OPTIONS FOR LEGISLATION AND STANDARD SETTING TO IMPLEMENT THE GHS

A Guidance Document to support implementation of the Globally Harmonized Systems of Classification and Labelling of Chemicals

















INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNEP, UNIDO, UNITAR, WHO and OECD

For additional information, please contact: **United Nations Institute for Training and Research (UNITAR)** Chemicals and Waste Management Programme

(WMO building)

Email: cwm@unitar.org

7 bis, Avenue de la Paix, CH-1202 Geneva 2, Switzerland

ACKNOWLEDGEMENTS

We would like to thank the stakeholders involved in the Global Partnership to Implement the GHS for their support and guidance in planning this work.

We would like to thank our core donors – the Governments of Germany and Switzerland – for their financial contributions that support UNITAR's GHS programme, both in general and for specific GHS-related activities.

TABLE OF CONTENTS

Al	pout this Guidance Document	08
Ex	recutive Summary	09
Pa	Part A Introduction	
1.	Introduction to the GHS	23
2.	Building block approach	25
3.	Options for legislation and standard setting to implement the GHS	27
Pa	art B International Law, current treaties and related instruments of re	ele-
va	ince to the GHS	29
4.	Treaties, and related instruments, incorporating GHS provisions as mandatory re-	
	quirements	29
5.	Treaties, and related instruments, of relevance in the context of GHS implementation	on
	but not requiring its mandatory application	39
6.	Non-binding instruments	47
7.	Trade agreements	51
Pa	art C Examples of National Law	52
8.	European Union countries	53
9.	United States of America	55
10.	Canada	58
11.	Australia	60
12.	New Zealand	63
13.	China	66
14.	Japan	69
15.	South Africa	70
16	Other countries	71

TABLE OF CONTENTS

Part D Development of GHS National Instruments, Step-by-Step **72** 17. Political aspects 72 18. Legal Analysis 78 19. Legal implementation of the GHS 83 20. Working methods for legal analysis and development of a national legal implementation framework 84 21. Elements to be taken into account in drafting legislation 85 22. Legal process 94 23. Transitional measures 94 24. Updating 95 25. Feedback to the United Nations 96 26. Feedback from non-governmental organizations 97 Part E Other Relevant Tools for the development of GHS related **legislation** 98 27. Publication and public availability of laws, regulations and standards 98 28. GHS classification tools 98 29. Guidance 99 30. Emergency response 100 31. Training guidance 101 Conclusion 103 **Annex 1: List of Acronyms** 105

Annex 3: FAO/WHO Recommendations for Hazard Classification of Pesticides

110

118



Annex 2: Law or standards: Basic Principles

TABLE OF CONTENTS

Annex 4: Article 2 of the TBT Agreement	122		
Annex 5: Example of cooperation between two different administrative departments i	n		
relation to the implementation of specific GHS provisions	125		
Annex 6: Purpose and scope of the EU CLP regulation	127		
Annex 7: Scope and purpose of the USA hazard communications standard (29CFR,Part			
1910)	130		
Annex 8: GHS paragraphs referring to decisions to be taken by competent authorities			
	135		
Annex 9: Training requirements in the USA hazard communication standard (29 CFR, Par			
1910)	149		
Annex 10: Driver training requirements in ADR	150		
Annex 11: Feedback on GHS implementation to be transmitted to the United Nations Sec-			
retariat	152		
Annex 12: Questionnaire sent to non-governmental organizations and summary replies			
	154		

ABOUT THIS GUIDANCE DOCUMENT

This document is intended to provide guidance for countries that choose to develop legislation and/or standards in order to give effect to the GHS.

The document has five parts. Part A provides a background and context for the GHS. It first introduces the concept of chemical hazard communication and provides an overview of key GHS provisions including an overview of the hazard classes and details on hazard communication. Part B provides examples of international treaties of relevance in relation to GHS implementation. It also contains examples of non-binding instruments, such as recommendations, developed by international organizations committed to the promotion of implementation of the GHS, and accepted internationally as relevant. Part C contains examples of national legislation, which may be considered by countries that intend to develop GHS-based national legislation or to reconsider their existing legislation. Part D suggests a step-by-step approach for the development of GHS implementation legal instruments, bearing in mind the examples provided in Parts B and C. Part E contains information on other relevant tools that can be used for GHS implementation in support of legislation. Annexes provide further information, mainly to illustrate cases in the preceding text.

This guidance document is for countries that have already adopted or are looking to adopt a national GHS system. It is intended to help with further steps to develop national legislation and/or standards in the light of their own constitutional legal practices, regional, bilateral or multilateral agreements they would be bound to comply with, or multilateral treaties they may be Parties to, by providing examples of countries that have already developed such legislation or standards, alongside other relevant information.

The guidance is flexible in nature; it is not meant to be prescriptive. Each country can consider the suggested step-by-step approach and make decisions on the best option to be used for development of legislation and standard setting for implementation of the GHS in accordance with its own preferences, priorities and national circumstances, in the light of already existing international legislation and of the experience of other countries. It is hoped that users will find that this guidance plays a constructive and practical role in implementing the GHS.

A list of acronyms used in this document is provided in Annex 1.



EXECUTIVE SUMMARY

INTRODUCTION

One important tool for addressing the need for safe chemicals management is the GHS. The GHS is an international standard for chemical classification and hazard communication. It is also a tool that countries can use as a basis for establishing comprehensive national chemical safety programmes. The GHS is a logical and comprehensive approach for:

- Defining hazards of chemicals;
- Applying hazard criteria, using an agreed methodology, to classify chemicals; and
- Communicating hazard information on labels and Safety Data Sheets (SDS).

The GHS has the ultimate goal of ensuring that information on chemical hazards is made available to workers and consumers in a harmonized and comprehensible format (on labels and in SDS) in countries around the world. It represents an important effort to harmonize national systems worldwide, in order to improve chemical safety across all relevant sectors and enhance the protection of human health and the environment. Countries have been encouraged to use the GHS as a key resource for activities on chemical hazard communication, in accordance with their own needs and capabilities.

The GHS can play a central role in conveying information about chemical hazards to users for the entire chemical supply chain, provide all countries with a consistent means of classifying and labelling hazardous chemicals, and help to ensure that coherent information is provided on all imported and exported chemicals.

The GHS classification and hazard communication elements can be seen as the foundation of programmes to ensure the safe use of chemicals. The two key steps are to 1) identify intrinsic hazard(s) (i.e. classification) and then 2) to communicate that information.

The GHS defines hazard classes; 29 classes as per the 9th revision (2021). Some of these hazard classes are sub-divided in hazard categories, some with sub-categories. All hazard classes are "building blocks"; within each hazard class, each hazard category may be seen as a building block. Countries are free to determine which of the GHS building blocks will be applied in their national systems, including depending on the sector intended to be regulated.

While the GHS itself is not legally binding at a global level, countries that implement the GHS may want to develop legally binding implementation measures to ensure its implementation.

As per the ILO and UNITAR guidance on Developing a National GHS Implementation Strategy, countries wishing to develop legally binding implementation measures should first conduct a legal analysis, focusing on understanding their current legislation or regulations for hazard classification and communication, and the changes needed to implement the GHS.

This new Guidance Document on "Options for legislation and standard setting to implement the GHS" provides additional information and explanations on options for legal implementation of the GHS on the basis of actions that have been taken in various countries or by relevant regional and international organizations to implement the GHS through legislation.

International law, treaties and related instruments of relevance to the GHS

Based on principles of laws and standards summarized in annex 2, four main cases of relevant international instruments are considered in Part B: binding treaties that incorporate GHS provisions as mandatory requirements; those which are of relevance for the GHS but do not require mandatory application of the GHS provisions; non-binding instruments; and trade agreements.

Binding treaties that incorporate GHS provisions as mandatory requirements

Transport sector

In the transport sector, the United Nations Recommendations on the Transport of Dangerous Goods contain detailed provisions for classification of dangerous goods and hazard communication which have served, since the 1950s, as a basis for harmonization of the various national, regional and international legal instruments that regulate the five modes of transport: sea, air, road, rail and inland waterways. These provisions are now based on the GHS.

In accordance with the GHS building block approach, only hazards of concern during transport are addressed, i.e. all physical hazards and nearly all their categories, hazards to health (only the highest categories of acute toxicity and corrosivity), and hazards to

the aquatic environment (only acute 1 and chronic 1 and 2 toxicity).

As safety and protection of the environment during international transport are regulated under multilateral treaties, the said provisions have been incorporated into such treaties or regulations of mandatory application under such treaties. The main instruments are:

- International Maritime Dangerous Goods (IMDG) Code, applicable under the International Convention for the Safety of Life at Sea (SOLAS, 1974) and under the International Convention for International Convention for the Prevention of Pollution from Ships (1973) as modified by the Protocol of 1978 thereto (MARPOL 73/78)
- ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI), applicable under the Convention on International Civil Aviation
- Agreement concerning the international carriage of dangerous goods by road (ADR)
- Regulations concerning the International Carriage of Dangerous Goods by Rail (RID),
 as appendix C to the Convention concerning International Carriage by Rail) (COTIF)
- Regulations concerning the international transport of dangerous goods by rail (Annex 2 to the Agreement on International Goods Transport by Rail (SMGS)
- European Agreement concerning the international carriage of dangerous goods by inland waterways (ADN)

Although the above treaties only apply to international transport, most countries which are parties to them apply also their transport of dangerous goods provisions to domestic traffic. Those which are not Parties, and this is often the case for instruments relating to inland transport, usually develop their own national regulations based on the UN Recommendations or the above-mentioned instruments.

For the specific case of road transport, and notwithstanding the GHS, countries which have not yet developed national regulations may wish to note that they have been encouraged by the United Nations General Assembly, in the context of improving global road safety, to consider becoming party to ADR or to apply its provisions¹.

Industrial accidents

The UNECE Convention on the Transboundary Effects of Industrial Accidents uses the GHS classification criteria (classes and categories) to identify substances and mixtures which, when present in an installation, leads to the designation of the installation as a hazardous facility covered by the scope of the Convention.

Regional economic integration organization treaties

Regional economic integration organizations are institutions through which countries seek to improve their economic development. Economic integration organizations may establish common rules, standards and practices in a variety of areas, including those concerned by the GHS.

Depending on the clauses of the Treaty establishing them, regional economic integration organizations may have the power to set up legally-binding agreements between their member States or rules and regulations which take precedence over national law, or directives that member States are bound to transpose into national law, or recommendations that member States are invited to apply through national law.

Several such organizations have already taken steps to require or recommend implementation of the GHS in one or several relevant sectors. A comprehensive example is the European Union (EU) which requires through:

- A directive, its member States to apply ADR, ADN and RID (and therefore their related GHS provisions) to the inland transport sector within the EU;
- The CLP Regulation, the application of the GHS classification and labelling provisions, in all other sectors, with some exceptions in accordance with GHS building block approach:
- The REACH Regulation, the use of GHS SDSs as appropriate under the scope of REACH;

The EU has adapted all its other instruments relating to chemical management accordingly.

Similarly, the Commission of the Eurasian Economic Union (EAEU) approved, in 2017, a Technical Regulation "On the safety of chemical products" dealing with hazard classification and hazard communication; labelling and SDSs; identification; new substances notification; registration of substances and mixtures and conformity assessment. The entry into force is scheduled for 30 November 2022, once the register of existing chemical substances in the EAEU, with their GHS classification, is available (expected 1 October 2021 for substances;

June 2027 for mixtures) and the work on procedures for notification of new substances and mixtures has been completed. For the time being, the standards which have been identified for GHS application under this Technical Regulation are the national (GOST) standards of the Russian Federation which had been developed for implementation of the GHS in the Russian Federation, and which may currently be applied on a voluntary basis.

No other regional economic integration organizations have developed the same kind of supranational legislation that would entail effective and comprehensive application of the GHS, although some have developed some sectoral instruments in relation to international inland transport of dangerous goods (ASEAN, MERCOSUR, Great Mekong sub-region) or in the agriculture (pesticides) sector (Andean Community). Such entities and countries which have limited administration resources may find it valuable to share resources and develop regional instruments that could contribute to a regional approach to implementation of the GHS rather than individual and perhaps inconsistent national approaches.

Treaties, and related instruments, of relevance in the context of GHS implementation but not requiring its mandatory application

Workplace

Most treaties concerning occupational health and safety have been developed by the International Labour Organization (ILO). In relation to chemicals, the most prominent is the 1990 Chemicals Convention (C170)², as supplemented by the 1990 Chemicals Recommendation, and by the ILO Code of Practice on Safety and the Use of Chemicals at work.

A significant feature of the Convention is its provisions on chemical hazard communication designed to ensure that information on hazards and related preventive and protective measures flows from manufacturers and importers to the users. This includes requirements for the classification and labelling of chemicals. At the workplace, the employer is required to ensure that all chemicals are identified, and that adequate information is available through labelling and safety data sheets.

The GHS can also be a useful tool in the context of implementation of several other ILO conventions dealing with other related subjects, e.g. industrial accidents, occupational cancer, air pollution in the working environment, asbestos, benzene, safety and health in construction, safety and health in mines.

Control of production, use and movement of chemicals and hazardous waste Several conventions have been developed, notably under the auspices of the United Nations Environment Programme (UNEP) in order to control the production, use, transboundary movement and disposal of chemicals and hazardous wastes, in particular those presenting hazards to human health or to the environment.

For hazardous waste, these are:

The GHS itself was developed through cooperation between several organizations and governments, but at the initiative of ILO which had in mind to provide governments, workers and employers with a useful tool to comply with their obligations under the Chemicals Convention and related recommendations.

- The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal
- The Bamako Convention on the ban of the import into Africa and the control of transboundary movement and management of hazardous wastes within Africa

The hazard classification criteria of these conventions are mainly derived from those of the UN Recommendations on the transport of dangerous goods, but Parties to the Basel Convention have started a review of these criteria to better take account of GHS hazards not regulated under transport legislation but which may be of concern in the context of disposal, to the extent possible bearing in mind the complex nature of the composition of hazardous wastes.

For chemicals, the main ones are:

- The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
- The Stockholm Convention on Persistent Organic Pollutants

These conventions apply to specific chemicals, and decisions by parties to include them under their scope are usually taken on a case-by-case basis; knowledge of the GHS classification of a given chemical, and availability of SDS, is useful when considering whether or not a chemical should be covered by the scope of these conventions, though is not the only criterion.

Similarly, the use of the GHS may be of interest in the context of implementation of some other conventions dealing with very specific chemicals but is not required or absolutely needed, e.g. the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, or the Montreal Protocol on Substances that Deplete the Ozone Layer.

Non-binding instruments

There are a number of other instruments which have been developed by the international community which are of recommendatory nature, but which have a strong influence on the effective implementation of the GHS. The GHS itself is such an instrument but there are others. As seen above, the United Nations Recommendations on the Transport of Dangerous Goods are the main GHS implementing tool in the transport sector since the recommended provisions have been effectively introduced in the main transport conven-

tions and in national regulations worldwide.

In the agriculture sector, FAO and WHO guidelines and recommendations relating to classification and labelling of pesticides have been widely used in the world for many years by pesticide regulators and are well known by end-users. Nevertheless, they were not entirely consistent with the GHS and therefore WHO and FAO have joined efforts to revise and update their publications in order to take account of the GHS. For the time being:

- The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification has been amended to include a column indicating, for each pesticide, the GHS acute toxicity hazard of the active ingredient
- FAO and WHO have developed criteria for defining "Highly Hazardous Pesticides" including some GHS criteria
- The FAO/WHO International Code of Conduct on the Distribution and Use of Pesticides, Guidelines for the Registration of Pesticides (2010) refers to the GHS in relation to classification of pesticides
- FAO and WHO have issued a revised version of their guidelines for labelling (see "FAO/WHO International Code of Conduct for the Management of Pesticides, Guidelines on Good Labelling Practices for Pesticides (revised, August 2015)"

Trade agreements

One agreement which may be considered as important in relation to GHS implementation is the Technical Barriers to Trade (TBT) Agreement. The TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognises WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or protection of the environment. The TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade.

Regulatory measures that are taken by countries in a sector in relation to chemical classification and hazard communication are normally intended to protect human health and environment, and they cannot be overridden by trade rules. Nonetheless, in the spirit of the TBT Agreement they should be based on the GHS which should be considered as the only international standard extensively covering classification of hazardous chemicals and hazard communication. Moreover, in relation to the predictability of the trading environment it would also be important that any deviation from the GHS in national technical

regulations or standards be clearly identified.

The key provisions of the TBT Agreement in this respect are contained in its article 2, which is reproduced in annex 4.

Examples of national law

The GHS is a relatively new instrument, and not all countries in the world have been able so far to issue national legislation ensuring its implementation in all relevant sectors. The four sectors of main relevance for the GHS as a regulatory tool are workplace, transport, agriculture and consumer, and this can be done in different ways depending on each country's legal traditions, customs and system. Part C provides examples in 15 different countries.

Use of supranational law

This is the case of all EU Member States and the example of Ireland is provided. EU law covers all sectors, and EU countries are bound to apply directly the two main regulations (REACH and CLP) that implement the GHS and to transpose into national law the provisions of miscellaneous directives that are also of relevance.

Sectoral national laws and regulations fully incorporating GHS provisions

Canada and the United States of America have amended their existing legislation applicable to the workplace and transport sectors to take account of the GHS. The applicable regulations incorporate, as full text, the relevant GHS provisions selected in accordance with the building block approach.

Countries wishing to follow this approach of reproducing GHS text in various pieces of sectoral legislation should bear in mind that the GHS is amended every two years and that they should therefore develop appropriate mechanisms for regular updating of each piece of legislation, as and when may be needed.

Sectoral or multisectoral national laws and regulations incorporating the GHS provisions by reference to the UN GHS publication

Some countries have chosen not to replicate the UN GHS text in their legislation, but rather to make it applicable by direct reference in the legislation. The advantage is that

this solution saves considerable administration resources, but this is normally possible only when regulating by reference is allowed according to national law and if the official language of the country is one of the six UN languages in which the GHS is published.

Countries choosing this option should remain aware that the GHS leaves it up to the competent authorities of each country to make decisions themselves in certain areas, e.g. choice of building blocks but also for a number of miscellaneous cases that may occur, as listed in annex 8. Therefore, besides references to the UN GHS text, the national legislation should still specify how to deal with these cases.

The examples of New Zealand (multisectoral, plus specific workplace and specific transport national legislation), Australia (workplace) and South Africa (workplace) are provided.

Use of national standards

Instead of transposing GHS text into their national legislation, several countries have preferred the option of issuing national standards reflecting the GHS text in their national language. Such standards are developed in accordance with the rules governing the elaboration of standards by the national standardization body instead of those governing a formal legal process of elaboration and adoption of national regulations linked to formal legislation. They are usually considered as private standards that can be applied on a voluntary basis and are not of mandatory application per se. National GHS standards may cover the whole GHS (classification, labelling, SDS), but they are often split into several parts, i.e. standard for classification (sometimes one standard for each GHS hazard class, a standard for labelling, and a standard for SDS).

National GHS standards have been published at least in Brazil, China, Israel, Japan, Russian Federation, Singapore and South Africa.

Once a national standard is available, governments may decide to make their application, or application of parts thereof, mandatory in specific sectors through national legislation. This is the case in Brazil (workplace), China (several sectors), Japan (several sectors). Governments may also decide to confer mandatory status to standards relating to public safety and health or protection of the environment in the context of trade law (manufacture of products, import, export, placing on the market).

Further examples

Only a few examples are provided in this Guidance Document. Additional information on the status of implementation of the GHS in other countries may be found on the UNECE website at https://unece.org/ghs-implementation-0. All countries are encouraged to provide information to the UNECE secretariat using the GHS information submission form available on the website.

Development of national GHS implementation instruments step-by-step

Political aspects

When administrations or stakeholders in a country want to develop GHS-based regulatory systems, or to modify their existing regulatory systems for the purpose of implementing the GHS, the difficulty is to provide justification and arguments to legislators, as such initiatives are usually dependent on national political priorities.

In most countries that have implemented the GHS, it has been necessary to demonstrate the advantages not only in terms of social benefits linked to the existence of appropriate safety regulations, but also in terms of economic benefits linked to intersectoral harmonization and trade facilitation.

Governments are usually receptive to international mandates provided in resolutions, decisions or even recommendations emanating from the highest bodies of international organizations such as the main bodies of the United Nations and its specialized agencies, United Nations Conferences, or other intergovernmental organizations.

This Guidance Document provides a list of international or regional mandates that can be used by administrations as incentives to justify the initiation of legal work for GHS implementation purposes, as issued by:

- International conferences: UNCED, WSSD, ICCM
- United Nations: General Assembly, ECOSOC, ESCAP
- UN Specialized Agencies: ILO, FAO, WHO
- OECD
- Regional economic integration organizations: European Union, SADC



Legal analysis

Once the principle of developing new or amending existing legislation has been agreed, it is recommended to carry out a legal analysis of the existing situation and options. This would focus on understanding the current legislation or regulations for hazard classification and communication, and the changes needed to implement the GHS. Based on the results of the analysis, governments can examine the potential options for the development of a legal implementation framework. Competent authorities adopting the GHS may thus choose different implementing instruments according to their circumstances, needs and already existing legal framework. Section 18 contains a detailed list of questions that should be considered for understanding the current legal environment for chemicals management and of considerations for developing the legal framework.

Legal implementation of the GHS

After the legal analysis, countries may wish to focus their efforts on a GHS legal implementation framework. This could be a plan that would include actions required for legal GHS implementation.

The plan should determine which sectors have to be regulated in accordance with the GHS and, if there is already existing legislation in each of these sectors, whether it would have simply to be updated or amended, or whether all relevant legislation would have to be fundamentally revised.

If a country considers that implementation should be made broadly or sectorally through regional law, and there is support from other countries for such an approach, the said countries may wish to consider concluding a multilateral agreement for this purpose or addressing the issue at the level of a regional integration organization.

If the country considers that domestic implementation of the GHS should be realized through national law only, there are many options listed in section 19, and some of which are given as examples in Part C.

Working methods for legal analysis and development of a national legal implementation framework

The legal analysis and development of the legal implementation framework can be conducted in a number of ways depending on a country's individual GHS capacity

building process. In this respect, reference is made to the UNITAR/ILO Guidance on the development of a National GHS Strategy for implementation of GHS. This work can be done by separate sectoral working groups or by multisectoral working groups. In any case, national coordination and cooperation between sectoral administrations involved is considered necessary, in order to develop a common national vision of GHS national implementation, ensure consistency in its application, and to avoid duplication of, and inconsistencies between, various sectoral requirements.

Elements to be taken into account in drafting legislation

Section 21 provides detailed information on the different elements to be taken into account in drafting legislation: defining the purpose and scope; providing definitions; identifying building blocks concerned; deciding on issues left to the discretion of each country; addressing the classification and hazard communication provisions; defining clearly the respective obligations of all entities that have to comply with the requirements; identifying enforcement authorities and stating penalties for various types of infringements; including training requirements; eventually providing lists of GHS classified chemicals.

Legal process

The legal processes to be followed for adoption of laws and regulations are specific to each country, depending on the constitution, legal system, legal customs and practices.

Transitional measures

When introducing new legislation or amending existing legislation, it may be beneficial to provide for transitional measures to allow sufficient time for manufacturers, importers, suppliers, employers, workers, emergency responders and any other concerned entity to adapt to the new regulatory environment, including in relation to training and awareness-raising.

Updating

When developing GHS-related legislation, countries should bear in mind that the GHS is not a static instrument and is updated every two years. In general, classification and labelling provisions are rather stable, but they may be amended from time to time, or extended to cover new classes. Therefore, it is necessary to envisage updating mechanisms to keep GHS-related legislation in line with amended versions of the GHS.

Feedback

All countries which are member States of the United Nations have the possibility to provide feedback to the UN Sub-Committee of experts on the GHS, even when they do not participate in its work as full members or observers.

The feedback from countries may be:

- Feedback related to practical implementation of the GHS, including experiences, problems encountered and suggestions for improvement;
- Feedback concerning implementation through legislation or standards in each country

Feedback may be provided directly to the secretariat by following the procedure and submission form available on its website https://unece.org/transportdangerous-goods/ghs-implementation-information-submission-form

Information may also provided by non-governmental stakeholders through non-governmental organizations that have been granted consultative status by the United Nations Economic and Social Council or by the GHS Sub-Committee itself, and by intergovernmental organizations which may participate in the work of the Sub-Committee.

Other relevant tools for implementation of GHS-related legislation

Part E contains information on additional tools that may have to be used or could be useful in relation to GHS implementation, in particular:

- Considerations about publication and public availability of laws, regulations and standards
- Information on GHS implementation tools (United Nations Manual of Tests and Criteria, OECD Test Guidelines for Testing Chemicals)
- Guidance provided by the UNSCEGHS, and examples of guidance provided by some countries in relation to the implementation of their own legislation (European Union, USA, Canada)
- Guidance relating to emergency response and sources of emergency response information
- Examples of training guidance

An increasing number of governments and international organizations have taken steps to transpose GHS provisions of recommendatory nature into treaties and national legislation in order to implement the GHS provisions effectively through mandatory requirements of legal instruments. There is a wide range of legal options for GHS implementation and each country may choose the one which is best suited to its needs.

When doing so, and while acknowledging the flexibility provided by the GHS, it is worth remembering one of the original objectives of the GHS; global harmonization. This guidance contains some recommendations on the way to proceed to contribute to the achievement of this goal when developing legislation.



1. Introduction to the GHS

The production and use of chemicals are fundamental economic activities and important for the development of all countries, at all stages. Directly or indirectly, chemicals affect the lives of all humans and are essential to our food supply (e.g. fertilizers, pesticides, food additives, packaging), our health (e.g. pharmaceuticals, cleaning materials), and our daily existence (e.g. appliances, fuels). However, there are potential adverse affects to human health and the environment from use of and exposure to these chemicals.

The first step in safe chemical use is to identify the hazards they may pose such as physical hazards or hazards to health and the environment (e.g. if they are flammable, or can cause cancer or be hazardous to aquatic environments) and to communicate appropriate precautions and measures to be taken to handle or use the chemical safely or in the event of an accident (i.e. transferring information through hazard communication). This inherently complex knowledge must be organised so that essential information on the hazards and corresponding control measures can be identified and conveyed to the user in a format that is easy to understand. The hazard classification and labelling process, along with appropriate training and education, is a primary tool for establishing effective information transfer. Understanding the degree of hazard a chemical represents leads to the correct control action(s) and safe use. This knowledge should be available within reasonable effort and cost.

Chemical hazard information can be conveyed in a variety of ways, for example, in the form of a label on a container; in the form of safety data sheets (SDS) provided with the hazardous chemical; or through placards, posters or markings. This information generally includes an indication of the hazard(s) in text form and/or with symbols. In addition to the hazard information, information may also include statements regarding safe use or handling, or other types of precautionary measures.

In the workplace, for example, safety data sheets (SDS) should be made available to the worker. In the transport sector, documents supplement the information on placards or markings: information is contained in the transport document and emergency response may be derived from the "UN" number indicated on packages or on placards through consultation of specific booklets or databases adapted to the mode of transport concerned. In the context of most workplace and transport chemical hazard communication systems, user training to access the information and take proper steps for protection should also be routinely provided. In consumer settings, however, the label may be the only communication mechanism available to provide information to promote safe

handling and use.

One important tool for addressing the need for safe chemicals management is the GHS. The GHS is an international standard for chemical classification and hazard communication³. It is also a tool that countries can use as a basis for establishing comprehensive national chemical safety programs. The GHS is a logical and comprehensive approach for:

- Defining hazards of chemicals;
- Applying hazard criteria, using an agreed methodology, to classify chemicals; and
- Communicating hazard information on labels and Safety Data Sheets (SDS).

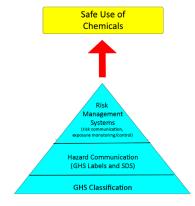
The GHS has the ultimate goal of ensuring that information on chemical hazards is made available to workers and consumers in a harmonized and comprehensible format (on labels and in SDS) in countries around the world. It represents an important effort to harmonize national systems worldwide, in order to improve chemical safety across all relevant sectors and enhance the protection of human health and the environment. Countries have been encouraged to use GHS as a key resource for activities on chemical hazard communication, in accordance with their own needs and capabilities.

1.1 The GHS as a foundation for chemical safety

The GHS can play a central role in conveying information about chemical hazards to users for the entire chemical supply chain, provide all countries with a consistent means of classifying and labelling hazardous chemicals, and help to ensure that coherent information is provided on all imported and exported chemicals worldwide.

The GHS classification and hazard communication elements can be seen as the foundation of programmes to ensure the safe use of chemicals, as shown in Figure 1. The two key steps to ensure the safe use of chemicals

Figure 1: GHS as the basis for National Chemicals Management Systems



are to 1) identify intrinsic hazard(s) (i.e. classification) and then 2) to communicate that information.

²⁴

The GHS document – sometimes referred to as the "Purple Book" – in all six UN languages, as well as meeting documents and other information for the SCEGHS, can be found at the GHS Secretariat website at: https://unece.org/about-ghs.

1.2 Historical and background information on the GHS

Historical and background information on the GHS and its benefits may be found in Part 1 (Introduction) of the GHS itself, and also in the ILO/UNITAR documents entitled "Understanding the Globally Harmonized System of Classification and Labelling of Chemicals (GHS): A companion Guide to the Purple Book" and "Developing a National GHS Implementation Strategy".

1.3 International management of the GHS

Responsibility for the maintenance, updating and promotion of the GHS at the international level rests with the United Nations Sub-Committee of Experts on the GHS (UNSCEGHS), established for these purposes in 1999 by the United Nations Economic and Social Council as a sub-committee of the Committee of experts on the transport of dangerous goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (UNCETDG/GHS). The UNSCEGHS works in close cooperation with the Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) which is its focal point for physical hazards, and with OECD which is its focal point for hazards to health and to the environment. UNITAR and ILO are its focal points for capacity building.

The United Nations Economic Commission for Europe (UNECE) provides secretariat services to the UNSCEGHS, and as a consequence information on its meetings and related documents is available on the UNECE website⁶.

2. Building block approach

The GHS (8th revision, 2019) defines 29 hazard classes (17 classes of physical hazards, 10 classes of hazards to health and two classes of hazards to the environment). Some of these hazard classes are sub-divided in hazard categories and sometimes even sub-categories.

All hazard classes are "building blocks" and , within each hazard class, each hazard category may be seen as a building block.

According to the GHS, countries are free to determine which of the GHS building blocks will be applied in their national systems, including depending on the sector intended to be regulated. The GHS addresses a full range of intrinsic hazards that may be presented by chemicals, but implementing the GHS does not mean that this full range need be subject to regulations. Each country may decide which hazards, and within each hazard which hazard categories, need be taken into account in the regulations depending on the sector to be regulated. 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 should follow the harmonized



⁴ https://cwm.unitar.org/publications/publications/cw/ghs/GHS_Companion_Guide_final_June2012_EN.pdf

⁵ https://cwm.unitar.org/publications/publications/cw/ghs/GHS_GD_September2010.pdf

⁶ https://unece.org/info/events/unece-meetings-and-events?f%5B0%5D=area%3A205&f%5B1%5D=program%3A196&f%5B3%5D=subarea_of_activity%3A209

classification scheme and the harmonized label elements.

Within their jurisdiction and keeping in mind the goal of full harmonization as well as international conventions, competent authorities may decide which hazard classes they apply.

NOTE: In the GHS, the term "competent authority" » is defined as « any national body(ies) or authority(ies) designated or otherwise recognized as such in connection with the GHS ». In this specific context, it should be understood as the national entity that is empowered by law to regulate within a given jurisdiction.

For a given hazard class, competent authorities have the possibility not to apply all categories. Nevertheless, in order to preserve consistency, some restrictions to this principle have been set, as follows:

- a. The classification criteria such as the cut-off values or concentration limits for adopted hazard categories should not be altered. However, adjacent sub-categories (e.g. carcinogenicity Categories 1A and 1B) may be merged into one category. Nevertheless, adjacent hazard categories should not be merged if it results in renumbering the remaining hazard categories. Furthermore, where sub-categories are merged, the names or numbers of the original GHS sub-categories should be retained (e.g. carcinogenicity Category 1 or 1A/B) to facilitate hazard communication;
- b. Where a competent authority adopts a hazard category, it should also adopt all the categories for higher hazard levels in that class. As a consequence, when a competent authority adopts a hazard class, it will always adopt at least the highest hazard category (Category 1), and, where more than one hazard category is adopted, these hazard categories will form an unbroken sequence.

The decision concerning the choice of hazards and hazard categories may be based on risk assessment. 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.

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.

It is noted, however, that the goal of the GHS is to achieve worldwide harmonization. Therefore, while differences between sectors may persist, the use of an identical set of categories at a worldwide level within each sector should be encouraged. In the transport sector this can be easily



achieved by implementing the UN Recommendations on the Transport of Dangerous Goods. So far, no such recommendations of worldwide scope exist for other sectors, but cooperation between countries at regional level may be a solution for trying to define common sectoral regulatory approaches.

3. Options for legislation and standard setting to implement the GHS

While the GHS itself is not legally binding, countries that implement the GHS may want to develop legally binding implementation measures to ensure full implementation of the GHS. (See examples in Part C)

Box 1: Information on GHS implementation

The UNECE provides, on its website, information on the status of implementation of the GHS in various countries worldwide which is regularly updated on the basis of information provided by countries, see https://unece.org/ghs-implementation-0.

Updates can be transmitted using the contact form at https://unece. org/transportdangerous-goods/ghs-implementation-information-submission-form

The information provided by UNECE (see Box 1) so far shows that many countries have not yet taken steps to implement the GHS through national legislation, and that even in some countries with industrial infrastructure, existing multisectoral legal frameworks and significant implementing capacities, this has not necessarily been achieved in all sectors.

Despite the support provided by UNITAR, ILO and certain governments and organizations for helping developing countries in developing their own National GHS Implementation Strategy along the lines described in the Guidance Document on *Developing a National GHS Implementation Strategy*⁷, only a few countries that have received such support have managed to develop suitable national legislation. The main obstacles seem to be the lack of dedicated resources in the national administrations that are usually expected to initiate legislative actions for the sector they are responsible for, and the difficulty to put in place the recommended coordination mechanisms. It should also be borne in mind that the GHS is updated every two years, and proper implementation through legislation requires continuous follow-up by administrations to keep national legislation in pace with international developments.



In the Guidance Document on Developing a National GHS Implementation Strategy, section 7.5, it was suggested that countries wishing to develop legally binding implementation measures to ensure full implementation of the GHS should first conduct a legal analysis. This would focus on understanding the current legislation or regulations for hazard classification and communication, and the changes needed to implement the GHS. Based on the results of the analysis, governments could examine the potential options for the development of a legal implementation framework. Competent authorities adopting the GHS may thus choose different implementing instruments according to their circumstances, needs and already existing legal framework. In this respect, some basic principles on law and standards are recalled in annex 2.

This guidance document on "Options for legislation and standard setting to implement the GHS" provides additional information and explanations on options for legal implementation of the GHS on the basis of actions that have been taken in various countries or by relevant regional and international organizations to implement the GHS through legislation.

CURRENT TREATIES AND RELATED INSTRUMENTS OF RELEVANCE TO THE GHS

This part provides examples of international treaties and related instruments such as regulations, codes, standards and recommendations of relevance to GHS implementation. Countries willing to implement the GHS should check whether they are already parties to such treaties as, in such cases they may already be bound to comply with the provisions of such treaties in certain sectors. It also contains examples of non-binding instruments, such as recommendations, developed by international organizations committed to the promotion of implementation of the GHS, and accepted internationally as relevant in this context.

For treaties, there are two categories:

- Those which require the use of GHS provisions for compliance with their essential requirements;
- Those which do not require the use of GHS provisions but the implementation of which would or could benefit from such a use (i.e. the application of GHS provisions is not mandatory under the treaty but would result in effective compliance with certain essential requirements of the treaty; usually, these are treaties which leave it up to each party to decide how to implement the essential requirements of the treaty).

4. Treaties, and related instruments, incorporating GHS provisions as mandatory requirements

Apart from treaties governing regional integration organizations and treaties governing international transport, there are currently very few treaties that require mandatory application of the GHS or parts thereof.

4.1 Transport sector

Regulations concerning international transport of dangerous goods (which include hazardous chemicals but also other types of dangerous products showing hazards other than chemical hazards, such as infectiousness, radioactivity, electrical hazards, high temperature) are contained in treaties administered under the auspices of international organizations such as the International Maritime Organization (IMO), the International Civil Aviation Organization (ICAO), and the United Nations Economic Commission for Europe (UNECE), that are committed, at the request of the United Nations Economic and Social Council (ECOSOC), to give effect to the Model Regulations

annexed to the United Nations Recommendations on the Transport of Dangerous Goods. These Model Regulations contain, among others, classification criteria and hazard communication elements consistent with those of the GHS as relevant for the transport sector. The provisions contained in these Model Regulations are regularly updated to be kept in line with the GHS, and the process is facilitated by the fact that the United Nations Recommendations on the Transport of Dangerous Goods and the GHS are both developed and kept up-to-date by the same body; the UN ECOSOC Committee of Experts on the Transport of Dangerous Goods and on the GHS (see also section 1.2 of the introduction to this document)

Not all hazards or hazard categories covered by the GHS are subject to the transport regulations since some hazards or hazard categories are considered as not a source of risk in the context of a transport operation.

Box 2: GHS hazards or hazard categories not subject to transport regulations:

For physical hazards: flammable gases of category 2; flammable liquids of category 4

For health hazards: Acute toxicity (oral, dermal, inhalation of vapours, inhalation of gases) categories 4 and 5; Skin corrosion/irritation: categories 2 and 3; Serious eye damage/Eye irritation: all categories; Respiratory or skin sensitization: all categories; Germ cell mutagenicity: all categories; Carcinogenicity: all categories; Reproductive toxicity: all categories; Specific target organ toxicity (single exposure and repeated exposure): all categories; Aspiration hazard: all categories

For hazards to the aquatic environment: Acute categories 2 and 3 (except for carriage in bulk in sea-going or inland waterway oil or chemical tankers); Chronic 3 and 4 (except for carriage in bulk in sea-going or inland waterway oil or chemical tankers)

For hazards to the ozone layer: all categories

The treaties concerned are as follows:

Maritime transport:



International Convention for the Safety of Life at Sea (SOLAS), 1974 (166 contracting parties) which requires the mandatory application of the International Maritime Dangerous Code (IMDG Code); the International Code for the Construction and Equipment of Ships carrying Chemicals in Bulk (IBC Code), the International Code for the Construction and Equipment of Ships carrying Gases in bulk (IGC Code), the International Maritime Solid Bulk Cargoes Code (IMSBC Code).

International Convention for the Prevention of Pollution from Ships (1973) as modified by the Protocol of 1978 thereto (MARPOL 73/78) (159 Contracting Parties) and in particular, its annexes I (oil, 159 parties), II (noxious liquid substances in bulk, 159 parties), III (harmful substances in packaged form, 149 parties) and V (garbage, 154 parties)

Air transport:



Convention on International Civil Aviation (193 Contracting Parties) and its annex 18 which requires, in principle and subject to possible notified State variations, mandatory application of the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI)

International Air Transport Association (IATA) Dangerous Goods Regulations. Private regulations, not legally binding under international law but consistent with ICAO TI and application recommended by IATA as standard for the 292 member airlines of the Association. Cannot legally override ICAO TI.

Road transport:



Agreement concerning the International Carriage of Dangerous Goods by Road (ADR, 1957, 52 Contracting Parties)

Rail transport:



Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) (appendix C to the Convention concerning International Carriage by Rail) (COTIF) (45 Contracting Parties in Western Europe, Central Europe, West Asia and North Africa)

Regulations concerning the international transport of dangerous goods by rail (Annex 2 to the Agreement on International Goods Transport by Rail (SMGS) (12 Contracting Parties in Central Europe, Eastern Europe, Central Asia and Eastern Asia)



Inland waterway transport:

European Agreement concerning the international carriage of dangerous goods by inland waterways (ADN, 2000) (18 Contracting Parties)

4.2 Industrial accidents

The UNECE Convention on the Transboundary Effects of Industrial Accidents⁸ aims to prevent, prepare for and respond to major industrial accidents involving hazardous activities, including to those that may have transboundary effects. Hazardous activities under the Convention comprise the production, use, storage, handling or disposal of hazardous substances. Some examples of hazardous activities are fertilizer or chemical plants, petroleum storage facilities or mine tailings facilities. Parties to the Convention or countries that have committed to implement its provisions are required to identify their hazardous activities, notify potentially affected countries about them (before any accident should happen) and put in place appropriate prevention, preparedness and response measures.

Annex I to the Convention, which includes a list with the hazardous substances covered under the Convention, is divided into two parts: part I contains the GHS classes and categories of substances and mixtures covered, while part II lists named substances. If any of the substances or mixtures in annex I are present at an installation in quantities equal to or greater than those specified, this indicates that a hazardous facility is covered under the scope of the Convention and that its provisions must be applied, if the hazardous facility has the potential to cause transboundary effects.

All information related to the Convention and its implementation (including guidance materials) is available at the Convention website⁹.



https://unece.org/environment-policy/industrial-accidents

⁹ https://unece.org/DAM/env/documents/2017/TEIA/Publication/ECE_CP_TEIA_33_final_Convention_publication_ March_2017.pdf

4.3 Regional economic integration organizations

Regional economic integration organizations are institutions through which countries seek to improve their economic development. Economic integration organizations may establish common rules, standards and practices in a variety of areas, including those concerned by the GHS.

They are normally established under a Treaty, and depending on the clauses of the Treaty, they may establish legally-binding agreements between their member States or rules and regulations which take precedence over national law, or directives that member States are bound to transpose into national law, or recommendations that member States are invited to apply through national law.

Certain treaties allow regional economic integration organizations to become parties as a single entity, provided that their member States have transferred competence in respect of matters governed by the treaty, including the competence to enter into treaties in respect of these matters, to these organizations. This is the case of the UNECE Convention on the Transboundary Effects of Industrial Accidents mentioned under section 7.2.

Several such organizations have already taken steps to require or recommend implementation of the GHS in one or several relevant sectors.

European Union (EU)

The European Union (27 member States) has comprehensively adapted its chemical management regulatory system to the GHS. It is recalled that in the EU system, Regulations are of direct application and that requirements of Directives have to be transposed into national law.

The main legal instrument implementing the classification and labelling provisions of the GHS is Regulation (EC) n° 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances ("CLP")¹⁰, in force since 20 January 2009, for application to agriculture (pesticides/biocides), industry and consumer sectors (not transport).

In addition to classification criteria and labelling provisions, the CLP contains a list of substances and mixtures and their GHS classification in the EU (See also Box 8 for application of the building block approach and specific CLP provisions).



The use of GHS Safety Data Sheets (SDSs) for the provision of information to recipients of substances and mixtures in the EU is required by Article 31 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and its Annex II as amended by Commission Regulation (EU) 2020/878¹¹.

Box 3: CLP Building block approach

CLP includes all GHS classes and categories, except:

- Flammable liquids Cat.4
- Acute toxicity Cat. 5
- Skin corrosion/irritation Cat.3
- Severe eye damage/Eye irritation Cat.2B
- Aspiration hazard Cat.2
- Hazard to the aquatic environment: Acute toxicity Cat. 2 and Cat. 3

CLP includes a few additional labelling and packaging rules (compatible with GHS):

- Labelling of small size packagings (article 29)
- Special labelling rules for certain substances and mixtures (CLF annex II, part 1)
- Additional hazard statements for certain mixtures (CLP annex II, part 2)
- Child resistant fastenings (CLP annex II, part 3)
- Tactile warning of danger (CLP annex II, part 3)
- Rules for situations covered both by CLP and transport regulations (e.g. article 33 for labelling)
- Labelling for plant protection products, EUH401 mention (CLP annex II, part 4)

Other EU legal instruments on chemical management take account the CLP, and therefore the GHS, in the following areas:

- Detergents: Regulation (EC) n° 1336/2008 and n° 648/2004
- Cosmetics: directive 2008/112/EC amending76/768/EEC
- Toy safety: directive 2008/112/EC amending directive 88/378/CEE
- Limitation of volatile organic components emissions: directive 2008/112/EC amending directives 1999/13/EC and 2004/42/CE;
- End-of-life vehicles: directive 2008/112/EC amending directive 2000/53/EC
- Limitation of the use of certain hazardous substances in electric and electronic equipment: directive «WEEE» 2012/19/EU
- Control of major-accident hazards involving dangerous substances (Seveso III): directive 2012/18/EU;
- Placing of plant protection products on the market: regulation(EC) n° 1107/2009 (PPPR)
- Making available on the market and use of biocidal products: regulation (EU) n° 528/2012
 (BPR)
- Chemical agents at work: directive 98/24/EC
- Carcinogens and mutagens at work: directive 2004/37/EC
- Young workers : directive 94/33/EC
- Pregnant or breastfeeding workers: directive 92/85/EEC
- Safety and/or health sign at work: directive 92/58/EEC
- Ecolabel award scheme: regulation (EC) n° 1980/2000
- Aerosol dispensers: directive 75/324/CEE
- Export and imports of hazardous chemicals: regulation (EU) n° 649/2012
- Hazardous waste: directive 2008/98/EC and decision 2000/532/EC
- Waste batteries and accumulators: directive 2006/66/EC
- Ambient air quality assessment and management: directive 1996/62/EC

Detailed information on all these regulations and directives may be found on the website of the European Chemicals Agency at https://echa.europa.eu/legislation and https://echa.eu/legislation and

In the inland transport sector, directive 2008/68/EC requires member States to apply the provisions of ADR, RID and ADN to domestic traffic (see also section 7.1 above).

The EAEU has five members (Armenia, Belarus, Kazakhstan, Kyrgyzstan and the Russian Federation). On 3 March 2017, by Decision No. 19/2017, the EAEU Commission approved Technical Regulation TR EAEU 041/2017 "On the safety of chemical products". This Technical Regulation deals with hazard classification and hazard communication; labelling and SDSs; identification; new substances notification; register of substances and mixtures of the EAEU; conformity assessment within the state registration.

The entry into force is scheduled for 30 November 2022, once the register of existing chemical substances in the EAEU, with their GHS classification, is available (expected 1 October 2021 for substances) (1 June 2027 for mixtures) and the work on procedures for notification of new substances and mixtures has been completed.

According to article 51 of the EAEU Treaty¹², Technical Regulations are established in relation to a single list of products concerned.

According to article 52, Technical Regulations of the Union are directly applicable in the territory of the Union. The procedure for enforcement and transitional provisions are determined by the Technical Regulation and (or) an act of the Commission. The international, regional (interstate) standards, and in case of their absence (before adoption of regional (interstate) standards) - national (state) standards of state members can be applied to fulfil the requirements of the technical regulation and for assessment of conformity on a voluntary basis.

For the time being, the standards which have been identified for application under Technical Regulation TR EAEU 041/2017 are the national (GOST) standards of the Russian Federation which had been developed for implementation of the GHS in the Russian Federation, and which may currently be applied on a voluntary basis:

National standards aligned with GHS Rev.4:

GOST 32419-2013 "Classification of chemicals. General requirements"

GOST 32423-2013 "Classification of mixtures (health hazards)"

GOST 32424-2013 "Classification of chemicals for environmental hazards. General princi ples"

GOST 32425-2013 "Classification of mixtures (environmental hazards)"

GOST 31340-2013 "Labelling of chemicals. General requirements"

The above-mentioned GOST standards are currently under revision to match the 7th revised edition of the GHS.

National standard aligned with GHS Rev.1

GOST 30333:2007 on SDSs (Chemical production safety passport. General requirements) which should be replaced by GOST R 58475-2019 for application by 1 June 2022.

Recommendations on the compilation of SDS and labelling:

GOST R 50.1.102-2014 "Guidance on the compiling of safety data sheets in accordance with GOST 30333"

GOST R 50.1.101-2014 "Guidance on the selection of precautionary statements for the label ling in accordance with GOST 31340"

Common market of the South (MERCOSUR)

Currently, MERCOSUR includes four countries of South America: Argentina, Brazil, Paraguay and Uruguay.

So far, in relation to GHS implementation, only the transport sector has been addressed by MER-COSUR since the Agreement on the facilitation of the transport of dangerous goods in MERCOS-UR is based on the 17th revised edition of the UN Recommendations on the Transport of Dangerous Goods, and only in relation to international transport by road and rail between the four States.

Andean Community

The Andean Community includes Bolivia, Colombia, Ecuador and Peru.

So far, the only instrument developed which implements the GHS is in the agriculture sector and concerns pesticides of agricultural use. It is called "Technical Manual for registration and control of chemical pesticides for agricultural use" and has been published in the official gazette as Resolution N°2075 of 2 August 2019.

Association of Southeast Asian Nations (ASEAN)

Ten countries are members of ASEAN: Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam.

Protocol No. 9 to the ASEAN Framework Agreement on the Facilitation of Goods in Transit requires the use of the Model Regulations annexed to the UN Recommendations on the Transport of Dangerous Goods or of ADR for dangerous goods in transit, which implies implementation of the GHS in the transport sector, but for transit only.

Great Mekong Sub-Region

Annex 1 (Carriage of dangerous goods) to the Greater Mekong Subregion Cross-Border Transport Facilitation Agreement requires classification and labelling of dangerous goods to be made in accordance with the Model Regulations annexed to the UN Recommendations on the Transport of Dangerous Goods or with ADR in case of international carriage of dangerous goods by road, when cross-border movement of such goods is permitted. The six Contracting Parties to this agreement are China, Cambodia, Lao, Myanmar, Thailand and Vietnam.

Central African Economic and Monetary Community (CEMAC)

In 1999, CEMAC (Cameroon, Central African Republic, Chad, Democratic Republic of the Congo, Equatorial Guinea and Gabon) adopted regulations concerning the transport of dangerous goods by road which are partly based on old provisions of ADR but which are not fully in line with the UN Model Regulations nor current ADR and therefore cannot be considered as an instrument properly implementing the GHS in the transport sector. Updating these regulations could provide an opportunity for implementation of GHS in the road transport sector.

Other regional economic integration organizations

There are many other regional economic integration organizations in the world which have a mandate covering a wide range of sectors of GHS relevance including agriculture, labour, industry, transport, trade, environment, health, and which have the possibility to establish supranational rules and regulations in relevant sectors. The advantage is that this may reduce the administrative burden of the national departments concerned in relation to the development and updating of legislation. Another advantage is that the GHS implementing instruments may then be developed taking account the specific regional situation and address specific common concerns. On the other hand, this also requires the availability of expertise and staff resources in the secretariat of the organization concerned, and strong cooperation between the competent authorities of each country member of the organization, and the ability for each country to organize implementation and enforcement measures.

In addition to the above-mentioned organizations, other organizations that could be involved in developing implementation instruments:

- Africa: the Arab Maghreb Union (UMA); the Common Market for Eastern and Southern Africa (COMESA); the Community of Sahel-Saharan States (CEN-SAD); the East African Community (EAC); the Economic Community of Central African States (ECCAS); the Economic Community of West African States (ECOWAS); the Intergovernmental Authority on Development (IGAD) and the Southern African Development Community (SADC).
- Latin America and the Caribbean: Caribbean Community (CARICOM)



Asia-Pacific: Pan-Beibu Gulf (PBG) Economic Cooperation; Greater Tumen Initiative (GTI);
 Central Asian Regional Economic Cooperation (CAREC)

5. Treaties, and related instruments, of relevance in the context of GHS implementation but not requiring its mandatory application

5.1 Workplace

13

The main instruments of universal scope dealing with occupational safety and health have been developed by ILO. These instruments usually consist of a Convention, legally-binding for all its Contracting Parties, which contain usually broad requirements in the area addressed by the Convention. Contrary to transport conventions listed in 7.1- which deal with chemical safety issues in the context of international transport operations of concern to several, and sometimes many different countries- ILO Conventions mainly operate in the area of domestic policy. A convention is usually accompanied by non-binding Recommendations, supplemented sometimes by codes of practice also not of mandatory application. However, these recommendations and codes of practice are very useful in the sense that they provide detailed guidance on how to apply the conventions, including sometimes to countries that do not wish to be bound by the Convention but are interested in applying at least some of its requirements on a voluntary basis.

The report "ILO Instruments on Chemical Safety - Analysis and synergies with other international frameworks on the sound management of chemicals"¹³ published on 1 January 2020 provides an overview of all major ILO instruments addressing chemical hazards for human health and safety, as well as the environment.

The main ILO instruments addressing chemical hazards are the Chemicals Convention, 1990 (No. 170) (22 Contracting Parties) and the Chemicals Recommendation, 1990 (No. 177). They are both general in scope and concern all risks relating to chemicals. Convention No. 170 provides for a com¬prehensive national framework for the safe use of chemicals at work, including the formulation, implementation and periodic review of a coherent national policy. The instruments also provide for the responsibility of employers and for the duties and rights of workers at the level of the undertaking, as well as specific responsibilities of suppliers and exporting states.

A key feature of the Convention is its provisions on chemical hazard communication designed to ensure that information on hazards and related preventive and protective measures flows from manufacturers and importers to the users. This includes requirements for the classification and labelling of chemicals, as well as regulating the production, handling, storage and transport of chemicals, the disposal and treatment of chemical wastes, the release of chemicals and the maintenance, repair and cleaning of equipment and containers for chemicals. At the workplace, the employer is required to ensure that all chemicals are identified, and that adequate information is

available through labelling and safety data sheets, as well as to take all the necessary measures to eliminate, minimize or control exposure.

Instead of prohibiting the use of certain substances, the instruments prioritize prevention and only allow protective measures as a last resort if risks cannot be prevented, eliminated or minimized. The <u>ILO Code of Practice on Safety and the Use of Chemicals at Work</u>¹⁴ provides detailed guidance on labelling and classification at the workplace level as well as on responsibilities and duties for promoting occupational safety and health.

These instruments were developed before the publication of the first version of the GHS. The ILO initiated GHS development as a follow-up to the adoption of the Chemicals Convention, 1990 (No. 170) and had an important role in steering its development initially under the umbrella of the International Programme for Chemical Safety (IPCS) and then the Interorganization Programme for the Sound Management of Chemicals (IOMC).

It should be borne in mind that ILO was one of the three focal points that participated in the drafting of the GHS (with OECD and the UN Committee of Experts on the Transport of Dangerous Goods). Special attention was paid to the provisions of these specific ILO instruments, and care was taken to ensure that the GHS would include all necessary elements, such as hazard classes and categories, their respective classification criteria, and hazard communication elements such as labels and SDS in order to help countries in complying with the obligations of the Chemicals Convention and provisions of the Chemicals Recommendations and the Code of practice. Therefore, it is not surprising that parties to the Convention are considered to have implemented its hazard classification and hazard communication requirements when they have included the GHS provisions in their national legislation concerning this sector.

Box 4: Extracts of the ILO Chemicals Convention

Art. 6, Classification: Competent bodies must establish systems and specific criteria appropriate for the classification of all chemicals, and mixtures of chemicals, according to the type and degree of their hazards, taking into account the UN Recommendations on the transport of dan¬gerous goods. The classification system must be progressively extended.

Arts. 7 and 8, Labels and Safety Data Sheets (SDS): Chemicals must be labelled. The label¬ling of hazardous chemicals must clearly explain their hazards. Employers must be provided with SDS for hazardous chemicals. The format and content of labels and SDS must be prescribed by the competent body.

Art. 9, Suppliers: Chemical suppliers must ensure that the requirements of Arts. 6-8 are met for the chemicals they supply.

The use of relevant GHS provisions may also facilitate the implementation of a number of other ILO Conventions and Recommendations and compliance of parties with their obligations even though these instruments do not specifically require it, for example:

- Major Industrial Accidents Convention, 1993 (No. 174) and related Recommendation No. 181, and Code of Practice
- Occupational Safety and Health Convention, 1981 (No. 155) and related Recommendation No.
 164
- List of Occupational Diseases Recommendation, 2002 (No. 194)
- Occupational Cancer Convention, 1974 (No. 139) and related Recommendation No. 147
- Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No. 148) and related
 ed Recommendation No. 156
- Asbestos Convention, 1986 (No. 162) and related Recommendation No. 172
- Benzene Convention, 1971 (No. 136) and related Recommendation No. 144
- Safety and Health in Agriculture Convention, 2001 (No. 184) and related Recommendation (No. 192) and Codes of Practice (Agriculture, Forestry Work)
 - NOTE: The Code of Practice on Safety and Health in Agriculture specifically references the GHS and provides guidance on its application as well as on the use of Safety Data Sheets.
- Safety and Health in Construction Convention, 1988 (No. 167) and related Recommendation No.
 175 and Code of Practice

 Safety and Health in Mines Convention, 1995 (No. 176) and related Recommendation No. 183 and Codes of Practice (Opencast mines, Underground coal mines)

Conversely ILO chemical safety instruments may be seen as providing a complementary legal framework to assist countries in practically implementing a number of GHS provisions.

5.2 Health and environment: registration of hazardous chemicals; risk evaluation; control of use, import, export; restrictions, prohibitions

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal

The Basel Convention counts 187 Contracting Parties and its provisions centre around the following principal aims:

- the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management; and
- a regulatory system applying to cases where transboundary movements are permissible.
 (See also http://www.basel.int/TheConvention/Overview/tabid/1271/Default.aspx)

Hazardous wastes are defined as wastes falling within a category of waste streams or of wastes having certain constituents, e.g. wastes from the production, formulation and use of organic solvents, or wastes having zinc compounds as constituents, described in Annex I, and presenting also hazardous characteristics described in Annex III which in fact correspond to hazard classes defined in the UN Recommendations on the Transport of Dangerous Goods. In addition, waste may be considered hazardous under the laws of either the exporting country, the importing country, or any of the countries of transit. The Convention does not cover radioactive waste but covers products other than chemicals, e.g. infectious clinical waste.

The Convention does not refer to the GHS in relation to the criteria to be used to classify hazardous wastes, but since Annex III refers to UN classes of dangerous goods to be regulated in the
context of transport and since the classification criteria for these UN classes are reflecting GHS
criteria, there is a consequential link to the GHS. Nevertheless, as explained in box 2 under section
4.1, not all GHS hazards or hazard categories are subject to transport regulations, while the Basel
Convention addresses not only the movement of wastes but also their disposal which may justify
taking account of other hazards or hazard categories not regulated in relation to transport safety.
As a consequence, Parties to the Convention have initiated a review of Annex III in the light of the
GHS, and this work is expected to be carried out at least until 2023.



Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa

The Bamako Convention (25 Contracting Parties) is similar to the Basel Convention in the sense that the list of hazardous characteristics in its Annex II is the same as that of Annex III of the Basel Convention, but the scope is different since it bans the import of hazardous wastes into Africa and regulates their transboundary movement within the African continent only. (See also https://www.unenvironmental-environmental)

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

The Rotterdam Convention's (161 Contracting Parties) objective is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Convention is open to regional economic integration organizations.

The Convention regulates, for the purpose of protection of human health and of the environment, the import and export of certain chemicals all uses of which, as an industrial chemical or as a pesticide, is prohibited (banned chemicals) by one or several Contracting Parties or virtually all uses of which as an industrial chemical or as a pesticide is prohibited but for which certain specific uses remain authorized (severely restricted chemicals) by one or several Contracting Parties.

It also regulates, for the same purpose, the import and export of "Severely hazardous pesticide formulations" which are defined as a chemical formulated for pesticidal use that produces severe health or environmental effects observable within a short period of time after single or multiple exposure, under conditions of use.

The chemicals which are subject to the Convention as banned chemicals, severely restricted chemicals or severely hazardous pesticide formulation are listed by name in Annex III of the Convention. The import or export of the listed chemicals from one Party to another one is subject to a notification and consent procedure known as the "Prior Informed Consent Procedure" or "PIC procedure".

The decision to include a chemical in Annex III is made by the Parties after review of:

- Notifications made by any Party that has taken final regulatory action in order to ban or severely restrict the use of a chemical;
- Proposals made by any Party that is a developing country or a country with an economy in transition and that is experiencing problems caused by a severely hazardous pesticide formulation under conditions of use in its territory, in accordance with procedures described in the Convention, notably the analysis of the information provided as requested in annexes I and IV and in the light of criteria established in Annexes II and IV. These criteria do not refer specifically to GHS classification. Nevertheless, the information to be provided includes information on toxicological and ecotoxicological properties of the chemical, as well as on its hazard classification where the chemical is subject to hazard classification requirements. As a consequence, providing information on the GHS classification of a chemical would be particularly useful in the review process.

In addition, in relation to import/export procedures, Article 13 on information to accompany exported chemicals, includes requirements concerning labelling and SDS, taking account relevant international standards/internationally recognized standards, see box 5. Although not explicitly mentioned in this article, use of the GHS would certainly be a key manner in which to satisfy these requirements.

Box 5: Rotterdam Convention

Article 13 Information to accompany exported chemicals

•••

- 2. Without prejudice to any requirements of the importing Party, each Party shall require that both chemicals listed in Annex III and chemicals banned or severely restricted in its territory are, when exported, subject to labelling requirements that ensure adequate availability of information with regard to risks and/or hazards to human health or the environment, taking into account relevant international standards
- 3. Without prejudice to any requirements of the importing Party, each Party may require that chemicals subject to environmental or health labelling requirements in its territory are, when exported, subject to labelling requirements that ensure adequate availability of information with regard to risks and/or hazards to human health or the environment, taking into account relevant international standards.
- 4. With respect to the chemicals referred to in paragraph 2 that are to be used for occupational purposes, each exporting Party shall require that a safety data sheet that follows an internationally recognized format, setting out the most up-to-date information available, is sent to each importer.
- 5. The information on the label and on the safety data sheet should, as far as practicable, be given in one or more of the official languages of the importing Party.

.....

Full information on the Convention, procedures, implementation, guidance etc may be found at http://www.pic.int/Home/tabid/855/language/en-US/Default.aspx

The Stockholm Convention (183 Contracting Parties) is an international environmental treaty that aims to eliminate or restrict the production and use of persistent organic pollutants (POPs).

All parties must prohibit the production and use of all POPs listed in Annex A (subject to certain exemptions and transitory requirements for certain substances) and restrict the use and production of POPs listed in Annex B. The import of substances listed in Annexes A and B as well as the export of substances in Annex B is only possible for the purpose of their environmentally-sound disposal (as well as for several exceptional reasons listed in the Convention). The export of substances in Annex A is prohibited (apart from a few special exceptions).

For POPs in Annex C, Parties must reduce their total release as much as possible and, where feasible, eliminate them, by inter alia developing and implementing an action plan to identify and address their release, by adopting available and feasible measures against their release, by promoting the development of less harmful substitutes, and by promoting the use of the best available technologies for their reduction or elimination.

The inclusion of chemicals in Annexes A, B and C is made after consideration of proposals submitted by Contracting Parties and in accordance with the procedure of article 8 which includes the provision of information requested in Annex D, notably information on the persistence and bio-accumulation properties of the chemical, and toxicity and ecotoxicity data that evidence adverse effects on human health and the environment. Although no reference is made to the GHS in the Convention, the GHS Chapter 4.1 classification criteria for hazard to the aquatic environment notably in relation to bioaccumulation and chronic toxicity and the guidance on hazards to the aquatic environment contained in Annex 9 of the GHS would be of relevance in the listing decision-making process. Part 3 of the GHS also covers the whole range of adverse effects to human health. A GHS safety data sheet would also contain, in its section 12, Ecological information such as toxicity, persistence and degradability, bioaccumulative potential, mobility in soil and other adverse effects, that could be used in this process, while toxicological information may be found in section 11.

Furthermore, in its article 10, the Convention requires Contracting Parties to promote and facilitate public information, awareness and education. Paragraph 4 of the said article states that "In providing information on persistent organic pollutants and their alternatives, Parties may use safety data sheets, reports, mass media and other means of communication, and may establish information centres at national and regional levels".

Detailed information on the Convention may be found at http://chm.pops.int/Home/tabid/2121/
Default.aspx



Other conventions

As for the Rotterdam and the Stockholm conventions, the use of the GHS may be of interest in the context of implementation of some other conventions dealing with the control of very specific chemicals but is not required nor absolutely needed since the chemical substances concerned are already specifically identified, e.g. in the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, or the Montreal Protocol on Substances that Deplete the Ozone Layer.

6. Non-binding instruments

Some international organizations have issued recommendations which, as the GHS itself, are not legally binding and hence do not belong to the category of treaties. Some of these recommendations are worth noting because (a) they have been issued under the authority of high-level organs of the United Nations or its specialized agencies; (b) they are effectively implemented at a world-wide level through legally-binding instruments such as treaties and national legislation; and (c) they address directly questions of classification and labelling of chemicals.

6.1 Transport of dangerous goods

In the transport sector, the United Nations Economic and Social Council, which is one of the six main organs of the United Nations which coordinate and oversee the work of the UN specialized agencies such as ILO, IMO, ICAO, FAO, WHO and all others, established in 1953 a special Committee of experts on the Transport of Dangerous Goods tasked with elaborating recommendations for the worldwide harmonization of the classification, labelling and documentation requirements that were used at that time and that were not consistent depending on the mode of transport used and depending on countries. These Recommendations were first issued in 1956 and since then were updated regularly every two years still under the authority of ECOSOC. As of now, they are very broadly implemented, in particular through international instruments applicable to international transport (see also section 7.1 above) but also through national legislation applicable to domestic traffic throughout the world. In 1999, the mandate of the Committee was extended to cover GHS issues and this has facilitated implementation of the GHS through transport instruments (see also section 1.2).

6.2 Agriculture sector: Pesticides

Pesticides are internationally regulated under various sectoral regulatory systems, e.g. transport conventions (see 4.1 and 6.1), workplace (see 5.1), control of import/export (see 5.2). However, except for the transport sector, the international conventions do not provide detailed requirements

on how pesticides should be classified and labelled, i.e which GHS hazards or hazard categories should be taken into account depending on the sector concerned, although this may be addressed in national sectoral regulations.

In the transport sector, all physical hazards (Part 2 of the GHS) of the pesticide preparation transported have to be taken into account except for the few hazard categories that are not subject to the transport regulations. For health hazards (Part 3), only Acute Toxicity, categories 1 to 3, (Chapter 3.1 of the GHS) and Skin corrosion category 1, are to be taken into account. In order to determine the acute toxicity hazard category, reference is made to "The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification", but only as a relevant source of LD50 data that may be used for determining these categories. For pesticides hazardous to the aquatic environment, according to the UN Recommendations on the Transport of Dangerous Goods, only pesticides that do not present other transport regulated hazards (such as flammability, acute toxicity) need be identified as hazardous to the aquatic environment (because according to paragraph 10 of the UN Recommendations many of those possessing other hazards are deemed as being dangerous for the environment). Nevertheless, for maritime transport and inland transport, the MARPOL convention (Annex III), the IMDG Code, ADR, RID and ADN require that pesticides meeting the GHS criteria for hazard to the aquatic environment, as applicable to the transport sector, be identified/labelled as such, whether or not they possess other hazards.

FAO and WHO guidelines and recommendations relating to classification and labelling of pesticides have been widely used in the world for many years by pesticide regulators and are well known by end-users. Nevertheless, they were not entirely consistent with the GHS and therefore WHO and FAO have joined efforts to revise and update their publications in order to take account of the GHS. For the time-being:

- The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification has been amended to include a column indicating, for each pesticide, the GHS acute toxicity hazard of the active ingredient (2019 version, see https://apps.who.int/iris/bitstream/handle/10665/332193/9789240005662-eng.pdf?ua=1)
- » FAO and WHO have developed criteria for defining "Highly Hazardous Pesticides" including some GHS criteria, see box 6 (See also FAO/WHO International Code of Conduct for the Management of Pesticides, Guidelines on Highly Hazardous Pesticides, March 2016, http://www.fao.org/publications/card/fr/c/a5347a39-c961-41bf-86a4-975cdf2fd063/)
- » The FAO/WHO International Code of Conduct on the Distribution and Use of Pesticides, Guidelines for the Registration of Pesticides (2010) refers to the GHS in relation to classification of pesticides
- » FAO and WHO have issued a revised version of their guidelines for labelling (see "FAO/WHO International Code of Conduct for the Management of Pesticides, Guidelines on Good Labelling Practices for Pesticides (revised, August 2015)" (http://www.fao.org/3/a-i4854e.pdf)



In relation to classification of pesticides, the Guidelines for the Registration of Pesticides stated, in 2010, in paragraph 7.7:

All products should be classified according to their hazard, in accordance with the Globally Harmonized System for Classification and Labelling (GHS). As long as this system is not fully implemented, products can be classified according to the WHO hazard classification or any national regulation. Responsible authorities particularly in developing countries should consider the use of colour bands, warning statements and pictograms to reflect the different hazard classes of pesticides to minimize risks posed by pesticides.

In relation to classification and labelling, the Guidelines for Good Labelling Practices issued in 2015 contained more precise recommendations which are reproduced in annex 3:

Other relevant information from FAO: http://www.fao.org/agriculture/crops/thematic-sitemap/
theme/pests/code/list-guide-new/en/

Box 6: FAO/WHO Recommended definition of Highly Hazardous Pesticides

The Joint FAO/WHO Meeting on Pesticide Management recommended that highly hazardous pesticides should be defined as having one or more of the following characteristics:

- ► Criterion 1: Pesticide formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard; or
- ► Criterion 2: Pesticide active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); or
- ► Criterion 3: Pesticide active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); or
- ► Criterion 4: Pesticide active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); or
- ► Criterion 5: Pesticide active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention; or
- ► Criterion 6: Pesticide active ingredients and formulations listed by the Rotterdam Convention in its Annex III; or
- ► Criterion 7: Pesticides listed under the Montreal Protocol; or
- ► Criterion 8: Pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.

7. Trade agreements

In order to facilitate trade and develop their economy, many countries conclude trade agreements with other countries.

The World Trade Organization (WTO) (164 members) is the global international organization dealing with the rules of trade between nations, and at its heart are the WTO agreements. The goal is to help producers of goods and services, exporters, and importers conduct their business. One agreement which may be considered as important in relation to GHS implementation is the Technical Barriers to Trade (TBT) Agreement¹⁵. The TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognises WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or protection of the environment. The TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade. Through its transparency provisions, it also aims to create a predictable trading environment. See also https://www.wto.org/english/thewto e/whatis e/tif e/agrm4 e.htm#TRS

Regulatory measures that are taken by countries in a sector in relation to chemical classification and hazard communication are normally intended to protect human health and environment, and they cannot be overridden by trade rules, but in the spirit of the TBT Agreement they should be based on the GHS which should be considered as the only international standard extensively covering classification of hazardous chemicals and hazard communication. Moreover, in relation to the predictability of the trading environment it would also be important that any deviation from the GHS in national technical regulations or standards be clearly identified.

The key provisions of the TBT Agreement in this respect are contained in its article 2, which is reproduced in annex 4.

The Swedish Chemicals Agency (KEMI) has recently published a report PM 4/21 intended to investigate whether environmental provisions in regional trade agreements have been used to promote the implementation of the GHS, entitled "Have international trade agreements supported implementation of the Globally Harmonized System of Classification and Labelling of Chemicals, GHS?"¹⁶

The first version of the GHS was published by the United Nations in 2003. Since then, revised versions have been published every two years (GHS Rev.1 to GHS Rev.8) and the next version (Rev.9) is expected to be published in 2021.

While some countries or jurisdictions have legally implemented the GHS horizontally across all sectors (e.g. the EU), others have legally implemented it in certain sectors (e.g. workplace), and many countries, notably developing countries, are still at the start of the process of legal implementation. Nonetheless, it happens in such countries that some chemicals and products are placed on the market with labels and SDSs conforming to the GHS due to voluntary implementation by industry or by the fact they are imported from countries applying the GHS.

The GHS has been legally implemented widely in the transport sector because of the existence of international conventions governing international transport of dangerous goods for each mode of transport and of a mechanism at United Nations level for harmonization and regular coordinated updating of the technical provisions of these conventions on the basis of the United Nations Recommendations on the Transport of Dangerous Goods (see also sections 4.1 and 6.1 above). This is not necessarily true for domestic traffic for transport by road, rail or inland waterways. Many countries, economically interested in international trade and politically committed to transport safety, have national legislation applicable to domestic traffic in line with the UN Recommendations on the Transport of Dangerous Goods and the related system of international conventions, and therefore also in line with the GHS. However, many countries, in particular developing countries, have either obsolete legislation based on very old versions of the UN Recommendations, or simply no legislation at all regulating inland transport of dangerous goods.

In other sectors, in the absence of international conventions requiring specifically the use of the GHS, progress on the development of national legislation to implement the GHS has been slower, although the commitment of certain countries to give effect to the ILO Chemicals Convention (see 5.1) has been instrumental in developing legislation or adapting new legislation in the industrial workplace sector.

This Part contains some examples of how the GHS has been legally implemented in certain countries.

8. European Union countries (Supranational law and sectoral and multisectoral regulations)

As explained in section 4.3, the EU Regulations apply directly in EU member States, while the provisions of directives have to be transposed into national law. The main Regulation for GHS legal implementation is the CLP Regulation, which covers classification and labelling of chemicals in all sectors other than transport, while the REACH Regulation deals with registration, evaluation, authorization and restriction of chemicals and requires the provision of SDSs. The transport sector is covered by Directive 2008/68/EC concerning inland transport of dangerous goods requiring the application of ADR, RID and ADN to domestic traffic, and by the application of the international conventions referred to under 4.1 for maritime and air transport.

When the EU adopted the REACH and the CLP Regulations, these Regulations superseded previous directives dealing with classification and labelling of chemicals and SDSs which had been transposed into national legislation of each EU member State, including laws and regulations. As a consequence, although the REACH and CLP Regulations were directly applicable in areas within their scope, EU member States had to amend their legislation accordingly, e.g. in sectors like public health, workplace, agriculture and environment to avoid legal misunderstandings.

Ireland, as one of the 27 EU member States, may be given as an example.

In relation to CLP, Ireland has issued a statutory instrument named "Chemicals Act (CLP Regulation) Regulations 2011" which simply refers to the CLP Regulation and indicates that the official language applicable for the purposes of Article 7.2 of the CLP Regulation is English (see http://www.irishstatutebook.ie/eli/2011/si/102/made/en/pdf). This comes under the Chemicals Act 2008 (No. 13 of 2008) and Chemicals (Amendment) Act 2010 (No 32 of 2010), the main purpose of which is to facilitate the enforcement of certain EU Regulations concerning chemicals, including CLP and REACH, see also https://www.hsa.ie/eng/Legislation/Acts/Chemicals Acts 2008 and 2010 and the Guide/

For the workplace, the Safety, Health and Welfare At Work (Chemical Agents) Regulations, 2001 (http://www.irishstatutebook.ie/eli/2001/si/619/made/en/print#article4), issued under the Safety, Health, and Welfare Act 2005 (https://revisedacts.lawreform.ie/eli/2005/act/10/front/revised/en/html) was amended to replace references to the said directives by references to the new EU Regulations, see https://enterprise.gov.ie/en/Legislation/Legislation-Files/Safety-Health-and-Welfare-at-Work-Chemical-Agents-Amendment-Regulations-2015.pdf

For transport of dangerous goods by road, the statutory instrument giving effect to Directive 2008/68/EC is named the "European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment)(Amendment)Regulations 2019" (see http://www.irishstatutebook.ie/eli/2019/si/277/made/en/pdf). This instrument is issued under the "European Communities Act, 1972 (No. 27 of 1972) (as amended by section 2 of the European Communities Act 2007 (No. 18 of 2007) "

European legislation may also be of relevance to some European countries which are not members of the EU but which may be bound to apply EU Regulations or directives because of agreements such as the European Economic Area Agreement concerning the EU, Iceland, Liechtenstein and Norway, or because of bilateral agreements with the EU (e.g. Switzerland). For example the Swiss chemical legislation is contained in the "Federal Act on Protection against Dangerous Substances and Preparations" ("Chemical Act", "Chem A") (see https://www.admin.ch/opc/en/classified-compilation/19995887/index.html) and the related Swiss Federal Council "Ordinance on Protection against Dangerous Substances and Preparations "("Chemical Ordinance", "Chem O") requires the application of the technical provisions of the EU CLP Regulation for classification, labelling and packaging of chemicals, and of Annex II of the EU REACH Regulation for the issuance of SDSs. (See https://www.admin.ch/opc/en/classified-compilation/20141117/index.html).

Up to 31 December 2020, the United Kingdom of Great Britain and Northern Ireland (UK) was bound to apply all relevant EU instruments as mentioned under section 3 above. As the UK is no longer a member State of the EU, since 1 January 2021 it is no longer bound to apply these instruments except as otherwise specified in the "Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part".

In relation to CLP, at the time of writing this Guidance Document, in Great Britain, the EU CLP has been replaced by a "GB CLP". All EU CLP classification and labelling provisions in force on 31 December 2020 remained in the GB CLP, but since the GB CLP will be managed separately this does not mean that the GB CLP will continue to maintain the same provisions as in the EU CLP.

Northern Ireland is still bound to apply the EU CLP, except for direct supply of chemicals to the Great Britain market, for which the GB CLP applies¹⁷.

Similarly, the EU REACH has been replaced by a UK REACH, retaining the same principles, but applicable to access to the Great Britain market, while the EU REACH continues to apply to access to the Northern Ireland market.

For inland transport of dangerous goods, the UK, which is contracting party to ADR and RID, continues to require the application of the ADR and RID provisions to domestic traffic but is now free to deviate at least for domestic traffic in Great Britain.

9. United States of America (Sectoral national laws and regulations)

The GHS implementation approach in the USA is sectoral, i.e. there is no central regulation such as the EU CLP, and GHS legal implementation would have to be done through amendments to the current various sectoral pieces of legislation. For the time being, this has been done in two sectors only, transport and industrial workplace.

Transport

National transport of dangerous goods is regulated by the Hazardous Materials Regulations (Title 49 of the Code of Federal Regulations) (more precisely 49 CFR Parts 100 -185) which are issued under the Hazardous Material Transportation Act (Federal hazardous material transportation law) (see also https://www.phmsa.dot.gov/standards-rulemaking/hazmat/federal-hazardous-materials-transportation-law-overview). These Regulations take full account of the UN Recommendations on the Transport of Dangerous Goods and are regularly updated. They cover transport by all modes of transport, including pipelines. The latest version takes into account the 20th revised edition of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, and related international conventions, as well as GHS Rev.7 to the extent applicable to transport (See the Final rule 85 FR 27810¹⁸ of 11 May 2020).

Workplace

The relevant statutory document is the Hazard Communication Standard which has been issued by the Occupational Safety and Health Administration (OSHA) of the USA Department of Labor under the Occupational Safety and Health (OSH) Act of 1970 which allows the Secretary of Labor to promulgate standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment". The Hazard Communication Standard (HCS) is contained in Title 29 of the Code of Federal Regulations (29 CFR, Parts 1910, 1915, and 1926). It was revised in 2012 to take account of the relevant provisions of GHS Rev.3. The text was published in the Federal Register and is available at https://www.osha.gov/FedReg osha pdf/FED20120326.pdf together with ample information on the process of amendment to the previous HCS, justification for harmonizing the standard with the GHS, including cost/benefit analysis and outcome of consultations with the industry, labor organizations and civil society.

It specifies the GHS classes and hazard categories covered by the revised standard, and in particular that it does not cover the GHS hazard to the aquatic environment. Similarly, the standard requires the use of the GHS sixteen sections SDS format, but does not enforce sections 12-15 of the SDS because the information required under these sections is outside OSHA's jurisdiction.

Additional information and guidance is available at OSHA's website https://www.osha.gov/dsg/hazcom/index.html

Special attention is drawn to a PowerPoint presentation on the said website that summarizes the main features of this revision, see https://www.osha.gov/dsg/hazcom/schc_alliance_webinar_20120809.pptx

OSHA issued, in early 2021, a notice of proposed rulemaking (NPRM) to amend the HCS (§ 1910.1200), proposing to modify the HCS to maintain conformity with the 7th revised edition of the GHS and selected provisions of the 8th revised edition, align certain provisions with Canada and other U.S. agencies, and address issues that have developed since implementation of the 2012 standard¹⁹. The deadline for comments was 19 April 2021.

Other sectors

The USA legislation addresses chemical classification and hazard communication in other relevant sectors, but this legislation has not yet been brought in line with the GHS, which means that the hazard classification criteria and labelling requirements in these sectors are not in line with the global GHS context nor with the national transport or workplace legislation.

The legislations in question are mainly as follows:

Agriculture

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and related Title 40, Sub-Chapter E, Pesticides Program of the Code of Federal Regulations, and notably Part 152 on Pesticide Registration and Classification Procedures and Part 156 on Labeling Requirements for Pesticides and Devices), administered by the Environment Protection Agency (EPA)

EPA has not adopted GHS for pesticide product classification and labeling.

Following implementation of the GHS by OSHA for the workplace and its implications for Safety Data Sheets, EPA issued a Pesticide Registration Notice ((PR) (Notice 2012-1) (https://www.epa.gov/sites/production/files/2014-04/documents/pr2012-1.pdf) on 20 April 2012, to clarify its policy in order to avoid potential inconsistencies between EPA-approved labels for pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the SDSs that OSHA requires for these chemicals under the Hazard Communication Standard (HCS). Information on how GHS implementation in the GHS affects pesticide labelling can be found on the EPA website (https://www.epa.gov/pesticide-labels/pesticide-labels-and-ghs-comparison-and-samples)

Control

Other relevant acts administered and regulated by EPA are:

- Toxic Substances Control Act (TSCA);
- Federal Food, Drug, and Cosmetic Act (FFDCA)

Consumers

Consumer Product Safety Act and the Federal Hazardous Substances Act (FHSA) and related Title 16 of the Code of Federal Regulations, Part 1500 on Hazardous Substances and articles²⁰ administered by the Consumer Product Safety Commission (CPSC).

In 2006, as it moved forward with its role in implementation of the GHS, the Commission decided that it would adhere to the mandates for risk-based decision making of the Consumer Product Safety Act, Federal Hazardous Substances Act, Flammable Fabrics Act, and Poison Prevention Packaging Act. In particular, with respect to the labelling of chronic health hazards in the consumer product setting, the Commission intended to follow the risk-based labelling option specified under Annex 5 of the GHS.

With the risk-based decision-making approach as its compass, it was expected that the CPSC staff assessment of GHS implementation issues then underway would identify questions that would require issuing guidance, revising existing regulations, and/or in some instances, seeking statutory revision. As the Commission addressed the recommendations resulting from the staff assessment it would also seek input on those aspects of GHS implementation that are of significant priority to stakeholders, including consumers, manufacturers, distributors and retailers of consumer products.

In 2007, CPSC compared selected portions of the Federal Hazardous Substances Act (FHSA) regulatory requirements to the Globally Harmonized System (GHS) for classification and labeling. This comparison identified some of the technical differences between the FHSA and GHS. A preliminary legal feasibility assessment was also conducted to assess what, if any, changes would be needed to the FHSA should certain provisions of the GHS be adopted and implemented. The work indicated that a more complete technical comparison was needed.



10. Canada (National law and regulations)

The situation in Canada is comparable to that in the United States, i.e. the GHS may be considered as legally implemented in the transport and workplace sectors, but not yet in agriculture nor in the consumer sectors

Transport

National legislation is based on the UN Recommendations on the Transport of Dangerous Goods and is therefore consistent with the GHS as applicable to this sector. It consists of Transportation of Dangerous Goods Regulations (TGDR) Transportation of Dangerous Goods Regulations (TDGR) (https://tc.canada.ca/en/dangerous-goods/tdg-regulations)

Issued under a Transportation of Dangerous Goods Act, 1992

Transportation of Dangerous Goods Act, 1992 (https://tc.canada.ca/en/dangerous-goods/trans-portation-dangerous-goods-act).

Workplace

The Workplace Hazardous Materials Information System (WHMIS) is Canada's national hazard communication standard for workplace chemicals. WHMIS is implemented through coordinated federal, provincial and territorial legislation. Supplier requirements are outlined at the national level, while each of the provincial, territorial and federal agencies responsible for occupational health and safety has established employer requirements within their respective jurisdictions (https://www.canada.ca/en/health-canada/services/environmental-workplace-health/occupational-health-safety/workplace-hazardous-materials-information-system.html).

WHMIS contains supplier requirements, including the cautionary labelling of containers and (material) safety data sheets ((M)SDS), outlined under the Hazardous Products Act and the Controlled Products Regulations, collectively known as WHMIS 1988.

Following the creation of the GHS, a review was conducted in order to determine the most optimal means for implementing the GHS in Canada for workplace chemicals, whether by revising current legislation, creating new legislation, consolidating, or a combination of options. It was determined the optimal approach was to:

- Amend the existing Hazardous Products Act (amended on June 19, 2014) https://laws-lois. justice.gc.ca/eng/acts/h-3/
- Repeal the Controlled Products Regulations
- Implement the Hazardous Products Regulations (came into force on February 11, 2015) https://laws-lois.justice.gc.ca/eng/regulations/sor-2015-17/index.html



As in the case of US OSHA Hazard Communication Standard, the text of the Hazardous Products Regulations published in the Canada Gazette includes significant information on the background justifying the replacement of the previous regulations, as a "Regulatory Impact Analysis Statement", see Hazardous Products Regulations http://canadagazette.gc.ca/rp-pr/p2/2015/2015-02-11/pdf/g2-14903.pdf

This further required amendments to the Hazardous Materials Information Review Act, as well as the Canada Labour Code.

Collectively, the Hazardous Products Act and the Hazardous Products Regulations, known as WH-MIS 2015, are the Canadian implementation of the GHS, administered by Health Canada. Canada incorporated the 5th revised edition of the GHS into WHMIS, with the exception of the Flammable Gases and Aerosols hazards, which are aligned with the 3rd revised edition of the GHS.

To give suppliers, employers and workers time to adjust to the new system, WHMIS 2015 implementation took place gradually over a three-stage transition period that was synchronized nationally across federal, provincial and territorial jurisdictions (https://www.canada.ca/en/health-canada/services/environmental-workplace-health/occupational-health-safety/work-place-hazardous-materials-information-system/whmis-transition.html).

Through the transition, which ended on 30 November 2018, Health Canada continued to disseminate information and train inspectors through already established stakeholder and partner committees. The Canadian Centre for Occupational Health and Safety, in partnership with Health Canada, developed two e-Courses:

- WHMIS 2015:An Introduction (https://www.ccohs.ca/products/courses/whmis-ghs-intro/);
- WHMIS 2015 for Workers (https://www.ccohs.ca/products/courses/whmis_workers/).

Other sectors

The other pieces of legislation in Canada that would still need be amended to align with the GHS are:

- Consumer Product Safety Act and associated Consumer Chemicals and Container Regulations, 2001
- Pest Control Products Act and associated regulations

Canada-US alignment

At the time of writing this document, Canada is working on aligning the Hazardous Products

Regulations with the 7th revised edition of the GHS. This initiative falls under the Canada-United States (U.S.) Regulatory Cooperation Council, where in accordance with the Memorandum of Understanding between Health Canada – Healthy Environments and Consumer Safety Branch and the U.S. Department of Labor – Occupational Safety and Health Administration, Canada and the U.S. will continue to maintain alignment on the implementation of the GHS. (https://www.canada-united-states-regulatory-cooperation-council.html).

It is also noted that the GHS is specifically referenced in the recently concluded Canada-United States-Mexico Agreement (CUSMA) with "potential areas of cooperation include: (a) their respective implementation of the United Nations Globally Harmonized System for Classification and Labeling of Chemicals (GHS)."²¹

11. Australia (recommendatory sectoral federal laws and regulations and individual states sectoral laws with reference to federal recommended regulations)

In order to harmonize the legislations of its various states and territories, Australia has a system which consists in issuing model acts, regulations and codes of practice at the national level, which do not have legal effects per se but are directed to all jurisdictions (national, individual states and territories) which are competent for enacting their own legislation. These model instruments take legal effect only once implemented through the legislation of the said jurisdictions.

Transport

The instruments that implement the GHS in the transport sector (inland national transport by road and rail) are:

- the Australian Dangerous Goods Code (ADG Code) (see https://www.ntc.gov.au/sites/default/files/assets/files/ADG%20Code%207.7 0.pdf)
- the Australian Code for the transport of explosives by road and rail (see https://www.safe-workaustralia.gov.au/system/files/documents/1702/australian_code transport explosives-road rail 3rd edition.pdf)

Both are based on the UN Recommendations on the Transport of Dangerous Goods and reflect the classification and labelling provisions of the GHS to the extent applicable to transport.

The ADG Code is issued by the National Transport Commission and should be read in conjunction with the specific dangerous goods transport legislation that have been enacted in the relevant

state or territory. Such jurisdictional legislation is based on the Model Act on the Transport of Dangerous Goods by Road and Rail and the Model Subordinate Instrument on the Transport of Dangerous Goods by Road and Rail, also issued by the National Transport Commission. (https://www.legislation.gov.au/Details/F2007L03868)

The Australian Code for the transport of explosives by road and rail has been prepared by the Australian Forum of Explosives regulators (AFEr) and was endorsed by the Workplace relations Minister's Council which assumes responsibility for coordinating national uniform explosives laws in Australia.

Workplace

Safe Work Australia is the national policy body responsible for the development and evaluation of the model Work Health and Safety laws. These are available at https://www.safeworkaustralia.gov.au/law-and-regulation/model-whs-laws#model-whs-regulations and are comprised of:

- a model WHS Act
- model WHS Regulations, in particular Part 7.1 and Schedules 6, 7, 8, 9, 11, 12, 13, and 15
- model Codes of Practice (managing risks of hazardous chemicals in the workplace; labelling of workplace hazardous chemicals; preparation of safety data sheets for hazardous chemicals)

Additional information may be found on the SafeWork Australia website, see

- https://www.safeworkaustralia.gov.au/chemicals
- https://www.safeworkaustralia.gov.au/topic/labelling-chemicals
- https://www.safeworkaustralia.gov.au/sds

The model laws have been developed for implementation by all jurisdictions (that is, the national level, states and territories). However, they do not apply in a jurisdiction unless the jurisdiction has separately taken action to implement the laws as their own WHS laws.

In the case of Australia, it is interesting to note that, contrary to the approaches followed by the EU, USA and Canada, the model WHS Regulations do not reproduce extensively the text of the GHS classification criteria, but rather refers to the text of the GHS in this respect (See Box 7).

Box 7: Australian Model WHS Regulations

Definitions (Part 1.1, section 5)

Hazardous chemical means a substance, mixture or article that satisfies the criteria for a hazard class in the GHS (including a classification referred to in Schedule 6), but does not include a substance, mixture or article that satisfies the criteria solely for one of the following hazard classes:

- a. acute toxicity—oral—category 5;
- b. acute toxicity—dermal—category 5;
- c. acute toxicity—inhalation—category 5;
- d. skin corrosion/irritation—category 3;
- e. serious eye damage/eye irritation—category 2B;
- f. aspiration hazard—category 2;
- g. flammable gas—category 2
- h. acute hazard to the aquatic environment—category1, 2 or 3
- i. chronic hazard to the aquatic environment—category1, 2, 3 or 4,
- j. hazardous to the ozone layer.

Correct classification (Schedule 9, Part 1)

1. A substance or mixture (other than a research chemical, sample for analysis or waste product) is correctly classified if a determination is made about whether the substance or mixture can be classified into a hazard class under the GHS including a mixture classification referred to in Schedule 6.

Note: The Schedule 6 tables replace some tables in the GHS.

- 2. A substance or mixture that is a research chemical, sample for analysis or waste product is correctly classified if, so far as is reasonably practicable having regard to the known or suspected properties of the substance or mixture:(a) a determination is made about the identity of the substance or mixture; and (b) a determination is made about whether the substance or mixture can be classified into a hazard class under the GHS.
- 3. An article that contains a substance or mixture that may be released during the use, handling or storage of the article is correctly classified if the substance or mixture is correctly classified.

12. New Zealand (National sectoral or multisectoral laws and regulations referring to UN text) Management of hazardous substances and control

New Zealand was the first country in the world to legally implement the GHS, in 2006, through its national legislation, mainly the Hazardous Substances and New Organisms (HSNO) Act 1996 and related regulations ("notices") issued by the Environment Protection Agency in order to control the import, manufacture and use (including disposal) of manufactured chemicals that have hazardous properties defined in accordance with GHS criteria.

For the text of the HSNO Act, see https://legislation.govt.nz/act/public/1996/0030/latest/ DLM381228.html

The latest versions of the related notices are:

- Hazardous Substances (Classification) Notice 2017, see <a href="https://www.epa.govt.nz/assets/Up-loads/Documents/Hazardous-Substances/EPA-Notices/b92eb74c04/Hazardous-Substances-EPA-Notices-EPA-Notice
- Hazardous Substances (Labelling) Notice 2017, see https://www.epa.govt.nz/assets/Uploads/
 Documents/Hazardous-Substances/EPA-Notices/31fb7a7c7d/Hazardous-Substances-Labelling-Notice-2017.pdf
- Hazardous Substances (Safety Data Sheets) Notice 2017, see https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/EPA-Notices/89b79e19ad/Hazardous-Substances-Safety-Data-Sheets-Notice-2017.pdf

Information on these notices and on other notices issued under the HSNO Act may be found on the EPA website at https://www.epa.govt.nz/industry-areas/hazardous-substances/rules-for-hazardous-substances/

These notices were based on GHS Rev.5.

The classification notice 2017 has been revised into a "Hazardous Substances (Classification) Notice 2020", for entry into force on 30 April 2021, based on GHS Rev.7. Some significant changes have been made, since this notice now refers directly to the GHS classes and categories, without reproducing any GHS text, see draft (made available pending publication in the Gazette) <a href="https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/GHS2/Exposure Draft-Hazardous-Substances-Hazardous-Substa

GHS classes and categories not subject to the classification are indicated in Part C, clause 10, sub-clauses (4) and (5), see box 8.

Box 8: New Zealand, Hazardous Substances (Classification) Notice 2020

Clause 10, Hazardous substance classification under GHS

- 1. For the purposes of clause 9, the classes and categories of hazardous substances in the GHS, as modified by this notice, are part of the hazard classification system.
- 2. A hazardous substance is correctly classified if it is classified in accordance with the GHS as modified by this notice, or in accordance with clause 15.
- 3. For the purpose of subclause (2), the definitions in the GHS apply; however, to the extent of any inconsistency with a provision in this notice, the provision of this notice prevails.
- 4. Despite subclauses (1) and (2), the following classes or categories in the GHS are not part of the hazard classification system:
 - ► acute oral toxicity Category 5;
 - acute dermal toxicity Category 5;
 - ► acute inhalation toxicity Category 5;
 - skin irritation Category 3;
 - ► aspiration hazard Category 2;
 - ► hazardous to the aquatic environment acute Categories 2 and 3;
 - ► hazardous to the ozone layer.
- 5. The GHS category eye irritation Category 2 is part of the hazard classification system, however:
 - ► the subcategories 2A and 2B are not adopted;
 - ► substances that would fall into those subcategories fall into eye irritation Category 2.

The other notices are also being reviewed accordingly and the draft, with track changes showing expected modifications are also available on the EPA website at https://www.epa.govt.nz/pub-lic-consultations/decided/proposal-to-change-the-classification-system-for-hazardous-substanc-es-in-new-zealand/exposure-drafts/

Workplace

The Health and Safety at Work Act, 2015 (HSW Act) gives Worksafe New Zealand the responsibility for establishing workplace controls for hazardous substances, and this Agency is the principal enforcement and guidance agency in workplaces. In 2017, Worksafe New Zealand issued the Health and Safety at Work (Hazardous Substances) Regulations 2017, and this led to a share of responsibilities between EPA and Worksafe explained on the EPA website https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Guidance/c474ba8540/Roles-summa-ry-EPA-WorkSafe.pdf

Information on Worksafe New Zealand may be found at https://www.worksafe.govt.nz/top-ic-and-industry/hazardous-substances/

In the HSW (Hazardous Substances) Regulations 2017, hazardous substances are defined by reference to section 2 (1) of the HSNO Act, except that ecotoxicity is not covered by the Regulations. References are also made to the notices issued by EPA under the HSNO Act.

Transport

Land transport of dangerous goods is regulated in New Zealand through the Land Transport Rule: Dangerous Goods 2005, as amended²². The rule incorporates by reference relevant parts of the United Nations Recommendations on the Transport of Dangerous Goods and related legal instruments (IMDG Code, ICAO Technical Instructions) as well as New Zealand Standard 5433:2012 "Transport of dangerous goods on land".

Part 24A of the Maritime Rules (carriage of cargoes—dangerous goods) and Part 92 of the Civil Aviation Rules (carriage of dangerous goods) apply to hazardous substances transported by sea or air and require the application of the international instruments referred to in sub-section 4.1 of this Guidance Document both for national and international transport, which implies implementation of the GHS to the extent it applies to the transport sector.

As some notices issued by EPA under the HNSO Act and the HSW (Hazardous Substances) Regulations 2017 have some effects on transport, the Ministry of Transport has issued a document "Dangerous Goods Regulatory System Map" describing the components of the current regulatory system for managing dangerous goods across the transport system in New Zealand, including interactions between those components. It explains the relationship between the international dangerous goods legal frameworks, the domestic dangerous goods legal frameworks and the overlapping HSNO Act and WSH Act frameworks, as well as some other peripheral Acts, see https://www.transport.govt.nz//assets/Uploads/Report/DangerousGoodsRegulatorySystemMap.pdf



13. China (National law and regulations referring to national standards plus national standards)

Management of Hazardous Chemicals

The safe management of hazardous chemicals is regulated by Decree 591 of the State Council of China "Regulations on the Safe Management of Hazardous Chemicals". A non-official translation in English has been made by an independent firm named "Chemical Inspection and Regulation Service (CIRS)" and is freely accessible on their website at http://www.cirs-reach.com/China Chemical Regulation/Regulations on safe management on hazardous chemicals China 2011.

Article 3 of the decree states: "Hazardous chemicals refer to highly toxic substances and other chemicals which are toxic, corrosive, explosive, flammable or are combustion-supporting and can do harm to people, facilities or the environment. The Catalogue of Hazardous Chemicals should be determined, promulgated and properly adjusted in accordance with the hazard identification and classification by the State Administration of Work Safety as well as the Ministry of Industry and Information Technology, the public security authorities, the Ministry of Environmental Protection, the Ministry of Health, the quality supervision, inspection and quarantine department, the transport department, the railway department, the civil aviation department and the agricultural department under the State Council."

The Regulations further determine the role and responsibilities of each governmental entity concerned. These entities have issued various orders in accordance with their respective jurisdictional competences, e.g. GHS SDSs and labels are required by new substance notifications under MEP Order 7 and HazChem registration under SAWS Order 53

Article 15 of the decree states that manufacturers of hazardous chemicals shall provide safety data sheets consistent with the hazardous chemicals that are produced, post or affix a chemical safety label on the package (including outer packaging). The contents in safety data sheets and chemical safety labels should meet the requirements of relevant national standards. Manufacturers should make an announcement and amend the safety data sheets and chemical safety labels in time if new hazard information of the hazardous chemical is discovered.

Decree 591 also prohibits distributors from selling hazardous chemicals without SDSs and labels. For imported and exported chemicals, the Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) checks the compliance of labels and Safety Data Sheets with the applicable national standards and regulations implementing the GHS (Announcement No.30 of 2012). In this respect, China issued a wide range of GHS compulsory or recommendatory national standards intended for GHS implementation that have to, or may be used to, give effect to the various



sectoral legislations.

At present (February 2021), the applicable standards are:

For the general rule on classification and hazard communication:

For classification (mandatory application):

- GB 13690–2009 General rule for classification and hazard communication of chemicals (applicable as from 1 May 2010, but expected to be replaced by GB 30000.1-2013)
- GB 30000.2-2013: Explosives
- GB 30000.3-2013: Flammable gases
- GB 30000.4-2013: Aerosols
- GB 30000.5-2013: Oxidising gases
- GB 30000.6-2013: Gases under pressure
- GB 30000.7-2013: Flammable liquids
- GB 30000.8-2013: Flammable solids
- GB 30000.9-2013: Self-reactive substances and mixtures
- GB 30000.10-2013: Pyrophoric liquids
- GB 30000.11-2013: Pyrophoric solids
- GB 30000.12-2013: Self-heating substances and mixtures
- GB 30000.13-2013: Substances and mixtures which in contact with water release flammable gases
- GB 30000.14-2013: Oxidizing liquids
- GB 30000.15-2013: Oxidizing solids
- GB 30000.16-2013: Organic peroxides
- GB 30000.17-2013: Corrosive to metals
- GB 30000.18-2013: Acute toxicity
- GB 30000.19-2013: Skin/corrosion irritation
- GB 30000.20-2013: Serious eye damage/irritation
- GB 30000.21-2013: Respiratory or skin sensitization
- GB 30000.22-2013: Germ cell mutagenicity
- GB 30000.23-2013: Carcinogenicity
- GB 30000.24-2013: Reproductive toxicity
- GB 30000.25-2013: Specific target organ toxicity-Single exposure
- GB 30000.26-2013: Specific target organ toxicity-Repeated exposure
- GB 30000.27-2013: Aspiration hazard
- GB 30000.28-2013: Hazardous to the aquatic environment
- GB 30000.29-2013: Hazardous to the ozone layer

GB 30000.2-2013 to GB 30000.29-2013 are fully aligned with GHS Rev.4 and are of mandatory application since 1 November 2014, replacing former standards issued in 2006.

For **labelling** (mandatory application):

GB 15258–2009: General rules for preparation of precautionary labels for chemicals (applicable as from 1 May 2010)

GB 190-2009 - "Packaging Labels for Dangerous goods" (based on 15th revised edition of the UN Recommendations on the Transport of Dangerous Goods)

For **Safety Data Sheets** (Recommended application)

GB T 16483–2008: Safety Data Sheet for chemical products content and order of sections (applicable as from 1 February 2009)

GB T 17519-2013 Guidance on the compilation of safety data sheet for chemical products (applicable as from 31 January 2014)

Useful information on the China Regulatory System is available on the CIRS website:

Decree 591:

http://www.cirs-reach.com/news-and-articles/regulations-on-safe-management-of-hazard-ous-chemicals-in-china-decree-591.html

China GHS- Classification, Labelling, Packaging and SDSs:

http://www.cirs-reach.com/news-and-articles/china-ghs-classification,-labeling-and-packaging-of-chemcials-and-sds-in-china.html

China Hazardous Chemical Regulations:

http://www.cirs-reach.com/news-and-articles/hazardous-chemical-management-regulations-in-china-2015.html

Transport

For international transport of dangerous goods by air and sea, China applies the international regulations mentioned in sub-section 4.1.

For domestic traffic, the regulatory system is organized in accordance with Chapter 5 (Safety management of transportation) (articles 43 to 65) which defines the roles and responsibilities of the various administrative departments responsible for regulating each mode transport.

The modal regulations apply the classification and labelling provisions contained in the UN Recommendations on the Transport of Dangerous Goods.



Two national standards, consistent with the 16th revised edition of the UN Recommendations on the Transport of Dangerous Goods, and of mandatory application, make the link between the transport regulations and the GHS:

GB 6944-2012: Classification and code of dangerous goods

GB 12268-2012: List of dangerous goods.

For road transport of dangerous goods, the Ministry of Transport issued announcement No.68 of 6 September 2018, on the issuance of standard JT/T617-2018 "Regulations concerning road transportation of dangerous goods". The revised standard takes account of the provisions of the UN Recommendations on the Transport of Dangerous Goods and Model Regulations and the ADR. It contains seven parts (JT/T617.1 to JT/T617.7) addressing: general provisions, classifications, listing of dangerous goods; use of transport packagings; consignment procedures (covering labelling/marking/placarding); Conditions of carriage, loading, unloading and handling; Transport conditions and operational requirements. The standard was implemented as from 1 Dec. 2018. These standards were made applicable as from 1 January 2020 by the 2019 "Measures for Safety Administration of Road Transport of Dangerous Goods"

14. Japan (National laws and regulations referring to national standards)

National standards JIS Z 7252:2014 (Classification) and JIS Z 7253:2012 (Hazard communication: Labelling and SDSs), based on GHS Rev.4, are currently applicable. Revised versions JIS Z 7252:2019 and JIS Z 7253:2019, based on GHS Rev.6, may already be used but will become of mandatory application as from May 2022.

The following GHS hazard categories are not included:

- acute toxicity category 5;
- skin irritation category 3;
- aspiration toxicity category 2.

GHS labels and Safety Data Sheets are mandatory only for chemicals regulated under the Industrial Safety and Health Law, the Pollutant Release and Transfer Register (PRTR) law and the Poisonous and Deleterious Substances Control Law. However, a wider implementation of GHS classification and hazard communication elements is encouraged. Implementation for consumer products is voluntary.

Other relevant laws are:

Chemical Substances Control Law, see https://www.meti.go.jp/policy/chemical-management/en-glish/cscl/index.html

Fire Service Law, see http://www.japaneselawtranslation.go.jp/law/detail/?ft=2&yo=%E6%B6%888%E9%98%B2%E6%B3%95&ky=&page=1&re=02



Although Japan applies international legal instruments for carriage of dangerous goods by air and sea, domestic inland transport of dangerous goods is regulated under different laws depending on the hazards presented by the dangerous goods (e.g. Fire Service Law for chemicals with physical hazards) and, for domestic inland transport, the system is not fully in line with the UN Recommendations on the Transport of Dangerous Goods and the GHS

GHS classification results as well as several support tools and guidance documents are available on the website of the National Institute of Technology and Evaluation, see https://www.nite.go.jp/chem/english/ghs/ghs_manuals.html.

GHS classification tool for mixtures as well as other support tools are available on the website of the Ministry of Economy, Trade and Industry (see https://www.meti.go.jp/policy/chemical_management/english/index.html).

15. South Africa (non-mandatory national standards; mandatory regulations referring to the UN GHS text)

The South African Bureau of Standards developed and published standard SANS 1024:2019, "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)" on the basis of GHS Rev.4. This standard is not legally binding on its own.

In March 2021, the Minister of Employment and Labour of South Africa issued, under section 43 of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), Regulations on Hazardous Chemical Agents, 2021²³, implementing the GHS in the workplace sector. The Regulations shall apply from 29 September 2022. They define the GHS classes and categories which are regulated, and require classification of Hazardous Chemical Agents accordingly, as well as their labelling and issuance of SDSs in accordance with the GHS. The GHS is defined as the "Globally Harmonized System of classification and labelling of chemicals, a guidance document developed by the United Nations for standardising and harmonising the classification and labelling of chemicals globally, as may be updated from time to time", which means that, in principle, there is no need to update the Regulations whenever the GHS is updated as long as the GHS classes and categories subject to the Regulations remain the same.

16. Other countries

In addition to the examples listed in the above sections, information on the status of implementation of the GHS in other countries may be found on the UNECE website at https://unece.org/ghs-implementation-0.



17. Political aspects

Because of the different status of their economic and social development, countries do not have the same political priorities. In relation to chemical safety management, some countries have developed very comprehensive systems of laws, regulations and standards addressing chemical classification and related hazard communication. When administrations or stakeholders in these countries want to modify their existing regulatory systems for the purpose of implementing the GHS, the difficulty is to provide justification and arguments to rulemakers or political lawmakers for amending well-functioning systems, or vice-versa convincing stakeholders in industry or civil society that they would have to adapt to a new system, bearing in mind the workload implied for the administrations and lawmakers, the costs of awareness-raising and training, and possibly the costs for the chemical industry. In some countries, the chemical safety regulatory system may be basic or even simply absent in some or all sectors. The development of chemical safety regulatory systems, or even safety regulations in general, may not be a political priority compared with more crucial economic and social development needs such as development of health systems, agriculture and food production, energy, transport systems, and industrial development.

In most countries that have implemented the GHS, it has been necessary to demonstrate the advantages of implementing the GHS not only in terms of social safety benefits linked to the existence of appropriate safety regulations but also in terms of economic benefits linked to intersectoral harmonization in a given country and trade facilitation linked to international multisectoral harmonization. An example is given in section 9 above for the United States of America. Another example is the preparatory work undertaken by the European Commission in advance of the proposal for the EU CLP Regulation, see https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0355:FIN:EN:HTML

However, there are other political incentives that can be used to convince governments and law-makers to initiate the development of legislation implementing the GHS. Governments are usually receptive to international mandates provided in resolutions, decisions or even recommendations emanating from the highest bodies of international organizations such as the main bodies of the United Nations and its specialized agencies, United Nations Conferences, or other intergovernmental organizations to the extent they are addressed to their own members.



For justifying legal work on GHS implementation, the following examples of incentives may be referred to:

Multisectoral incentives (General)

United Nations Conference on Environment and Development (UNCED), Rio de Janeiro, June 1992

Agenda 21, para 19.27; "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".

World Summit on Sustainable Development (WSSD), Johannesburg, September 2002 WSSD Plan of implementation, para. 23(c): (WSSD)..." encourage countries to implement the GHS as soon as possible with a view to having the system fully operational by 2008."

United Nations Economic and Social Council (ECOSOC)

Resolutions 2003/64 of 25 July 2003, 2005/53 of 27 July 2005, 2007/6 of 23 July 2007, 2009/19 of 29 July 2009, 2011/25 of 27 July 2011, 2013/25 of 25 July 2013, 2015/7 of 8 June 2015, 2017/13 of 8 June 2017 and 2019/7 of 6 June 2019 on the work of the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification of Chemicals

Operative Paragraphs 3 and 5 of Section B of Resolution 2003/64, reiterated in equivalent form in subsequent resolutions:

"3. Invites all Governments to take the necessary steps, through appropriate national procedures and/or legislation, to implement the Globally Harmonized System, as soon as possible and no later than 2008;"

. . .

"5. Invites the regional commissions, United Nations programmes, the specialized agencies and other organizations concerned to promote the implementation of the Globally Harmonized System and, where relevant, to amend their respective legal international instruments addressing transport safety, work safety, consumer protection or the protection of the environment so as to give effect to the Globally Harmonized System through such instruments;"

International Conference on Chemicals Management

First session, 4-6 February 2006, Dubai

The Conference adopted the Dubai Declaration on International Chemicals Management and the Overarching Policy Strategy (OPS). The Conference also recommended the use and further development of the Global Plan of Action as a working tool and guidance document. Together these

three documents constitute the Strategic Approach to International Chemicals Management (SA-ICM)²⁴.

According to para. 15 b. of the OPS, one of the objectives of SAICM is to ensure that information on chemicals throughout their life cycle is available for all stakeholders and that such information is disseminated in appropriate languages by making full use of, among other things, the media, hazard communication mechanisms such as the GHS and relevant provisions of international agreements. According to para. 15 h, another objective is to promote implementation of the common definitions and criteria contained in the GHS.

The GHS is also included as a SAICM work area in the Global Plan of Action, as well as the Overall Orientation and Guidance to guide implementation:

"Collection and systems for the transparent sharing of relevant data and information among all relevant stakeholders using a life cycle approach, such as the implementation of the Globally Harmonized System of Classification and Labelling of Chemicals"

It is expected that a new policy framework (replacing the OPS) will be finalized in 2021 or 2022²⁵, and it is likely that the GHS will be re-affirmed as a fundamental element of the sound management of chemicals and waste. Such an affirmation and associated targets and indicators will provide further political support to the importance of the GHS.

Organization for Economic Cooperation and Development (OECD)

Decision-Recommendation of the Council on the Cooperative *Investigation and Risk Reduction of Chemicals, OECD/LEGAL/0441

11

HAVING REGARD to the work done by the United Nations in the area of chemical safety, in particular in the development of the Globally Harmonised System of Classification and Labelling of Chemicals(GHS), an internationally agreed system for hazard classification and hazard communication for chemicals for improving harmonisation globally;

HAVING REGARD to paragraph 23(c) of the Plan of Implementation of the World Summit on Sustainable Development, which encourages United Nations' members to implement the GHS; HAVING REGARD to the Dubai Declaration on International Chemicals Management and the Overarching Policy Strategy, adopted by the International Conference on Chemicals Management of 4 to 6 February 2006, as part of the Strategic Approach to International Chemicals Management (SAICM);

HAVING REGARD to the Resolution of the Council on the Implementation of the Strategic Ap-



http://www.saicm.org

²⁵ The COVID-19 pandemic has severely impacted international consultations and agreements; no date is yet set to finalize the new framework

proach to International Chemicals Management (SAICM) [C(2008)32];

.....

IX. DECIDES that Adherents shall implement the GHS in order to further hazard communication in the supply chain. Such implementation can be done by Adherents applying those elements of the GHS that are appropriate to them and may vary by product category and stage in the lifecycle"

Sectoral incentives

Agriculture (pesticides)

WHO/FAO Recommendations concerning implementation of GHS: see under sub-section 9.2 above "Guidelines for the registration of pesticides, 2010" and "Guidelines on Good Labelling Practices for Pesticides (revised, August 2015)"

Southern Africa Development Community (SADC): Guidelines on Pesticide Management and risk reduction (November 2019)

"We

Governments of[SADC Member States)

.

ARTICLE 12 Classification and Labelling of Pesticides

- 1. Member States are encouraged to adopt the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the hazard classification of pesticides.
- 2. Member States are encouraged to ensure that all pesticides which are distributed or sold in the country are properly labelled in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the FAO/WHO Guidelines on Good Labelling Practice for Pesticides (Supplement 4). "

Transport

United Nations General Assembly

Resolution 74/299 of 31 August 2020 on "Improving global road safety":

"The General Assembly

. . .

7.Reaffirms the role and importance of the United Nations legal instruments on road safety, such as the 1949 Convention on Road Traffic, the 1968 Convention on Road Traffic, the 1968 Convention on



Road Signs and Signals, the 1958 and 1998 agreements on technical vehicle regulations, the 1997 agreement on periodic technical inspection of vehicles and the 1957 agreement on the transport of dangerous goods, in facilitating road safety at the global, regional and national levels, and commends Member States that have acceded to these international legal instruments on road safety;

8.EncouragesMember States that have not yet done so to consider becoming contracting parties to the United Nations legal instruments on road safety and, beyond accession, applying, implementing and promoting their provisions or safety regulations;

...."

United Nations Economic and Social Council (ECOSOC)

Recurrent resolutions on the work of the Committee of experts on the Transport of Dangerous Goods (1953-1999) and, since 2001, on the work of the Committee of experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification of Chemicals. Last one: Resolution 2019/7, section A (Transport of Dangerous Goods), operative para. 4:

"4. Invites all interested Governments, the regional commissions, the specialized agencies and the international organizations concerned to take into account the recommendations of the Committee when developing or updating appropriate codes and regulations;"

United Nations Economic and Social Commission for Asia and Pacific (ESCAP)

Publication in 1997 of Guidelines for the Establishment of National and Regional Systems for Inland Transportation of Dangerous Goods, recommending the implementation of the United Nations Recommendations on the transport of dangerous goods

Workplace

Completion of the GHS was recognized by ILO as a major achievement in the sense that the GHS fully reflected the principles defined in ILO Chemicals Convention, 1990 (No.170) and its accompanying Recommendations,1990 (No. 177). It was endorsed unanimously by its Governing Body in November 2001. The Governing Body noted in particular that it was the first time within the ILO that a non-binding technical standard with universal coverage had been elaborated fully on a consensus basis and through voluntary cooperation between national institutions and various intergovernmental, regional and non-governmental organizations. The ILO was fully recognized as the initiator and leader in bringing the GHS project to completion²⁶.

Examples of regional incentives

Southern Africa Development Community (SADC)

SADC, through its Technical Regulations Liaison Committee (SADCTRLC) has established the need to put in place a regionally acceptable mechanism for the classification and labelling of chemicals in the region. According to the SADCTRLC report²⁷, the Committee has identified the UN GHS framework as a suitable basis on which to base regional regulation of trade in chemicals in SADC. Regional regulation of chemicals has benefits to the regional chemical industry, government, workers and consumers in general. Additionally, implementation of the GHS facilitates trade by simplifying labelling symbols and safety data sheets presentation through harmonization. As the GHS is being implemented globally, chemicals exported from the region to other parts of the world will be more readily accepted when they are classified and labelled in accordance with UN GHS guidelines. Prior to SADCTRLC resolving to implement chemicals technical regulations based on the UN GHS in the region, four SADC countries had already started work on its implementation in their jurisdictions with two of them aligning their chemicals regulations management to the first edition of the UN GHS. To implement the GHS regionally, the SADTRLC has worked with SADC-STAN to develop a harmonised regional GHS standard upon which the regional GHS technical regulations will be based. Based on the harmonization principles outlined in the TBT Annex to the SADC Protocol on Trade, adoption of the GHS will allow a harmonised labelling and classification system to be applied across the entire value chain of chemicals in the region resulting in enhanced regional performance in the use of chemicals. It is noted that the issues to be addressed through the GHS are cross cutting between Trade, Transport, Labour and Environmental and Consumer Protection departments. For this reason it will be important to have effective coordination between all stakeholders. The successful implementation of the GHS technical regulation regionally will serve as an important test case for broader regional cooperation in the area of technical regulations in SADC; an important activity with respect to trade facilitation and regional integration.

European Union

29

As mentioned under sub-section 4.3, the European Union has comprehensively adapted its chemical management regulatory system to the GHS. The EU continues to attach great importance to the GHS, as shown in the European Commission proposal for a "EU Strategy for Sustainability Towards a Toxic-Free Environment"²⁸. This strategy, approved by the Council of the European Union on 15 March 2021²⁹, put in place a long-term vision for the EU chemicals policy aiming to achieve a high level of protection of human health and the environment, while contributing to strengthening the competitiveness of the EU industry, through the production and use of safe and sustainable chemicals that enable the green and digital transitions by substituting and minimising substances



https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwi8gpXa9rXwAhWP-aQKHRp_Bv8QFjABegQIBBAD&url=http%3A%2F%2Fwww.sadctrlc.org%2FDocuments%2FGHS%2FSADC%2520GHS%2520POLI-CY%2520Document%2520Feb%25202012%2520Draft%25203_1.pdf&usg=AOvVaw3OYg9xiLiJ9kl33zPpbYqn. Final text not available on internet at the time of publishing. Please contact UNITAR for updates and/or the latest version

²⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN

https://www.consilium.europa.eu/media/48827/st06941-en21.pdf

of concern, as far as possible, and phasing out the most harmful chemicals for non-essential societal uses.

The EU Strategy underlines that "A wide diversity of international, regional and national instruments and responses associated with the sound management of chemicals and waste are already in place. However, the global governance remains extremely fragmented, and standards and compliance vary widely across countries. For example, as of 2018, over 120 countries had not implemented the GHS. This fragmentation has hampered the overall impact and effectiveness of existing organisations, programmes and initiatives." As a consequence, the EU will promote, together with industry, the implementation of the GHS as the means for identifying chemical hazards and communicating them to operators, workers and consumers. In its conclusions, the EU Council emphasized that the implementation and the further development of the GHS for classification and labelling was a key instrument for the effectiveness of chemicals management in all countries.

18. Legal analysis

Once a decision to implement the GHS through legal instruments or standards has been taken in a country, and before deciding which option to choose, it is recommended to carry out a legal analysis of the existing situation, in accordance with sub-section 7.5 of the UNITAR/ILO Guidance on the development of a National GHS Strategy for implementation of GHS.

This would focus on understanding the current legislation or regulations for hazard classification and communication, and the changes needed to implement the GHS. Based on the results of the analysis, governments can examine the potential options for the devel-

Box 9: Case Study: Legal Analysis for the GHS in Canada

A GHS legal analysis in Canada revealed key pieces of existing legislation and regulations that may be affected by the GHS:

- ► Hazardous Products Act (PART I), Consumer Chemicals and Containers Regulations, 2001
- ► Hazardous Products Act (PART II), Controlled Products Regulations (for workplace chemicals)
- ▶ Pest Control Products Act, Pest Control Products Regulations
- ► Transportation of Dangerous Goods Act, 1992, Transportation of Dangerous Goods Regulations

Legal review continued in order to determine the most optimal means for implementing the GHS, whether by revising current legislation, creating new legislation, consolidating, or a combination of options. Decisions were taken in relation to workplace chemicals and transport of dangerous goods, but how to address consumer products and pest control products was still under discussion in 2021. opment of a legal implementation framework. Competent authorities adopting the GHS may thus choose different implementing instruments according to their circumstances, needs and already existing legal framework.

A legal analysis provides an overview of the existing regulatory framework, and a context for policy decisions on implementation. The analysis is conducted in two parts, first looking at the current situation, then comparing it with what should be in place to implement the GHS.

The legal analysis can reveal areas for legal or regulatory reform in order to ensure that the national legislative and regulatory framework for chemical hazard communication is compatible and consistent with the GHS. This involves a comparison of existing requirements (if applicable) in all sectors to the provisions of the GHS, identification of GHS requirements not provided in national regulatory system, identification of conflicts between GHS and national requirements, and determination of potential implications of GHS implementation.

The legal analysis can result in a number of scenarios, for example: countries may, for a given sector, find out that a legislative and regulatory framework addressing the above issues is already in place. In this case, the identified gaps would highlight the need to make existing legislation compatible with the GHS (e.g. ensuring the various classification criteria, pictograms, and SDS format are aligned with GHS provisions). The analysis should thus address classification criteria, as well as labelling and SDS requirements for all four sectors affected by the GHS, taking into consideration which elements are appropriate for each. Alternatively, the legal analysis may reveal that for a given sector a regulatory framework for chemical hazard communication is absent, thus pointing to the need for development of new legislation, regulations or standards.

The following are some relevant questions to guide the analysis:

Understanding the current legal environment for chemicals management

Consistency with constitutional block (see annex 2)

- Are there any provisions in the Constitution or other fundamental texts in the constitutional block that would have to be taken into account when deciding on options for the appropriate legislative and regulatory approaches?
- Are there any provisions in the Constitution or other fundamental texts in the constitutionality block that would prevent implementation or partial implementation of the GHS?

Consistency with conventional block (see annex 2)

- Is the country a Contracting Party to multilateral treaties/agreements dealing with chemicals management in general or sectoral aspects of chemicals management such as those listed under 4.1 or 4.2 above or others, and requiring mandatory application of GHS provisions?
- If this is the case, are obligations resulting from membership in these specific treaties well understood by all country administrative departments, even when the scope of the treaty does not necessarily fall within the jurisdictional competency of a given administrative department?
- Is the country a Contracting Party to other multilateral treaties of relevance to chemicals management but not requiring mandatory application of the GHS, such as those listed under section 5?
- In this latter case, has the country taken steps to issue national legislation requiring application of the GHS for the purpose of implementation of the said treaties at national level? If not, can the existing implementing national legislation be amended/ revised to take due account of the GHS?

Consistency with conventional block (regional integration organizations) (see annex 2)

- Is the country a member of a regional integration organization that is empowered to issue supranational rules and regulations (such as the European Union, see subsection 4.3 above)?
 - » If this is the case, has the regional integration organization already issued legal instruments governing, globally or sectorally, chemicals management, that its members are bound to apply or to take into account in their national legislation (e.g. such as those listed under subsection 4.3)? In other words, is chemicals management, globally, or any sectors, such as agriculture/pesticides, under the remit of regional institutions rather than purely domestic regimes?
 - » If this not the case are these regional integration organizations currently intending to develop supranational legislation, globally or sectorally, in areas of relevance to GHS application? If not, is the country willing to discuss the matter with other members of the organization before starting GHS implementation work at national level? Are there specific sectors that the country would like to be addressed at regional level rather than national level? Would a regional regulation similar to the EU CLP would facilitate GHS implementation in relation to sectoral national legislation of chemicals management, or would simple reference to the United Nations GHS document or part thereof be sufficient to satisfy the need for use of classification criteria, labelling requirements and SDSs provisions (e.g. see Part C, section 12, New Zealand example)?

Legality block (see annex 2)

- What health, safety, environment or other national laws exist which address chemicals management, sectorally or multisectorally, that would justify development of rules/regulations in the regulatory block relevant to chemical hazard classification and communication (e.g., data collection, classification criteria, labelling and SDS preparation)?
- Is there any GHS relevant sector not addressed (e.g. industrial workplace, transport, agriculture, consumer, control of chemicals use)? In case of legislation gaps, which governmental entity(ies) should be involved?
- Which sectors are covered by the existing legal framework? Does the existing legal framework assign clear ministerial responsibilities to cover all four sectors affected by the GHS?
- Are there import and export control laws (e.g., application of the Rotterdam Convention) relevant to controlling the entry of and information about chemicals?
- Is there any legislation related to training for understanding of GHS classification and/or related chemical hazard communication? Which target audience should receive training in this respect?
- Are there any requirements to report information on the effects and/or exposure (human and environmental) to chemicals and/or on incidents/accidents involving hazardous chemicals?
- Do existing legal instruments related to chemicals management include compliance and enforcement provisions?
- What parts of the chemicals lifecycle are covered by existing legal instruments?
- What is current legislation regarding access to information and protection of confidential business information (CBI)?

Regulatory block (see annex 2)

Subject to the existence of relevant legislation under the conventional block or the legality block:

- What regulations or standards (if any) exist which address requirements relevant to chemical hazard classification and communication (e.g., data collection, classification criteria, labelling and SDS preparation) in relation to current legislation?
- If transport sector is covered by the existing system, is it consistent with the internationally harmonized system based on the UN Recommendations on the Transport of dangerous Goods, Model Regulations?
- If the agriculture/pesticides sector is covered by the existing system, is it consistent with the FAO/WHO recommendations referred to under subsection 6.2? Are measures envisaged to bring the national system fully in line with GHS in accordance with the said recommendations?
- What hazard classification and communication elements are covered by the existing systems?
 Are they specific to the country or related to international or regional commitments?

- If import and export control laws (e.g., application of the Rotterdam Convention) exist, are GHS elements used in implementing regulations or other secondary legislation instruments relevant to controlling the entry of and information about chemicals? If lists of chemicals have been established for this purpose, have they been established using GHS classification criteria, and which ones?
- Do the regulations include lists of chemicals showing their classification and related hazard communication elements? On which basis have they been prepared? Have they been compared with other similar lists established in other countries? Should they be amended to reflect GHS classification criteria and hazard communication elements?
- Are there any regulations or standards related to training for chemical hazard communication?
 Under which legislation?
- Are there any requirements to report information on the effects and/or exposure (human and environmental) to chemicals?
- Do existing legal instruments related to chemicals management include compliance and enforcement provisions?
- What parts of the chemicals lifecycle is covered by existing regulations? (This could be different for different sectors.)
- What are current legislation or regulations regarding access to information and protection of confidential business information (CBI)?

An example of questions asked in relation to adapting the USA regulations on labelling of pesticides (40 CFR, Part 156) to the GHS is provided in Annex 6.

18.1 Considerations for developing the legal framework

- If regulatory requirements exist, to what extent are relevant provisions compatible with the requirements of the GHS?
- Which regulatory adjustments need to be made to ensure compatibility?
- Are there any duplicative existing regulations that should be addressed?
- Do existing legal instruments provide a clear mandate and framework to ensure support for relevant government agencies to implement chemical hazard communication programs and the GHS?
- If a legal framework for sound chemical hazard classification and/or communication in a given sector is not in place, what specific reform measures need to be undertaken to ensure that national regulatory framework provides for comprehensive and effective implementation of the GHS?
- Which GHS sectors are not covered by the existing legislative framework?
- What are the deviations for hazard classification and communication between the existing system and the GHS requirements?
- What timeframe (including provision for transition periods) should be used in implementing



new or amended regulations?

- Are there sufficient resources at governmental level (centrally or within sectoral administrative departments) for:
 - » Accompanying the legislative process when GHS implementation requires new laws or amending existing laws (i.e. including eventually actions and follow-up at Parliament level);
 - » Developing regulations or amending existing ones, including process of consultation with stakeholders;
 - » Publishing legal texts, including translation when the country has several languages;
 - » Administering legislation/regulations, e.g. various legal processes, publishing guidance, updating legislation (bearing in mind that the GHS is updated every two years), ensuring enforcement, etc;
 - » Meeting administrative obligations relating to membership in certain treaties;
 - » Inter-ministerial cooperation and cooperation with relevant authorities of other countries;
 - » Representing the country at intergovernmental meetings as may be required depending on regional/international cooperation agreements/arrangements or treaties.

19. Legal implementation of the GHS

Based on the outcomes of the legal analysis, countries may wish to focus their efforts on a GHS legal implementation framework. This could be a plan that would include actions required for legal GHS implementation.

The plan should determine which sectors have to be regulated in accordance with the GHS and, if there is already existing legislation in each of these sectors, whether it would have simply to be updated or amended, or whether the whole legislative system would have to be fundamentally reviewed. I.e. which pieces of legislation need chemical classification criteria to determine which chemicals are to be regulated and how, and which pieces of legislation contain or should contain requirements for chemical hazard communication as foreseen in the GHS.

If a country considers that implementation should be made totally or sectorally through regional law, and there is support from other countries for such an approach, the said countries may wish to consider concluding a multilateral agreement for this purpose or addressing the issue at the level of a regional integration organization they are members of, in which case the form of such an agreement would have to be agreed between themselves or would have to be decided in conformity with the applicable rules of the regional organization.

If the country considers that domestic implementation of the GHS should be realized through national law only, there are many options, some of which are given as examples in Part C.

- Single consolidated Act, with GHS specific secondary legislation such as regulations, decrees and orders
- New law encompassing all or several GHS sectors, with GHS specific secondary legislation such as regulations, decrees and orders
- New laws, by sector, with related specific sectoral secondary legislation (regulations and standards by sector
- Amending existing laws (e.g., in relation to scope of secondary legislation, delegation of authority, designation of responsible department(s) for administration of the laws, and secondary legislation)
- Developing new secondary legislation to give effect to new laws or amending existing laws, e.g. for covering gaps in the existing legislative system
- Amending existing secondary legislation to incorporate directly the relevant GHS elements
- Amending existing secondary legislation to incorporate GHS elements by reference to the UN GHS document, or to standards reflecting the UN GHS elements applicable in the country
- Developing new national standards, or amending existing ones dealing with classification and labelling of chemicals and SDS, to reflect the appropriate GHS elements applicable at national level, and which can be referred to for mandatory application under sectoral secondary legislation(s)

20. Working methods for legal analysis and development of a national legal implementation framework

The legal analysis and development of the legal implementation framework can be conducted in a number of ways depending on a country's individual GHS capacity building process. In this respect, reference is made to the UNITAR/ILO Guidance on the development of a National GHS Strategy for implementation of GHS. In some cases, the legal analysis will be included within each sectoral working group, where legal issues are reviewed in the situation and gap analysis and recommendations are developed for regulatory changes or new legislation as part of the sectoral implementation plans. In other cases, countries may consider establishing a multi-sector working group on legislation to ensure coordination and a coherent approach to regulatory changes.

In any case, national coordination and cooperation between sectoral administrations involved is absolutely necessary, first in order to develop a common national vision of GHS national implementation and ensure consistency in application of the national strategy, and also to avoid duplication of, and inconsistencies between, various sectoral requirements, and to check consistency with commitments resulting from membership in certain treaties which are not necessarily known by sectoral departments not involved in the administration of such treaties.

An example of cooperation between the USA Department of Transportation and Department for



Labor Occupational Safety and Health Administration, Joint Guidance Memorandum on the Labelling of Hazardous Chemicals for Bulk Shipment, may be found at https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/joint_phmsa_memo_09192016.pdf (see also annex 5).

21. Elements to be taken into account in drafting legislation

21.1 Purpose and scope

Usually any legal instrument, be it treaty, law or regulation, contains a clear indication of its purpose and scope. In the case of GHS, this is normally related to the sector(s) covered, possible exceptions or exemptions. Examples are given in annex 6 (EU CLP Regulation) and annex 7 (USA 29 CFR)

21.2 Definitions

Legal instruments and standards also contain definitions. When reference is made to the GHS, it is recommended to indicate which version is referred to. See for example box 10.

21.3 Building blocks

The GHS has been developed in an as exhaustive manner as possible, but it is up to each country and each sectoral jurisdiction to decide how to apply it in accordance with certain principles. The building block approach is explained in section 2.4, and some examples are given in boxes 8, 12 and 14 and in section

Box 10: Definitions, references to GHS/UN Model Regulations on TDG, New Zealand

Hazardous Substances (Hazard Classification)
Notice 2020

...

4.Definitions

(1) In this notice, unless the context otherwise requires—

...

GHS means the Globally Harmonized System of Classification and Labelling of Chemicals, 7th revised edition, 2017, published by the United Nations

....

UN Model Regulations means the 21st revised edition of the Recommendations on the Transport of Dangerous Goods Model Regulations, 2019, published by the United Nations

•••

16. When a law or regulation applies only in relation to certain building blocks (hazard classes and hazard categories), it is recommended to specify which building blocks are concerned or which ones are excluded from the scope.

In the transport sector, on the basis of the UN Recommendations on the Transport of Dangerous

Goods and related modal international legal instruments, there is already broad agreement on which building blocks should be covered, see box 10.

In other sectors, such as agriculture (pesticides), workplace or consumer this is left to the judgement of each country. While this is consistent with the GHS, the main purpose of the GHS was global harmonization and therefore individual countries may wish to cooperate in order to harmonize as far as possible their sectoral approaches, at least at the regional level, in relation to the building blocks to be regulated in specific sectors. The building block approach was originally designed so that countries with comprehensive regulatory systems in place would not have to re-design drastically their regulations or systems and could adapt them to take account of the GHS classes and categories deemed relevant in each regulated sector. Where existing systems are not in place, competent authorities for specific sectors should consider carefully whether the whole range of building blocks would have to be adopted or whether some of these building blocks are not relevant for the sector, bearing in mind that once a competent authority adopts a hazard category for a sector to be regulated, it should also adopts all the categories for higher hazard levels in that hazard class in the same regulated sector.. In this decision-making process, it is highly recommended that the competent authority take account of the internationally applied practices for the concerned sector (see Part B) and, if not addressed internationally, try to cooperate with neighbouring countries to define a regional approach and also to consider approaches adopted by countries which possess regulatory experience in chemical management.

21.4 Decisions left to the discretion of the competent authority³⁰

In some cases, the GHS leaves it up to the competent authority to decide on how to deal with certain issues, such as:

- Use of non-standardized or supplemental information
- Confidential business information specifics
- Specific labelling arrangements (e.g. definition of a minimum size for labels and/or pictograms; precedence rules for allocation of symbols and hazard statements; provisions for labelling of small packagings and workplace labelling; use of product identifiers; location of GHS information on the label
- Cut-off values requiring communication of certain hazard information for carcinogens, reproductive toxicity and specific target organ toxicity through repeated exposure on the label and on the SDS or through the SDS alone
- Requirement to provide SDS's for mixtures not meeting the criteria for classification as hazardous but which contain hazardous ingredients in certain concentrations
- Requirement to include a statement in the label, the SDS or both, indicating that x % of the mixture consists of ingredient(s) of unknown toxicity
- Requirement to provide information on specific hazards that do not result in classification

21.5 Classification and hazard communication provisions

There are different possible options for introducing the relevant GHS provisions in secondary legislation. They may be introduced in full in one piece of sectoral legislation, e.g. as in the USA Hazard Communication Standard (29 CFR, Part 1910, see also section 9 above) or separately in different regulations (e.g. for EU countries, classification and labelling requirements are contained in the CLP Regulation, while the requirements for SDS are contained in the REACH Regulations). They may also be incorporated by reference either to the UN GHS text directly (see New Zealand in section 12 above) or to national standards reproducing GHS text (see China in section 13 and Brazil in Box 11).

The advantage of referring to the UN text is that this simplifies considerably the process of regular updating, see section 24. The UN text is available in pdf format free of charge from the GHS secretariat website (https://unece.org/ghs-rev8-2019) in all six UN languages (English, French, Spanish, Arabic, Chinese and Russian) and editable files are made available to governmental administrations by the secretariat upon request.

For countries which do not use any of the UN languages as official language, referring to the UN text may cause a legal problem as their constitution may require that legislation be published or available in the country official language. And if they want to develop legislation in their national language, they would have no other choice than to translate the text of the GHS provisions. Some countries have translated the GHS in their own official language (e.g. Japan) which may make it easier to update in the light of the recurrent amendments to the UN text. It is then still possible to make the GHS applicable by reference in the legislation. Others have issued national standards reflecting the GHS text in their official language, which are then referred to as applicable texts in the national legislation (e.g. Brazil). Others have chosen to translate the GHS provisions and incorporate them in their national legislation (e.g. Turkey). In addition, to the extent that it serves as an example of GHS implementation, the CLP legislation within the EU is translated into all EU Member State languages, including non-UN languages such as Portuguese, which may be useful to Portuguese-speaking countries in their implementation process.

When introducing GHS provisions in national regulations or standards, it is not only important to specify which revised edition of the GHS is introduced, it is also important to make sure that the provisions are the same as those of the GHS. It may be recommended not to designate a national regulation as a GHS national regulation or standard if there are deviations, other than those allowed under 21.3 and 21.4 above, from the GHS. In any case, if such deviations exist, they should be clearly identified. This is important for example in relation to international trade and to the application of the TBT Agreement (see section 7 above and article 2 of the TBT Agreement in annex 4).

Box 11: Reference to national standards - Brazil workplace sector

Regulatory norm No.26 (on hazard communication) of the Ministry of Labour implemented the GHS in the workplace. Technical provisions for the implementation of the GHS are given in the standards developed by the Brazil Association of Technical Standards (ABNT)

The first version of standard ABNT NBR 14725 was released in 2009. The Standard has 4 parts, addressing terminology, hazard classification, labelling and safety data sheets.

In June 2019, ABNT updated part 2 of standard. A number of corrections and amendments to other parts of the standard were published since their first release in 2009, as follows:

- ► ABNT NBR 14725-1:2009 Terminology (corrected in 2010)
- ABNT NBR 14725-2:2019, Amend.1 (2019) Hazard Classification System
- ► ABNT NBR 14725-3:2017 Labelling
- ► ABNT NBR 14725-4:2014 Safety Data Sheet or FISPQ

For pure substances: Since 27 February 2011, classification must be done using NBR 14725-2, packing and labelling using NBR 14725-3 and SDS must be authored using NBR 14725-4. For mixtures: Since 1 June 2015, all mixtures must be classified, packed and labelled in accordance with NRB 14725-2 and 3 respectively and SDS authored using NBR 14725-4.

Standard 14725 is currently being revised to bring it into line with the 7th revised edition of the GHS. The consultation period for submission of comments to the proposed draft ended on 19 November 2020.

21.6 Obligations, enforcement and penalties

The legislation (law or regulations as appropriate) should define clearly the obligations of those who have to comply with the regulatory requirements (classification of chemicals, labelling and provision of safety data sheets, but also registration of chemicals, training requirements, information of authorities as relevant). This may concern manufacturers, importers, exporters, suppliers, employers, workers and carriers, among others.

The legislation (law or regulations as appropriate) should also identify the enforcement authorities and penalties in case of infringement, see for example the case of Ireland referred to under section 8 above, Chemicals Act 2008 (No. 13 of 2008) and Chemicals (Amendment) Act 2010 (No 32 of 2010), Parts 4 and 6.

21.7 Training

The GHS refers in its section 1.4.9 to the importance of training all target audiences to recognize and interpret label and/or SDS information, and to take appropriate action in response to chemical hazards. Key target audiences include emergency responders, those using chemicals in the workplace, involved in label and SDS preparation, and the transport and supply of hazardous chemicals, and the general public. Training requirements should be appropriate for and commensurate with the nature of the exposure. Consequently, training requirements for producers and users will differ. Requiring mandatory training of individuals of certain target audiences through legislation is not always possible, e.g. in the case of consumers. Nevertheless, certain legislations (labour, transport, agriculture) may include mandatory training requirements e.g. for:

- Workers who are exposed to chemicals in the processes of manufacture, transfer (e.g. filling, emptying)
- Workers who are exposed when using chemicals for certain professional purposes (e.g. painting, gluing, cleaning)
- Workers exposed when releasing chemicals to the environment (agriculture/pesticides)
- Workers not using chemicals and not likely to be exposed, but handling containers containing chemicals and who may be exposed in case of incidents or accidents (transport workers, storage)

Emergency responders

Training of workers using chemicals is in fact required by the ILO Chemicals Convention No. 170 as supplemented by the ILO Chemicals Recommendations No. 177, as shown in boxes 12 and 13 below.

See also the examples given in Annex 9 (Training requirements in the USA Hazard Communication Standard) and Annex 10 (Driver training requirements in ADR).

Box 12: ILO Chemicals Convention, 1990 (No. 170)

Article 15

INFORMATION AND TRAINING

Employers shall:

- a. inform the workers of the hazards associated with exposure to chemicals used at the workplace;
- b. instruct the workers how to obtain and use the information provided on labels and chemical safety data sheets;
- c. use the chemical safety data sheets, along with information specific to the workplace, as a basis for the preparation of instructions to workers, which should be written if appropriate;
- d. train the workers on a continuing basis in the practices and procedures to be followed for safety in the use of chemicals at work.

Box 13: ILO Chemicals Convention, 1990 (No. 177)

26. Workers should receive:

- a. information on the classification and labelling of chemicals and on chemical safety data sheets in forms and languages which they easily understand;
- information on the risks which may arise from the use of hazardous chemicals in the course of their work;
- c. instruction, written or oral, based on the chemical safety data sheet and specific to the workplace if appropriate;
- d. training and, where necessary, retraining in the methods which are available for the prevention and control of, and for protection against, such risks, including correct methods of storage, transport and waste disposal as well as emergency and firstaid

Consumers may also be exposed when using chemicals in a private environment, e.g. D.I.Y, cleaning, gardening. They may be trained through educational programmes regarding the interpretation of label information on products they use. This may also be applicable to workers such as household cleaners or other labourers that work in a "home" environment while using consumer products. Other tools, such as awareness raising campaigns, the use of posters, brochures and the media, can all assist in ensuring that the chemical hazard communication process improves chemical safety.

21.8 Chemical classification lists

The GHS provides chemical classification criteria, but no list of chemicals classified in accordance with these criteria. One of its objectives 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.

Some countries have developed inventories as well as lists of substances mainly in the context of legislation governing registration, placing on the market, import, export and use restrictions. These lists are sometimes used also in the context of implementation of GHS as they may define for which chemicals GHS should be applied in the country. When implementing GHS some countries have also developed lists showing the GHS classification of specific substances. The classification shown in the lists may be mandatory. Other countries have developed these lists as guidance.

For example, the EU CLP Regulation contains, in its Annex VI, a list of "harmonized classification and labelling of hazardous substances" that has been established for certain hazardous substances according to certain criteria and procedures³¹. The classification and labelling elements indicated in this list are of mandatory application under the scope of the CLP Regulation, but only for the hazards specified in the list. For hazardous substances that are not required to be included in this list, and for substances included in the list possessing hazards not identified in the list, there is nevertheless an obligation for manufacturers and importers to notify the European Chemicals Agency (ECHA) of the classifications and label elements, and for the ECHA to establish and manage a publicly available inventory of classification and labelling of substances including those listed in CLP Annex VI and those notified by manufacturers and importers³².

Another example is Malaysia which has also established a list of chemicals which have been nationally classified in accordance with the GHS criteria. The list is included in the Code of Practice on Chemicals Classification and Hazard Communicatio³³. Substances listed in that list have to be

³¹ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20201114&from=EN

³² https://echa.europa.eu/information-on-chemicals/cl-inventory-database

³³ https://www.dosh.gov.my/index.php/list-of-documents/osh-info/chemical-management-1/2217-industry-code-of-practice-on-chemicals-classification-and-hazard-communication-2014-pdf/file

classified and labelled according to the list indications. Substances not included in the list have to be treated in accordance with the procedures detailed in Part 2 of the Code.

The Japanese government has also established a list³⁴ of hazardous substances intended to provide a reference for preparing a GHS label or SDS. The information contained therein is based on information sources and guidance for classification and judgement described in the GHS Classification Guidance for the Japanese Government. To include the same classification result in a label or SDS for Japan is NOT mandatory. Using other literature, test results etc. as evidence and including different content from this classification result in a label or SDS are allowed.

These are examples, but many lists providing information on GHS classification of specific substances are available in many countries, and countries wishing to obtain information on particular substances may usefully consult such lists. However, it should be borne in mind that the information provided in such lists for a given chemical is not always consistent because not all countries use the same information sources, and the lists are often established for specific regulatory purposes not encompassing all GHS sectors. Unless otherwise specified in the applicable legislation, the ultimate responsibility for providing accurate information in labels and safety data sheets is expected to rest with the manufacturer, importer or supplier.

Countries wishing to establish their own lists of chemicals with their GHS classification may wish to consult the lists established by other countries when doing so, but they should then check carefully what the status of such lists is in the country concerned; for which purpose(s) they have been established; which criteria were used for determining the GHS classification; and what the process is for identifying, as hazardous, substances that are not on the list.

International sources of information on chemical classification

OECD has developed or contributed to a number of tools to assist countries with hazard and exposure assessment³⁵ and GHS implementation. This is the case for instance of the eChemPortal, an online portal containing data sources and information on chemicals, developed and made available by OECD in cooperation with the European Chemicals Agency (ECHA). The eChemPortal provides exposure and use information on chemicals and direct links to collections of chemical hazard and risk information prepared for government chemical review programmes at national, regional and international levels. Classification results according to national/regional hazard classification schemes or to the GHS are also provided when available. A GHS classification search function is also available in eChemPortal which can be used to search two of the databases which participate in eChemPortal. It is intended in the future to extend the range of databases which can be searched using this GHS classification search.

The ASEAN-Japan Chemical Safety Database (AJCSD)³⁷ is developed by ASEAN countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines; Singapore, Thailand and Vietnam) and Japan under AMEICC Working Group on Chemical Industries. The database includes chemical regulatory information, GHS classification results, risk and hazard information.

Since the 1980s, ILO and WHO collaborate in the International Chemical Safety Cards (ICSCs) project with the cooperation of the European Commission. The project prepares and disseminates data sheets (ICSCs) with essential safety and health information on chemicals in a clear and concise way. To date, over 1,700 Cards are available in more than ten languages. The primary aim of the Cards is to promote the safe use of chemicals in the workplace and the main target users are workers and those responsible for safety and health at work. ICSCs are prepared in English by a group of experts that meets regularly to review the Cards before making them public. This international peer-review process followed in the preparation of ICSCs ensures the authoritative nature of the Cards. Subsequently, national institutions participating in the project translate the Cards from English into their respective local languages. The information provided in the Cards is in line with the ILO Chemicals Convention (No. 170) and Recommendation (No. 177), European Commission Communication COM/2017/012, and the GHS criteria. Since 2006, the GHS classification is being added to the Cards as they are reviewed or created and, at present, about 40 percent of the collection of Cards has been updated according to GHS. ICSCs have no legal status and may not meet all requirements included in national legislation. The Cards should complement any available Chemical Safety Data Sheet but cannot be a substitute for any legal obligation on a manufacturer or employer to provide chemical safety information. However, it is recognized that ICSCs might be the principal source of information available for both management and workers in less developed countries or in small and medium-sized enterprises.

- www.ilo.org/icsc
- www.who.int/teams/environment-climate-change-and-health/chemical-safety-and-health/ health-impacts/international-chemical-safety-cards
- https://www.who.int/ipcs/publications/icsc/en/

For the transport sector, Part 3 of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, contains the list of dangerous goods most commonly carried, under the form of entries identified by a "UN number" and a "name and description" to which specific transport provisions are assigned, including classification and labelling provisions according to the GHS as applied to the transport sector (which means that hazards and hazard categories that are deemed of no concern in the transport regulatory context are not identified in this list). Some entries are specific, i.e. they cover one specific chemical substance or mixture listed by name. Others are generic, i.e. they may be used for individual chemical substances or mixtures that are not listed by name but meet the transport classification criteria. Unless otherwise specified, the classification/labelling provisions indicated in the list for substances and mixtures identified by name are of mandatory application under all legal instruments referred to in sub-section 4.1 above. For sub-



stances and mixtures not mentioned by name, it is the consignor's responsibility to assign them to the appropriate generic entry. When the provision of safety data sheet is required, the transport information should be provided in section 14 of the SDS. However, it should be borne in mind that SDSs are mainly intended to provide comprehensive information about chemicals for use in work-place chemical control regulatory frameworks. The information contained therein may also be of interest to target audiences other than employers and workers in the industrial workplace, including the transport sector, but the physical availability of SDSs during transport operations is not necessarily required by transport regulations since information of relevance to the transport sector is already required in the transport documentation and hazard communication systems specific to each mode of transport have been developed for emergency response.

22. Legal process

The legal processes to be followed for adoption of laws and regulations are specific to each country. In many cases, new laws or amendments to existing laws have to be proposed by a member of the parliament, or in some cases may also be proposed by the government. They are then debated, amended, adopted, and enacted in accordance with the national process.

New regulatory texts, or amendments to existing regulatory texts, are prepared by the administrative department(s) responsible for the administration of laws under which these regulatory texts are intended to be issued, subject to processes of consultation with all actors of target audiences concerned including, for example, impact studies, costs versus safety and environmental benefits assessments, feasibility and enforceability. A good example of subjects that may be addressed and of conclusions is given in the preamble to the final rule for amendments to the US Hazard Communication Standard adopted in 2012 to give effect to the GHS in the workplace sector, see https://www.osha.gov/FedReg_osha_pdf/FED20120326.pdf

Once adopted, the regulatory text is usually issued as a final rule (e.g. in the USA) or under cover of an ordinance, decree, order or any type of relevant statutory instrument.

23. Transitional measures

When introducing new legislation or amending existing legislation, it may be beneficial to provide for transitional measures in order to allow sufficient time for manufacturers, importers, suppliers, employers, workers, emergency responders and any other entity concerned to adapt to the new regulatory environment, including in relation to training and awareness-raising.



Box 14: Transitional measures for application of GHS provisions in EU legislation

The EU Regulation on classification, labelling and packaging of substances and mixtures (CLP) aligned previous EU legislation on classification, labelling and packaging of chemicals to the GHS. The main objectives was to facilitate international trade in chemicals and to maintain the existing level of protection of human health and environment. The CLP Regulation was published in the Official Journal 31 December 2008 and entered into force on 20 January 2009. According to the Regulation, the deadline for substance classification according to the new rules was 1 December 2010. For mixtures, the deadline was 1 June 2015. The CLP Regulation replaced the then existing rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC) after this transitional period.

24. Updating

When developing GHS related legislation, countries should bear in mind that the GHS is not a static instrument and is updated every two years, see also 1.2 above. In general, classification and labelling provisions are rather stable, but they may be amended from time to time, or extended. For example a new hazard class for desensitized explosives was introduced in 2015.

The best way for a government to follow the developments is to participate in the work of the United Nations Sub-Committee of Experts on the GHS. The documentation concerning the work of this sub-committee is available at https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece.org/info/events/unece-meetings-and-events?f%5B0https://unece-meetings-and-events?f%5B0https://unece-meetings-and-events?f%5B0https://unece-meetings-and-events?f%5B0https://unece-meetings-and-events?f%5B0https://unece-meetings-and-events?f%5B0https://unece-meetings-and-events?f%5B0<a href="ht

For those countries that do not participate in the work of the Sub-Committee, they may follow the developments by consulting the UNECE website.

New revised editions are made available usually around June or July of odd years for the English and French versions, and between August and December of odd years for the other UN languages (see https://unece.org/ghs-rev8-2019)

The collection of amendments to the previous version are made available between March and July of odd years and are available at https://unece.org/reports-32 with a document symbol reading ST/SG/AC.10/../Add.3. For example, amendments to GHS/Rev.7 (leading to GHS/Rev.8) were issued under the symbol ST/SG/AC.10/46/Add.3. Those modifying GHS/Rev.8 (leading to GHS/Rev.9), adopted in December 2020, should be issued in document ST/SG/AC.10/48/Add.3 at https://unece.org/transport/events/ac10-ecosoc-committee-experts-transport-danger-ous-goods-and-globally-harmonized.

The updating procedure depends on the type of instrument(s) used for GHS implementation. When the GHS is implemented through a legal instrument, the updating has to be done in accordance with the legal amendment procedure related to the instrument. For example, the EU CLP Regulation was amended in 2019 by Commission Regulation (EU) 2019/521³⁸ to take into account the 6th and 7th revised editions of the GHS. In the United States of America, the Occupational Safety and Health Administration (OSHA) issued, in early 2021, a notice of proposed rulemaking (NPRM) to amend the Hazard Communication Standard (HCS) (§ 1910.1200) to take into account the 7th revised edition of the GHS.

When the GHS is implemented through national standards, i.e. standards which are not of mandatory application *per se*, the updating is done in accordance with the process applicable to the amendment or revision of standards of the national standardization body. For example, the updating of the Brazilian national standard ABNT NBR 14725 to bring it in line with the 7th revised edition of the GHS is done in accordance with the procedures of the Brazil Association of Technical Standards. The standard, on its own, is not of mandatory application, but its application in the workplace sector is required by Regulatory Norm No.26 (see also box 11). In this specific case, any amendment to or revision of the technical standard does not require any amendment to the regulatory norm itself, since the regulatory norm, apart from requiring the application of the GHS for classification, labelling and the safety data sheet, simply states that the provisions of the "official technical standard" (without providing a precise reference) have to be complied with.

When a country is envisaging issuing new legislation or standards to take account of the GHS, it is highly recommended to use the latest available version of the GHS. The need for recurrent updating should also be borne in mind when deciding how to introduce GHS provisions, see also section 21.5 above.

25. Feedback to the United Nations

According to the United Nations Economic and Social Council resolution 1999/65, the functions of the United Nations Sub-Committee of experts on the GHS are to:

- a. Act as custodian of the GHS, managing and giving direction to the harmonization process;
- b. Keep the system up to date, as necessary, considering the need to introduce changes to en-



sure its continued relevance and practical utility, and determining the need for and timing of the updating of technical criteria, while working with existing bodies, as appropriate;

- c. Promote understanding and use of the system and encourage feedback;
- d. Make the system available for worldwide use and application;
- e. Make guidance available on the application of the system, and on the interpretation and use of technical criteria to support consistency of application;
- f. Prepare work programmes and submit recommendations to the Committee.

The feedback expected by the Sub-Committee from countries is:

- a. Feedback related to practical implementation of the GHS, including problems encountered and suggestions for improvement;
- b. Feedback concerning effective implementation through legislation or standards in each country

In particular, in its resolution 2019/7, C, operative paragraph 6, the Council invited Governments, the regional commissions, United Nations programmes, specialized agencies and other organizations concerned to provide feedback to the Sub-Committee on the steps taken for the implementation of the Globally Harmonized System in all relevant sectors, through international, regional or national legal instruments, recommendations, codes and guidelines, including, when applicable, information about the transitional periods for its implementation;

At its December 2020 session, the SCEGHS agreed that, to facilitate data collection in a consistent and harmonized way, governments, and other entities, could provide the information directly to the secretariat in a standardized way, as reflected in annex 11. For the submission form and procedure, see https://unece.org/transportdangerous-goods/ghs-implementation-information-submission-form

26. Feedback from non-governmental organizations

Organizations and associations representing the various GHS target audiences, such as workers, suppliers, industry, carriers, consumers have also the possibility to provide feedback to the UN-SCEGHS, but only through non-governmental organizations representing their interest which have been granted consultative status by the UN Economic and Social Council or the Sub-Committee itself, or other stakeholders with which they have working relationships (e.g. their national governments or UN bodies).

When preparing this document, UNITAR has sought comments from such NGOs on the current status of implementation of the GHS worldwide and their views on actions taken by governments so far. A questionnaire was circulated, with some organizations providing feedback; their answers, which can be useful to governments starting GHS implementation, are summarized in annex 12.

FOR IMPLEMENTATION OF GHS RELATED LEGISLATION

27. Publication and public availability of laws, regulations and standards

For laws and regulations to be complied with, they have first to be published and made available to the public. Usually they are published in the national official journal, which can be consulted in certain public places or purchased at low cost. Nowadays they are also often made available in electronic format for free on governmental websites. Normally they fall within the public domain, which means they are not copyrighted and may be copied and disseminated without restriction, although the practices may differ depending on the countries.

According to article 2(4) of the Berne Convention for the Protection of Literary and Artistic Works, Paris Act of July 24, 1971, as amended on September 28, 1979, "It shall be a matter for legislation in the countries of the Union [i.e. parties to the Convention] to determine the protection to be granted to official texts of a legislative, administrative and legal nature, and to official translations of such texts."

This issue of public availability arises when the GHS is implemented through standards. The policy of international standardization organizations and of many national standardization bodies is that, since their standards are private standards which are not mandatory, they do not fall within the public domain, so they are not made available freely in any form and they are copyrighted which means that they cannot be easily reproduced and disseminated for public information purposes. Therefore, when governments decide to implement the GHS through reference to GHS national standards for mandatory application, they may wish to require that these standards are made available for public consultation in conditions equivalent to those that would apply in the case of laws and regulations.

28. GHS classification tools

Classification of chemicals in accordance with GHS criteria normally requires the availability of appropriate test data. When such data are not available, or are considered to be obsolete or not reliable, it may be necessary to proceed with tests. The GHS itself provides, for each hazard class, indications on test methods which are suitable. These are usually contained in:

• For physical hazards, the UN Manual of Tests and Criteria, available in the six UN languages at



https://unece.org/rev7-files

For hazards to health or to environment, mainly the OECD Test Guidelines for Testing Chemicals referred to in the various GHS chapters, available in English and French at https://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm, or certain other standards also referred to in the GHS

29. Guidance

Once legislation is in place, it is usually necessary for the administration concerned by a given sector to produce additional material to facilitate effective implementation and compliance. This may take the form of administrative acts such as circulars or directives e.g. for designating bodies accredited for performing certain functions such as testing and control, or for indicating administrative procedures to follow in order to comply with some regulatory requirements.

This may also consist in issuing codes of practice or any form of guidance that may facilitate interpretation of legal requirements and practical compliance.

Such guidance may be found in the GHS itself, mainly in its eleven annexes.

Guidance developed by the UNSCEGHS in relation to the application of specific classification criteria may be found at https://unece.org/transportdangerous-goods/ghs-guidance together with guidance (not necessarily endorsed by the Sub-Committee) developed by industry stakeholders in relation to the application of the classification criteria for some sector-specific chemicals (ores and concentrates for marine transport, petroleum substances).

Examples of guidance developed by countries for application of their own GHS-based legislation are given below:

European Union

- https://echa.europa.eu/regulations/clp/understanding-clp
- https://echa.europa.eu/information-on-chemicals
- https://echa.europa.eu/guidance-documents/guidance-on-clp

USA

- https://www.osha.gov/dsg/hazcom/
- https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf
- https://www.osha.gov/Publications/OSHA3844.pdf
- https://www.osha.gov/Publications/OSHA3695.pdf
- https://www.osha.gov/dsg/hazcom/guidance.html
- https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/joint_phmsa_memo_09192016.pdf

Canada

- https://www.canada.ca/content/dam/hc-sc/documents/services/environmental-workplace-health/reports-publications/occupational-health-safety/joint-guidance/hc-osha-guidance-eng.pdf
- https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/guidance-preparing-safety-data-sheets-according-globally-harmonized-system-classification-labelling-chemicals-pest-products-canada.html
- https://www.canada.ca/en/health-canada/services/environmental-workplace-health/ reports-publications/occupational-health-safety/guidance-hazardous-products-whmis-2015-supplier-requirements.html
- https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/occupational-health-safety/preparing-maintaining-true-copy-label.html
- https://www.canada.ca/en/health-canada/services/environmental-workplace-health/ reports-publications/occupational-health-safety/guidance-hazardous-products-whmis-2015-supplier-requirements/errata.html

30. Emergency response

For hazardous chemicals, efficient emergency response is directly linked to the availability of information through hazard communication systems adapted to the various situations that may occur. It can be organized privately, e.g. in the case of large chemical companies at the places of manufacture and storage, or may require the involvement of public entities such as fire brigades, civil protection services, public health emergency services, and poison centres.

Examples of guidance available in this respect are:

Workplace

- https://www.osha.gov/SLTC/emergencypreparedness/guides/index.html
- https://ec.europa.eu/jrc/en/publication/emergency-response-planning-chemical-accident-hazards-key-points-and-conclusions-seveso-enforcement
- http://mem.ie/wp-content/uploads/2017/02/Guidance-Document-10-Seveso-III-V.1.pdf

Transport

Maritime transport

- IMO Emergency response procedures for ships carrying dangerous goods
- IMO Medical First Aid Guide for use in accidents involving dangerous goods



ICAO indicative elements for emergency response on board aircrafts

Inland transport

North America:

North America Emergency Response Guidebook: https://www.tc.gc

Europe:

- For emergency responders: http://www.ericards.net/ and http://www.ericards.net/ psp/ericards.psp search?p lang=1
- For road vehicle crew: instructions in writing: https://unece.org/linguistic-versions-adr-in-structions-writing
- For crew of inland navigation vessels: instructions in writing: https://unece.org/linguistic-ver-sions-adn-instructions-writing

Poison centres

European Union

According to Article 45 of the CLP Regulation, companies placing hazardous mixtures on the market are obliged to provide information about certain hazardous mixtures to the relevant national bodies. The national bodies make this information available to poison centres so that they can give advice to the citizens or medical personnel in the event of an emergency. Annex VIII to the CLP Regulation, adopted in March 2017, defines the harmonised requirements for poison centre notifications (PCN) applicable as of 1 January 2021.

31. Training guidance

Section 20.7 above addresses training for recommended inclusion as a mandatory requirement in legislation. The question of how training has to be carried out, or designating or accrediting appropriate training bodies if relevant, may be addressed in legislation, but administrations may also provide guidance for implementation in this respect, for example:

https://www.oshatraining.com/ghs-training-resources.php

GHS training may be provided by a variety of bodies in the private or public sectors, e.g.:

https://www.whsc.on.ca/Files/Product-Sheets/Globally-Harmonized-WHMIS-Training Aug17.
 aspx

GHS training may also be included in academic programmes

 https://www.unipg.it/en/ects/ects-course-catalogue-2020-21?annoregolamento=2020&layout=insegnamento&idcorso=235&idinsegnamento=193773

The UNITAR GHS e-learning course run twice a year, in English and Spanish. (https://www.unitar.org/event/event-pillars/planet)

In practice, GHS training may not be worthwhile if it is not related to a legislative context. It does not make much sense to train workers for the purpose of improving their understanding of GHS hazard communication tools, or to launch public information campaigns to sensitise consumers if there is no legal requirement for implementation of GHS hazard communication or if different non-GHS based chemical hazard communication systems are allowed in a given country, for example for chemicals imported from countries that have not implemented the GHS. GHS training and information campaigns may be more effective once legislation has been enacted and is in force, or during the transition period preceding entry into force. Depending on the legislation, different sectors may have to be addressed separately.



The GHS is a relatively new system, since the document was first published by the United Nations in 2003. The idea was that, by providing a unique globally hazard classification and compatible labelling system, including safety data sheets and easily understandable symbols, worldwide multisectoral harmonization could be achieved if all countries and international treaties used systematically the provisions of the GHS when their chemical safety management regulatory systems contained classification and hazard communication requirements. It was also anticipated that the GHS would:

- a. enhance the protection of human health 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.

The GHS itself is of a recommendary nature, and it leaves it up to governments and international organizations concerned to decide how to best implement it. In a first stage, governments and international organizations that already had regulatory systems related to chemicals management in place started to consider how to modify these systems to take account of the GHS. Some of them have managed to revise and amend their systems in all sectors, while others have focused on specific sectors. In countries that did not have significant chemicals management regulatory systems, some governments started to develop legislation, while others issued standards reflecting the GHS or parts thereof that could be used on a voluntary basis.

This document shows that besides membership in international treaties governing sectoral chemicals management, there is a wide variety of legal options that countries, especially those without any system in place, may wish to choose to implement the GHS, either regionally or nationally. Each country should choose the option which is best suited to its needs.

When doing so, countries should not lose sight of the original objective of the GHS, which is global harmonization. Although the GHS leaves some flexibility for choosing the relevant elements to be used for sectoral implementation (building block approach), it is recommended that countries that develop legislation/regulations:

- Implement consistently the GHS in all their regulatory systems applying to various sectors; for this, close cooperation between all ministries/departments concerned and consultation of the non-governmental entities is essential;
- Do not introduce additions to or variations or deviations from the provisions of the GHS in

their regulations, unless such deviations are specifically facilitated by the GHS; in this respect, refer to the UN Sub-Committee of Experts on the GHS if they wish to modify some provisions of the GHS;

- Identify clearly the building blocks covered (or not covered) by any sectoral legislation, as well
 as competent authority decisions when decisions are left to their discretion according to the
 GHS;
- Co-operate, at least regionally, with relevant authorities of other countries to try to agree on common GHS sectoral approaches (e.g. for determining which building blocks should apply to a given sector, as is the case for transport regulations based on the UN Recommendations on the Transport of Dangerous Goods);
- Put in place proper mechanisms to keep abreast of developments at the United Nations level (amendments to the GHS) and to regularly update their own regulatory systems accordingly;
- Provide for adequate transitional measures when new legislation is issued or existing legislation is amended for the purpose of implementation of the GHS;
- Make regulatory texts easily accessible to those who have to comply with them.

In relation to the use of non-mandatory standards for implementation of the GHS, this may appear as an attractive solution for starting implementation; however, it may not lead to harmonization since complying with different non-GHS-related rules or standards would also be permitted.



ANNEX: LIST OF ACRONYMS

ABNT	Brazil Association of Technical Standards
ADG Code	Australian Dangerous Goods Code
ADN	European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement Concerning the International Carriage of Dangerous Goods by Road
AFEr	Australian Forum of Explosive regulators
AJCSD	ASEAN-Japan Chemical Safety Database
AQSIQ	Administration for Quality Supervision, Inspection and Quarantine (China)
ASEAN	Association of Southeast Asian Nations
ASTM	American Society for Testing and Materials
ATE	Acute Toxicity Value
BBA	Building Block Approach
CA	Competent Authority
CAS	Chemical Abstract Service
СВІ	Confidential Business Information
CEMAC	Central African Economic and Monetary Community
CEN	European Committee for Standardization
CFR	Code of Federal Regulations (USA)
CIRS	Chemical Inspection and Regulation Service (China)
CJEU	Court of Justice of the European Union
CLP	Regulation (EC) n° 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances
COTIF	Convention on International Carriage by Rail
CPCS	Consumer Product Safety Commission (USA)
CUSMA	Canada-United States-Mexico Agreement
DOT	Department of Transportation (USA)
EAEU	Eurasian Economic Union
EC	European Commission (of the European Union)

ECHA	European Chemicals Agency (European Union)
ECHR	European Court of Human Rights
ECOSOC	Economic and Social Council (UN)
ECOWAS	Economic Cooperation of West African States
EN	European Standard
EPA	Environment Protection Agency (USA, New Zealand)
ESCAP	Economic and Social Commission for Asia and the Pacific (UN)
EU	European Union
FAO	Food and Agriculture Organization
FFDCA	Federal Food, Drug and Cosmetic Act (USA)
FHSA	Federal Hazardous Substance Act (USA)
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act (USA)
GB	Great Britain
GB	Guobiao standard (Chinese standard, national, mandatory)
GB/T	Guobiao standard (Chinese standard, national, recommended)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GOST	Russian standard
HCS	Hazard Communication Standard (USA)
HMR	Hazardous Material Regulations (USA)
HPT	Human Patch Tests
HSNO	Hazardous Substances and New Organisms (New Zealand)
HSW	Health and Safety at Work (New Zealand)
IATA	International Air Transport Association
IBC Code	International Bulk Chemical Code
IGC Code	International Gas Carrier Code
IMSBC Code	International Maritime Solid Bulk Cargoes Code



ICAO	International Civil Aviation Organization
ICAO TI	ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air
ICCA	International Council of Chemical Associations
ICSCs	International Chemical Safety Cards
IFCS	Intergovernmental Forum on Chemical Safety
IEC	International Electrotechnical Commission
ILO	International Labour Organization
IMDG Code	International Maritime Dangerous Goods Code
IMO	International Maritime Organization
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
JIS	Japanese Industrial Standard
JT	Chinese standard, Highway and Transportation (Ministry of Transport), mandatory
JT/T	Chinese standard, Highway and Transportation (Ministry of Transport), recommended
KEMI	Swedish Chemicals Agency
MARPOL 73/78	International Convention for the Prevention of Pollution from Ships (1973) as modified by the Protocol of 1978 thereto
MEP	Ministry of Environment Protection (China)
MERCOSUR	Common Market of the South (South America)
NGO	Non-governmental organization
OECD	Organisation for Economic Cooperation and Development
OPS	Overarching Policy Strategy
OSHA	Occupational Safety and Health Administration (USA)
PCN	Poison Center Notification (EU)
PHMSA	Pipeline and Hazardous Materials Safety Administration (USA)
POPs	Persistent Organic Pollutants

REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SADC	Southern African Development Community
SADCSTAN	SADC Cooperation in standardization
SADCTRLC	SADC Technical Regulations Liaison Committee
SAICM	Strategic Approach to International Chemicals Management
SANS	South African National Standard
SARP	Standards and Recommended Practices (ICAO)
SAWS	State Administration of Work Safety (China)
SDS	Safety Data Sheet
SME	Small and Medium-sized Enterprise
SMGS	Agreement on the International Goods Transport by Rail
STOT	Specific Target Organ Toxicity
ТВТ	Technical Barriers to Trade (Agreement, WTO)
TDGR	Transport of Dangerous Goods Regulations (Canada)
TSCA	Toxic Substance Control Act (USA)
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNECE	United Nations Economic Commission for Europe
UNITAR	United Nations Institute for Training and Research
UNRTDG	United Nations Recommendations on the Transport of Dangerous Goods
UNSCEGHS	UN Subcommittee of Experts on the GHS
UNSCETDG	UN Subcommittee of Experts on the Transport of Dangerous Goods
UNCETDG/GHS	UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals
UK	United Kingdom of Great Britain and Northern Ireland
US	United States of America



USA	United States of America
WHMIS	Workplace Hazardous Materials Information System (Canada)
WHO	World Health Organization
WHS	Work Health and Safety (Australia)
WTO	World Trade Organization
WSSD	World Summit on Sustainable Development



ANNEX: LAW OR STANDARDS:

BASIC PRINCIPLES

In the Guidance Document on *Developing a National GHS Implementation Strategy*³⁹, section 7.5, it was suggested that countries wishing to develop legally binding implementation measures to ensure full implementation of the GHS should first conduct a legal analysis. This would focus on understanding the current legislation or regulations for hazard classification and communication, and the changes needed to implement the GHS. Based on the results of the analysis, governments could examine the potential options for the development of a legal implementation framework. Competent authorities adopting the GHS may thus choose different implementing instruments according to their circumstances, needs and already existing legal framework.

Before making such a choice, and when deciding which legal option would be suitable for the country, some basic principles should be borne in mind.

1. Legislation and hierarchy of norms

The notion of hierarchy of norms was first formulated by an Austrian jurist named Hans Kelsen (1881-1973), author of the 1920 Austrian constitution and who wrote, inter alia, a book entitled "Pure Theory of Law" (in German: Reine Rechtslehre) which was first published in 1934.

According to Hans Kelsen, any legal norm receives its validity from compliance with a higher

According to Hans Kelsen, any legal norm receives its validity from compliance with a higher standard, thus forming a hierarchical order. The more important they are, the fewer the norms are: the superposition of norms thus acquires a pyramidal shape; the theory of pyramid of standards. This order is said to be "static" because the lower norms must meet the higher norms, but it is also "dynamic" because a norm can be modified according to the rules enacted by the norm that is superior to it.

The legal system and respective importance of the various legal instruments in this system may vary depending on the country and its constitution, but in general the pyramid includes different blocks of legal instruments.

The norm placed at the top of the pyramid is, in many legal systems, the Constitution. Since the Constitution itself could only be made mandatory by a higher norm, and such a norm did not exist, Hans Kelsen brought into play the concept of "fundamental norm", which consists mainly of a necessary methodological presupposition.

Constitutional block

The top level of the pyramid contains a block which may be called the constitutional block. It in-



cludes the Constitution but may also include other texts considered as fundamental in the State, e.g. in France the Declaration of Human and Citizen Rights and the Charter of Environment. All these texts in the constitutional block are considered to be at the same level and take precedence over legislation situated at lower levels of the pyramid. However, the supremacy of this block may compete with international rules. In the Europe Union, this is the case with the Court of Justice of the European Union (CJEU) and the European Court of Human Rights (ECHR) which give primacy to international commitments.

Nowadays, all States have their own constitution, except Israel, New Zealand and the United Kingdom.

Conventional block

Under the constitutional block normally comes the conventional block, also called the block of supralegality, which is the set of of rules of law originating from treaties, conventions and agreements concluded between States or between States and international organizations. treaties, conventions, bilateral or multilateral agreements to which the State is party.

Once a State has expressed its consent to be bound by the provisions of a treaty, and the conditions for entry into force of the said treaty have been fulfilled, the State becomes party to the treaty and is bound under international law to observe its provisions.

According to article 26 of the Vienna Convention on the Law of Treaties (1969), "Every treaty in force is binding upon the parties to it and must be performed by them in good faith." Before expressing the consent to be bound, it should be checked that the treaty does not contain provisions incompatible with the constitution. Otherwise a modification of the constitution or other texts in the constitutional block may have to be considered. Similarly, a treaty may contain provisions concerning a subject already addressed under national law, and therefore, before expressing a consent to be bound, care should be taken to avoid legal conflicts either with existing national law or provisions contained in another treaty to which the State is party. Depending on the legal system of the country, the rank of international treaties in the national normative hierarchy is not always obvious.

In countries such as the United Kingdom, Canada, Australia and many countries of the Commonwealth, international law and domestic law are separated (a dualistic system). Ratification of a treaty gives rise to international legal rights and obligations, but, to be applied at the national level, legal norms provided by treaties need to be transformed into national norms in accordance with the national legislative procedure. As a consequence, conflicts between national and international norms are avoided.

Annex 2, Box 1: Separation of international law and domestic law

The position was outlined by the majority of the High Court of Australia in a key case called *Minister for Immigration and ethnic Affairs v Teoh*. In this case (paragraph 25) the majority of the Court held that it was well established that the provisions of an international treaty to which Australia is a party do not form part of Australian law unless those provisions have been incorporated into domestic law by statute and that such provisions cannot operate as a direct source of individual rights and obligations under the law.

https://jade.io/article/67887

In other countries such as many European and Latin American countries, the legal system is monistic. International law and national law are considered parts of a single legal order, and international treaties ratified by a State become binding at the national level as international legal norms. Therefore conflicts may arise between international and national norms e.g. when ratification of a treaty has not been accompanied with the deletion of existing conflicting norms from national law. In such cases, courts of justice may have to apply certain legal principles to solve disputes such as "superior norms suppress inferior ones", "later norms suppress previous ones", or "particular norms suppress general ones", or consider the respective ranks of the authorities that have adopted the norms (e.g. parliament versus government). Some constitutions include a statement that international treaties take precedence over national law.

Annex 2, Box 2: Statements of prevalence of international law over domestic law

Article 55 of the French Constitution of 1958 states that "Treaties or agreements duly ratified or approved shall, upon publication, prevail over laws, subject, with respect to each treaty or agreement, to its application by the other party".

Article 87 of the Ivory Coast Constitution of 2016 states that "Treaties or agreements duly ratified shall, upon publication, prevail over laws, subject, with respect to each treaty or agreement, to its application by the other party".

Such treaties also belong to the conventional block and may lead to the issuance of legislation that takes precedence over national law. For example, European Union Regulations are directly applicable and take precedence over national law, without any need for transposition in national law. European Union directives are not directly applicable, but all member States are required under the obligations resulting from their membership of the European Union to transpose the provisions contained in directives into national law for national application. Some States, non-members of the European Union (e.g. Norway, Switzerland, Iceland, Liechtenstein) have concluded bilateral agreements with the European Union under which they are also bound to apply certain EU Regulations and directives.

Legality block

The legality block includes two levels: first, organic laws, also known as Institutional Acts or Organic Statutes, which are intermediates between the constitution and ordinary law; then ordinary laws (also known as statutes or Acts of Parliament, or primary legislation) (developed and adopted by or requiring endorsement by the Parliament) and, depending on the countries, other legislative texts such as legislative ordinances or autonomous regulations that remain under the control of Parliament but may be directly edicted by the Government under certain conditions. Depending on the constitution, this block may have to be split between additional different hierarchical levels, e.g. in the case of federal states (respective hierarchy of federal law and individual states law and definition of legislative areas falling within federal and individual state competency).

General Principles of Law

Unlike laws, these are not necessarily available in written form, but result from principles established e.g. by the constitution, by Acts of Parliament, or by jurisprudence, and they should be taken into account by the administration when establishing regulations or administrative acts.

Regulatory block

The regulatory block includes statutory instruments such as regulations issued under cover of decrees or orders issued by the executive authorities (Head of State, ministers, authorized agencies) in order to implement the law and as permitted by the law. They are also known as secondary legislation or delegated legislation. They are normally issued after public consultation of all entities concerned by the effective implementation of the regulatory texts (civil society, worker unions, public administrations, Industry, enforcement bodies, etc). As for the legality block, depending on the country, the national legislation may in some cases allow regions or municipalities to issue regulations in specific areas provided that such regulations do not contradict superior norms.

The contractual block and administrative acts cover all documents issued by the administration, such as directives, guidance documents, administrative circulars or ordinances intended to facilitate or provide guidance for effective application of laws and regulations

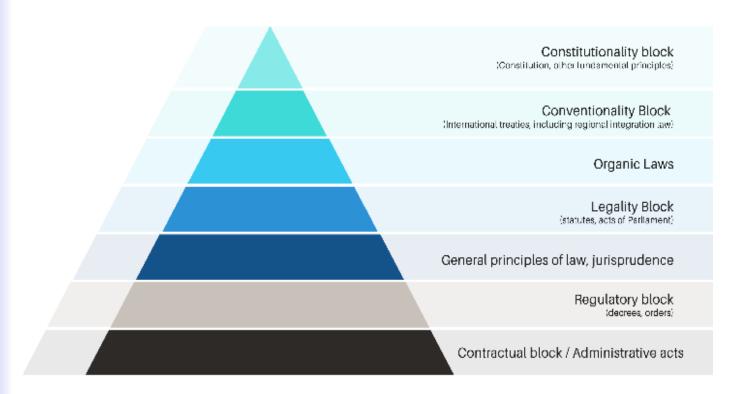


Figure 1: Pyramid of norms (example)

2. Standards

The word "standard" may have different meanings. A standard is usually understood as a technical document intended to standardize the way how to comply with the essential requirements of a legal instrument belonging to the conventionality block, the legality block or the regulatory block. However, the term is also sometimes used to designate one of these legal instruments rather than a recommended way to comply with a legal instrument. As a consequence, when a country adopts a standard for the purpose of GHS Implementation, it is not always clear whether compliance with the provisions of the standard is mandatory or not.

When the term "standard" is used, it is therefore important to understand its meaning in a specific legal context depending on whether the standard has been elaborated for rule-making purposes, in which case it could become a public standard of mandatory application falling in the regulatory block described above, or it has been elaborated simply as a way agreed by specialists of a given activity of doing something in relation to that activity, in which case it could simply be a private standard of voluntary application.



Examples are given below:

ILO Standards

According to ILO⁴⁰, **International labour standards** are legal instruments drawn up by the ILO's constituents (governments, employers and workers) and setting out basic principles and rights at work. They are either **Conventions** (or **Protocols**), which are legally binding international treaties that may be ratified by member states, or **Recommendations**, which serve as non-binding guidelines. In many cases, a Convention lays down the basic principles to be implemented by ratifying countries, while a related Recommendation supplements the Convention by providing more detailed guidelines on how it could be applied. Recommendations can also be autonomous, i.e. not linked to a Convention.

The ILO has developed various means of supervising the application of Conventions and Recommendations in law and practice following their adoption by the International Labour Conference and their ratification by States.

ICAO Standards

In the context of the Convention on International Civil Aviation ("Chicago Convention")⁴¹, a Standard is defined by ICAO as "any specification for physical characteristics, configuration, material, performance, personnel or procedure, the uniform application of which is recognized as necessary for the safety or regularity of international air navigation and to which Contracting States will conform in accordance with the Convention"⁴².

A Recommended Practice is defined by <u>ICAO</u> as "any specification for physical characteristics, configuration, material, performance, personnel or procedure, the uniform application of which is recognized as desirable in the interest of safety, regularity or efficiency of international air navigation and to which Contracting States **will endeavour to conform** in accordance with the Convention".

This means that, within this specific legal context, "standards" and "recommended practices" (SARPs) are granted a different status in the hierarchy of norms. Nevertheless, in practice, they are managed by ICAO and included in annexes to the Chicago Convention which are not integral parts of the Convention and do not possess the same legal binding status as the Convention itself. They are intended to help Contracting Parties in complying with their obligation, under article 37 of the Convention, to "collaborate in securing the highest practicable degree of uniformity in regulations, standards, procedures and organization in relation to aircraft, personnel, airways and auxiliary services in all matters in which such uniformity will facilitate and improve air navigation". But under article 38 of the Convention, each Contracting Party retains the right to adopt regulations and

⁴² Assembly Resolution A36-13, Appendix A. ICAO Doc 9902, Assembly Resolutions in force as of 28 September 2007



 $^{40 \}qquad https://www.ilo.org/global/standards/introduction-to-international-labour-standards/conventions-and-recommendations/lang--en/index.htm$

⁴¹ https://www.icao.int/publications/Documents/7300_cons.pdf

procedures differing from these SARPs, provided that such national deviations (known as "State variations") are notified to ICAO.

Use of the term "standard" to designate regulations

In the United States of America, OSHA standards are rules that describe the methods that employers must use to protect their employees from hazards. The Hazard Communication Standard (HCS) is contained in Title 29 of the Code of Federal Regulations (29 CFR, Parts 1910, 1915, and 1926).

Standards developed by standardization bodies

In the context of the World Trade Organization (WTO) Technical Barriers to Trade Agreement (TBT), a distinction is made between Technical Regulations and Standards. Annex 1 of the TBT indicates that for the purposes of the Agreement the following definitions shall apply:

1. Technical regulation

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

2. Standard

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production meth ods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

It further indicates in an explanatory note that "This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus."

This type of standards may be elaborated by non-governmental bodies, such as national standardization bodies (e.g. ASTM standards in the Unites States of America), regional standardization bodies (e.g. EN standards), or international standardization bodies (e.g. ISO and IEC standards). According to the European Committee for Standardization (CEN), "a standard is a technical document designed to be used as a rule, guideline or definition. It is a consensus-built, repeatable



way of doing something. Standards are created by bringing together all interested parties such as manufacturers, consumers and regulators of a particular material, product, process or service. A European Standard (EN) automatically becomes a national standard and therefore is included in the standards catalogue of CEN's Members (34 member countries)".

This type of standards may also be developed by regional or international intergovernmental bodies within their mandate, and the GHS itself may be considered as an international standard of recommended application.

Although such standards are not of mandatory application per se, they may be made of mandatory application by reference by legal instruments described in section 1 of this Annex.

However, incorporation of certain standards by reference in legislation is not always possible, depending on national constitution or legislation. For example, in certain countries the standard would have to be available in the national language(s). In addition, in certain countries, it would have to be made available to, and usable by, the public in the same way as legal texts, which may be a problem in relation to the copyright policy of standardization organizations such as CEN, IEC and ISO.

Annex 2, Box 3: Case study - Free public accessibility to compulsory standards in France

According to article 17 of the French decree 2009-697 of June 16, 2009 relating to standardization: "The standards are of voluntary application. However, the standards may be made compulsory by decree signed by the Minister for Industry and the Minister(s) concerned. The standards made compulsory can be consulted free of charge on the website of the French Standardization Association (AFNOR)."

On 29 February 2016, the Minister of Environment issued an order requiring, in its article 2, the mandatory application of test methods described in EN standards 378-2, 13184, and 14624 for testing equipment containing certain refrigerants and fluorinated greenhouse gases. As the said standards were not available free of charge on the AFNOR website, the issue was brought to the attention of the French "Conseil d'Etat". AFNOR indicated that due to the CEN copyright policy, it was not entitled to make the French "NF" version of these EN standards available free of charge on its website. As a result, the Conseil d'Etat decided to invalidate the said order. (6th Chamber, 28.07.2017, no. 402752).

The order was later re-issued as a revised version, with article 2 no longer requiring compliance with the said standards but referring to them as acceptable methods of compliance.

ANNEX: FAO/WHO RECOMMENDATION FOR HAZARD CLASSIFICATION OF PESTICIDES

(Refer to section 5 of the FAO/WHO International Code of Conduct for the Management of Pesticides, Guidelines on Good Labelling Practices for Pesticides (revised, August 2015) (http://www.fao.org/3/a-i4854e.pdf)

5.3 Physical hazards

It is recommended that the classification of physical hazards of a pesticide product follows the GHS. That is, classification criteria and label elements (hazard symbol, signal word and hazard statement) are those defined in the GHS. However, not all physical hazards described in the GHS are relevant to pesticides, because substances would not be authorized as a pesticide if they would pose such hazards (e.g. explosive substances or self-reactive substances). Table 5.1⁴³ provides further guidance on the physical hazards that are likely to be relevant for pesticides.

Reference should be made to the GHS Purple Book for the criteria for classification as well as for label elements recommended for the various hazard categories.

In case a pesticide product poses more than one GHS physical hazard, all relevant symbols, signal words and hazard statements should be shown on the label.

5.4 Health hazards

Two international classification systems for health hazards of pesticides are presently in use, the GHS and the WHO Recommended classification of pesticides by hazard. The GHS has become the international standard for classification and labelling of chemicals, including pesticides. However, many countries still apply the WHO classification for pesticide labelling purposes. Therefore, health hazard classifications by both systems are discussed below.

5.4.1 GHS hazard classification

The GHS can be used to classify a pesticide according to a wide range of potential health hazards, ranging from acute toxicity to various chronic effects (Table 5.2)⁴⁴.

For labelling purposes, the pesticide formulation or end-user product should in principle be classified, not the active ingredient, although for chronic health hazards generally only data on the active ingredient will be available (and can therefore be used). Reference should be made to the GHS for the criteria for classification of health hazards [6].

It is **not recommended** to mix the GHS classification with the WHO classification for pesticide labelling (for instance, the WHO classification for acute toxicity should not be combined with the GHS for other health hazards). To avoid possible conflicts in classification and confusion for users, **either** the GHS **or** the WHO classification should be applied to classify and assign label elements for all health hazards in a given country.

In addition to the hazard communication elements discussed above, human health risk assessment of the use of the pesticide product may result in specific precautionary statements and pictograms to be included on the label.

The WHO recommended classification of pesticides by hazard is primarily used to classify a pesticide according to acute toxicity (Table 5.3)⁴⁵. The WHO classification also covers the chronic hazards of some pesticides (e.g. carcinogenicity, reproductive toxicity), as far as internationally acceptable evaluations are available. It does not systematically review chronic hazards of all pesticides, however.

The WHO classification applies different classification criteria and classes from the GHS. In addition to providing the classification criteria (similar to the GHS), the WHO classification also lists peer-reviewed acute toxicity data (oral and dermal LD50 values) for the active ingredients, which can be used for comparison with data available from pesticide registration dossiers or other sources used at the national level.

For labelling purposes, the **pesticide formulation** or end-user product should in principle be classified, not the active ingredient. although for chronic health hazards generally only data on the active ingredient will be available (and can therefore be used). Reference should be made to the WHO Recommended classification of pesticides by hazard for the criteria for classification of health hazards.

It is **not recommended** to mix the WHO classification with the GHS classification for pesticide labelling (for instance, the WHO classification for acute toxicity should not be combined with the GHS for other health hazards). To avoid possible conflicts in classification and confusion for users, **either** the GHS **or** the WHO classification should be applied to classify and assign label elements for all health hazards in a given country.



The GHS is increasingly being adopted by individual countries and by international organizations for the classification and labelling of chemicals. Harmonized classification and labelling, both across borders and across chemical groups, is important to improve comprehension of chemical risks and facilitate trade in chemical products. FAO and WHO therefore recommend the progressive adoption of the GHS for classification and labelling of pesticides. However, many countries still apply the WHO *Recommended classification of pesticides by hazard*. This is why both systems have been discussed in the sections above.

Countries that wish to make the transition from the WHO classification to the GHS for pesticide labelling should best do so at a fixed date and for all pesticide labels at the same time. However, sufficient advance warning should be provided to pesticide manufacturers and distributors for them to be able to design new labels and prepare the logistics of the transition. Government and private extension and advisory services should also adapt their training and information materials on pesticides. This preparatory time should also be used by the regulator to inform pesticide users about any changes in hazard symbols, signal words and hazard statements.

WHO amended its classification in 2009, to bring it more in line with the GHS, although the two systems are not identical. Countries that still apply the old, WHO 2004 classification and wish to implement the GHS for pesticide labelling are recommended to do so directly, and not apply the WHO 2009 classification as an intermediate solution. The latter would result in two subsequent changes of classification and labelling which leads to increased costs for pesticide industry and likely increased confusion among pesticide users.

A particular complication may occur in countries that have adopted the GHS for classification and labelling of household and industrial chemicals but maintain the WHO classification for health hazards of pesticides. Since Safety Data Sheets (SDS) for chemicals are generally recommended to follow the GHS, contradictions in hazard communication between the label and the SDS can occur: Different signal words, hazard statements and hazard symbols may be applied on the label and the SDS of the same pesticide product. This situation is obviously not recommendable and should be addressed during the preparation of the transition.

5.5 Environmental hazards

At present, only hazards to the aquatic environment and hazards to the ozone layer are classified by the GHS. No other environmental hazards are covered (Table 5.4)⁴⁶

For labelling purposes, the pesticide formulation or end-user product should in principle be classified, not the active ingredient. Reference should be made to the GHS for the criteria for classification of environmental hazards.

In case a pesticide product poses more than one GHS environmental hazard, the following precedence of hazard statements to be shown on the label applies:

- If the statement H410 "very toxic to aquatic life with long lasting effects" is assigned, the statement H400 "very toxic to aquatic life" may be omitted.
- If the statement H411 "toxic to aquatic life with long lasting effects" is assigned, the statement H401 "toxic to aquatic life" may be omitted.
- If the statement H412 "harmful to aquatic life with long lasting effects" is assigned, the statement H402 "harmful to aquatic life" may be omitted.

In addition to the hazard communication elements discussed above, environmental risk assessment of the use of the pesticide product may result in specific precautionary statements and pictograms to be included on the label. This will apply to the hazards covered by the GHS but also to a much wider range of environmental risks, such as possible adverse effects on birds, wildlife, livestock, bees, natural enemies of pests, soil organisms and processes, groundwater, etc.

In case a pesticide product poses more than one GHS health hazard, the following precedence of relevant symbols and signal words to be shown on the label applies:

- If the skull-and-crossbones applies for one of the hazards, the exclamation mark for another hazard should not appear;
- If the corrosive symbol applies, the exclamation mark should not appear where it is used for skin or eye irritation;
- If the health hazard symbol appears for respiratory sensitization, the exclamation mark should not appear where it is used for skin sensitization or for skin or eye irritation.

All assigned hazard statements should appear on the label, though. The only exception is:

- If the statement H314 "causes severe skin burns and eye damage" is assigned, the statement H318 "causes serious eye damage" may be omitted.
- Furthermore, if hazard colour bands are shown on the label, and the pesticide product poses more than one GHS health hazard, only the most hazardous colour band is shown on the label.

ANNEX: ARTICLE 2 OF THE TBT

AGREEMENT

Article 2: Preparation, Adoption and Application of Technical Regulations by Central Government Bodies

With respect to their central government bodies:

- 2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.
- 2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.
- 2.3 Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.
- 2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.
- 2.5 A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4. Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.



- 2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.
- 2.7 Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.
- 2.8 Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.
- 2.9 Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:
 - 2.9.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation;
 - 2.9.2 notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;
 - 2.9.3 upon request, provide to other Members particulars or copies of the proposed technical regulation and, whenever possible, identify the parts which in substance deviate from relevant international standards;
 - 2.9.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.
- 2.10 Subject to the provisions in the lead-in to paragraph 9, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 9 as it finds necessary, provided that the Member, upon adoption of a technical regulation, shall:
 - 2.10.1 notify immediately other Members through the Secretariat of the particular technical regulation and the products covered, with a brief indication of the objective and the ratio nale of the technical regulation, including the nature of the urgent problems;
 - 2.10.2 upon request, provide other Members with copies of the technical regulation;2.10.3 without discrimination, allow other Members to present their comments in writing,discuss these comments upon request, and take these written comments and the results of

these discussions into account.

- 2.11 Members shall ensure that all technical regulations which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them.
- 2.12 Except in those urgent circumstances referred to in paragraph 10, Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member.



ANNEX: EXAMPLE OF COOPERATION BETWEEN TWO DIFFERENT ADMINISTRATIVE DEPARTMENTS IN RELATION TO IMPLEMENTATION OF SPECIFIC GHS PROVISION

September 19, 2016
Labeling of Hazardous Chemicals for Bulk Shipments Joint Guidance

Memorandum Prepared by PHMSA's Office of Hazardous Materials Safety and OSHA

Introduction

The U.S. Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) and the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA)⁴⁷ are responsible for enforcing distinct and separate safety standards that address appropriate labeling of chemical hazards in transportation⁴⁸ (PHMSA) and in the workplace (OSHA). PHMSA's labeling requirements are contained in the U.S. Hazardous Materials Regulations (HMR; 49 CFR Parts100-180) and apply to transportation of hazardous materials in commerce. OSHA's labeling requirements are specific to the workplace and are found in the Hazard Communication Standard (HCS 2012), 29 CFR§ 1910.1200. For the purposes of this memorandum, labeling also includes DOT placarding, signs, and other markings. PHMSA and OSHA are aware of a number of questions from stakeholders concerning the labeling required by each agency.

The purpose of this memorandum is to provide clarity on the general applicability of, and overall relationship between, DOT's labeling requirements under the HMR and OSHA's labeling requirements for bulk shipments under the HCS2012.

DOT HMR Labeling Requirements

DOT's HMR requires labeling to be displayed or provided with a shipment during transportation in commerce. The HMR provides a comprehensive labeling system to communicate to personnel involved in the transportation of hazardous materials, including emergency responders and the general public, the potential dangers of handling packages containing hazardous materials or a sudden uncontrolled release of hazardous materials during transportation. During transportation, DOT's HMR governs hazard communication labeling requirements.

Transportation means the movement of property and loading, unloading, or storage incidental to the movement (see 49CFR§107.1). Loading, unloading, and storage incidental to movement are defined in 49CFR§171.8.



OSHA's Workplace means an establishment, jobsite, or project, at one geographical location containing one or more work areas. A work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

HCS 2012 labeling is not required on shipping containers in transport, even when DOT's HMR does not require labeling in transportation.

OSHA HCS 2012 Labeling Requirements for Bulk Shipments in DOT Containers (e.g., tanker trucks, rail cars)

OSHA's HCS 2012 requires labeling of hazardous chemicals in the workplace, both before and after transportation in commerce. OSHA requires labeling on the immediate container of hazardous chemicals. Regarding bulk shipments of hazardous chemicals, the HCS 2012 requires either labeling the immediate container with hazard information or transmitting the required label with shipping papers, bills of lading, or by other technological or electronic means so that it is immediately available to workers in printed form on the receiving end of a shipment. The OSHA HCS 2012 requirements for shipped material apply independently of whether the same material is subject to HMR labeling requirements during transportation.

Note on Bulk Shipments Bearing Both DOT and OSHA HCS 2012 Labels

The HMR prohibits the display on a package of any marking or label that could be confused or conflict with a label required by the HMR. Specifically, 49 CFR§ 172.401(b) states:

"No person may offer for transportation and no carrier may transport a package bearing any marking or label which by its color, design, or shape could be confused with or conflict with a label prescribed by this part."

However, the prohibition in 49 CFR§ 172.401(b) does not apply to packages labeled in conformance with certain international standards, including the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (see 49 CFR§172.401(c)). The provisions of 49 CFR§ 172.401(c) apply only to labeling in accordance with the GHS, and subsequently in accordance with OSHA 29 CFR§1910.1200(f). The GHS labeling provisions, including as implemented by OSHA, require all hazard communication elements to be located on the label and these hazard communication elements must only appear as part of a complete GHS label. As such, the display of a marking or label not required by DOT's HMR, but conforming to OSHA's HCS 2012 and consistent with the GHS is not a violation of the HMR. This includes packages meeting the definition of a "bulk package" as defined by the HMR. In other words, an HCS 2012-compliant OSHA label and a DOT HMR label or marking may both appear on the same package.

Note: The DOT and OSHA are aware of some examples of pictograms/symbols displayed on bulk packages that are not consistent with the HCS (29CFR § 1910.1200) and that are not compliant with hazard communication required by the HMR (49CFR Parts100-180). Such labeling is prohibited by the HMR.





ANNEX: PURPOSE AND SCOPE OF THE

EU CLP REGULATION

(Extracts from REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006)

Article 1. Purpose and scope

- 1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by:
- a. harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;
- b. providing an obligation for:
 - i. manufacturers, importers and downstream users to classify substances and mixtures placed on the market;
 - ii. suppliers to label and package substances and mixtures placed on the market;
 - iii. manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;
- c. providing an obligation for manufacturers and importers of substances to notify the Agency of such classifications and label elements if these have not been submitted to the Agency as part of a registration under Regulation (EC) No 1907/2006;
- d. establishing a list of substances with their harmonised classifications and labelling elements at Community level in Part 3 of Annex VI;
- e. establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (c) and (d).
- 2. This Regulation shall not apply to the following:
- a. radioactive substances and mixtures within the scope of Council Directive 96/29/Euratom of
 13 May 1996 laying down basic safety standards for the protection of the health of workers and
 the general public against the danger arising from ionising radi-ation (1);
- b. substances and mixtures which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit

- c. non-isolated intermediates;
- d. substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under controlled conditions in accordance with Community workplace and environmental legislation.
- 3. Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste (1) is not a substance, mixture or article within the meaning of Article 2 of this Regulation.
- 4. Member States may allow for exemptions from this Regulation in specific cases for certain substances or mixtures, where necessary in the interests of defence.
- 5. This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:
- a. medicinal products as defined in Directive 2001/83/EC;
- b. veterinary medicinal products as defined in Directive 2001/82/EC;
- c. cosmetic products as defined in Directive 76/768/EEC;
- d. medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;
- e. food or feeding stuffs as defined in Regulation (EC) No 178/2002 including when they are used:
 - i. as a food additive in foodstuffs within the scope of Directive 89/107/EEC;
 - ii. as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;
 - iii. as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003;(iv) in animal nutrition within the scope of Directive 82/471/EEC.
- 6. Save where Article 33 applies this Regulation shall not apply to the transport of dangerous goods by air, sea, road, rail or inland waterways.

Article 33 Specific rules for labelling of outer packaging, inner packaging and single packaging

1. Where a package consists of an outer and an inner packaging, together with any intermediate packaging, and the outer packaging meets labelling provisions in accordance with the rules on the transport of dangerous goods, the inner and any intermediate packaging shall be labelled in accordance with this Regulation. The outer packaging may also be labelled in accordance with this Regulation. Where the hazard pictogram(s) required by this Regulation relate to the same hazard as in the rules for the transport of dangerous goods, the hazard pictogram(s) required by this Regulation need not appear on the outer packaging.



- 2. Where the outer packaging of a package is not required to meet labelling provisions in accordance with rules on the transport of dangerous goods, both the outer and any inner packaging, including any intermediate packaging, shall be labelled in accordance with this Regulation. However, if the outer packaging permits the inner or inter¬mediate packaging labelling to be clearly seen, the outer packaging need not be labelled.
- 3. Single packages that meet the labelling provisions in accordance with the rules on the transport of dangerous goods shall be labelled both in accordance with this Regulation and the rules on the transport of dangerous goods. Where the hazard pictogram(s) required by this Regulation relate to the same hazard as in rules on the transport of dangerous goods, the hazard pictogram(s) required by this Regulation need not appear.

ANNEX: SCOPE AND PURPOSE OF THE USA HAZARD COMMUNICATION

STANDARD (29CFR, PART 1910)

1910.1200(a)

Purpose.

1910.1200(a)(1)

The purpose of this section is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Revision 3. The transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

1910.1200(a)(2)

This occupational safety and health standard is intended to address comprehensively the issue of classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legislative or regulatory enactments of a state, or political subdivision of a state, pertaining to this subject. Classifying the potential hazards of chemicals and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. Under section 18 of the Act, no state or political subdivision of a state may adopt or enforce any requirement relating to the issue addressed by this Federal standard, except pursuant to a Federally-approved state plan.

1910.1200(b)

Scope and application.

1910.1200(b)(1)

This section requires chemical manufacturers or importers to classify the hazards of chemicals



which they produce or import, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers.)

1910.1200(b)(2)

This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

1910.1200(b)(3)

This section applies to laboratories only as follows:

1910.1200(b)(3)(i)

Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

1910.1200(b)(3)(ii)

Employers shall maintain any safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to laboratory employees when they are in their work areas;

1910.1200(b)(3)(iii)

Employers shall ensure that laboratory employees are provided information and training in accordance with paragraph (h) of this section, except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section; and, 1910.1200(b)(3)(iv)

Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor under this rule, and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled in accordance with paragraph (f) of this section, and that a safety data sheet is provided to distributors and other employers in accordance with paragraphs (g)(6) and (g)(7) of this section.

1910.1200(b)(4)

In work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows:

1910.1200(b)(4)(i)

Employers shall ensure that labels on incoming containers of hazardous chemicals are not re-

moved or defaced;

1910.1200(b)(4)(ii)

Employers shall maintain copies of any safety data sheets that are received with incoming shipments of the sealed containers of hazardous chemicals, shall obtain a safety data sheet as soon as possible for sealed containers of hazardous chemicals received without a safety data sheet if an employee requests the safety data sheet, and shall ensure that the safety data sheets are readily accessible during each work shift to employees when they are in their work area(s); and, 1910.1200(b)(4)(iii)

Employers shall ensure that employees are provided with information and training in accordance with paragraph (h) of this section (except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section), to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container.

1910.1200(b)(5)

This section does not require labeling of the following chemicals:

1910.1200(b)(5)(i)

Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

1910.1200(b)(5)(ii)

Any chemical substance or mixture as such terms are defined in the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

1910.1200(b)(5)(iii)

Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;

1910.1200(b)(5)(iv)

Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, Firearms and Explosives; 1910.1200(b)(5)(v)

Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission;



and,

1910.1200(b)(5)(vi)

Agricultural or vegetable seed treated with pesticides and labeled in accordance with the Federal Seed Act (7 U.S.C. 1551 et seq.) and the labeling regulations issued under that Act by the Department of Agriculture.

1910.1200(b)(6)

This section does not apply to:

1910.1200(b)(6)(i)

Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

1910.1200(b)(6)(ii)

Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 U.S.C. 9601 et seq.) when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations.

1910.1200(b)(6)(iii)

Tobacco or tobacco products;

1910.1200(b)(6)(iv)

Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);

1910.1200(b)(6)(v)

Articles (as that term is defined in paragraph (c) of this section);

1910.1200(b)(6)(vi)

Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the workplace;

1910.1200(b)(6)(vii)

Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies);

1910.1200(b)(6)(viii)

Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

1910.1200(b)(6)(ix)

Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended; 1910.1200(b)(6)(x)

Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered under this section;

1910.1200(b)(6)(xi)

Ionizing and nonionizing radiation; and,

1910.1200(b)(6)(xii)

Biological hazards.



ANNEX: GHS PARAGRAPHS REFERRING

TO DECISIONS TO BE TAKEN BY COMPETENT AUTHORITIES

This annex reproduces the text of GHS paragraphs which leave it up to competent authorities to decide how to apply certain provisions.

1.1.2.6.1 Other scope limitations

Competent authorities are best placed to determine in regulations or standards the appropriate risk assessment procedures and risk management measures

1.1.3.1.1 Harmonization of the application of the GHS

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

1.1.3.1.5 Guidance on the interpretation of the BBA

Competent authorities may decide which hazard classes they apply.

Competent authorities have the possibility not to apply all categories

Where a **competent authority** adopts a hazard category, it should also adopt all the categories for higher hazard levels in that class. As a consequence, when a **competent authority** adopts a hazard class, it will always adopt at least the highest hazard category (Category 1), and, where more than one hazard category is adopted, these hazard categories will form an unbroken sequence

1.3.3.2 Use of cut-off values/concentration limits

For the purposes of the GHS, the terms "cut-off value" and "concentration limit" are equivalent and are meant to be used interchangeably. **Competent authorities** may choose whether to use either term to define thresholds that trigger classification.

1.4.6.3.1 Use of non-standardized or supplemental information

Competent authorities may require additional information, or suppliers may choose to add supplementary information on their own initiative.

1.4.7.2: General guidance on updating of information

1.4.7.2.2.....The **competent authority** may choose to specify a time limit within which the information should be revised...

1.4.7.2.3 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.

1.4.8.2 and 1.4.8.3 Confidential business information

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) to (c)]

1.4.8.3

...

- (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 substance or 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.

...

(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.

1.4.10.4.2.3 Pictograms and reproduction of the hazard pictograms

Pictograms prescribed by the GHS but not the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, 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 Recommendations on the Transport of Dangerous Goods, Model Regulations pictograms in other use settings where the package is not covered by the Model Regulations.

1.4.10.5.2 Information required on a GHS label

• • •

(c) Precautionary statements and pictograms

(i)....The GHS label should include appropriate precautionary information, the choice of which is with the labeller or the **competent authority**. Annex 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**;



(d) Product identifier

. . . .

- (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 corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, skin or respiratory sensitization, or specific target organ toxicity (STOT), when these 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;
- (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;
- (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.

1.4.10.5.3.1 Precedence for the allocation of symbols

For substances and mixtures covered by the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, the precedence of symbols for physical hazards should follow the rules of the UN Model Regulations. In workplace situations, the **competent authority** may require all symbols for physical hazards to be used.....

1.4.10.5.3.3 Precedence for allocation of hazard statements

All assigned hazard statements should appear on the label, except where otherwise provided in this sub-section. The **competent authority** may specify the order in which they appear. However, to avoid evident duplication or redundancy in the information conveyed by hazard statements, the following precedence rules may be applied: [(a) to (d)]

Competent authorities may decide whether to require use of the above precedence rules, or to leave the choice to the manufacturer/supplier.

Table A3.1.2 in Annex 3 includes specified combinations of hazard statements. Where a combined hazard statement is indicated, the **competent authority** may specify whether the combined hazard statement or the corresponding individual statements should appear on the label, or may leave the choice to the manufacturer/supplier.

1.4.10.5.4.1 Location of GHS information on the label

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.

1.4.10.5.4.2 **Supplemental information**

1.10.5.4.2 **Supplemental information**

The **competent authority** has the discretion to allow the use of supplemental information subject to the parameters outlined in 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

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**.

1.4.10.5.4.4 Labelling of small packagings

...

- (c)Where the volume of a hazardous substance or mixture is so low and the supplier has data demonstrating, and the **competent authority** has determined, that there is no likelihood of harm to human health and/or the environment, then the label elements may be omitted from the immediate container;
- (d)Competent authorities may allow certain label elements to be omitted from the immediate container for certain hazard classes/categories where the volume of the substance or mixture is below a certain amount;

...

1.4.10.5.5 Special labelling arrangements

The **competent authority** may choose to allow communication of certain hazard information for carcinogens, reproductive toxicity and specific target organ toxicity through repeated 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).

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

Where a substance or mixture is classified as corrosive to metals but not corrosive to skin and/or eyes, the **competent authority** may choose to allow the hazard pictogram linked to "corrosive to metals" to be omitted from the label of such substances or mixtures which are in the finished state



as packaged for consumer use.

1.4.10.5.5.1 Workplace labelling

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.

1.4.10.5.5.2 Consumer product labelling based on the likelihood of injury

All systems should use the GHS classification criteria based on hazard, however competent authorities may authorize consumer labelling systems providing 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. specific target organ toxicity (STOT)) 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.

1.5.2 Criteria for determining whether an SDS should be produced

An SDS should be produced for all substances and mixtures which meet the harmonized criteria for physical, health or environmental hazards under the GHS and for all mixtures which contain ingredients that meet the criteria for carcinogenic, toxic to reproduction or specific target organ toxicity in concentrations exceeding the cut-off limits for SDS specified by the criteria for mixtures (see 1.5.3.1). The **competent authority** may also require SDS?s for mixtures not meeting the criteria for classification as hazardous but which contain hazardous ingredients in certain concentrations (see 1.5.3.1).

1.5.3.1.3 and 1.5.3.1.4 SDS: Cut-off values/concentration limits

Some **competent authorities** (CA) may require SDS's 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 or toxic to the aquatic environment ingredients in concentrations equal to or greater than 1% (footnote 1).

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

Footnote 1: The cut-off values for classification of mixtures are normally specified by concentrations expressed as % of the ingredients. In some cases, for example acute toxicity (human health), the cut-off 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 ingredients. Similarly acute aquatic toxicity classification may be calculated on the basis of acute aquatic toxicity values (see Chapter 4.1) and where appropriate, corrosion/irritation by adding up concentrations of ingredients (see Chapters 3.2 and 3.3). Ingredients are taken into consideration for application of the formula 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 an SDS.

1.5.3.3 **SDS** content

The SDS should provide a clear description of the data used to identify the hazards. The minimum information in Table 1.5.2 should be included, where applicable and available, on the SDS under the relevant headings (footnote 2). 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.

Table 1.5.2 Minimum information for an SDS

NOTE: The order of the physical and chemical properties presented in Section 9 may be followed on the SDS as shown in this table, but is not mandatory. The **competent authority** may decide to prescribe an order for Section 9 of the SDS, or they may leave it to the preparer of the SDS to re-order the properties, if deemed appropriate.

2.2.4.2 Guidance (flammability)

Where insufficient data are available to use these methods, tests by a comparable method recognized by the **competent authority** may be used.

2.6.2 Classification criteria for flammable liquids

NOTE 3: Viscous flammable liquids such as paints, enamels, lacquers, varnishes, adhesives and polishes may be regarded as a special group for some regulatory purposes (e.g. transport). The classification or the decision to consider these liquids as non-flammable may be determined by the pertinent regulation or **competent authority**.

2.6.2 Decision logic for flammable liquids (footnote 1)

Gas oils, diesel and light heating oils in the flash point range of 55 °C to 75 °C may be regarded as a special group for some regulatory purposes as these hydrocarbons mixtures have varying flash point in that range. Thus classification of these products in Category 3 or 4 may be determined by the pertinent regulation or competent authority.

2.16 Classification corrosive to metals (note to table 2.16.2)



NOTE: Where a substance or mixture is classified as corrosive to metals but not corrosive to skin and/or eyes, some **competent authorities** may allow the labelling provisions described in 1.4.10.5.5.

3.1 Classification criteria for Category 5

3.1.2.5, footnote 1 Guidance on Acute toxicity category 5 inhalation values

The OECD Task Force on Harmonization of Classification and Labelling (HCL) did not include numerical values in Table 3.1.1 above for acute inhalation toxicity Category 5 but instead specified doses "equivalent" to the range of 2000-5000 mg/kg bodyweight by the oral or dermal route (see Note (g) to Table 3.1.1). In some systems, the competent authority may prescribe values.

3.1.3.6.2.1 Data are not available for one or more ingredients of the mixture

Where an ATE is not available for an individual ingredient of the mixture, but available information such as listed below can provide a derived conversion value, the formula in 3.1.3.6.1 may be applied. This may include evaluation of: (a) Extrapolation between oral, dermal and inhalation acute toxicity estimates (footnote 2)

. . .

Footnote 2: When mixtures contain ingredients that do not have acute toxicity data for each route of exposure, acute toxicity estimates may be extrapolated from the available data and applied to the appropriate routes (see 3.1.3.2). However, competent authorities may require testing for a specific route. In those cases, classification should be performed for that route based upon the **competent authority's** requirement.

3.1.3.6.2.2 Classification criteria for mixtures and

3.1.5.2 Decision logic 3.1.2 for acute toxicity, footnote 2

In the event that an ingredient without any useable information for classification is used in a mixture at a concentration \geq 1%, it is concluded that the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture should be classified based on the known ingredients only, with the additional statement that x percent of the mixture consists of ingredient(s) of unknown acute (oral/dermal/inhalation) toxicity. The **competent authority** can decide to specify that the additional statement(s) be communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier.

3.2.2 Classification criteria for substances (skin corrosion/irritation)

(a) Category 1 (skin corrosion)

This category may be further divided into up to three sub-categories (1A, 1B and 1C) which can be used by those **authorities** requiring more than one designation for corrosivity

Corrosive substances should be classified in Category 1 where sub-categorization is not required by a **competent authority** or where data are not sufficient for sub-categorization.

When data are sufficient, and where required by a **competent authority**, substances may be classified in one of the three sub-categories 1A, 1B or 1C

.....

(d) Category 3 (mild skin irritation)

This category is available for those authorities that want to have more than one skin irritation category (e.g. for classifying pesticides).

3.2.5.3.2.3, 3.2.5.3.2.4 and 3.2.5.3.2.5 Guidance on the use of human data for classification as skin corrosion or skin irritation

3,2,5,3,2,3

Some **competent authorities** do not allow HPT testing solely for hazard identification (see 1.3.2.4.7) while some competent authorities recognize the use of HPT for classification as skin irritant.

3.2.5.3.2.4 HPT (Human Patch Tests)

Specific criteria for HPT results leading to classification as category 2 (skin irritation), category 3 (mild irritation) or not classified, have not been established at the international level. Therefore, the results of an HPT are generally used within a weight of evidence assessment. However, some **competent authorities** may provide specific guidance. A clearly negative result in an HPT with a sufficient number of volunteers after exposure to the undiluted substance for 4 hours can justify no classification.

3.2.5.3.2.5

Human case reports may be used for classification as corrosive if irreversible damage to the skin was observed. There are no internationally accepted classification criteria for irritation. Therefore, where **competent authorities** have not provided specific guidance on this matter, expert judgement may be required to evaluate whether the exposure duration and any available long-term follow-up information are sufficient to allow for a conclusion on classification. Cases resulting in irritation or no effects may not be conclusive on their own but can be used in a weight of evidence assessment.

3.3.2.1.2.1 and 3.3.2.1.2.2 Eye irritation (Category 2)/Reversible effects on the eye

3.3.2.1.2.1

Substances that have the potential to induce reversible eye irritation should be classified in Category 2 where further categorization into Category 2A and Category 2B is not required by a competent authority or where data are not sufficient for further categorization. When a chemical is classified as Category 2, without further categorization, the classification criteria are the same as those



for Category 2A.

3.3.2.1.2.2

For those **authorities** wanting more than one designation for reversible eye irritation, categories 2A and 2B are provided:

(a) When data are sufficient and where required by a **competent authority** substances may be classified in Category 2A or 2B in accordance with the criteria in Table 3.3.2;

. . . .

3.4.2.1.1.1 and 3.4.2.1.1.2 Respiratory sensitizers (hazard categories)

Respiratory sensitizers shall be classified in Category 1 where sub-categorization is not required by a **competent authority** or where data are not sufficient for sub-categorization.

Where data are sufficient and where required by a competent authority, a refined evaluation according to 3.4.2.1.1.3 allows the allocation of respiratory sensitizers into sub-category 1A, strong sensitizers, or sub-category 1B for other respiratory sensitizers.

3.4.2.2.1.1 and 3.4.2.2.1.2 Skin sensitizers (hazard categories)

Skin sensitizers shall be classified in Category 1 where sub-categorization is not required by a **competent authority** or where data are not sufficient for sub-categorization.

Where data are sufficient and where required by a **competent authority**, a refined evaluation according to 3.4.2.2.1.3 allows the allocation of skin sensitizers into sub-category 1A, strong sensitizers, or sub-category 1B for other skin sensitizers."

3.4.3.1 Classification of mixtures when data are available for the complete mixture When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture can be classified by weight of evidence evaluation of these data. Care should be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive. (For special labelling required by some competent authorities, see the note to Table 3.4.5 of this chapter and 3.4.4.2.)

Table 3.4.5 Cut-off values/concentration limits (note) Some **competent authorities** may require SDS and/or supplemental labelling only, as described in 3.4.4.2 for mixtures containing a sensitizing ingredient at concentrations between 0.1 and 1.0% (or between 0.1 and 0.2% for a gaseous respiratory sensitizer). While the current cut-off values reflect existing systems, all recognize that special cases may require information to be conveyed below that level.

4.1.3.6 Classification of mixtures with ingredients without any useable information

In the event that no useable information on acute and/or chronic aquatic toxicity is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: "x % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment". The **competent authority** can decide to specify that the additional statement is communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier.

4.1.5.1.1 Decision logic 4.1.1 "Footnote 3:

If not all ingredients have information, include the statement "x % of the mixture consists of ingredients(s) of unknown hazards to the aquatic environment" on the label. The **competent authority** can decide to specify that the additional statement be communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier. Alternatively, in the case of a mixture with highly toxic ingredients, if toxicity values are available for these highly toxic ingredients and all other ingredients do not significantly contribute to the hazard of the mixture, then the additivity formula may be applied (see 4.1.3.5.5.5). In this case and other cases where toxicity values are available for all ingredients, the short-term (acute) classification may be made solely on the basis of the additivity formula.

4.1.5.2.4 Decision logic 4.1.4 "Footnote 10:

In the event that no useable information on acute and/or chronic aquatic toxicity is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: "x % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment". The **competent authority** can decide to specify that the additional statement be communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier.

Table A1.8 and A1.15 Labelling of self-reactive and mixtures and organic peroxides in transport (note a)

For Type B, under the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, special provision 181 may apply (Exemption of explosive label with competent authority approval. See Chapter 3.3 of the UN Model Regulations for more details).

A3.1.2.4 Hazard statements

All assigned hazard statements should appear on the label unless otherwise specified in 1.4.10.5.3.3. The competent authority may specify the order in which they appear. Also, where a combined hazard statement is indicated for two or more hazard statements, the competent authority may specify whether the combined hazard statement or the corresponding individual state-



ments should appear on the label, or may leave the choice to the manufacturer/supplier.

A3.2.1.4 **Precautionary statements**

Precautionary statements should, as an important part of hazard communication, appear on GHS labels, generally along with the GHS hazard communication elements (pictograms, signal words and hazard statements). Additional supplemental information, such as directions for use, may also be provided at the discretion of the manufacturer/supplier and/or competent authority (see Chapter 1.2 and 1.4.6.3). For some specific chemicals, supplementary first aid, treatment measures or specific antidotes or cleansing materials may be required. Poisons Centres and/or medical practitioners or specialist advice should be sought in such situations and included on labels.

A3.2.4.1, A3.2.4.2 and A3.2.4.3 Use of precautionary statements

TableA3.2.1 to A3.2.5 show the core part of the precautionary statements in bold print. This is the text, except as otherwise specified, that should appear on the label. Derogations from the recommended labelling statements are at the discretion of competent authorities (see A3.2.5).

When a forward slash or diagonal mark "/" appears in a precautionary statement text, it indicates that a choice has to be made between the phrases they separate. In such cases, the manufacturer or supplier can choose, or the **competent authorities** may prescribe one or more appropriate phrase(s). For example P280 "Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/" could read "wear eye protection" or "wear eye and face protection".

When three full stops "..." appears in a precautionary statement text, they indicate that all applicable conditions are not listed. For example in P241 "Use explosion-proof [electrical/ventilating/lighting/...] equipment", the use of "..." indicates that other equipment may need to be specified. Further details of the information to be provided may be found in column (5) of the tables. In such cases the manufacturer or supplier can choose, or the **competent authorities** may prescribe the other conditions to be specified.

A3.2.5.1.1 Omission of precautionary statements where the advice is not relevant

Subject to any requirements of **competent authorities**, those responsible for labelling may decide to omit other precautionary statements for a hazard class and category where the information is clearly not appropriate or is adequately addressed by other information on the label, taking into account the nature of the user (e.g. consumer, employers and workers), the quantity supplied, and the intended and foreseeable circumstances of use. Where a decision is made to omit a precautionary statement the manufacturer or supplier of the substance or mixture should be able to demonstrate that the precautionary statement is not appropriate for the intended and foreseeable use, including potential emergency situations.

A3.2.5.3.1 Variations of text not affecting the safety message

Subject to any requirements of **competent authorities**, the precautionary statements that appear on labels or in safety data sheets may incorporate minor textual variations from those set out in the GHS where these variations assist in communicating safety information and the safety advice is not diluted or compromised. These may include spelling variations, synonyms or other equivalent terms appropriate to the region where the product is supplied and used.

Table A.3.2.2. Prevention precautionary statements, Column (5) Conditions for use

P230Manufacturer/supplier or the competent authority to specify appropriate material.

P231Manufacturer/supplier or the **competent authority** to specify appropriate liquid or gas if "inert gas" is not appropriate.

P250, P261Manufacturer/supplier or the competent authority to specify applicable conditions.

P264 ...Manufacturer/supplier or the **competent authority** to specify parts of the body to be washed after handling.

P280 ...Manufacturer/supplier or the **competent authority** to specify the appropriate personal protective equipment.

Manufacturer/supplier or the **competent authority** may further specify type of equipment where appropriate.

P284 Manufacturer/supplier or the **competent authority** to specify equipment.

Table A.3.2.3. Response precautionary statements, Column (5) Conditions for use P316 Competent Authority or manufacturer / supplier may add, "Call" followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor.

P321 ...Reference to supplemental first aid instruction manufacturer/supplier or the **competent authority** may specify a cleansing agent if appropriate.

P352 Manufacturer/supplier or the **competent authority** may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.

P353 text in square brackets to be included where the manufacturer/supplier or the **competent authority** considers it appropriate for the specific chemical.

P378 ... Manufacturer/supplier or the competent authority to specify appropriate media.

Table A.3.2.4. Storage precautionary statements, Column (5) Conditions for use

P401 ... Manufacturer/supplier or the **competent authority** to specify local/regional/national/international regulations as applicable.

P406 ... Manufacturer/supplier or the **competent authority** to specify other compatible materials.
P410 may be omitted for chemicals under pressure filled in transportable cylinders in accordance with packing instruction P200 or P206 of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, unless those chemicals under pressure are subject to (slow) de-



composition or polymerization, or the competent authority provides otherwise.

P411 ...Manufacturer/supplier or the **competent authority** to specify temperature using applicable temperature scale.

P412 ...Manufacturer/supplier or the **competent authority** to use applicable temperature scale.

P413 ...Manufacturer/supplier or the **competent authority** to specify mass and temperature using applicable scale.

Table A.3.2.5. Disposal precautionary statements, Column (5) Conditions for use

P501 Manufacturer/supplier or the **competent authority** to specify whether disposal requirements apply to contents, container or both.

P503 Manufacturer/supplier or the **competent authority** to specify appropriate source of information in accordance with local/regional/national/international regulations as applicable

A4.2.1 SDS: Scope and application

The **competent authority** (CA) may also require SDS for mixtures not meeting the criteria for classification as hazardous but which contain hazardous ingredients in certain concentrations (see Chapter 3.2). The CA may also require SDS for substances or mixtures that meet the criteria for classification as hazardous for non-GHS classes/end-points.

A4.3 SDS: Information required for the preparation of the SDS

This section describes the GHS information requirements for SDS's. Additional information may be required by **competent authorities**.

A4.3.2.3 SDS: Other hazards which do not result in classification

To communicate combustible dust hazards, and thus a potential risk of dust explosions under the approach described in Annex 11 in a standardized manner, **competent authorities** may allow the use of the phrases identified in A11.2.7.3 on labels, SDSs and/or in operating instructions or may leave the choice to the manufacturer or supplier.

A4.3.3. SDS Section 3: Composition/information on ingredients

A4.3.3.1.1, A4.3.3.2.2

For information on ingredients, the **competent authority** rules for Confidential Business Information (CBI) take priority over the rules for product identification. When applicable, indicate that confidential information about the composition was omitted.

The concentrations of the ingredients of a mixture should be described as:

[a...]

(b) ranges of percentages in descending order by mass or volume if such ranges are acceptable to the appropriate **competent national authority**."



A4.3.13.1.1 Disposal methods

Provide information for proper disposal, recycling or reclamation of the substance or mixture and/ or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of the national competent authority.

A5.1.2 Consumer product labelling based on the likelihood of injury

The work on the GHS has not addressed harmonization of this type of approach. Therefore, specific procedures to apply this approach would have to be developed and applied by the **competent authority**.

A5.2 General principles

Risk-based labelling can only be applied by the **competent authorities** to the chronic health hazards of chemicals in the consumer product setting.

A5.2.2.9 Example of risk-based labelling

The **competent authority** will need to establish what level of risk is acceptable to implement such an approach to consumer product labelling for chronic effects. For example, CPSC recommends labelling for a cancer hazard if the lifetime excess risk exceeds one-in-a-million from exposure during "reasonably foreseeable handling and use".

Annex 7

Example 3, footnote

Some **competent authorities** may require a GHS label on the outer packaging in the absence of a transport label.

Example 9

This example illustrates one way to label containers where the manufacturer/supplier or competent authority has determined there is insufficient space to place the GHS pictogram(s), signal word, and hazard statement(s) together, as provided in 1.4.10.5.4.1, on the surface of the container.

It is recognized that some regulatory systems (e.g. pesticides) may have specific requirements for the application of labels using a multilayer or booklet style format. Where this is the case, labelling would be undertaken in accordance with the **competent authority's** requirements.

Example 10

This example illustrates ways to label sets or kits where the manufacturer/supplier or **competent authority** has determined there is insufficient space to place together on each inner container within the kit, the GHS pictogram(s), signal word and hazard statement(s) in accordance with 1.4.10.5.4.1.





ANNEX: TRAINING REQUIREMENT IN THE USA HAZARD COMMUNICATION STANDARD (29 CFR, PART 1920)

§1910.1200

...

(h) Employee information and training.

(h)(1) Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new chemical hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and safety data sheets.

(h)(2) Information. Employees shall be informed of:

- i. The requirements of this section;
- ii. Any operations in their work area where hazardous chemicals are present; and,
- iii. The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and safety data sheets required by this section.

(h)(3) Training. Employee training shall include at least:

- i. Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);
- ii. The physical, health, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, of the chemicals in the work area;
- iii. The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,
- iv. The details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system used by their employer; the safety data sheet, including the order of information and how employees can obtain and use the appropriate hazard information.

ADR, Annex B, Part 8, Chapter 8.2 "Requirements concerning the training of vehicle crew" (Extracts)

Training of drivers

...

8.2.1.1 Drivers of vehicles carrying dangerous goods shall hold a certificate issued by the competent authority stating that they have participated in a training course and passed an examination on the particular requirements that have to be met during carriage of dangerous goods.

...

- 8.2.2.3.2 Subjects to be covered by the basic training course shall be, at least:
- a. General requirements governing the carriage of dangerous goods;
- b. Main types of hazard;
- c. Information on environmental protection in the control of the transfer of wastes;
- d. Preventive and safety measures appropriate to the various types of hazard;
- e. What to do after an accident (first aid, road safety, basic knowledge about the use of protective equipment, instructions in writing, etc.);
- f. Marking, labelling, placarding and orange-coloured plate marking;
- g. What a driver should and should not do during the carriage of dangerous goods;
- h. Purpose and the method of operation of technical equipment on vehicles;
- i. Prohibitions on mixed loading in the same vehicle or container;
- j. Precautions to be taken during loading and unloading of dangerous goods;
- k. General information concerning civil liability;
- I. Information on multimodal transport operations;
- m. Handling and stowage of packages;
- n. Traffic restrictions in tunnels and instructions on behaviour in tunnels (prevention of incidents, safety, action in the event of fire or other emergencies, etc.);
- o. Security awareness.

...

8.2.2.8.5 Model for the training certificate for drivers of vehicles carrying dangerous goods



ADR DRIVER TRAINING CERTIFICATE

**

1. (CERTIFICATE No.)*

2. (SURNAME)*

3. (OTHER NAME(S))*

(Insert ver photograph) 4. (DATE OF BIRTH dd/mm/yyyy)*

driver photograph) 5. (NATIONALITY)*

6. (DRIVER SIGNATURE)*

7. (ISSUING BODY)*

8. VALID TO: (dd/mm/yyyy)*

FRONT

BACK

VALID FOR CLASS(ES) OR UN Nos.:

TANKS TANKS OTHER THAN

9. (Enter Class or UN Number(s))* 10. (Enter Class or UN Number(s))*

8.2.3 Training of persons other than the drivers holding a certificate in accordance with 8.2.1, involved in the carriage of dangerous goods

Persons whose duties concern the carriage of dangerous goods by road shall have received training in the requirements governing the carriage of such goods appropriate to their responsibilities and duties according to Chapter 1.3. This requirement shall apply to individuals such as personnel who are employed by the road vehicle operator or the consignor, personnel who load or unload dangerous goods, personnel in freight forwarding or shipping agencies and drivers of vehicles other than drivers holding a certificate in accordance with 8.2.1, involved in the carriage of dangerous goods by road.



ANNEX: FEEDBACK ON GHS IMPLEMEN-

TATION TO BE TRANSMITTED TO THE UNITED NATIONS SECRETARIAT

(See also https://unece.org/transportdangerous-goods/ghs-implementation-information-submission-form)

At its December 2020 session, the UN Sub-Committee of Experts on the GHS agreed that information on the implementation of the GHS should be submitted to the secretariat as follows:

"18. The form will include items below, which have been identified by the Sub-Committee as being the most relevant to governments and industry when analysing the technical aspects of the implementation worldwide:

- a. The competent national regulatory authority exercising jurisdiction over application of the GHS (by sector, as appropriate)
- b. Exact reference to the implementing tool (e.g. Regulation, decree, order, administrative decision, national standard) where the applicable GHS provisions may be found, and reference to the legal instrument (treaty, law, act) under which this implementing tool has been issued, including a link to the relevant website, it the text is available online. If the implementing tool is a national standard, indicate if it is of mandatory or non-mandatory application. If it is of mandatory application, reference to the legal instrument requiring its mandatory application.
- c. Date of publication
- d. Date of entry into force and transitional periods if any
- e. Scope of application (sectors and type of chemicals covered): consumer, industrial, agricultural chemicals; chemicals listed or addressed in other pieces of legislation;
- f. Information about lists of chemicals classified in accordance with the GHS to be used at national level and their status (mandatory/voluntary).
- g. Information about the edition of the GHS that is implemented as well as expected timeline for revisions to take account of the updates adopted by the Sub-Committee every two years
- h. Provisions allowing imported chemicals classified and labelled in accordance with more recent revised editions of the GHS
- Hazard classes and categories implemented in each sector
- j. Details on provisions left to the discretion of the competent authority, e.g.:
 - i. Use of non-standardized or supplemental information
 - ii. Confidential business information specifics
 - iii. Specific labelling arrangements (e.g. definition of a minimum size for labels and/or pictograms; precedence for allocation of allocation of symbols and hazard statements; provi-

- sions for labelling of small packagings and workplace labelling; use of product identifiers; location of GHS information on the label)
- iv. Cut-off values requiring communication of certain hazard information for carcinogens, reproductive toxicity and specific target organ toxicity through repeated exposure on the label and on the SDS or through the SDS alone
- v. Requirement to provide SDS's for mixtures not meeting the criteria for classification as hazardous but which contain hazardous ingredients in certain concentrations
- vi. Requirement to include a statement in the label, the SDS or both, indicating that x % of the mixture consists of ingredient(s) of unknown toxicity
- vii. Requirement to provide information on specific hazards that do not result in classification

19. The form could be shared with industry representatives and international organisations interested in monitoring the status of implementation of the GHS to collect information among their stakeholders. All the information collected could then be compiled together and made publicly available."



ANNEX: QUESTIONNAIRE SENT TO

NON-GOVERNMENTAL ORGANIZATIONS AND SUMMARY OF REPLIES

(1) Are you generally satisfied with the way the GHS has been implemented through legis lation/standards in the various sectors and countries that members of your organization are involved or work in? Please explain your answer

Some qualified positive comments

GHS was intended as a global system that would facilitate hazard communication through the use of standardised approaches, symbols and sentences to classify and communicate chemical hazards. In that respect it has certainly proved beneficial.

Hazard communication has also a key role to play when it comes to trade ensuring that companies in different countries are able to communicate easily about the characteristics of their products to ensure they are used and managed safely. Facilitating trade has proven less effective.

But in general, lack of satisfaction in the way GHS implementation is moving forward

Issues mentioned are:

- National/regional additions, variations and deviations without prior information of the UN Subcommittee of experts on the GHS in order to eventually get an official review of the UN GHS provisions concerned
- Many countries lack capacity in terms of resources, expertise, infrastructures, etc. to implement the GHS
- Fragmented implementation, e.g. different sectors not covering all hazard classes
- In some countries, the legislative instruments are not adequate. For example, a voluntary implementation via a standard should lead to a legal instrument within a reasonable amount of time
- Lack of enforcement in some countries
- Lack of harmonization (still important deviations)
- Difficulties arise in part from the fact that the GHS is still a new framework and will evolve for some years to come. As a consequence, different editions of the GHS are implemented in different countries reducing the benefits of using the same system. Approaches taken by New Zealand and Australia in accepting classifications against other editions of the GHS can certainly help in removing some of these barriers.



- More challenging to address is the building block approach, where national requirements can be really different. This can create communication and supply issues. Agreeing an approach within a customs union might help solve this particular issue.
- In many parts of the world, national legislation for the crop protection sector is based on the FAO labelling guidance, which incorporates the WHO classification scheme. These were updated very late, especially the WHO classification scheme. This means that GHS is not implemented in this sector in many parts of the world. Additionally there were some political decisions made in the update of WHO classifications for certain substances which mean that there "GHS classification" according to WHO does not accurately reflect the data and the GHS classification scheme. This is unhelpful and questions the validity of the WHO scheme. For parts of the world that have their own legislation, the experience is generally mixed.
- In Africa, the biggest challenges are re political will and priorities, as in the hierarchy it is not well recognised as being a priority. Some countries have had draft regulations for some sectors for several years but despite efforts from the administration, it takes a long time to get through the red tape, including parliamentary red tape, and there is some reluctance from the industry to change. National Standards are often outdated with lack of capacity and obstruction in the committees by non-experts who do not understand the importance in keeping up to date on changes. Also National Departments tend to work in silos with their own boundaries rather than coordinating with others which can lead to a disconnect.
- The building block approach, where countries could adopt just those parts of the GHS which they deemed suitable, and apply them only to those sectors of legislation that they wished was important in aiding the adoption of the GHS. Over time, this has become a barrier to international consistency and simplifying trade of goods. It would be valuable for all economies for the UN to provide examples of the successful implementation of GHS across a range of industry and society sectors.
- Some countries currently apply the GHS system to workplace chemicals only, leaving domestic use of chemicals and agricultural chemicals regulated by older systems. The result is that for full compliance the label for a product may have to cover similar requirements across two or more classification systems. The result is that even in a well developed economy, there is a level of technical noncompliance so high that it is effectively impossible to patrol with the limited resources available to regulate.
- Complaints that in many developing countries the GHS is seen as concerning environment only, and this leads to lack of interest of authorities in other sectors, often amplified by lack of cooperation/exchange of information between sectoral departments.
- (2) Can you give an example of legal or non-legal implementation practice (country, region, sector) that you find particularly effective and why?
- a. Implementation practices such as the choice of the legal instrument, the publication of guidance documents to support the implementation, a grace period, tools and database availability,

especially for SMEs for their self-classification and prepare SDS, institutional strength (clear mandate, adequate workforce, budget, etc.), enforcement effectiveness are just some examples of good practices.

The legal implementation in Europe with the legal instrument of 'regulation' demonstrated to be effective along with the supporting guidance documents provided by ECHA.

Japan and Australia authority provide good database to SMEs to search for chemical classification and regulatory information and tools to classify mixtures, please see details below. Safe Worker Australia provides Hazardous Chemical Information System (HCIS). HCIS is an internet advisory service that assists to find information on chemicals that have been classified in accordance with the (GHS) by an authoritative source, such as the European Chemicals Agency (ECHA) or the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). HCIS is provided for guidance only and is not a comprehensive database of all hazardous chemicals. http://hcis.safeworkaustralia.gov.au/HazardousChemical

Japan NITE-CHRIP is a database provided information on Risk Assessments and Laws & Regulations, etc., of chemical substances. Including Laws and Regulations in Japan and other countries, Chemical Hazard and Risk Information, and Test Data and Reports. https://www.nite.go.jp/en/chem/chrip/chrip_search/systemTop

Singapore set up a National GHS task force to oversee the whole implementation process in the country. This GHS task force including representatives from both competent authorities and industry members (SCIC, Safety officer associations and institutions etc). It is important to have the views from different parties to ensure the effectiveness of the work plan. The TF also developed a GHS standard (SS586) to provide the clear requirement for companies to follow and developed GHS guidebook as well as other GHS guide book/ posters, leaflets, FQA, GHS website and Self GHS checklist as part of compliance aid to the companies. Training is also applied to the regulars that involved in the GHS inspections and also those may need to implement GHS in their respective department / functions as well. Apart from that, the TF also develop GHS awareness seminar and different GHS training courses to meet the needs (such as GHS users' courses, GHS classification course). The TF also conducted GHS workshop to share and exchange the requirement and practices with other countries. Training is one of the mandatory GHS requirements in SG. Apart from that, SCIC also conducted the GHS sharing with other industry / trade associations as well. Furthermore, the TF also have developed a mechanism / tool when company wants to ask any question related to GHS implementation. People can send their question through the WHS website and such question will forward to the GHS expert in SCIC to provide answers and advice. Moreover, SG divided the implementation into different phrases. First to start with chemical suppliers / manufacturers (including trader as they are also importer) and then users.



Other countries such as Malaysia, Thailand, Indonesia, Philippines, Vietnam as well as Cambodia, Laos and Myanmar also conducted GHS training.

Malaysia DOSH has developed a tool called ICOP to provide clear requirement and guidance to company for the GHS implementation. They also provide training, checklist to companies. To provide support to local SME and companies, DOSH developed a GHS classification list of 226 chemicals which included in part I of the ICOP. They also reviewed and include more classification into Part 1.

Thailand Chemical industry council and PH chemical industry council also provide a lot of GHS training to the local companies as well as school.

For ASEAN, the ICCA ARCP (ASEAN Regulatory Cooperation Project) provided a platform for both regulators and industry members to share their experience and practice on the GHS implementation.

b. Regional approaches such as the EU CLP do have their advantages as they facilitate trade between companies operating within the same customs union. It also reduces the burden on exporting companies that only have to comply with a single classification and labelling system to access several national markets (although admittedly, the use of different languages in different countries within a customs union pauses its own challenges). The added benefits of operating within a customs union is that it also creates a supportive regulatory ecosystem where authorities can share the regulatory burden maximising the resources available to ensure the system works effectively or even establish an agency to centralise expertise and reduce costs. It also facilitates collaboration across companies as a higher number of regulatory experts are available in a given region, which helps when it comes to defining a sectorial approach to implementation. Access to expertise within consultancies is also more readily available.

Having a standardised system can also help in creating consensus on the way a substance should be classified and handled at global level.

- c. The European implementation was a pretty good model for implementation. There were a number of features that were especially good:
- A staged implementation: first for substances and then for mixtures. This recognises that you need the GHS classification for substances before you can classify for mixtures
- A sensible transition period: 5 years for total implementation, including a further 2 years for stocks that were already labelled and in the supply chain – the amount of time that products spend in the supply chain is frequently overlooked
- Extensive guidance material produced with the help of industry. The EU recognised that often industry has more expertise than the government and in the EU, the governments and industry

- worked together to produce practical guidance
- The EU produced a "quick and dirty" translation table that could be used for a limited time to convert classifications under the old scheme to GHS. This helped to reduce the resource needed and also to cope with situations where the original data used to classify is no longer available.
- The EU legislation contains a relatively painless mechanism to update the technical aspects in line with changes to GHS
- The process for defining its' list of classifications (the Risk Assessment Committee) is a good model as it is open and transparent. The downside is the amount of time and resource required, but this is a justified cost were a number of features that were especially good.
- d. The building block approach, where countries could adopt just those parts of the GHS which they deemed suitable, and apply them only to those sectors of legislation that they wished was important in aiding the adoption of the GHS. Over time, this has become a barrier to international consistency and simplifying trade of goods. It would be valuable for all economies for the UN to provide examples of the successful implementation of GHS across a range of industry and society sectors.
- e. New Zealand's acceptance of labelling developed to the standards of recognised large or trade-relevant economies assists in import and adoption of new chemicals. Australia's transport sector has a system that allows a similar degree of flexibility to recognise other (international) labelling. The Australian workplace safety system does not have such flexibility.
- (3) Can you give an example of legal implementation practice that, in your view, should be avoided and why?
- a. A non-comprehensive list is provided below:
- Implementation without a reasonable consultation process (e.g. Argentina, Costa Rica)
- No adequate engagement of all stakeholders, e.g. downstream users
- Copy/paste of UN purple book without given considerations to the national specificities and/or to the options within the purple book
- Short timeline for implementation (e.g. Argentina)
- GHS implementation not coordinated in a broader chemical management schemes (e.g. India, Colombia)
- Copy/paste of GHS implementing legislations (e.g. Chile) without considering all implications and the national specifics and without considering the major trading partners
- Failure to resolve conflicts in the existing legislations
- Lack of coordination between the various ministries of the government (e.g. in Brazil Environmental Hazards are in the scope of the ABNT Standard non-legal document driving the GHS implementation in the country but they are not in the Scope of the NR-26 the legal document



approved by the Ministry of Labour driving the GHS implementation in the workplace. Environmental aspects is regulated by Environmental Ministry and no legal document has been published approving GHS implementation on Environmental side.)

- In Philippines, there are two authorities (DOLE & DENR) both published top regulation to cover different application products in 2014 and 2015, but with different timeline and even no guidance under DOLE till now.
- GHS implementation without proper industry and government training
- Non-alignment of content aimed at overcoming conflicts to facilitate international trade (to avoid non-tariff barriers)
- The development of a list of mandatory GHS classifications for each country/region does not help harmonisation at international level
- The application of the building blocks approach and of the options within the purple book should be harmonised within a given country in order to avoid gaps or confusion

Also, it should be avoided to have two of more agencies to govern the GHS implementation. This may cause confusion to the industry members if they have different requirement and implementation timeline especially not agency will communicate and discuss/ exchange views with each other. It would be good to have a GHS task force to develop including all competent agencies that involve in the control of chemical substances and appoint one agency as the lead for the GHS implementation. And it is important to involve industry members in the team to allow more comprehensive views and especially discuss about the timeline for the implementation and transition.

- b. When some countries implemented GHS, they decided to update their list of national classifications. They started in a good direction by asking companies to submit the information that they had on substances. However they then "checked the literature" to see if there was other information and, if this indicated a more severe classification, they used this information I preference to the information submitted by the companies. Unfortunately the "check the literature" process was not very controlled and information with questionable quality was sometimes used instead of information with verifiable quality. This resulted in classifications that were not supported by reliable information. The goal in classification is to derive classifications that are accurate: using unreliable information is contrary to this goal.
- c. A chemical classification is the backbone of establishing effective risk management controls to ensure that sites, people and the environment are safe. As such, from an industry's perspective, it very much requires a 'Goldilocks approach' where the classification system offers effective protection to ensure the potential risks presented by the substance are identified and managed properly, whilst not triggering unnecessary and costly risk management measures.
- d. Before legal implementation is undertaken in a given jurisdiction, it is important to ensure that the level of expertise needed in terms of knowledge and technical capability for the national

authority are properly understood. Effective implementation requires adequate resources and sufficient expertise as chemicals can include very complex compounds.

It is best to avoid cutting corner and simply copy-pasting existing frameworks such as the EU CLP. This particular system was developed within a very advanced and mature regulatory ecosystem where both authorities and industry have extensive expertise. The legal text is also tailored to work with the EU member states judicial system, which will be different in other parts of the world.

Equally, picking only parts of other established regulatory frameworks can be problematic. For example, definitions for important terms can get missed out and the resulting regulatory text may not work as a consequence. Where authorities lack the expertise to be able to address such issues, it can lead to major and unnecessary difficulties as they may not be receptive to comment and recommendations for improvement.

- e. Avoid the development of conflicting or overlapping regulatory regimes for chemicals. Apply the GHS over all sectors involved in chemical regulation (and harmonise with transport), or reframe existing legislation around the GHS, to avoid complex overlayering of different regulatory and classification systems, and to make it simple to adopt new technology.
- (4) If you are not satisfied with the current situation, can you explain why and what kind of legislation improvement you would suggest (in relation to national, regional or international law, and in relation to the sector(s) members of your organization are involved in)?
- a. Some examples:
- Convergence within a region and consideration of the main trading partners
- Legislation always associated with a consultation with all impacted stakeholders and giving appropriate timing to respond
- Clear guidance in relation to the requirements where the GHS UN gives freedom to the national competent authorities (building blocks, options...)
- b. Time is needed to allow for the system to evolve and expertise in different less experienced jurisdictions to grow. GHS is still a new system and as expertise grows and the system matures, the issues encountered are likely to become less prominent.

Before implementation is undertaken, as with any regulatory framework, basic elements should be considered including a good understanding of national needs and priorities: What is to be regulated and for what purpose?

Further, when it comes to metals and metal compounds, they have very different properties to that of organic chemicals and as such, it is important to take such essential differences into consider-



ation when establishing a classification system.

- c. The biggest problems are when there are different organisations involved in the labelling of crop protection products. Typically this means:
- Within a country, there is one organisation that regulates labelling of crop protection products and another organisation that regulates workplace issues, including the SDS

For example, in the US Crop Protection labelling is regulated by EPA under the FIFRA regulations. This has not adopted GHS but uses some labelling elements that are similar to GHS labelling elements. Safety Data Sheets are regulated by OSHA which has implemented GHS. FIFRA contains a clause about "misbranding" and EPA initially decided that a GHS compliant SDS could be considered to be misbranding under FIFRA. A compromise was eventually developed but it involves extra work. In many cases this situation could be avoided by a coordinated implementation of GHS across the various sectors. Where there are good reasons for different sectors to take different approaches, it is essential to check and resolve issues of interaction: our experience is that it's very rare for a product to spend its entire life in one sector only.

2. Within a country or region where there is one set of legislation but where implementation is the accountability of multiple organisations

For example, in the EU there is one piece of legislation that implements GHS for all sectors, but for the Crop Protection industry, our product labels are approved by the individual countries and these countries believe that they also have to approve the GHS classification and labelling. As a result, we frequently find significant differences in the "GHS classification" between different countries when the same set of information has been provided. There are multiple reasons for this, most of which are not to do with legitimate differences in interpretation of data. To avoid this, we recommend either a single approval body or separating the accountability for classification from enforcement by companies being accountable for the classification and labelling and authorities focusing on enforcement of the legislation.

- d. Detailed in 3 above. How about a single national system, regulated centrally with a single, national Competent Authority?
- (5) In relation to the development of GHS legislation or implementation instruments in coun tries that have not yet put in place relevant rules, regulations or other instruments, what would be your recommendation to these countries? What mistake do you think they should avoid? And why?
- a. A mistake that should be avoided is implementing GHS without a proper evaluation of existing GHS implementations, especially among the trading partners.

"Advanced" countries should put in place mechanisms of cooperation to support the implementa-

tion of GHS in developing countries

The implementation timeline should be mindful of all stakeholders needs

To adopt / accept the requirement and practices developed by other countries. It will be good start to learn about the practice in other countries. Set up training / capacity building plan for both regulators and industry members. then see what is the most important sector that need to be implement. Take a phrase approach then implement all as the same time.

Refer to guestion 3 for further details.

- b. Include as little country specific information as possible. Accept variations on wording where there is no significant change in meaning. Be prepared to drop existing regulatory regimes in favour of the GHS rather than create complex overlayers of regulation of chemicals.
- c. In addition to comments under (3), it is important for countries to look to implement the latest edition of the GHS and to ensure that the regulatory system includes sufficient flexibility to allow for updates to be easily integrated. It is also worth considering what may be required to build up capability within the required authorities as well as relevant sectors of industry. To be able to do so, it is also essential to understand what sectors of industry are actually established in a particular territory.

Where existing regional bodies are established (e.g. APEC), it is worth seeking opportunities to engage with counterparts with more advanced levels of expertise with the view to learn from their experience and expertise.

d. Various examples:

- Allow sufficient time for implementation, including time to learn about GHS. The EU period of 7 years may sound a long time, but in reality it would have been difficult to implement much quicker
- Take a 2 staged approach: implement for substances first and then implement for mixtures once GHS is implemented for substances
- Industry and public sector should work together, both when developing legislation and during the implementation phases
 - » Particularly for multinational companies, there may already be considerable GHS experience and expertise within the organisation and public sector should not be reluctant to take advantage of this experience
- If the existing labelling system is visually very different to GHS, then there should be educational measures so that people understand the new labels when they see them
- Develop a legal mechanism that allows legislation to be easily updated to keep it in line with changes in GHS
- If a list of classifications is to be implemented, make sure that the process follows the principles
 defined by the GHS Sub-Committee: the process used in the EU is not a bad model to copy.



e. Developing countries would benefit by more training for officials in policy and putting in place internationally aligned GHS regulations to assist and benefit trade.

Additional training for technical and regulatory personnel is necessary.

A two- pronged approach is needed to educate the politicians as well as the implementing regulators for success in developing countries.

- (6) Do you see advantages to the development of regional legislation (e.g. as in the EU) ver sus national legislation? If yes or no, why?
- a. Yes, we do see advantages because this ensure consistency by definition. However, consideration should be given to the legal framework of the region (e.g. choice of Regulations as legal instrument (direct implementation in all Member States) rather than Directives in EU). In other regions, e.g. AP or in southern African countries, such legal cohesion does not exist.
- b. In smaller countries and economies in particular, regional consistency of adoption of the GHS improves compliance and access to a broader range of products and new technologies with consistent and compliant labelling. Significant potential benefits from a regional approach in Africa, South-east Asia and Oceania (e.g. Australia and New Zealand plus Pacific nations).
- c. Yes. As mentioned before under (2), trade is very dependent on the ability to communicate easily. It also allows for regional expertise to grow and help ensure the establishment of a regional network of experts within authorities sharing the burden of establishing effective regulatory controls whilst hopefully reducing compliance costs for industry.
- d. If there are existing or natural connections between countries, then we see advantages to developing regional legislation such as
- Sharing workload for developing legislation
- Facilitating trade between countries in the region
- Reducing costs for industry

However there needs to be the political will to develop common legislation, which will typically involve compromise and to implement in the same way. The two big risks of regional legislation are inconsistent application within the countries and countries that are politically unwilling to accept legislation that they have not developed.

e. A regional approach would be beneficial for developing countries, but in doing so they should use the latest updated versions of the GHS and UN Model Regulations on the Transport of Dangerous Goods. Not easy to get an agreement for GHS as developing countries in the same region have different priorities and developmental stages which should make it helpful to pool resources.

