edition of the Recommendations on the Transport of Dangerous Goods published by the United Nations (ST/SG/AC.10/1/Rev.13~~2~~).

UNSCEGHS means the "United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals".

UNSCETDG means the "United Nations Sub-Committee of Experts for the Transport of Dangerous Goods".

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CHAPTER 1.~~2~~3

CLASSIFICATION OF HAZARDOUS SUBSTANCES AND MIXTURES

1.3.1 Introduction

~~1.~~ Development of the GHS began with the work on classification criteria by the OECD Task Force on Harmonisation of Classification and Labelling (Task Force on HCL) for health and environmental hazards, and by the UNCETDG/ILO Working Group for Physical Hazards.

1.3.1.1. *OECD ~~t~~Task F~~f~~orce on HCL for health and environmental hazards*

~~2.~~1.3.1.1.1 The work of the OECD Task Force on HCL was generally of three related kinds:

(a) Comparison of the major classification systems, identification of similar or identical elements and, for the elements which were dissimilar, development of a consensus on a compromise;

(b) Examination of the scientific basis for the criteria which define the hazard class of concern (e.g. acute toxicity, carcinogenicity), gaining expert consensus on the test methods, data interpretation and level of concern, and then seeking consensus on the criteria. For some hazard classes, the existing schemes had no criteria and the relevant criteria were developed by the Task Force;

(c) Where there was a decision-tree approach (e.g. irritation) or where there were dependent criteria in the classification scheme (acute aquatic toxicity), development of consensus on the process or the scheme for using the criteria.

~~3.~~1.3.1.1.2 The Task Force on HCL proceeded stepwise in developing its harmonised classification criteria. For each hazard class the following steps were undertaken:

(a) Step 1: A thorough analysis of existing classification systems, including the scientific basis for the system and its criteria, its rationale and an explanation of how it is used. Step 1 documents were prepared and amended as required after discussion by the Task Force ~~–~~on HCL for the following hazard classes: Eye Irritation/Corrosion, Skin irritation/Corrosion, Sensitising Substances, Germ Cell Mutagenicity, Reproductive Toxicity, Specific Target Organ/Systemic Toxicity, and Chemical Mixtures;~~.~~

(b) Step 2: A proposal for a harmonised classification system and criteria for each hazard class and category was developed. A Step 2 document was prepared and amended as required after discussion by the Task Force on HCL~~.~~;

(c) Step 3:

~~a.~~ (i) Task Force ~~–~~on HCL reached consensus on the revised Step 2 proposal; or

~~b.~~ (ii) If attempts at consensus building failed, the ~~OECD~~ Task Force on HCL identified specific non consensus items as alternatives in a revised Step 2 proposal for further discussion and resolution.

(d) Step 4: Final proposals were submitted to the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology for approval and subsequently to the IOMC CG-HCCS for incorporation into the GHS.

1.3.1.2 *UNCETDG/ILO Working Group on Physical Hazards*

~~4.~~ The UNCETDG/ILO Working Group for Physical Hazards used a similar process to the OECD Task Force on HCL. The work involved a comparison of the major classification systems, identification of similar or identical elements and for the elements, which were dissimilar, development of a consensus on a compromise. For physical hazards, however, the transport definitions, test methods and classification criteria were used as a basis for the work since they were already substantially harmonized. The work proceeded through examination of the scientific basis for the criteria, gaining consensus on the test methods, data interpretation and on the criteria. For most hazard classes, the existing schemes were already in place and being used by the transport sector. On this basis, a portion of the work focused on ensuring that workplace, environment and consumer safety issues were adequately addressed.

1.3.2 General considerations on the harmonized classification system

1.3.2.1 *Scope of the ~~Harmonised Classification~~ System*

~~5.~~1.3.2.1.1 The classification system applies to pure chemical substances, their dilute solutions and to mixtures of chemical substances. "Articles" as defined in the US OSHA Hazard Communication Standard (29 CFR 1910.1200), or by similar definition, are outside the scope of the system.

~~6.~~1.3.2.1.2 One objective of the harmonised hazard classification system is for it to be simple and transparent with a clear distinction between classes and categories in order to allow for "self classification" as far as possible. For many hazard classes the criteria are semi-quantitative or qualitative and expert judgement is required to interpret the data for classification purposes. Furthermore, for some hazard classes (e.g. eye irritation, explosives or self-reactive substances) a decision tree approach is provided to enhance ease of use.

1.3.2.2 *Concept of "Classification"*

~~7.~~1.3.2.2.1 The GHS uses the term "hazard classification" to indicate that only the intrinsic hazardous properties of substances or mixtures are considered.

~~8.~~1.3.2.2.2 Hazard classification incorporates only 3 steps, ~~viz.,~~ i.e.:

- (a) identification of relevant data regarding the hazards of a substance or mixture;
- (b) subsequent review of those data to ascertain the hazards associated with the substance or mixture; and
- (c) a decision on whether the substance or mixture will be classified as a hazardous substance or mixture and the degree of hazard, where appropriate, by comparison of the data with agreed hazard classification criteria.

~~9.~~1.3.2.2.3 As noted in IOMC Description and Further Clarification of the Anticipated Application of the Globally Harmonized System text in the *Purpose, Scope and Application* (Chapter 1.1, paragraph ~~10~~1.1.2.4) , it is recognised that once a chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting.

1.3.2.3 *Classification criteria* ~~*Presentation of criteria*~~

~~10.~~ The classification criteria for substances and mixtures are presented in Parts 2 and 3 of this document, each of which is for a specific hazard class or a group of closely related hazard classes. The recommended process of classification of mixtures is based on the following sequence:

~~(1)~~ (a) Where test data are available for the complete mixture, the classification of the mixture will always be based on that data;~~.~~

~~(2)~~ (b) Where test data are not available for the mixture itself, then ~~the~~ bridging principles included and explained in each specific chapter should be considered to see whether they permit classification of the mixture;~~.~~

In addition, for the health and environmental classes,

~~(3)~~ (c) If (1) test data are not available for the mixture itself, and (~~2~~ii) the available information is not sufficient to allow application of the above mentionned bridging principles, then the agreed method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture.

1.3.2.4 *Available data, test methods and test data quality*

~~11.~~1.3.2.4.1 The GHS itself does not include requirements for testing substances or mixtures. Therefore, there is no requirement under the GHS to generate test data for any hazard class. It is recognised that some parts of regulatory systems do require data to be generated (e.g. pesticides), but these requirements are not related specifically to the GHS. The criteria established for classifying a mixture will allow the use of available data for the mixture itself and /or similar mixtures and /or data for ingredients of the mixture.

~~12.~~1.3.2.4.2 The classification of a chemical substance or mixture depends both on the criteria and on the reliability of the test methods underpinning the criteria. In some cases the classification is determined by a pass or fail of a specific test, (e.g. the ready biodegradation test for substances or ingredients of mixtures), while in other cases, interpretations are made from dose/response curves and observations during testing. In all cases, the test conditions need to be standardised so that the results are reproducible with a given chemical substance and the standardised test yields “valid” data for defining the hazard class of concern. In this context, validation is the process by which the reliability and the relevance of a procedure are established for a particular purpose.

~~13.~~1.3.2.4.3 Tests that determine hazardous properties, which are conducted according to internationally recognised scientific principles, can be used for purposes of a hazard determination for health and environmental hazards. The GHS criteria for determining health and environmental hazards are test method neutral, allowing different approaches as long as they are scientifically sound and validated according to international procedures and criteria already referred to in existing systems for the hazard of concern and produce mutually acceptable data. Test methods for determining physical hazards are generally more clear-cut, and are specified in the GHS.

1.3.2.4.4 *Previously classified chemicals*

~~14.~~ One of the general principles established by the IOMC-CG-HCCS states that test data already generated for the classification of chemicals under the existing systems should be accepted when classifying these chemicals under the harmonised system thereby avoiding duplicative testing and the unnecessary use of test animals. This policy has important implications in those cases where the criteria in

the GHS are different from those in an existing system. In some cases, it may be difficult to determine the quality of existing data from older studies. In such cases, expert judgement will be needed.

1.3.2.4.5 *Substances / Mixtures posing special problems*

~~15.~~ The effect of a substance or mixture on biological and environmental systems is influenced, among other factors, by the physico chemical properties of the substance or mixture and/or ingredients of the mixture and the way in which ingredient substances are biologically available. Some groups of substances may present special problems in this respect, for example, some polymers and metals. A substance or mixture need not be classified when it can be shown by conclusive experimental data from internationally acceptable test methods that the substance or mixture is not biologically available. Similarly, bioavailability data on ingredients of a mixture should be used where appropriate in conjunction with the harmonised classification criteria when classifying mixtures.

1.3.2.4.6 *Animal welfare*

~~16.~~11. The welfare of experimental animals is a concern. This ethical concern includes not only the alleviation of stress and suffering but also, in some countries, the use and consumption of test animals. Where possible and appropriate, tests and experiments that do not require the use of live animals are preferred to those using sentient live experimental animals. To that end, for certain hazards (skin and eye irritation/corrosion) testing schemes starting with non-animal observations/measurements are included as part of the classification system. For other hazards, such as acute toxicity, alternative animal tests, using fewer animals or causing less suffering are internationally accepted and should be preferred to the conventional LD_{50} test.

1.3.2.4.7 *Evidence from humans*

~~17.~~ For classification purposes, reliable epidemiological data and experience on the effects of chemicals on humans (e.g. occupational data, data from accident databases) should be taken into account in the evaluation of human health hazards of a chemical. Testing on humans solely for hazard identification purposes is generally not acceptable.

1.3.2.4.8 *Expert judgement*

~~18.~~ The approach to classifying mixtures includes the application of expert judgement in a number of areas in order to ensure existing information can be used for as many mixtures as possible to provide protection for human health and the environment. Expert judgement may also be required in interpreting data for hazard classification of substances, especially where weight of evidence determinations are needed.

1.3.2.4.9. *Weight of evidence*

~~19.~~1.3.2.4.9.1 For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a substance or a mixture is made on the basis of the total weight of evidence. This means that all available information bearing on the determination of toxicity is considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.

~~20.~~1.3.2.4.9.2 The quality and consistency of the data are important. Evaluation of substances or mixtures related to the material being classified should be included, as should site of action and mechanism

or mode of action study results. Both positive and negative results are assembled together in a single weight of evidence determination.

~~21.~~1.3.2.4.9.3 Positive effects which are consistent with the criteria for classification in each chapter, whether seen in humans or animals, will normally justify classification. Where evidence is available from both sources and there is a conflict between the findings, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification. Generally, data of good quality and reliability in humans will have precedence over other data. However, even well-designed and conducted epidemiological studies may lack sufficient numbers of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness and quality of both the human and animal data relative to the expected frequency of occurrence of effects and the impact of potentially confounding factors.

~~22.~~1.3.2.4.9.4 Route of exposure, mechanistic information and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a ~~lower~~less stringent classification may be warranted. When it is clear that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified.

~~23.~~1.3.2.4.9.5 Both positive and negative results are assembled together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

1.3.3 Specific considerations for the classification of mixtures

1.3.3.1 *Definitions*

~~24.~~1.3.3.1.1 In order to ensure a full understanding of the provisions for classifying mixtures, definitions of certain terms are required. These definitions are for the purpose of evaluating or determining the hazards of a product for classification and labelling, and are not intended to be applied in other situations such as inventory reporting. The intent of the definitions as drawn is to ensure that ~~1~~(a) all products within the scope of the Globally Harmonised System are evaluated to determine their hazards, and are subsequently classified according to the GHS criteria as appropriate; and ~~2~~(b) the evaluation is based on the actual product involved, i.e. on a stable product. If a reaction occurs during manufacture and a new product results, a new hazard evaluation and classification must take place to apply the GHS to the new product.

~~25.~~1.3.3.1.2 Working definitions have been accepted for the following terms: substances, mixture, alloy (see ~~Annex 1~~Chapter 1.2 for other Definitions and Abbreviations used in the GHS).

Substance: Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Mixture: Mixtures or solutions composed of two or more substances in which they do not react.

Alloy: An alloy is a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purpose of classification under the GHS.

~~26.~~1.3.3.1.3 These definitions should be used to maintain consistency when classifying substances and mixtures in the GHS. Note also that where impurities, additives or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class.

~~27.~~1.3.3.1.4 It is recognised, as a practical matter, that some substances may react slowly with atmospheric gases, e.g. oxygen, carbon dioxide, water vapour, to form different substances; or they may react very slowly with other ingredient substances of a mixture to form different substances; or they may self-polymerise to form oligomers or polymers. However, the concentrations of different substances produced by such reactions are typically considered to be sufficiently low that they do not affect the hazard classification of the mixture.

1.3.3.2 *The Use of cut-off values/Concentration limits*

~~28.~~1.3.3.2.1 When classifying an untested mixture based on the hazards of its ingredients, generic cut-off values or concentration limits for the classified ingredients of the mixture are used for several hazard classes in the GHS. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the harmonised cut-off value/concentration limit that still pose an identifiable hazard. There may also be cases where the harmonised cut-off value/concentration limit is considerably lower than could be expected on the basis of an established non-hazardous level for an ingredient.

~~29.~~1.3.3.2.2 Normally, the generic cut-off values/concentration limits adopted in the GHS should be applied uniformly in all jurisdictions and for all sectors. However, if the classifier has information that the hazard of an ingredient will be evident below the generic cut-off values/concentration limits, the mixture containing that ingredient should be classified accordingly.

~~30.~~1.3.3.2.3 On occasion, conclusive data may show that the hazard of an ingredient will not be evident when present at a level above the generic GHS cut-off values/concentration limit(s). In these cases the mixture could be classified according to those data. The data should exclude the possibility that the ingredient would behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture should not contain ingredients that would affect that determination.

~~31.~~1.3.3.2.4 Adequate documentation supporting the use of any values other than the generic cut-off values/ concentration limits should be retained and made available for review on request.

1.3.3.3 *Synergistic or antagonistic effects*

~~32.~~1.3.3.3.1 When performing an assessment in accordance with the GHS requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

CHAPTER 1~~3~~.4

HAZARD COMMUNICATION: LABELLING

1.4.1 Objectives~~,~~ ~~and~~ scope and application

~~1.~~1.4.1.1 One of the objectives of the work on the Globally Harmonised System (GHS) has been the development of a harmonised hazard communication system, including labelling, safety data sheets and easily understandable symbols, based on the classification criteria developed for the GHS ~~Globally Harmonised System~~. This work was carried out under the auspices of the ILO, by the ILO Working Group on Hazard Communication using the same 3-step procedure outlined for the harmonisation of classification in *Classification of Hazardous Substances and Mixtures* (Chapter 1.~~2~~3, paragraph ~~3~~1.3.1.1.2).

~~Application of the harmonised hazard communication system~~

~~2.~~1.4.1.2 The harmonised system for hazard communication includes the appropriate labelling tools to convey information about each of the hazard classes and categories in the GHS. the use of symbols, signal words or hazard statements other than those which have been assigned to each of the GHS hazard classes and categories would be contrary to harmonisation.

~~3.~~1.4.1.3 The ILO Working Group considered the application of the General Principles described in the IOMC CG/HCCS Terms of Reference[1] as they apply to hazard communication and recognised that there will be circumstances where the demands and rationale of systems may warrant some flexibility in whether to incorporate certain hazard classes and categories for certain target audiences.

~~4.~~1.4.1.4 For example, the scope of the UN ~~RTDG~~ Model Regulations encompasses only the most severe hazard categories of the acute toxicity hazard class. This system would not label substances or mixtures falling within the scope of the less severe hazard categories (e.g. those falling within the oral range > 300mg/kg). However, should the scope of that system be amended to incorporate substances and mixtures falling in these less severe hazard categories, they should be labelled with the appropriate GHS labelling tools. The use of different cut-off~~s~~ values to determine which products are labelled in a hazard category would be contrary to harmonisation.

~~5.~~1.4.1.5 It is recognised that the UN ~~RTDG m~~Model R~~r~~egulations provide label information primarily in a graphic form because of the needs of its target audiences. Therefore the UN ~~RTDG~~ Model Regulations may choose not to include signal words and hazard statements ~~in the model regulations~~ as part of the information provided on the label.

1.4.2 Terminology

~~6.~~1.4.2.1 A description of common terms and definitions related to hazard communication is included in ~~Annex 1~~Chapter 1.2: Definitions and Abbreviations.

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[1] *IOMC, Coordinating Group for the Harmonization of Chemical Classification Systems, Revised Terms of Reference and Work Programme (IOMC/HCS/95 – 14 January 1996).*

1.4.3 Target audiences

~~7.~~1.4.3.1 The needs of the target audiences that will be the primary end-users of the harmonized hazard communication scheme have been identified. Particular attention was given to a discussion of the manner in which these target audiences will receive and use the information conveyed about hazardous chemicals. Factors discussed include the potential use of products, availability of information other than the label and the availability of training.

~~8.~~1.4.3.2 It was recognized that it is difficult to completely separate the needs of different target audiences. For example, both workers and emergency responders use labels in storage facilities, and products such as paints and solvents are used both by consumers and in workplaces. In addition, 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). That said, there are certain characteristics which are particular to the different target audiences. The following paragraphs in this section consider the target audiences and the type of information they need.

~~9.~~**1.4.3.3** *Workplace*: -Employers and workers need to know the hazards specific to the chemicals used and or handled in the workplace, as well as information about the specific protective measures required to avoid the adverse effects that might be caused by those hazards. In the case of storage of chemicals, potential hazards are minimised by the containment (packaging) of the chemical, but in the case of an accident, workers and emergency responders need to know what mitigation measures are appropriate. Here they may require information which can be read at a distance. The label, however, is not the sole source of this information, which is also available through the SDS and workplace risk management system. The latter should also provide for training in hazard identification and prevention. The nature of training provided and the accuracy, comprehensibility and completeness of the information provided on the SDS may vary. However, compared to consumers for example, workers can develop a more in depth understanding of symbols and other types of information.

~~10.~~1.4.3.4 *Consumers*: The label in most cases is likely to be the sole source of information readily available to the consumer. The label, therefore, will need to be sufficiently detailed and relevant to the use of the product. There are considerable philosophical differences on the approach to providing information to consumers. Labelling based on the likelihood of injury (i.e. risk communication) is considered to be an effective approach in this respect by some consumer labelling systems, whilst others take account of the 'right to know' principle in providing information to consumers which is solely based on the product's hazards. Consumer education is more difficult and less efficient than education for other audiences. Providing sufficient information to consumers in the simplest and most easily understandable terms presents a considerable challenge. The issue of comprehensibility is of particular importance for this target audience, since consumers may rely solely on label information.

~~11.~~1.4.3.5 *Emergency responders*: Emergency responders need information on a range of levels. To facilitate immediate responses, they need accurate, detailed and sufficiently clear information. This applies in the event of an accident during transportation, in storage facilities or at workplaces. Fire fighters and those first at the scene of an accident for example, need information that can be distinguished and interpreted at a distance. Such personnel are highly trained in the use of graphical and coded information. However, emergency responders also require more detailed information about hazards and response techniques, which they obtain from a range of sources. The information needs of medical personnel responsible for treating the victims of an accident or emergency may differ from those of fire fighters.

~~12.~~1.4.3.6 *Transport*: ~~**(UN RTDG model regulations)**~~ The UN ~~RTDG m~~Model R~~r~~egulations for the Transport of Dangerous Goods cater for a wide range of target audiences although transport workers and emergency responders are the principal ones. Others include employers, those who offer or accept

dangerous goods for transport or load or unload packages of dangerous goods into or from transport vehicles, or freight containers. All need information concerning general safe practices that are appropriate for all transport situations. For example, a driver will have to know what has to be done in case of an accident irrespective of the substance transported: (e.g. report the accident to authorities, keep the shipping documents in a given place, etc.) Drivers may only require limited information concerning specific hazards, unless they also load and unload packages or fill tanks, etc. Workers who might come into direct contact with dangerous goods, for example on board ships, require more detailed information.

1.4.4 Comprehensibility

~~13.~~1.4.4.1 Comprehensibility of the information provided has been one of the most important issues addressed in the development of the hazard communication system (see also Comprehensibility, Chapter 4.2). The aim of the harmonized system is to present the information in a manner that the intended audience can easily understand. The GHS identifies some guiding principles to assist this process:

- (a) Information should be conveyed in more than one way~~;~~.
- (b) The comprehensibility of the components of the system should take account of existing studies and literature as well as any evidence gained from testing~~;~~.
- (c) The phrases used to indicate degree (severity) of hazard should be consistent across different hazard types**.**

~~14.~~1.4.4.2 The latter point was subject to some debate concerning the comparison of severity between long-term effects such as carcinogenicity and physical hazards such as flammability. Whilst it might not be possible to directly compare physical hazards to health hazards, it may be possible to provide target audiences with a means of putting the degree of hazard into context and therefore convey the same degree of concern about the hazard.

1.4.4.3 *Comprehensibility testing methodology*

~~15.~~ A preliminary review of the literature undertaken by the University of Maryland indicated that common principles related to comprehensibility could be applied to the development of the harmonised hazard communication scheme. The University of Cape Town developed these into a comprehensive testing methodology to assess the comprehensibility of the hazard communication system (see also Comprehensibility, Chapter 4.2). In addition to testing individual label components, this methodology considers the comprehensibility of label components in combination. This was considered particularly important to assess the comprehensibility of warning messages for consumers where there is less reliance on training to aid understandability. The testing methodology also includes a means of assessing SDS comprehensibility. A summary description of this methodology is provided in Annex ~~6~~5.

1.4.5 Translation

~~16.~~ Options for the use of textual information present an additional challenge for comprehensibility. Clearly words and phrases need to retain their comprehensibility when translated, whilst conveying the same meaning. The IPCS Chemical Safety Card Programme has gained experience of this in translating standard phrases in a wide variety of languages. The EU also has experience of translating terms to ensure the same message is conveyed in multiple languages e.g. hazard, risk etc. Similar experience has been gained in North America where the North American Emergency Response Guidebook, which uses key phrases, is available in a number of languages**.**

1.4.6 Standardization

~~17.~~1.4.6.1 To fulfil the goal of having as many countries as possible adopt the system, much of the GHS is based on standardised approaches to make it easier for companies to comply with and for countries to implement the system. Standardisation can be applied to certain label elements – symbols, signal words, statements of hazard, precautionary statements – and to label format and colour and to SDS format**.**

1.4.6.2 *Application of standardization in the harmonized system*

~~18.~~ For labels, the hazard symbols, signal words and hazard statements have all been standardised and assigned to each of the hazard categories. These standardised elements should not be subject to variation, and should appear on the GHS label as indicated in the Chapters for each hazard class in this document. For safety data sheets, the chapter *Hazard Communication: Safety Data Sheets* (Chapter ~~1.4~~1.5) provides a standardised format for the presentation of information. Whilst precautionary information was considered for standardisation, there was insufficient time to develop detailed proposals. However, there are examples of precautionary statements and pictograms in Annex ~~4~~ 3 and it remains a goal to develop them into fully standardised label elements.

1.4.6.3 *Use of non-standardized or supplemental information*

~~19.~~1.4.6.3.1 There are many other label elements which may appear on a label which have not been standardised in the harmonised system. Some of these clearly need to be included on the label, for example precautionary statements. Competent authorities may require additional information, or suppliers may choose to add supplementary information on their own initiative. In order to ensure that the use of non-standardised information does not lead to unnecessarily wide variation in information or undermine GHS information, the use of supplementary information should be limited to the following circumstances:

- (a) the supplementary information provides further detail and does not contradict or cast doubt on the validity of the standardised hazard information; or;
- (b) the supplementary information provides information about hazards not yet incorporated into the GHS.

In either instance, the supplementary information should not lower standards of protection.

~~20.~~1.4.6.3.2 The labeller should have the option of providing supplementary information related to the hazard, such as physical state or route of exposure, with the hazard statement rather than in the supplementary information section on the label, see also paragraph ~~49~~1.4.10.5.4.1.

1.4.7 Updating information

~~21.~~1.4.7.1 All systems should specify a means of responding in an appropriate and timely manner to new information and updating labels and SDS information accordingly. The following are examples of how this could be achieved.

1.4.7.2 *General guidance on updating of information*[2]

~~22.~~1.4.7.2.1 Suppliers should respond to “new and significant” information they receive about a chemical hazard by updating the label and safety data sheet for that chemical. New and significant information is any information that changes the GHS classification of the substance or mixture and leads to a resulting change in the information provided on the label or any information concerning the chemical and appropriate control measures that may affect the SDS. This could include, for example, new information on the potential adverse chronic health effects of exposure as a result of recently published documentation or test results, even if a change in classification may not yet be triggered.

~~23.~~1.4.7.2.2 Updating should be carried out promptly on receipt of the information that necessitates the revision. The competent authority may choose to specify a time limit within which the information should be revised. This applies only to labels and SDS for products that are not subject to an approval mechanism such as pesticides. In pesticide labelling systems, where the label is part of the product approval mechanism, suppliers cannot update the supply label on their own initiative. However when the products are subject to the transport of dangerous goods requirements, the label used should be updated on receipt of the new information, as above.

~~24.~~1.4.7.2.3 Suppliers should also periodically review the information on which the label and safety data sheet for a substance or mixture is based, even if no new and significant information has been provided to them in respect of that substance or mixture. This will require e.g. a search of chemical hazard databases for new information. The competent authority may choose to specify a time (typically 3 – 5 years) from the date of original preparation, within which suppliers should review the labels and SDS information.

1.4.8 Confidential business information

~~25.~~1.4.8.1 Systems adopting the GHS should consider what provisions may be appropriate for the protection of confidential business information (CBI). Such provisions should not compromise the health and safety of workers or consumers, or the protection of the environment. As with other parts of the GHS, the rules of the importing country should apply with respect to CBI claims for imported substances and mixtures.

~~26.~~1.4.8.2 Where a system chooses to provide for protection of confidential business information, competent authorities should establish appropriate mechanisms**,** in accordance with national law and practice, and consider:

— (a) whether the inclusion of certain chemicals or classes of chemicals in the arrangements is appropriate to the needs of the system;

— (b) what definition of "confidential business information" should apply, taking account of factors such as the accessibility of the information by competitors, intellectual property rights and the potential harm disclosure would cause to the employer or supplier's business; and

— (c) appropriate procedures for the disclosure of confidential business information, where necessary to protect the health and safety of workers or consumers, or to protect the environment, and measures to prevent further disclosure.

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[2] *~~Paragraphs 22-24~~Sub-section 1.4.7.2 is ~~are~~ not part of the agreed text on hazard communication developed by the ILO Working Group on Hazard Communication, but ~~have~~ has been provided here as additional guidance on the issue of updating of information in this Chapter.*

~~27.~~1.4.8.3 Specific provisions for the protection of confidential business information may differ among systems in accordance with national law and practice. However, they should be consistent with the following general principles:

(a) For information otherwise required on labels or safety data sheets, CBI claims should be limited to the names of chemicals, and their concentrations in mixtures. All other information should be disclosed on the label and/or safety data sheet, as required;~~.~~

(b) Where CBI has been withheld, the label or chemical safety data sheet should so indicate;~~.~~

(c) CBI should be disclosed to the competent authority upon request. The competent authority should protect the confidentiality of the information in accordance with applicable law and practice;~~.~~

(d) Where a medical professional determines that a medical emergency exists due to exposure to a hazardous chemical or a chemical mixture, mechanisms should be in place to ensure timely disclosure by the supplier or employer or competent authority of any specific confidential information necessary for treatment. The medical professional should maintain the confidentiality of the information;~~.~~

(e) For non-emergency situations, the supplier or employer should ensure disclosure of confidential information to a safety or health professional providing medical or other safety and health services to exposed workers or consumers, and to workers or workers' representatives. Persons requesting the information should provide specific reasons for the disclosure, and should agree to use the information only for the purpose of consumer or worker protection, and to otherwise maintain its confidentiality;~~.~~

(f) Where non-disclosure of CBI is challenged, the competent authority should address such challenges or provide for an alternative process for challenges. The supplier or employer should be responsible for supporting the assertion that the withheld information qualifies for CBI protection.

1.4.9 Training

~~28.~~1.4.9.1 Training users of hazard information is an integral part of hazard communication. Systems should identify the appropriate education and training for GHS target audiences who are required to interpret label and/or SDS information and to take appropriate action in response to chemical hazards. Training requirements should be appropriate for and commensurate with the nature of the work or exposure. Key target audiences for training include workers, emergency responders, and those involved in the preparation of labels, SDS and hazard communication strategies as part of risk management systems. Others involved in the transport and supply of hazardous chemicals also require training to varying degrees. In addition, systems should consider strategies required for educating consumers in interpreting label information on products that they use.

1.4.10 Labelling procedures

~~29.~~1.4.10.1 *Scope*

~~29~~ The following sections describe the procedures for preparing labels in the GHS, comprising the following:

— (a) Allocation of label elements;
— (b) Reproduction of the symbol.;
— (c) Reproduction of the hazard pictogram;.
— (d) Signal words;.
— (e) Hazard statements;.
— (f) Precautionary statements and pictograms;.
— (g) Product and supplier identification;.
— (h) Multiple hazards and precedence of information;.
— (i) Arrangements for presenting the GHS label elements;.
— (j) Special labelling arrangements.

1.4.10.2 ***Allocation of label elements***

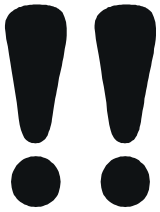
30. The tables in the individual Chapters for each hazard class detail the label elements (symbol, signal word, hazard statement) that have been assigned to each of the hazard categories of the GHS. Hazard categories reflect the harmonised classification criteria. A summary of the allocation of label elements is provided in Annex 21. There are special arrangements, which apply to the use of certain mixture concentrations in the GHS to take account of the information needs of different target audiences. These are further described in paragraph 53 1.4.10.5.4of this chapter. .

1.4.10.3 *Reproduction of the symbol*

~~31.~~29. The following hazard symbols are the standard symbols which should be used in the GHS. With the exception of the new symbol which will be used for certain health hazards, the exclamation mark and the fish and tree, they are the standard symbol set used in the UN ~~RTDG m~~Model R~~r~~egulations.

Flame	Flame over circle	Exploding bomb	Corrosion
			

Gas cylinder	Skull and crossbones	Exclamation Mark	Environment
			

Double Exclamation Mark


~~**Pictograms**~~

~~32. A pictogram means a composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information~~.

1.4.10.4 *Reproduction of the hazard pictogram*

1.4.10.4.1 *Shape and colour*

~~33.~~1.4.10.4.1.1 All hazard pictograms used in the ~~harmonised system~~GHS should be in the shape of a square set at a point.

~~34.~~1.4.10.4.1.2 Pictograms prescribed by the UN~~RTDG~~ Model Regulations will use a background and symbol colour as specified by those regulations. An example of the pictogram used in the ~~UNRTDG~~ UN Model Regulations for flammable liquid is provided below.

Pictogram for flammable liquid in the UN ~~RTDG~~ M~~m~~odel R~~r~~egulations


~~35.~~1.4.10.4.1.3 Pictograms prescribed by the GHS but not the UN ~~RTDG~~ M~~m~~odel R~~r~~egulations should have a black symbol on a white background with a red frame sufficiently wide to be clearly visible. However, when such a pictogram appears on a label for a package which will not be exported, the Competent Authority may choose to give suppliers and employers discretion to use a black border. In addition, Competent Authorities may allow the use of UN ~~RTDG~~ Model Regulations pictograms in other use settings where the package is not covered by the UN ~~RTDG~~Model Regulations. An example of a GHS pictogram used for a skin irritant is provided below.
~~35.~~

GHS pictogram for skin irritant


10.4.10.5 *Allocation of label elements for p~~P~~ackages covered by the UN ~~RTDG~~ M~~m~~odel R~~r~~egulations and other labelling systems*

~~36.~~10.4.10.5.1 Where a UN ~~RTDG~~Model Regulations pictogram appears on a label, a GHS pictogram for the same hazard should not appear.

10.4.10.5.2 *Information required on a GHS label*

(a) Signal words[3]

~~37.~~ A signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The signal words used in the GHS are “Danger” and “Warning”. “Danger” is used for the more severe hazard categories (i.e. in the main for hazard categories 1 and 2), while “Warning” is used for the less severe. The tables in the individual Chapters for each hazard class detail the signal words that have been assigned to each of the hazard categories of the GHS.

(b) Hazard statements[3]

~~38.~~ A hazard statement means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including, where appropriate, the degree of hazard. The tables of label elements in the individual Chapters for each hazard class detail the hazard statements that have been assigned to each of the hazard categories of the GHS.

(c) Precautionary statements and pictograms[3]

~~39.~~ A precautionary statement means a phrase (and/or pictogram) that describes recommended measures that should be taken to minimise or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product. The GHS label should include appropriate precautionary information, the choice of which is with the labeller or the competent authority. Annex ~~4~~ 3 contains examples of precautionary statements, which can be used, and also examples of precautionary pictograms, which can be used where allowed by the Competent Authority.

~~**Product and supplier identification**~~

(d) Product identifier

~~40.~~ (i) A product identifier should be used on a GHS label and it should match the product identifier used on the SDS. Where a substance or mixture is covered by the UN ~~RTDG~~Model Regulations, the UN proper shipping name should also be used on the package~~:~~.

~~41.~~ (ii) The label for a substance should include the chemical identity of the substance. For mixtures or alloys, the label should include the chemical identities of all ingredients or alloying elements that contribute to acute toxicity, skin or eye corrosion, germ cell mutagenicity, carcinogenicity, reproductive toxicity, skin or respiratory sensitisation, or Target Organ Systemic Toxicity (TOST), when these

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[3] *The definitions for "signal word" and "hazard statement ~~Paragraphs 37-38,~~ and also part of the definition for "precautionary statement ~~text of paragraph 39~~ are not part of the agreed text on hazard communication developed by the ILO Working Group on Hazard Communication, but have been provided here as additional information. ~~on signal words, hazard statements and precautionary statements.~~*

hazards appear on the label. Alternatively, the Competent Authority may require the inclusion of all ingredients or alloying elements that contribute to the hazard of the mixture or alloy;~~.~~

~~42.~~ (iii) Where a substance or mixture is supplied exclusively for workplace use, the competent authority may choose to give suppliers discretion to include chemical identities on the SDS, in lieu of including them on labels~~.~~;

~~43.~~ (iv) The competent authority rules for CBI take priority over the rules for product identification. This means that where an ingredient would normally be included on the label, if it meets the competent authority criteria for CBI, its identity does not have to be included on the label.

(e) Supplier identification

~~44.~~ The name, address and telephone number of the manufacturer or supplier of the substance or mixture should be provided on the label.

1.4.10.5.3 *Multiple hazards and precedence of hazard information*

~~45.~~ The following arrangements apply where a substance or mixture presents more than one GHS hazard. It is without prejudice to the building block principle described in the *Purpose, Scope and Application* (Chapter 1.1). Therefore where a system does not provide information on the label for a particular hazard, the application of the arrangements should be modified accordingly.

1.4.10.5.3.1 Precedence for the allocation of symbols

~~46.~~ For substances and mixtures covered by the UN ~~RTDG~~Model Regulations, the precedence of symbols for physical hazards should follow the rules of the UN ~~RTDG~~Model Regulations. In workplace situations, the Competent Authority may require all symbols for physical hazards to be used. For health hazards the following principles of precedence apply:

— (a) if the skull and crossbones applies, the exclamation mark should not appear;

— (b) if the corrosive symbol applies, the exclamation mark should not appear where it is used for skin or eye irritation;

— (c) if the new health hazard symbol appears for respiratory sensitisation, the exclamation mark should not appear where it is used for dermal sensitisation or for skin or eye irritation.

1.4.10.5.3.2 Precedence for allocation of signal words

~~47.~~ If the signal word ‘Danger’ applies, the signal word ‘Warning’ should not appear.

1.4.10.5.3.3 Precedence for allocation of hazard statements

~~48.~~ All assigned hazard statements should appear on the label. The Competent Authority may choose to specify the order in which they appear.

1.4.10.5.4 *Arrangements for presenting the GHS label elements*

1.4.10.5.4.1 Location of GHS information on the label

~~49.~~ The GHS hazard pictograms, signal word and hazard statements should be located together on the label. The Competent Authority may choose to provide a specified layout for the presentation of these and for the presentation of precautionary information, or allow supplier discretion. Specific guidance and examples are provided in the Chapters on individual hazard classes.

~~50.~~ There have been some concerns about how the label elements should appear on different packagings. Specific examples are provided in Annex ~~7~~6.

1.4.10.5.4.2 Supplemental information

~~51.~~ The competent authority has the discretion to allow the use of supplemental information subject to the parameters outlined in ~~paragraphs 19-20~~1.4.6.3. The competent authority may choose to specify where this information should appear on the label or allow supplier discretion. In either approach, the placement of supplemental information should not impede identification of GHS information.

1.4.10.5.4.3 Use of colour outside pictograms

~~52.~~ In addition to its use in pictograms, colour can be used on other areas of the label to implement special labelling requirements such as the use of the pesticide bands in the FAO Labelling Guide, for signal words and hazard statements or as background to them, or as otherwise provided for by the competent authority.

1.4.10.5.5 *Special labelling arrangements*

~~53.~~ The competent authority may chose to allow communication of certain hazard information for carcinogens, reproductive toxicity and target organ systemic toxicity repeat exposure on the label and on the SDS, or through the SDS alone (see specific chapters for details of relevant cut-offs for these classes).

~~54.~~ Similarly, for metals and alloys, the competent authority may chose to allow communication of the hazard information through the SDS alone when they are supplied in the massive, non-dispersible, form.

1.4.10.5.5.1 Workplace labelling[4]

~~55.~~1.4.10.5.5.1.1 Products falling within the scope of the GHS will carry the GHS label at the point where they are supplied to the workplace, and that label should be maintained on the supplied container in the workplace. The GHS label or label elements should also be used for workplace containers. However, the competent authority can allow employers to use alternative means of giving workers the same information in a different written or displayed format when such a format is more appropriate to the workplace and communicates the information as effectively as the GHS label. For example, label information could be displayed in the work area, rather than on the individual containers.

[4] *Paragraphs ~~56-58~~ 1.4.10.5.5.1.2 to 1.4.10.5.5.1.4 are not part of the agreed text on hazard communication developed by the ILO Working Group on Hazard Communication, but have been provided here as additional guidance on the issue of workplace labelling.*

~~56.~~1.4.10.5.5.1.2 Alternative means of providing workers with the information contained in GHS labels are needed usually where hazardous chemicals are transferred from an original supplier container into a workplace container or system, or where chemicals are produced in a workplace but are not packaged in containers intended for sale or supply. Chemicals that are produced in a workplace may be contained or stored in many different ways such as: small samples collected for testing or analysis, piping systems including valves, process or reaction vessels, ore cars, conveyer systems or free-standing bulk storage of solids. In batch manufacturing processes, one mixing vessel may be used to contain a number of different chemical mixtures.

~~57.~~1.4.10.5.5.1.3 In many situations, it is impractical to produce a complete GHS label and attach it to the container, due, for example, to container size limitations or lack of access to a process container. Some examples of workplace situations where chemicals may be transferred from supplier containers include: containers for laboratory testing or analysis, storage vessels, piping or process reaction systems or temporary containers where the chemical will be used by one worker within a short timeframe. Decanted chemicals intended for immediate use could be labelled with the main components and directly refer the user to the supplier label information and SDS.

~~58.~~1.4.10.5.5.1.4 All such systems should ensure that there is clear hazard communication. Workers should be trained to understand the specific communication methods used in a workplace. Examples of alternative methods include: use of product identifiers together with GHS symbols and other pictograms to describe precautionary measures; use of process flow charts for complex systems to identify chemicals contained in pipes and vessels with links to the appropriate SDS; use of displays with GHS symbols, colour and signal words in piping systems and processing equipment; use of permanent placarding for fixed piping; use of batch tickets or recipes for labelling batch mixing vessels and use of piping bands with hazard symbols and product identifiers**.**

1.4.10.5.5.2 Consumer product labelling based on the likelihood of injury

~~59.~~ All systems should use the GHS classification criteria. Consistent with the IOMC scope paper, however, some consumer labelling systems will provide label information based solely on hazard, while other consumer labelling systems may provide information based on the likelihood of harm (risk-based labelling). In the latter case the Competent Authority would establish procedures for determining the potential exposure and risk for the use of the product. Labels based on this approach provide targeted information on identified risks but may not include certain information on chronic health effects (e.g. (Target Organ Systemic Toxicity (TOST)) following repeated exposure, reproductive toxicity and carcinogenicity), that would appear on a label based on hazard alone. A general explanation of the broad principles of risk-based labelling is contained in Annex ~~5~~4.

1.4.10.5.5.3 Tactile warnings

~~60.~~ If tactile warnings are used, the technical specifications shall conform with EN ISO standard 11683 (1997 edition) relating to tactile warnings of danger.

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CHAPTER ~~1.4~~1.5

HAZARD COMMUNICATION: SAFETY DATA SHEETS (SDS)

~~INTRODUCTION~~

~~1.The following sections describe the procedures for preparing Safety Data Sheets (SDS) in the GHS, comprising:~~

- ~~The role of the SDS in the harmonised system~~
- ~~When the SDS is required?~~
- ~~SDS format~~
- ~~SDS content~~
- ~~Example of a GHS SDS~~

1.5.1 The role of the Safety Data Sheets (SDS) in the Harmonised System

~~2.~~1.5.1.1 The SDS should provide comprehensive information about a chemical substance or mixture for use in workplace chemical control regulatory frameworks. Both employers and workers use it as a source of information about hazards, including environmental hazards, and ~~to obtain~~ as a source of advice on safety precautions. The information acts as a reference source for the management of hazardous chemicals in the workplace. The SDS is product related and, usually, is not able to provide specific information that is relevant for any given workplace where the product may finally be used, although where products have specialised end uses the SDS information may be more workplace-specific. The information therefore enables the employer (i) to develop an active programme of worker protection measures, including training, which is specific to the individual workplace and (ii) to consider any measures which may be necessary to protect the environment.

~~3.~~1.5.1.2 In addition, the SDS provides an important source of information for other target audiences in the GHS. So certain elements of information may be used by those involved with the transport of dangerous goods, emergency responders (including poison centres), those involved in the professional use of pesticides and consumers. However, these audiences receive additional information from a variety of other sources such as the UN ~~RTDG~~ Model Regulations document and package inserts for consumers and will continue to do so. The introduction of a harmonised labelling system therefore, is not intended to affect the primary use of the SDS which is for workplace users.

~~**When is a SDS required?**~~

~~4.When considering the obligation to compile and submit a SDS, the supplier of employer should consider two questions:~~

~~a) (a) Is a SDS required?; and~~
~~b) (b) What information is needed for the SDS?~~

1.5.2 Criteria for submission of a SDS

~~5.~~1.5.2.1 An SDS should be produced for all substances and mixtures which meet the harmonised criteria for physical, health or environmental hazards under the GHS and for all mixtures which contain substances that meet the criteria for carcinogenic, toxic to reproduction or target organ systemic toxicity in concentrations exceeding the cut-off limits for SDS specified by the criteria for mixtures (see paragraph 1.5.3.1~~6~~).The competent authority may choose also to require SDSs for mixtures not meeting the criteria

for classification as hazardous but which contain hazardous substances in certain concentrations (see paragraph ~~6~~1.5.3.1).

1.5.3 General guidance for compiling a Safety Data Sheet[1]

~~6.~~1.5.3.1 *Cut-off values/concentration limits*

1.5.3.1.1 An SDS should be provided based on the ~~following~~ generic cut-off values/concentration limit~~s~~ indicated in Table 1.5.1:

Table 1.5.1: Cut-off values/Concentration limits for each hazard class

Hazard Class	Cut-off value/Concentration Limit
Acute Toxicity	≥ 1.0%
Skin Corrosion/Irritation	≥ 1.0%
Serious damage to eyes/eye irritation	≥ 1.0%
Respiratory/Skin Sensitization[2]	≥ 1.0%
Mutagenicity: Category 1	≥ 0.1%
Mutagenicity: Category 2	≥ 1.0%
Carcinogenicity	≥ 0.1%
Reproductive Toxicity	≥ 0.1%
Target Organ Systemic Toxicity (Single Exposure)	≥ 1.0%
Target Organ Systemic Toxicity (Repeat Exposure)	≥ 1.0%
Hazardous to the Aquatic Environment	≥ 1.0%

[1] *Paragraphs ~~6.9~~1.5.3.1 to 1.5.3.4 are not part of the agreed text on hazard communication including SDSs developed by the ILO Working Group on Hazard Communication, but have been provided here as additional guidance on the compiling of an SDS.*

[2] *There has been considerable discussion about what to convey about sensitisation effects to those exposed, and at what point it should be conveyed. While the current cut-off value for mixtures is 1%, it appears that the major systems all believe information should be conveyed below that level. This may be appropriate both to warn those already sensitised, as well as to warn those who may become sensitised. This issue was not clear during the initial deliberations on the criteria for mixtures containing sensitisers, and thus has not been adequately discussed nor options explored.*

Before the system becomes implemented, this issue should be revisited by ~~the ECOSOC Subcommittee on the GHS~~ the SCEGHS as one of its first priorities. It should be noted that the sensitisation criteria for substances will also have to be re-opened to consider this issue and the inclusion of new information and evolving testing approaches that addresses the question of strong sensitisers versus those that are weaker. Appropriate hazard communication should be considered along with the discussions on the criteria and the availability of an appropriate test method.

~~7.~~1.5.3.1.2 As noted in the *Classification of Hazardous Substances and Mixtures* (Chapter 1.~~2~~3, ~~paragraphs 28-31~~section 1.3.3.2), there may be some cases when the available hazard data may justify classification on the basis of other cut-off values/concentration limits than the generic ones specified in the health and environment hazard class chapters (Chapters 3.2 to 3.10). When such specific cut-off~~s~~ values are used for classification, they should also apply to the obligation to compile an SDS.

~~8.~~1.5.3.1.3 Some competent authorities (CA) may require SDSs to be compiled for mixtures which are not classified for acute toxicity or aquatic toxicity as a result of application of the additivity formula, but which contain acutely toxic substances or substances toxic to the aquatic environment in concentrations equal to or greater than 1 %.[3]

~~9.~~1.5.3.1.4 In accordance with the building block principle, some competent authorities may choose not to regulate certain categories within a hazard class. In such situations, there would be no obligation to compile a SDS.

~~10.~~1.5.3.1.5 Once it is clear that a SDS is required for a substance or a mixture then the information required to be included in the SDS should in all cases be provided in accordance with GHS requirements.

1.5.3.2 *SDS format*

~~11.~~1.5.3.2.1 The information in the SDS should be presented using the following 16 headings in the order given below.

1. Identification
2. Hazard(s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information.

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[3] *The cut-off~~s~~ values for classification of mixtures are normally specified by concentrations expressed as % of the component substance. In some cases, for example acute toxicity (human health), the cut-off~~s~~ values are expressed as acute toxicity values (ATE). The classification of a mixture is determined by additivity calculation based on acute toxicity values (see Chapter 3.1) and concentrations of component substances. Similarly acute aquatic toxicity classification may be calculated on the basis of acute aquatic toxicity values (See Chapter 3.10) and where appropriate, corrosion/irritation by adding up concentrations of individual substances (See Chapters 3.2 and 3.3). Component substances are taken into consideration for application of the formula~~e~~ when the concentration is equal to or greater than 1 %. Some competent authorities (CA) may use this cut-off as a basis of obligation to compile a SDS*

1.5.3.3 *SDS content*

~~12.~~1.5.3.3.1 The SDS should provide a clear description of the data used to identify the hazards. The ~~following~~ minimum information in Table 1.5.2 should be included, where applicable and available, on the SDS under the relevant headings[4]. If specific information is not applicable or not available under a particular subheading, the SDS should clearly state this. Additional information may be required by competent authorities.

~~13.~~1.5.3.3.2 Some subheadings relate to information that is national or regional in nature, for example "EC number" and "occupational exposure limits". Suppliers or employers should include information under such SDS subheadings that is appropriate and relevant to the countries or regions for which the SDS is intended and into which the product is being supplied[5]

~~14.~~1.5.3.3.3 There are a number of internationally-recognised standards that provide guidance in the preparation of a SDS, including the ILO Standard under the Recommendation 177 on Safety in the Use of Chemicals at Work, the International Standard 11014 of the International Standard Organization (ISO), the European Union Safety Data Sheet Directive EEC/91/155 and the American National Standard Institute (ANSI) standard Z 400.1. Further guidance on preparation of a SDS may be developed by the GHS Subcommittee, based on the work of these organizations.

Table 1.5.2 Minimum information for a SDS

1.	**Identification of the substance or mixture and of the supplier**	• GHS product identifier. • Other means of identification. • Recommended use of the chemical and restrictions on use. • Supplier's details (including name, address, phone number etc). • Emergency phone number.
2.	**Hazards identification**	• GHS classification of the substance/mixture and any national or regional information. • GHS label elements, including precautionary statements. (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol e.g. flame, skull and crossbones.) • Other hazards which do not result in classification (e.g. dust explosion hazard) or are not covered by the GHS.

[4] *Where "applicable" means where the information is applicable to the specific product covered by the SDS.*
Where "available" means where the information is available to the supplier or other entity that is preparing the SDS

[5] *Paragraphs ~~13 14~~1.5.3.3.2 and 1.5.3.3.3 are not part of the agreed text on hazard communication including SDSs developed by the ILO Working Group on Hazard Communication, but have been provided here as additional guidance on the compiling of an SDS.*

3.	**Composition/information on ingredients** .	**<u>Substance</u>** • Chemical identity. • Common name, synonyms, etc. • CAS number, EC number, etc. • Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. <u>Mixture</u> • The chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels. ***NOTE**: For information on ingredients, the competent authority rules for CBI take priority over the rules for product identification.*
4.	**First aid measures**	• Description of necessary measures, subdivided according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion. • Most important symptoms/effects, acute and delayed. • Indication of immediate medical attention and special treatment needed, if necessary.
5.	**Fire-fighting measures**	• Suitable (and unsuitable) extinguishing media. • Specific hazards arising from the chemical (e.g. nature of any hazardous combustion products). • Special protective equipment and precautions for fire-fighters.
6.	**Accidental release measures**	• Personal precautions, protective equipment and emergency procedures. • Environmental precautions. • Methods and materials for containment and cleaning up.
7.	**Handling and storage**	• Precautions for safe handling. • Conditions for safe storage, including any incompatibilities.
8.	**Exposure controls/personal protection**.	• Control parameters e.g. occupational exposure limit values or biological limit values. • Appropriate engineering controls. • Individual protection measures, such as personal protective equipment.

9.	**Physical and chemical properties**	• Appearance (physical state, colour etc). • Odour. • Odour threshold. • pH. • melting point/freezing point. • initial boiling point and boiling range. • flash point. • evaporation rate. • flammability (solid, gas). • upper/lower flammability or explosive limits. • vapour pressure. • vapour density. • relative density. • solubility(ies). • partition coefficient: n-octanol/water. • auto-ignition temperature. • decomposition temperature.
10.	**Stability and reactivity**	• Chemical stability. • Possibility of hazardous reactions. • Conditions to avoid (e.g. static discharge, shock or vibration). • Incompatible materials. • Hazardous decomposition products.
11.	**Toxicological information**	—Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including: • information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); • Symptoms related to the physical, chemical and toxicological characteristics; • Delayed and immediate effects and also chronic effects from short- and long-term exposure; • Numerical measures of toxicity (such as acute toxicity estimates).
12.	**Ecological information**	• Ecotoxicity (aquatic and terrestrial, where available) • Persistence and degradability. • Bioaccumulative potential. • Mobility in soil. • Other adverse effects.
13.	**Disposal considerations**	• Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.

14.	**Transport information**	• UN number • UN Proper shipping name • Transport Hazard class(es) • Packing group, if applicable • Marine pollutant (Y/N) • Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises.
15.	**Regulatory information**	• Safety, health and environmental regulations specific for the product in question.
16.	**Other information including information on preparation and revision of the SDS**	

1.5.3.4 An Example of a GHS Safety Data Sheet (SDS)

~~*Under Review*~~
(Reserved)