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The Globally Harmonized System for the Classification and Labelling of Chemicals (The GHS)

Implementation of the GHS in Canada

Introduction

1. The Globally Harmonized System for the Classification and Labelling of Chemicals (the GHS) provides a common and coherent basis to defining and classifying hazards and communicating information on labels and safety data sheets. It provides the underlying infrastructure to establish a comprehensive national chemical safety programme.

2. There are benefits from chemicals but there are also potential adverse effects. No country has the ability to identify and specifically regulate every hazardous chemical product. Many countries have developed laws and regulations that require information to be transmitted through labels and/or safety data sheets. Existing laws for chemical classification and labelling are similar but the differences result in different labels and safety data sheets (SDSs) for different countries. For example, a chemical may be considered to be flammable or to cause cancer in one country but not in another. These differences impact both protection and trade. Protection in that countries that do not have specific requirements may see different label warnings or safety data sheet information for the same chemical. Trade is impacted as the need to comply with multiple regulations regarding hazard classification and labelling is costly and time consuming. Small and medium enterprises are effectively precluded from international trade in chemicals due to the regulatory burden of compliance. Given the complexity of developing and maintaining a comprehensive system, many countries do not have a comprehensive hazard communication system.

3. The harmonization of chemical classification and labelling systems benefits all countries, international organizations, chemical producers and users of chemicals by:
   - Enhancing protection of humans and environment by providing an internationally comprehensible system for hazard communication;
   - Facilitating international trade in chemicals whose hazards have been properly assessed and identified on an international basis.
   - Reducing need for duplicate testing and evaluation.
   - Providing a recognized framework for those countries without an existing system.

4. In 1989, the International Labour Organization (ILO) adopted a resolution concerning the harmonization of systems of classification and labelling and in 1990, it adopted Convention 170 and Recommendation 177 concerning the safety and protection of workers against the risks associated with the use of chemicals at work. The work of the ILO lead to the agreement reached at the 1992 United Nations Conference on the Environment and Development, i.e.,

   > *26. Globally harmonized hazard classification and labelling systems are not yet available to promote the safe use of chemicals, inter alia, at the workplace or in the home. Classification of chemicals*

can be made for different purposes and is a particularly important tool in establishing labelling systems. There is a need to develop harmonized hazard classification and labelling systems, building on ongoing work.

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

Programme Area B, Chapter 19, Agenda 21.

5. There were four major existing systems that were considered as the development of the GHS began: the UN Recommendations for the Transport of Dangerous Goods, the European Union Directives for Substances and Preparations, the United States of America's requirements for the workplace, consumer and pesticides and the Canadian requirements for the workplace, consumers and pest control products.

The Scope of the GHS

6. The UN Document for the GHS includes:

The work on harmonization of hazard classification and labelling focuses on a harmonized system for all chemicals, and mixtures of chemicals. The application of the components of the system may vary by type of product or stage of the life cycle. Once a chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting. Pharmaceuticals, food additives, cosmetics, and pesticide residues in food will not be covered by the GHS in terms of labelling at the point of intentional intake. However, these types of chemicals would be covered where workers may be exposed, and, in transport if potential exposure warrants.

7. The GHS covers all hazardous chemical substances, dilute solutions and mixtures. Pharmaceuticals, food additives, cosmetics and pesticide residues in food will not be covered at the point of intentional intake but will be covered where workers may be exposed and in transport.

8. There were a number of principles of harmonization that were established in the early stages of the development of the GHS. Some of the key principles include:

- The level of protection should not be reduced as a result of harmonization.
- The scope includes both hazard classification criteria and hazard communication tools (labels, Safety Data Sheets).
- Changes in all existing systems will be required.
- The GHS does not include requirements for testing.
- Target audiences include consumers, workers, transport workers and emergency responders.
- In relation to chemical hazard communication, confidential business information (CBI) should be protected.

The Elements of the GHS

9. The Globally Harmonized System includes provisions for both classification criteria and hazard communication elements, i.e., labels and safety data sheets.

Classification Criteria for Substances and Mixtures

Physical Hazard Classes

- Explosives
- Flammability – gases, aerosols, liquids, solids
- Oxidizers – liquid, solid, gases
- Self-Reactive
- Pyrophoric – liquids, solids
- Self-Heating
- Organic Peroxides
- Corrosive to Metals
- Gases Under Pressure
- Water activated flammable gases

Health and Environmental Hazard Classes

- Acute Toxicity
- Skin Corrosion/Irritation
- Serious Eye Damage/Eye Irritation
- Respiratory or Skin Sensitization
- Germ Cell Mutagenicity
- Carcinogenicity
- Reproductive Toxicity
- Target Organ Systemic Toxicity – Single and Repeated Dose
- Hazardous to the Aquatic Environment

Hazard Communication

Labels

- Product identifier
- Supplier identifier
- Chemical identity
- Hazard pictograms*
- Signal words*
- Hazard statements*
- Precautionary information

*Standardized

Safety Data Sheets (SDSs)

1. Identification
2. Hazards identification
3. Composition/information on ingredients

4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

The Building Block Approach

10. The harmonized elements of the GHS should be seen as a collection of building blocks from which a regulatory approach can be developed. Needs vary between sectors and therefore, the regulatory requirements of system will also vary to meet those needs. Therefore, while the full range of the GHS is available, all GHS elements need not be adopted if there is not a need. For example the transport sector includes classification and labelling elements for acute and physical hazards. It does not include chronic effects to date given the types of exposures expected in the transport of dangerous goods environment. 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.

Implementation of the GHS in Canada

11. There are four key sectors in Canada that will be affected by the implementation of the GHS in Canada. They include consumer chemical products, pest control products, the transportation of dangerous goods and the Workplace Hazardous Materials Information System.

Consumer Chemical Products

12. The Consumer Product Safety Bureau of Health Canada administers and enforces the *Consumer Chemicals and Containers Regulations*, 2001 (CCCR, 2001) under the *Hazardous Products Act*. These Regulations cover hazardous consumer chemical products such as cleaners, paints, solvents and adhesives that are not already regulated under other pieces of legislation such as the *Food and Drug Act* or the *Pest Control Products Act*.

13. The CCCR, 2001 establish classification criteria, labelling and packaging requirements for chemical products used by consumers. The classification criteria are based on a scientific assessment of the hazards that a product may pose during foreseeable use, where the contents may be toxic, corrosive, flammable or have quick skin-bonding characteristics, or where the

container may be pressurized. Labelling and packaging requirements are determined from the product classification and are prescribed by the regulations.

14. The CCCR, 2001 support Health Canada's goals to protect the health and safety of Canadians by reducing the number of injuries and deaths involving hazardous consumer chemical products.

Pest Control Products

15. In Canada, the federal legislation governing the regulation of pesticides is the *Pest Control Products Act* (PCPA). The Pest Management Regulatory Agency (PMRA) is responsible for administering the PCPA and registering pest control products. A company that wishes to sell a pest control product in Canada must submit a draft label and all information necessary for determining if the product is acceptable in terms of safety, merit and value. PMRA conducts an assessment of the risks and value of the product specific to its proposed use. PMRA's evaluation results either in the product being refused registration or in the product being granted registration and allowed for sale and use in Canada.

16. The product label that is approved as part of the registration process contains the conditions of registration that, along with the PCPA and the *Pest Control Product Regulations* (PCPR), govern the use of the product. Use of a product in a manner that is inconsistent with the directions or limitations on the label is prohibited. Any control product offered for sale in Canada must bear the approved label. The principal intended audience for the label is the user e.g. farmers, commercial applicators, homeowners. The role of the label is to communicate hazard, coupled with practical advice on risk mitigation (e.g. personal protective equipment, storage conditions, buffer zones around water and other sensitive locations).

17. The new *Pest Control Products Act* (PCPA 2002) which received Royal Assent on December 12, 2002 will not affect these fundamental aspects of the regulatory system when it comes into force.

Transportation of Dangerous Goods

18. The mission of the Transportation of Dangerous Goods (TDG) program is to promote public safety during the transportation of dangerous goods. Public safety for the purpose of the program is defined as the protection of people, property and the environment. To this end, TDG administers and enforces the *Transportation of Dangerous Goods Act, 1992*.

19. The TDG Directorate is the source of regulatory development, information and guidance on the national transportation of dangerous goods program. The program objective is to prevent the accidental release of dangerous goods during transport, and to ensure that appropriate response measures are in place in the event of an accidental release. The program delivers emergency response support.

20. The program is national and multi-modal in scope. It applies to all modes of transport, as well as to the manufacturing sectors for chemicals and for means of containment ranging from fibreboard boxes to rail tank cars. While the program primarily supports Transport Canada's strategic objective to promote high standards for a safe and secure transportation system, it also contributes to Canada's economic growth and social development, as well as the protection of the environment.

The Workplace Hazardous Materials Information System (WHMIS)

21. The implementation of the Workplace Hazardous Materials Information System (WHMIS) in 1988 established a national classification and hazard communication standard for chemicals intended for use in the Canadian workplace. Currently, it is the only program which, in addition to labels, requires safety data sheets, the main vehicle for hazard communication. Over 20 million pure chemical substances have been identified which can be formulated into millions of products which would be subject to WHMIS when manufactured and/or marketed in Canada. Thus, WHMIS will be the program most impacted by implementation of the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS). Through Memoranda of Understandings between the Minister of Health Canada and 13 provincial and territorial governments, the Occupational Health and Safety (OHS) agencies of those provinces and territories have agreed to conduct the inspection program for the WHMIS requirements of the *Hazardous Products Act* (HPA) in addition to administering employer WHMIS requirements established under their respective legislation. Over 400 Federal/Provincial/Territorial inspectors are currently designated.

22. In Canada, Health Canada administers the *Hazardous Products Act* (HPA)which requires suppliers of hazardous materials to provide Material Safety Data Sheets (MSDSs) and to label products as a condition for sale and importation. This applies to both consumer and industrial chemicals. By enforcing the HPA, (Part II, i.e., Controlled Products Regulation (CPR)) workers are protected from adverse effects of hazardous materials through provision of relevant information. WHMIS is referred to as Canada's right-to-know law and it was designed such that those marketing products in Canada would take full responsibility for the accuracy of the information regarding their marketed products. The key elements of the system are the provision of MSDSs, labelling of containers of hazardous materials and provision of worker education and training programs.

Possible Sector Issues for Consideration during Canadian Implementation of the GHS

Consumer Chemicals

23. In order to implement the GHS, existing classification and labelling systems such as the CCCR 2001, will need to be revised to incorporate the classification criteria and labelling elements of the GHS.

24. Annex 1 outlines a comparison of the classification criteria and labelling elements of the GHS with those identified health and physical hazard endpoints of the CCCR, 2001. Where possible, criteria were aligned where they were based on the same quantitative measure. This

allowed for a visual comparison to be made. A more detailed analysis follows each table to elaborate on the specific similarities or differences between each system and what would be needed to be changed in order to implement the GHS.

25. A key issue to be dealt with during the implementation of the GHS in Canada may be how the CCCR, 2001 will implement GHS endpoints for chronic hazards which are currently not regulated.

Pest Control Products

26. Pesticide labelling encompasses both a hazard-based and risk-based approach. Symbols are required to represent some physical hazards (i.e. flammability, explosivity, corrosivity) and acute health hazards. Other physical, health and environmental hazards are not shown on the labels of pest control products but are considered in the registration decisions as described below.

27. The hazards associated with pressurized containers and flammable, corrosive, irritating or acutely toxic products are consistently communicated by means of symbols and signal words which convey both the nature and level of the hazard. The symbols and signal words are provided in Schedule III of the *Pest Control Product Regulations* (PCPR). The *Registration Handbook* contains general guidance on label requirements for petitioners of pest control products. It includes criteria for identifying a product as flammable, corrosive, acutely toxic, or irritant. It also includes three levels of hazard in a progression of increasing severity to be reflected in the signal words CAUTION, WARNING, and DANGER and corresponding symbols. If more than one symbol is required, the most severe signal word is required with all of the hazard identifying words. If more than one signal word is required, there are operational criteria in place for use by the pesticide regulatory authority when verifying labels. Verification of the appropriateness of the symbols and signal words is performed following evaluation of the information submitted to support registration.

28. An application to register a pest control product must include information on several physical and chemical properties: explodability, flammability, oxidizing or reducing action, corrosion characteristics and the container. These properties are used to determine the appropriate hazard symbols. Methods used to determine the physical and chemical properties must be described or referenced. For technical active ingredients, the melting point, boiling point, vapour pressure and stability (metals, temperature) must be provided as well as the test method or reference to an established international protocol. This information is used in the risk assessment of the product.

29. Health (other than acute and irritation) and environmental hazards are not labelled but are evaluated through a risk assessment approach. This process includes the identification of hazards and the level of anticipated exposure when the product is used as intended. The exposure levels are combined with the hazard assessment to determine whether there are risks associated with the use of the product. If risk mitigation measures such as personal protective equipment, buffer zones to sensitive ecosystems, or other exposure reducing

measures are necessary and reasonable to achieve an acceptable level of risk, they are added to the label as a condition of use or else the registration of the product is not supported.

30. The PCPR stipulate the types of information to be provided on labels. These labelling requirements will be included in regulations under PCPA 2002 when it comes into force. However, a few changes will be incorporated.

31. The current PCPR requires that the active ingredient(s) and its concentration be identified on the label. There is no regulatory requirement for disclosure of any other hazardous ingredients. Under PCPA 2002, the active ingredient and any components (formulants and contaminants) of health or environmental concern that are identified on a Health Canada list are excluded from the definition of confidential business information. The regulations could therefore require that these components be listed on the Material Safety Data Sheet (MSDS) and on the label of a pest control product. Other components of a pest control product will be included in the definition of confidential business information and therefore will not be disclosed.

32. Material Safety Data Sheets are not currently required under the PCPA. The PCPA 2002 requires that an MSDS be provided to workplaces where a pest control product is used or manufactured. The content of the MSDS will be prescribed in the regulations.

33. The label of each pest control product must show the market class to which it has been designated. The purpose of these classes is to provide a framework for provincial regulation of the sale and use of registered pesticides. Classification has an important role in mitigating potential risks associated with pesticide use, because there is an ascending degree of hazard associated with the DOMESTIC, COMMERCIAL and RESTRICTED classes. The DOMESTIC class is for products marketed to consumers for use in and around a dwelling. The COMMERCIAL class is for products marketed for general use in the commercial activities specified on the label. Products within the RESTRICTED class are subject to specific limitations respecting their display, distribution, use, or operator qualifications, due to high inherent toxicity or intended use in environmentally sensitive areas. The market class to which a product is assigned depends on the intended uses, the package size, potential risks, and inherent hazards of the product. Acute toxicity is one criterion used to ensure that more hazardous products are not available in the DOMESTIC class and that highly hazardous products are limited to the RESTRICTED class.

34. The FPT Committee on Pest Management and Pesticides has proposed for public comment (November 2002) some modifications to the federal market class system to enable harmonization of provincial and federal classification systems. The proposed system would include 5 market classes: Lower Risk Domestic, Higher Risk Domestic, Lower Risk Commercial, Higher Risk Commercial, and Restricted. The intended uses, package size, potential risks and inherent hazards of a pest control product would continue to be important considerations in designating its appropriate market class. Acute toxicity remains an important criterion. The proposed LD50 (oral, dermal) and LC50 (inhalation) cut-values for the FPT market classes are generally consistent with cut-off values for Acute Toxicity

categories of the GHS. The proposal states that other hazards within the GHS may be incorporated in the FPT market classification system at a future date.

Transport

35. Although Dangerous Goods labelling is both hazard-based and risk-based requirements for chemicals are predominately the former. Only acute health and physical hazards are addressed.

36. With a few exceptions, labels for the nine Classes of Dangerous Goods are the same as those shown in the *United Nations Recommendations on the Transport of Dangerous Goods Model Regulations*. Symbols used for acute health and physical hazards are the same as those used in the GHS, where they are used.

37. Although there are no provisions for warning statements or signal words on labels, Class numbers must be displayed in the lower section of the square-on-point label.

38. In addition packages must be marked with the proper Shipping Name and corresponding UN number.

39. Safety Data Sheets are not currently required under TDG but, each consignment of Dangerous Goods must be accompanied by a Shipping Document. This document contains a description of the Dangerous Goods including the Shipping Name, primary and subsidiary classifications, the UN number, the Packing Group, and a 24-Hour telephone number.

40. Aquatic toxicity is addressed using the criteria from the International Maritime Dangerous Code (IMDG Code). Since the Sub-Committee of Experts on the Transport of Dangerous Goods have recently accepted the GHS criteria, it is expected that the TDG requirements will change.

Workplace Chemicals

41. The GHS includes harmonized classification criteria and hazard communication elements, i.e., labels and safety data sheets (SDSs). This document compares the GHS and the WHMIS sector in a number of categories; (a) GHS vs WHMIS for classification criteria, physical and health and environmental hazards, (b) classification criteria for mixtures, (c) hazard communication for labelling requirements, including symbols and (d) material safety data sheets (MSDSs).

42. In general, the GHS hazard classes and the overall classification criteria found within those hazard classes mirror those of the current WHMIS program. However, in many cases, the GHS has designated specific categories within hazard classes, which is a distinction not made in the existing WHMIS criteria. The GHS includes classification criteria for explosives which are exempt under WHMIS. Yet there are other hazard classes under WHMIS, such as Class D3, biohazardous materials, for which there is no GHS category.

43. There are a number of similarities between the key label elements found in the GHS and in WHMIS. Both systems require product identifier, supplier identifier, hazard symbols, hazard statement/risk phrases and precautionary information/first aid measures. Note that the definition of risk phrase in the *Controlled Products Regulations* (CPR) "means, in respect of a controlled product or a class, division or subdivision of controlled products, a statement identifying a hazard that may arise from the nature of the controlled product or the class, division or subdivision of controlled products" and is considered to be equivalent to a hazard statement. The GHS has standardized hazard statements but no specific phrases specified in the *CPR*. Currently, there are only suggested examples of risk phrases on the WHMIS Web site. The GHS includes identifying hazardous ingredients on a label but also includes that a competent authority may choose to give suppliers discretion to include chemical identities on the SDS rather than on the label. In addition, the current WHMIS label must have a statement such that a MSDS is available. WHMIS has the hatched border for which there is no comparable border under the GHS. Adoption of the GHS label in Canada will mean changes to the current WHMIS regulations.

44. Hazard symbols are another aspect of label requirements that are similar for both WHMIS and GHS. Generally, the hazard glyphs are similar in both systems but the symbol shape and colour are different. Upon implementation of GHS there will need to be changes to all of the currently used WHMIS hazard symbols which means that the *CPR* will have to be amended to replace its currently used symbols.

45. WHMIS has adopted a nine heading material safety data sheet (MSDSs) requirement (CPR Section 12 of and Schedule I). The 9 headings are: hazardous ingredients, preparation information, product information, physical data, fire or explosion hazard data, reactivity data, toxicological properties, preventative measures and first aid measures. However, as an administrative policy, MSDSs for WHMIS controlled products which use the International Labour Organization (ILO), International Standards Organization (ISO) or European Commission (EC) 16 heading format are accepted as meeting compliance requirements of CPR Section 12, provided that all 16 headings are disclosed (in the sequence recommended by these other standards) and that the required content specified under Schedule I, Column III of the *CPR* is addressed. Under the ILO heading "Regulatory Information", the following statement should appear: "This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations.*"

46. The GHS requirements for safety data sheet (SDS) are for a 16 heading modified ILO. The GHS MSDS 16 heading SDS has requirements for most of the information that is already required for in the WHMIS MSDS. There are some additional requirements such as transportation information and for classification, label elements and symbols.

47. Based on the fact that all chemicals and chemical products in commerce are made in a workplace (including consumer products), handled during shipment and transport by workers, and often used by workers, there is no complete exemption from the scope of the GHS for any particular type of chemical or product. Labelling of pharmaceuticals, food additives, cosmetics, and pesticide residues are not covered in the GHS at the point of

consumer use or intentional intake. However, these types of chemicals are covered under the GHS where workers may be exposed. Under WHMIS, a number of products are excluded, namely:

(*a*) explosive within the meaning of the *Explosives Act*;

(*b*) cosmetic, device, drug or food within the meaning of the *Food and Drugs Act*;

(*c*) control product within the meaning of the *Pest Control Products Act*;

(*d*) nuclear substance, within the meaning of the *Nuclear Safety and Control Act*, that is radioactive;

(*e*) hazardous waste;

(*f*) product, material or substance included in Part II of Schedule I of the *Hazardous Products Act* and packaged as a consumer product;

(*g*) wood or product made of wood;

(*h*) tobacco or a tobacco product as defined in section 2 of the *Tobacco Act*; or

(*I*) manufactured article.

Adoption of the GHS may provide impetus for a review of these exclusions.

Environmental Considerations

The essential purpose of the Canadian Environmental Protection Act, 1999 (CEPA 99) is to protect human health and the environment from the effects of toxic substances in the environment, other harmful substances and wastes. It is one of the legislative tools that the federal government uses to prevent and control pollution. In the management of toxic substances, Environment Canada administers the Act and shares with Health Canada the task of assessing and managing risks associated with toxic substances. In general CEPA has used a risk assessment approach to assess both new and existing substances to prevent pollution and protect the environment and human health. There are no provisions or regulations under CEPA that require labelling or the development of safety data sheets for chemicals. Safety data sheets are required to be included, if available, in the notification of information for assessment of new substances under CEPA but CEPA does not regulate or comment on the information found in these data sheets. Any safety data sheet considered in a new substance notification must comply with the requirements in subsection 11(1) of the *Hazardous Products Act*.

Although there are no labelling requirements under CEPA 99, several activities under the Act may include GHS considerations, for example: the control of new and existing toxic substances,

including inanimate and animate products of biotechnology (parts 5 and 6); the control of management of wastes (part 7) and development of environmental emergency plans (part 8).