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# The development of the globally harmonized system (GHS) of classification and labelling of hazardous chemicals

Chris Winder [a,*], Rola Azzi [b], Drew Wagner [c]

[a] *School of Safety Science, University of New South Wales, Sydney NSW 2052, Australia*
[b] *Chemical Safety and Applied Toxicology Research Group, School of Safety Science, University of New South Wales, Sydney NSW 2052, Australia*
[c] *National Occupational Health and Safety Commission, GPO Box 1577, Canberra ACT 2601, Australia*

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**Abstract**

The hazards of chemicals can be classified using classification criteria that are based on physical, chemical and ecotoxicological endpoints. These criteria may be developed be iteratively, based on scientific or regulatory processes. A number of national and international schemes have been developed over the past 50 years, and some, such as the UN Dangerous Goods system or the EC system for hazardous substances, are in widespread use. However, the unnecessarily complicated multiplicity of existing hazard classifications created much unnecessary confusion at the user level, and a recommendation was made at the 1992 Rio Earth summit to develop a globally harmonized chemical hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, that could be used for manufacture, transport, use and disposal of chemical substances. This became the globally harmonized system for the Classification and Labelling of Chemicals (GHS). The developmental phase of the GHS is largely complete. Consistent criteria for categorising chemicals according to their toxic, physical, chemical and ecological hazards are now available. Consistent hazard communication tools such as labelling and material safety data sheets are also close to finalisation. The next phase is implementation of the GHS. The Intergovernmental Forum for Chemical Safety recommends that all countries implement the GHS as soon as possible with a view to have the system fully operational by 2008. When the GHS is in place, the world will finally have one system for classification of chemical hazards.


*Keywords:* Toxicological risk assessment; Chemical hazard classification; Globally harmonized system; Toxic hazard; Physicochemical hazard; Environmental hazard

## 1. Introduction

In many countries, legislative and administrative measures have been introduced to deal with chemical hazards. Whilst the origin of such measures can be traced back to the development by the courts of common law principles such as the law of nuisance, and to certain ancient statutes, the subject is essentially of chemical hazard is relatively of recent origin. This combined with the development of legislation in response to local as well as international developments (for example, thalidomide, asbestos, persistent bioaccumulative toxic chemicals, hazardous wastes, ozone depleting chemicals, greenhouse gases and so on) has meant that the legislative control of chemicals has developed of its own accord. As a result, it is a highly complex area [1].

In 1992, the United Nations Conference on Environment and Development (the Rio Earth Conference) gave rise to the Agenda 21 Report [2]. This report outlined the responsibilities of States towards the achievement of sustainable development, and was adopted by heads of government in over 150 countries.

Chapter 19 of Agenda 21 addresses the environmentally sound management of toxic chemicals, including basic programs for:

- adequate legislation,
- information gathering and dissemination,

* Corresponding author. Tel.: +61 2 9385 5370; fax: +61 2 9385 6190.
*E-mail address:* c.winder@unsw.edu.au (C. Winder).

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- capacity for risk assessment and interpretation,
- establishment of risk management policy,
- capacity for implementation and enforcement,
- capacity for rehabilitation of contaminated sites and poisoned persons,
- effective education programs,
- capacity to respond to emergencies.

Chapter 19 of Agenda 21 recommends that national programs for the environmentally sound management of chemicals should be in place in all countries by the year 2000. It also called for the formation of an intergovernmental forum to improve coordination and management of chemicals, and the International Conference on Chemical Safety duly met in Stockholm in 1994. This conference considered mechanisms for the development and implementation of recommendations of Chapter 19 of Agenda 21. The Stockholm Conference established the Intergovernmental Forum on Chemical Safety (IFCS) and the International Program for the Sound Management of Chemicals (IOMC) as a means for discussing and exchanging information.

One recommendation from UNCED 1992 was, if feasible, and by the year 2000, to develop a globally harmonized hazard classification and compatible labelling system, that could be used for manufacture, transport, use and disposal of chemical substances, including material safety data sheets and easily understandable symbols. This recommendation:

- recognised the unnecessarily complicated multiplicity of existing hazard classifications that had be a product of political and administrative structures in the past,
- acknowledged that artificial and arbitrary distinctions in chemicals classifications create much unnecessary confusion at the user level,
- suggested a means of rectifying the problem (that is, a globally harmonized classification and labelling system).

## 2. Regulatory bodies responsible for hazardous classification of industrial/commercial products

Most nations take their obligations in controlling chemicals very seriously [3]. There has been intense activity in many nations over the past 30–40 years to identify and deal with problems arising out of the use of chemicals. In turn, this has produced a greater emphasis on regulatory control.

Chemicals control regulation is a highly complex area, in which scientific and legal issues are brought together. This is further complicated by historical precedents or jurisdictional subtleties. Chemical control legislation operates at different levels, with different jurisdictional demarcations and different administrative arrangements [4]. It may also deal with chemicals hazards in different ways; for example, contrast the difference between the hazards of

- 1000 mL of Xylene (a hazardous substance) will have a hazard of harmful vapours in use, and than, say,
- 10,000 L of Xylene (a Dangerous Goods), which has a hazard of flammability in storage.

The Australian Council of Trade Unions (ACTU) conducts a survey of Health and Safety representatives every 2 years or so. In 2000, the survey concentrated on chemicals in the workplace [5]. In 167 returned surveys, respondents reported:

- 88% of respondents said they use chemicals at work,
- 33% of respondents said that people at their workplaces have suffered health effects from chemicals at work,
- 75% of respondents had not had training about the safe use of chemicals at work,
- 66% of respondents said they are aware of legislation and associated responsibilities,
- 23% of respondents said that chemicals in their workplaces are not clearly labelled,
- 15% of respondents said that the label is not easy to understand,
- most respondents did not know the difference between “poisons,” “hazardous substances” and “dangerous goods”,
- over 50% of respondents believed that they have not been given adequate information about the chemicals in their workplace,
- 70% of respondents indicated that they would like more information,
- 81% of respondents said that not enough is being done by employers, employees and/or governments to ensure chemical safety at work,
- these problems were much worse in smaller businesses.

These findings were striking, bearing in mind that Australia has had poisons legislation since the 1960s, dangerous goods legislation since the 1970s, protection of the environment legislation by the 1970–1980s, and occupational health and safety legislation since the 1980s. All of this legislation covered (among other things) the classification, labelling and packing of consumer and industrial chemicals, and yet by 2000, there was still a substantial lack of knowledge and confusion at the workplace level about the handling and use of chemical substances.

Sectoral responsibilities within regulatory agencies will often take different approaches in the development of legislation, standards and administrative structures. Further, this complexity of legislation is not limited to one state or one nation. A summary review of the chemicals classification and control legislation in two nations (USA and Australia) and the European Union follows.

### *2.1. United States of America*

In the USA, four federal agencies are primarily responsible for regulating exposures to chemicals. These agencies administer over two dozen statutes, which have been enacted over time, and all have protection of health as their main goal.

Table 1 summarises the stepwise development of the major chemical control laws at the Federal level in the USA.

Other regulatory arrangements relating to consumer products include:

- Department of Transportation (DOT): Materials transported on US roadways, railways or airways must be shipped in appropriately labelled vessels. They are ranked into class A poisons and class B poisons. Class "A" poisons are considered extremely dangerous poisons, represent inhalation hazards and are defined as "poisonous gases or liquids of such nature that a very small amount of the gas or vapour of the liquid, mixed with air, is dangerous to life." These would, for example, include materials such as: phosgenes or cyanide producing materials. Class "B" poisons are materials that will produce death within 48 h in half or more than half of a group of 10 or more white laboratory rats weighing 200–300 g at single dose of 50 mg or less per kilogram of body weight when administered orally; or if administered by continuous contact with bare skin for 24 h or less it has to produce death to half or more than half of a group of ten or more rabbits at a dosage of 200 mg or less per kilogram of body weight.
- Consumer Product Safety Commission (CPSC): This government commission was created in 1972 and is responsible for assuring that the consumer is not exposed to any unduly hazardous products and that any potentially hazardous products are properly labelled. The CPSC plays the least important role of the US Federal agencies controlling hazardous chemicals [6]. The Commission is empowered to promulgate safety standards that will prevent or reduce an unreasonable risk of injury related to the consumer product. The Commission has the right to ban a product (CPSC, Section 8), if no feasible standard could adequately protect the public from "unreasonable risk of injury". In assessing this need for a standard or ban of a product, the agency needs balance the likelihood that a product will cause harm, and the severity of harm it will likely cause, against the effects of reducing the risk on the product's utility, cost and availability to consumers (Howells, 1998). The CPSC administers the Federal Hazardous Substances Act (FHSA), 1960. This act defines the severity of toxicity of substances based on certain criteria. A substance is considered "toxic" if it has the "capacity to produce injury or illness to humana through ingestion, inhalation, or absorption through any body surface". The rate of toxicity by ingestion or dermal absorption is based on acute toxicity tests conducted mostly on animals and concentration cut off values exist for toxic and highly toxic classifications (see Table 2).

  CPSC has prescribed labelling for products containing substances that are acutely toxic such as "DANGER" label for highly toxic and "WARNING" or "CAUTION" for other hazardous substances. The Labelling of Hazardous and Materials Act of 1988 (LHAMA) required the CPSC to also provide labelling for material that has the potential of producing chronic adverse health effects [7].
- Environmental Protection Agency (EPA): The US EPA has responsibility for registration and labelling of pesticides under the Federal Insecticide, Fungicide, and Rodenti-

Table 1
Major US chemical control laws and agencies

| Act or law | Responsible Federal Agency |
|---|---|
| Food and Drugs Act 1906 | FDA |
| Food, Drug and Cosmetic Act 1938, amended 1951, 1962 | FDA |
| Food Additives Amendment 1958 | FDA |
| Pesticide Residue Amendment 1954 | EPA |
| Consumer Product safety Act 1972 | Now CPSC |
| Medical Devices Amendment 1976 | FDA |
| Federal Hazardous Substances Act 1960 | CPSC |
| Poison Prevention Packaging Act 1970 | CPSC |
| Labelling of Hazardous Materials Amendment 1988 | |
| Occupational Health and Safety Act 1970 | OSHA |
| Consumer Products Safety Act 1972 | CPSC |
| Federal Water Pollution Control Act (Clean Water Act) 1948 | EPA |
| Amendments 1972, 1983, 1992, 1996 | |
| Safe Drinking Water Act 1974 | EPA |
| Amended in 1986, 1996 | |
| Clean Air Act 1970 | EPA |
| Amended 1977, 1990 | |
| Toxic Substances Control Act 1976 | EPA |
| Amended 1981, 1984, 1986 | |
| Resource Conservation and Recovery Act 1976 | EPA |
| Amended 1980, 1984, 1986 | |
| Federal Insecticide, Fungicide and Rodenticide Act 1947 | EPA |
| Amended 1972, 1988, 1996 | |
| Comprehensive Environmental Response, Compensation and Liability Act 1980 | EPA |
| Hazard Communication Standard 1983 | OSHA |
| Amended 1988 | |
| Superfund Amendments and Reauthorisation Act 1986 | EPA |

FDA: Food and Drug Administration; EPA: Environmental Protection Agency; CPSC: Consumer Product Safety Commission; OSHA: Occupational Safety and Health Administration.

Table 2
CPSC classification of the toxicity of materials based on acute oral or dermal toxicity tests

| Type of test | Toxic (mg/kg) | Highly toxic (mg/kg) |
|---|---|---|
| *Oral* (death after oral administration to half or more of a group of laboratory rats within 14 days) | Above 50–2000 | Below 50 |
| *Dermal* (death after continuous contact with skin for 24 h or less administration to half or more of a group of laboratory rabbits within 14 days) | Above 200– 2000 | Below 200 |

cide Act (FIFRA), 1996 and for regulation of chemicals and other potentially hazardous materials under the Toxic Substances Control Act (TSCA), 1976. The US EPA is responsible for establishing labelling and packaging standards for pesticides. It has also developed a set of testing guidelines, including acute testing guidelines, for use in the testing of pesticides and toxic substances and developing test data for submission to the agency for review. In contrast to most regulations that provide minimal specifications (species weight, dose, and duration of exposure and observation periods), the above-cited guidelines provide several pages of detailed information and testing procedures [7]).

- Occupational Health and Safety Administration (OSHA): The mission od the US OSHAs is to assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; encouraging continual improvement in workplace safety and health, including, among other things, the workplace control of chemicals. OSHA has also been working with the European Commission on development and implementation of the GHS.
- Department of Health, and Human Services, which has responsibility for:
  - The Food and Drug Administration (FDA), the agency that regulates pharmaceuticals, as well as through its Bureau of Foods, it exercises premarketing approval authority for the safety of direct and indirect food and colour additives used in food.
  - The Agency of Toxic Substances and Disease Registry (ATSDR), charged under Superfund legislation to assess the presence and nature of health hazards at specific Superfund sites, and to reduce or prevent illnesses that result from such exposures.

## 3. The European Union

While there were national systems for classification and labelling of chemicals in Europe (such as the UK Health and Safety Executive), the then European Economic Community (EEC) became the regulatory agency for chemicals in the 1960s. Regulatory instruments of the now European Union (EU) include regulations, directives, decisions, recommendations and opinions. Of these regulations and directives are binding on member states with specification of dates of compliance. Directives differ from regulations in that they specify objectives, but not the methods for compliance.

The EU introduced the first Directive on dangerous substances or chemicals harmful to people or the environment in 1967 (Council Directive 67/548/EEC introduced the administrative structures to harmonise the laws of Member States governing the testing, classification, packaging and labelling of dangerous substances). It has been amended and updated many times since 1967, and additional directives have broadened the scope of EU Chemicals policy. The more important of these directives and regulations have been:

- Council Directive 79/831/EEC was the sixth amendment, which introduced a pre-market testing and notification system for new chemical substances being marketed in the European Union. This included introduction of European Inventory of Existing Commercial Chemical Substances (EINECS) under Council Directive 81/437/EEC.
- Council Directive 82/501/EEC was the Seveso directive, introduced after the 1976 accident in the Italian town of Seveso and concerned with controlling the risks of exceptional or major accidents such as fire, explosions or major emissions and require various measures to be taken to prevent and contain such accidents and their consequences.
- Council Regulation 428/89/EEC was introduced for the control of the export of chemicals used in the development or production of chemical weapons.
- Commission Directive 91/155/EEC, which defined and outlined arrangements for the system of specific information relating to chemical products (dangerous preparations).
- Commission Directive 91/322/EEC on the establishment of indicative limit values for exposure to chemical, physical and biological agents in the workplace.
- Council Regulation 793/93/EEC dealt with the evaluation and control of substances (for example, existing chemicals) not covered under Directive 79/831/EEC. The Directive requires that a data notification procedure be undertaken for evaluating the risks posed by existing substances, including all those listed in EINECS (then containing 100,195 substances).
- Commission Regulation 1488/94/EEC laying down the principles for the assessment of risks to humans and the environment.
- Commission Directive 2001/58/EC on the establishment of indicative limit values for exposure to chemical, physical and biological agents in the workplace.

Many of these directives have been amended by later directives.

## 4. Australia

There are four national chemicals assessment and registration schemes, which cover food, industrial chemicals, pharmaceuticals and agricultural and veterinary chemicals. The schemes operate in a complementary manner to ensure there is no duplication or any unnecessary regulatory burden on industry.

The scope of each of the four chemicals assessment and/or registration schemes is defined by legislation. Legislation also specifies what chemical/chemical products are to be covered by each of the schemes, as well as the requirements for anyone involved in chemicals manufacture and/or importation.

In Australia, responsibility for chemical regulation in the health sector is shared by a number of Australian Govern-

ment Commonwealth bodies and in some cases in conjunction with New Zealand [8]. Specific legislation empowers the operation of various Commonwealth public health and Safety regulatory functions. While jurisdictional coverage and most government functions occur at the State/Territory level in Australia, responsibility for chemicals notification and assessment occurs at the Federal government levels. The main regulatory agencies are summarised in Table 3 with their specific legislation.

Other regulatory arrangements relating to consumer products are discussed below:

- Therapeutic Goods Administration (TGA): The Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health and Ageing, is a member of the TGA Group of Regulators and was established in 1991. The TGA is responsible for administering the provisions of the Therapeutic Goods Act 1989, and its Regulations and Orders. The objective of the Act, which came into effect on 15 February 1991, is to provide a national framework for the regulation of therapeutic goods in Australia and ensure their quality, safety and efficacy. The TGA is responsible for regulating the supply in Australia of therapeutic goods including prescription, non-prescription and complementary medicines (herbal products, vitamins, minerals and homoeopathic products) and therapeutic devices. Legislative amendments were made in 1999 to the Therapeutic Goods Act 1989, to cover processes for establishing national standards for drugs and poisons. This assists in providing national uniformity in the levels of control of drugs and poisons, including in the area of product labelling.

Table 3
Major Australian chemical control laws and agencies

| Act, Law, Statutory Standard | Responsible Federal Agency |
|---|---|
| Therapeutic Goods Act 1989 Standard for the Uniform Scheduling of Drugs and Poisons | TGA/DoHA |
| Agricultural and Veterinary Chemicals (Administration) Act 1992; Agriculture and Veterinary Chemicals Code Act 1994. | APVMA/DAFF |
| Food Standards Australia New Zealand Act (1991), Food Standards Code | FSANZ |
| Australian Dangerous Goods Code | FORS/DoT |
| Industrial Chemicals (Notification and Assessment) Act 1989 (National Industrial Chemical Notification Scheme or NICNAS) | DoHA/DEH/NOHSC |
| Trade Practices Act 1974, Prices Surveillance Act 1983 | ACCC |

ACCC: Australian Competition and Consumer Agency; APVMA: Australian Pesticides and Veterinary Medicines Authority; FSANZ: Food Standards Australia New Zealand; CPSC: Consumer Product Safety Commission; DAFF: Australian Department of Agriculture, Fisheries and Forestry; DoHA: Commonwealth Department of Health and Ageing; FORS: Federal Office of Road Safety, Commonwealth Department of Transport; DEH: Department of Environment and Heritage; NOHSC: National Occupational Health and Safety Commission.

- The Office of Chemical Safety, TGA Group of Regulators, within the Australian Government Department of Health and Ageing, comprises:
  - The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which has the objective of aiding in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals. Currently (with certain exemptions), all new industrial chemicals must be notified and/or assessed to NICNAS prior to their import or manufacture in Australia. NICNAS operates under Commonwealth legislation known as the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act). NICNAS aims to ensure the safe use of chemicals by making information on chemicals and their potential occupational health and safety, public health and environmental risk widely available to workers, the public, industry, and other State, Territory and Commonwealth government agencies.
  - The public health risk assessment for pesticides, veterinary medicines and other chemicals to which the public may be exposed.
  - Secretariat support and preparation of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), an Australian Government standard used by all jurisdictions in Australia for the classification, labelling, packaging and general control of drugs and poisons. The standard forms a major component of Poisons legislation in Australia, and assists in providing national uniformity in the levels of control of drugs and poisons.
  - Monitoring and compliance activities in relation to Australia's obligations for international drug treaty arrangements and other prohibited/controlled substances.

  The Office also has responsibilities for giving effect to Australia's obligations under international agreements relating to the regulation of chemicals, and for collecting statistics about chemicals.
- Australian Pesticides and Veterinary Medicines Authority: The APVMA (formerly the National Registration Authority for Agricultural and Veterinary Chemicals) was established in 1993 as an independent Statutory Authority in the Australian Government Portfolio of Agriculture, Fisheries and Forestry.

The APVMA administers legislation established under the National Registration Scheme on behalf of the Australian and State/Territory Governments and is responsible for the assessment, registration and regulation of agricultural and veterinary chemical products (including some domestic and household products such as insect sprays) up to, and including, the point of retail sale. Controlling the use of agricultural and veterinary chemicals is the responsibility of the relevant State/Territory authority.

The Australian system of agricultural and veterinary chemical registration (including standards and standard set-

ting processes) is aligned closely with international best practice. Before an agricultural or veterinary chemical product can be sold in Australia, it must be assessed and registered by the APVMA. Chemical companies are required to provide extensive data to demonstrate that a product will be effective for the uses described on the label, will be safe for humans and non-target species, and will not pose unacceptable risks to the environment or trade with other nations. When products are evaluated, the APVMA takes full account of the nature of the product, the amount and completeness of data for consideration, and the extent of consultation required between the APVMA, manufacturers, advisory agencies, and State/Territories Governments.

For specialist advice during the assessment process, the APVMA receives input from a number of Australian Government Agencies:

- The Therapeutic Goods Administration's Office of Chemical Safety within the Australian Government Department of Health and Aging evaluates toxicology data submitted by applicants to determine if any health risk may be posed to the community.
- The Australian Government Department of Environment and Heritage evaluates the environmental implications of products submitted for registration and recommends measures to avoid or minimise adverse environmental effects.
- The National Occupational Health and Safety Commission conducts occupational health and safety assessments to ensure that any risks arising out of workers' exposure to agricultural and veterinary chemical products are minimised.
- Food Standards Australia and New Zealand assesses the dietary intake implications of residues in food and in cooperation with the APVMA sets maximum residue limits.
- The Office of the Gene Technology Regulator provides advice in relation to products of gene technology.
- The National Health and Medical Research Council's Expert Advisory Group on Antimicrobial Resistance addresses the implications of the use of antibiotics in agriculture.
- The Australian Quarantine and Inspection Service advise on quarantine safety matters associated with imported biological products.

The APVMA operates several programs that monitor agricultural and veterinary chemicals after registration. The Chemical Review Program reconsiders the registration of agricultural and veterinary chemicals in the marketplace where potential risks to safety and performance have been identified. The APVMA's Manufacturers' Licensing Scheme requires all Australian based manufacturers of veterinary chemical products to be licensed and to meet standards described in a Code of Good Manufacturing Practice. In addition, the APVMA monitors compliance as well as the reporting of adverse experiences result from the use of agricultural and veterinary chemicals.

It is these features that underpin the credibility of Australia's agricultural and veterinary chemicals management system.

- Federal Office of Road Safety, Commonwealth Department of Transport and Regional Services: The Federal Office of Road Safety (FORS) promotes best practice and development of harmonised legislation for the transport of dangerous goods and explosives in Australia. It also coordinates implementation of the recommendations of United Nations Committee of Experts on the Transport of Dangerous Goods (UNCETDG) in Australia. The Department provides secretariat support and preparation of the Australian Dangerous Goods Code (ADG Code), an Australian Government standard used by all jurisdictions in Australia for the classification, labelling, packaging and general control of dangerous goods. The standard forms a major component of Dangerous Goods legislation in Australia, and assists in providing national uniformity in the levels of control of Dangerous Goods.
- National Occupational Health and Safety Commission (NOHSC): NOHSC is a tripartite statutory body, with government, employer and employee representation. It provides a forum for consultation and development and formulation of policies and strategies relating to occupational health and safety matters. There are three NOHSC regulatory instruments for the control of chemicals in the workplace:
  - The Hazardous Substances Regulatory Package,
  - The National Standard and Code of Practice for the Storage and Handling of Dangerous Goods,
  - The Major Hazards Facility Standard.
- Food Standards Australia New Zealand (FSANZ): Food Standards Australia New Zealand (FSANZ, formerly Australia New Zealand Food Authority (ANZFA)) a binational Statutory Authority that in cooperation with the Australian Commonwealth, State and Territory governments and the New Zealand Government, develops food standards and other regulatory measures for Australia and New Zealand. These standards are published in the Food Standards Code once they are approved by the FSANZ Board and then considered by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC; formerly the Australia New Zealand Food Standards Council (ANZFSC). ANZFRMC can request a review of any standard developed by FSANZ.

FSANZ develops food standards under the Food Standards Code, which include all food matters. In particular, in relation to chemicals that may be included in foods for a specific technological purpose or which may enter food products as a result of natural or accidental contamination, there are standards for food additives, processing aids and contaminants in the Food Standards Code with maximum levels set in various foods where appropriate. FSANZ develops the food standards but does not enforce them; this is the responsibility of the State, Territory and New

Zealand governments who adopt the standards in the Food Standards Code into their respective State, Territory and New Zealand Food Acts or Regulations. However, FSANZ has a coordination role to harmonise consistent interpretation of enforcement requirements.

- Australian Competition and Consumer Commission (ACCC): ACCC is an independent statutory authority formed in 1995. It administers the Trade Practices Act 1974 and the Price Surveillance Act 1983. The Act covers anti-competitive and unfair market prices, product safety/liability, mergers and acquisitions of companies and third party access to facilities of national significance.

## 5. International or multinational bodies

National initiatives are carried out by sovereign nations to deal with specific initiatives within their jurisdictional areas and responsibilities. However, for chemicals, some activities, for example classification and labelling, do not require constant duplication by numerous national agencies. Therefore, chemicals hazard identification, assessment and control is an area that may be better managed at the international or multinational level [9].

A number of international bodies have taken on chemicals related activity within the framework of the IFCS:

- United Nations: The UN has been at the forefront of chemicals control activities since its formation in 1945. Examples of activities include:
  - International Code of Conduct on the Distribution and Use of Pesticides: The International Code of Conduct was developed to address a number of difficulties associated with the use of pesticides in developing countries where adequate regulatory infrastructures are frequently lacking.
  - United Nations Environmental Program (UN-EP), London Guidelines for the Exchange of Information on Chemicals in International Trade: This set of guidelines is addressed to governments with a view to assisting them in the process of increasing chemical safety in all countries through exchange of information on chemicals in international trade. These guidelines are general in nature and are aimed at enhancing the proper management of chemicals through the exchange of scientific, technical, economic and legal information.
  - United Nations Transport of Dangerous Goods (UN-TDG): UN-TDG provides a basis for the development of harmonized regulations for all modes of transport, in order to facilitate trade and the safe, efficient transport of hazardous materials. It covers all aspects of transportation necessary to provide international uniformity. The regulations include a comprehensive criteria based classification system. Hazards regulated include explosivity, flammability, toxicity (oral, dermal, and inhalation), corrosivity, reactivity, radioactivity, infectious substance hazards and environmental hazards. This also include a system of hazard communication such as cover labelling, documentation and emergency response information. Many of the national and international regulations governing the transport of dangerous goods are based on the UN recommendations (including the USA and Australia), therefore facilitating compliance and decreasing confusion. Previously, some of the regulations were structured differently requiring transporters to be familiar with the unique structure of all applicable regulations. The lack of harmony of regulations can lead to frustration in compliance resulting in non-compliance that is detrimental to safety.
  - United Basel Convention on the Transboundary Transport of Hazardous Wastes.

- Organization for Economic Cooperation and Development (OECD): The OECD is an international organisation grouping of about 30 industrialised countries and country groupings. Member nations include the United States, Australia, New Zealand, Canada, Mexico, South Korea, Turkey and many of the developed nations of the European Economic Community. The OECD has formed expert groups to review toxicity testing requirements for the member nations and formulate testing guidelines, which would be acceptable to all members. These guidelines are a collection of the most relevant internationally agreed testing methods used by government, industry and independent laboratories to assess potential hazards of new and existing chemical substances and mixtures. It incorporates some procedures that are designed to reduce numbers of animals used in experiments and to limit the amount of pain they experience. OECD has published over 100 guidelines that are constantly updated or renewed. A recent published OECD guideline specific to acute oral toxicity testing is guideline 423, Acute Oral Toxicity – Acute Toxic Class Method, published on 22 March 1996 and updated December 2001 [10].

## 6. The globally harmonized system (GHS)

The presence of many chemicals hazard classification schemes management regimes for chemicals, both nationally and internationally, makes for a confused picture and makes it difficult to implement suitable chemicals control management. Calls for a harmonized system for chemical hazards classification and hazard communication began in the 1980s [11]. The need for a globally harmonized system for Classification and Labelling of Chemicals (GHS) was identified as countries had differing abilities to identify and systematically regulate every hazardous chemicals. Most countries with developed systems that require the transmission of information through labels and/or safety data sheets [8], but many countries have few, if any, requirements to communicate the hazard of chemicals. There are also existed many inconsisten-

cies in the classification and labelling of the same chemical between the different countries, or within different sectors in the same country or manufacturers. For example, some chemicals are classified as flammable or carcinogenic in one country and not in another. These differences in classification have a strong impact on both the protection to human health and environment, and on trade.

The GHS provides the infrastructure for a globalized, consistent approach to the classification of chemicals and a coherent and consistent approach to defining and classifying chemical hazards and communicating information on labels and safety data sheets [8]. Obviously, with systems already in place for classification and labelling of hazardous chemicals, the GHS serves as a focus for convergence of the existing systems. The GHS can then be used for the establishment of a comprehensive chemical safety program at the national or regional level.

Work on the GHS began in 1989, when the International Labour Organisation (ILO) adopted a resolution concerning the harmonisation of systems of classification and labelling [11]. In the early development of a globally harmonized system, the existing chemical classification and labelling systems of the following international organizations and countries were considered:

- OECD Chemicals Program,
- ILO Chemical Safety Tools,
- UN Recommendations for Transport,
- FAO Recommendations on Pesticides,
- UN Transport Recommendations,
- European Union (EU) directives on Dangerous Substances and Preparations,
- US requirements for Workplace, Consumers and Pesticides,
- Canadian Requirements for Workplace, Consumers and Pesticides.

The process of harmonisation fell under the umbrella of the Interorganizational Programme for the Sound Management of Chemicals (IOMC). The GHS covers all hazardous chemical substances, dilute solutions and mixtures but it does not cover pharmaceuticals, cosmetics, food additives, and pesticide residues in food except when workers are exposed and in transport [12,14]. The GHS considers that classification of a chemical substance depends on the criteria and on the reliability of the test methods underpinning the criteria. Tests that determine hazardous properties, which are conducted according to internationally recognized scientific principles, can be used for the purposes of a hazard determination for health and environmental hazards. The GHS criteria are test-method neutral, and are performance based, in the sense that they allow for any approach as long as it is scientifically sound and validated according to international procedures. Criteria for physical hazards are linked to specific test methods for hazard classes such as flammability and explosivity.

The new globally harmonized system of Classification and Labelling of Chemicals (GHS), which was adopted in December 2002, now moves to the front of the list of major regulatory issues facing virtually all government agencies with responsibility for regulating chemicals, as well as industry and unions over the coming years. This new system, the outcome of collaborative efforts of the World Health Organisation, the International Labour Organisation, the Organisation for Economic Cooperation and Development (OECD), and the United Nations, as well as member countries of the above organisations, has broadly supported from the chemical industry because of its promise to harmonize at international level the manner in which chemicals are classified according to their hazards and labelled using universally understandable pictograms, as well as a uniform system of safety data sheets.

The main GHS elements are classification criteria for substances and mixtures (for physical effects; toxic (health) effects; environmental effects) and requirements for hazard communication for chemicals (labels and safety data sheets) [13].

## 7. Classification criteria

A full explanation of classification criteria for physical, toxic and environmental effects can be found at: http://www.unece.org/trans/danger/publi/ghs/ghs_text-pdf/ghs-annex-2.pdf.

A summary of some of the main elements of the classification system is provided below. The communication of hazard in the GHS is based on the provision of signal words, hazard statements and pictograms, all of which are linked to the specific hazard of the substance or mixture.

### *7.1. Physical hazards*

Physical hazards are based on those of the United Nations Dangerous Goods System and include:

- *Explosives*, which are assigned to one of six subcategories (divisions) as used in the UN Dangerous Goods system (see Table 4).

- *Gases under pressure* are gases contained in a receptacle at a pressure not less than 280 kPa and at 20 °C or as a

Table 4
GHS Criteria, Explosion

| Division | Characteristics |
|---|---|
| 1.1 | Mass explosion hazard |
| 1.2 | Severe projection hazard |
| 1.3 | Fire, blast or projection hazard |
| 1.4 | Fire or projection hazard |
| 1.5 | May explode in fire |
| 1.6 | No hazard statement |

Table 5
GHS criteria, gases under pressure

| Category | Characteristics |
|---|---|
| Compressed gas | Entirely gaseous at a temperature below –50 °C |
| Liquefied gas | Partially liquid at a temperature above - 50 °C; a distinction is made between high pressure liquefied gas (critical temperature between −50 and +65 °C), and low pressure liquefied gas (critical temperature above +65 °C) |
| Refrigerated liquefied gas | Partially liquid because of its low temperature |
| Dissolved gas | Dissolved in a liquid phase solvent |

refrigerated liquid. This category is additional to the other hazards the gas may possess. There are four categories (see Table 5).

- Water activated flammable gases
- Flammability (gases, aerosols, liquids, solids).

- *A flammable gas* is one that has a flammable range with air at 20 °C and a standard pressure of 101.3 kPa (see Table 6).
- *A flammable liquid* is a liquid with a flash point of not more than 93 °C (see Table 7). Gas oils, diesel and light heating oils in the flash point range of 55–75 °C may be regarded as a special group for some regulatory purposes.
- *A flammable solid* is one that is readily combustible (for example, it spreads rapidly even after brief contact with ignition source) or may cause or contribute to fire through friction (see Table 8).
- *Aerosols* should be considered for classification as flammable if they contain any component, which is classified as flammable according to the GHS criteria, that is, flammable liquids, flammable gases or flammable solids.
- *Self-reactive substances* are those liable to undergo a strongly exothermic decomposition even without participation of oxygen, air and excludes explosives, organic peroxides and oxidisers.
- *Pyrophoric liquids and solids* are those that ignite within 5 min after coming into contact with air.
- *Self heating substances* are those which, by reaction with air and without energy supply, is liable to self heat.
- *Dangerous when wet substances* are those that emit flammable gases in contact with water, and include three categories, which describe gas evolution and speed of evolution (see Table 9).
- *Oxidising liquids and solids* excluding organic peroxides are those that cause or contribute to the combustion of other materials, usually by the generation of oxygen. There are separate criteria for oxidizing liquids and solids, each of which are categorised on the basis of UN transport recommendations into subcategories (three for liquids; three for solids),

- *Oxidising peroxides* are reactive substances or mixtures that are thermally unstable and which may undergo an exothermic, self accelerating decomposition,
- Substances and mixtures *corrosive to metals* those that by chemical reaction will materially damage or destroy metals.

Note that radioactivity hazards (present in the dangerous goods classification) are absent from this classification.

Table 6
GHS criteria, flammable gases

| Category | Characteristics |
|---|---|
| 1. Extremely flammable gases | Gases ignitable when in mixture of 13% or less by volume in air or having a flammable range with air of at least 12% regardless of the lower flammability limit |
| 2. Flammable gases | Gases, other than those of Category 1, that have a flammability range while mixed in air at 20 °C and a standard pressure of 101.3 kPa |

Table 7
GHS criteria, flammable liquids

| Category | Characteristics |
|---|---|
| 1 | Flash point below 23 °C and initial boiling point at or below 35 °C |
| 2 | Flash point below 23 °C and initial boiling point above 35 °C |
| 3 | Flash point at or above 23 °C and at or below 60 °C |
| 4 | Flash point greater than 60 °C and at or below 93 °C |

Table 8
GHS criteria, flammable solids

| Category | Characteristics |
|---|---|
| 1 | Metal powders: burning time 5 min or less, others: wetted zone does not stop fire and burning time is less than 45 s or burning rate is greater than 2.2 mm/s |
| 2 | Metal powders: burning time between 5 and 10 min, others: wetted zone stops spread of fire for at least 4 min and burning time is less than 45 s or burning rate is greater than 2.2 mm/s |

Table 9
GHS criteria, substances emitting flammable gases on contact with water

| Category | Characteristics |
|---|---|
| 1 | Reacts vigourously with water at ambient temperatures and demonstrates a tendency for the gas produced to ignite spontaneously, or reacts so that the rate of evolution of flammable gas is equal to or greater than 10 L/gas per kilogram of substance over 1 min |
| 2 | Evolution of flammable gas equal to or greater than 20 L/kg substance/h, and which does not meet the criteria of Category 1 |
| 3 | Evolution of flammable gas equal to or greater than 1 and 20 L/h gas evolution |

### 7.2. Toxicity

Toxicity (health) hazards are:

- *Single dose toxicity*, covering a range of toxicity endpoints by various routs of exposure (see Table 10).
- *Skin irritation and corrosion*. Category 1 is for corrosive effects and Categories 2 and 3 for irritation (see Table 11).
- *Eye irritation and serious eye damage*. Category 1 is for corrosive effects and Categories 2A and 2B for irritation (see Table 12).
- *Skin or respiratory sensitisation*. If evidence is available to allow a classification of sensitisation, both skin and respiratory sensitisation are in Category 1, but note the new symbol for serious effects for respiratory sensitisation (see Table 13).
- Single or repeated dose *target organ systemic toxicity (TOST)*. This uses similar criteria for both single and repeated exposures (see Table 14).
- *Genotoxicity and germ cell toxicity*. As with the EC criteria, there are two categories (see Table 15).

Table 10
GHS criteria, single dose toxicity

| | Toxicity category | | | | |
|---|---|---|---|---|---|
| | 1  | 2  | 3  | 4  | 5 |
| Oral (mg/kg) | 5 | 50 | 300 | 2000 | Oral $LD_{50}$ between 2000 and 5000 mg/kg |
| Dermal (mg/kg) | 50 | 200 | 1000 | 2000 | Indication of significant effect in humans |
| Gases (ppm) | 100 | 500 | 2500 | 5000 | Any mortality in Category 4 |
| Vapours (mg/L) | 0.5 | 2 | 10 | 20 | Indications from other studies |
| Dusts and mists (mg/L) | 0.05 | 0.5 | 1 | 5 | |

Table 11
GHS criteria, skin corrosion/irritation

| Destruction of skin tissue; visible necrosis in one or more of three animals | | | Reversible adverse effects in skin tissue | |
|---|---|---|---|---|
| Category 1  | | | Category 2  | Category 3 |
| Sub-category 1A | Sub-category 1B | Sub-category 1C | | |
| *Exposure*: 3 min or less<br>*Observations*: up to 60 min | *Exposure*: between 3 min and 1 h<br>*Observations*: up to 14 days | *Exposure*: between 1 and 4 h<br>*Observations*: up to 14 days | *Exposure*: less than 4 h<br>*Observations*: less than 14 days<br>Mean irritation score of 2.3–4 for erythema/eschar or for oedema at 24, 48 and 72 h in at least two of three tested animals persistent inflammation at the end of the observation period | Mean irritation score of 1.5–2.3 for erythema/eschar or for oedema in at least two of three tested animals at 24, 48 and 72 h |

Table 12
GHS criteria, serious eye damage/eye irritation

| Category 1  | Category 2 | |
|---|---|---|
| Adverse effects on conjunctiva, cornea, iris that have not reversed within the observation period (normally 21 days after exposure) in at least one animal, and/or | Reversible adverse effects on conjunctiva, cornea, iris | |
| In at least two of three tested animals, a positive response of corneal opacity with a mean score of 3 or above, and/or a mean score of more than 1.5 for iritis, at 24, 48 and 72 h | Mean irritation score in at least two of three tested animals of 1 or more for corneal opacity and or 1 or more for iritis, and/or mean scores of 2 or more for redness and/or 2 or more for conjunctival oedema (chemosis) | |
| | Subcategory 2A  | Subcategory 2B |
| | Reversible in 21 days | Reversible in 7 days |

Table 13
GHS criteria, respiratory or skin sensitisation

| | |
|---|---|
| Respiratory sensitisation | Category 1  Evidence in humans of specific respiratory sensitivity and/or Results of respiratory sensitivity from animal studies |
| Skin sensitisation | Category 1  Evidence in humans of sensitisation by skin contact in a substantial number of persons, or Results of skin sensitivity from appropriate animal studies |

Table 14
GHS criteria, single or repeated target organ systemic toxicity (TOST)

| Category 1 | Category 2 |
|---|---|
|  Significant toxicity in humans |  Presumed to be harmful to human health |
| Significant toxicity in humans<br>Reliable, good quality human case studies or epidemiological studies | Animal studies with significant toxic effects relevant to humans at generally moderate (as a guide) exposure |
| Presumed significant toxicity in humans<br>Animal studies with significant and/or severe toxic effects relevant to humans at a generally (as a guide) low exposures | Human evidence in exceptional cases |

- *Reproductive toxicity*. Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring (see Table 16).
- *Carcinogenicity*. As with the EC criteria, there are two broad categories (see Table 17).

Note that infectious hazards (present in the dangerous goods classification) are absent from this classification.

## 8. Environmental hazards

Environmental hazards include:

- Hazards to the aquatic environment, either by single or repeated dose exposures (see Tables 18 and 19).

## 9. Classification of mixtures

Mixtures will be classified according to a tiered approach [14]:

- if available, used test data for the mixture,
- if test data is not available for the mixture, use "bridging principles", if applicable,
- if no other information is available, estimate hazards based on the available information on the known ingredients, using toxicity additivity approaches.

## 10. Hazard communication criteria

Hazard communication for chemicals has always been a vexed problem, as different forms of information are required for different types of individuals, for example, users, workers, consumers, emergency responders and chemical handlers (transport, storage personnel and so on) have different information needs.

The existing systems for hazard communication use different approaches, and have evolved for different perceived needs of individuals exposed to chemicals. This includes rapid communication (for example, the dangerous goods diamond) to provision of immediate hazard information (for example, labels) to more detailed information (safety data sheets). The level of risk communication is more subjective, and depends on the user, need and risk, and the comprehensibility of such systems is important.

An ILO Working Group identified about 35 different types of information required by the (then) existing systems. The GHS attempts to standardize hazard communication so that the intended audience can better understand the hazards of the chemicals in use. In this, the GHS has established guiding principles:

- The problem of trade secret or confidential business information has not been addressed within the GHS, except in general terms. For example, non-disclosure of confidential business information should not compromise the health and safety of users.
- Hazard communication should be available in more than one form (for example, placards, labels or safety data sheets).
- Hazard communication should include hazard statements and precautionary statements.
- Hazard communication information should be easy to understand and standardised.
- Hazard communication phrases should be consistent with each other to reduce confusion.
- Hazard communication should take into account all existing research and any new evidence.

Key label elements include:

- Identification of the chemical product.

Table 15
GHS criteria, germ cell mutagenicity

| Category 1 | | Category 2 |
|---|---|---|
|  | |  |
| Subcategory 1A | Subcategory 1B | May induce heritable mutations in human germ cells |
| Known to produce heritable mutations in human germ cells<br>Positive evidence from human epidemiological studies | Should be regarded as if they produce heritable mutations in the germ cells of humans<br>Positive results in:<br>Human germ cell tests<br>In vivo heritable germ cell tests in mammals<br>In vivo somatic mutagenicity tests, combined with some evidence of germ cell mutagenicity | Positive evidence from tests in mammals and somatic cell tests<br>In vivo somatic genotoxicity supported by in vitro mutagenicity |

Table 16
GHS criteria, reproductive and developmental effects

| Category 1 | | Category 2 | |
|---|---|---|---|
|  | |  | |
| Known or presumed to cause effects on human reproductive ability/capacity or on development | | Suspected to cause effects on human reproductive ability/capacity or on development | |
| Subcategory 1A | Subcategory 1B | | |
| Known (based on human data) | Presumed (based on animal data) | | Additional category effects on lactation<br>Or effects via lactation |

Table 17
GHS criteria, carcinogenicity

| Category 1 | Category 2 | |
|---|---|---|
|  | |  |
| Known or presumed human carcinogen | | Suspected human carcinogen |
| Subcategory 1A | | Subcategory 1B |
| Known human carcinogen based on human evidence | Presumed human carcinogen based on demonstrated animal carcinogenicity | Limited evidence of human or animal carcinogenicity |

Table 18
GHS criteria, single exposure aquatic toxicity

| Category 1 | Category 2 | Category 3 |
|---|---|---|
|  |  | |
| 96 h $LC_{50}$ (fish) below 1 mg/L and/or<br>48 h $EC_{50}$ (crustacea) below 1 mg/L and/or<br>72 or 96 h $ErC_{50}$ (algae/or other aquatic plants) below 1 mg/L | 96 h $LC_{50}$ (fish) between 1 and 10 mg/L and/or<br>48 h $EC_{50}$ (crustacea) between 1 and 10 mg/L and/or<br>72 or 96 h $ErC_{50}$ (algae/or other aquatic plants) between 1 and 10 mg/L | 96 h $LC_{50}$ (fish) between 10 and 100 mg/L and/or<br>48 h $EC_{50}$ (crustacea) between 10 and 100 mg/L and/or<br>72 or 96 h $ErC_{50}$ (algae/or other aquatic plants) between 10 and 100 mg/L |

Table 19
GHS criteria, repeated exposure aquatic toxicity

| Category 1 | Category 2 | Category 3 | Category 4 |
|---|---|---|---|
| Has single dose toxicity below 1 mg/L<br>Lack of rapid degradability and/or<br>Lack of bioaccumulation log $K_{ow}$ above 4 (unless experimentally determined BCF below 500) | Has single dose toxicity between 1 and 10 mg/L<br>Lack of rapid degradation and/or<br>Lack of bioaccumulation log $K_{ow}$ above 4 (unless the experimentally determined BCF below 500 or), unless the chronic NOECs 1 mg/L | Has single dose toxicity between 10 and 100 mg/L<br>Lack of rapid degradation and/or<br>Lack of bioaccumulation (BCF above 500 or log $K_{ow}$ above 4)<br>Has NOEC above 1 mg/L | Has single dose toxicity above 100 mg/L<br>Is poorly soluble<br>Lack of rapid degradation and/or<br>Lack of bioaccumulation (BCF above 500 or log $K_{ow}$ above 4)<br>Has NOEC above 1 mg/L |

BCF: bioconcentration factor; log $K_{ow}$: octanol/water partition coefficient (logarithm); NOEC: no observable effect concentration.

- Identification of the product supplier (manufacturer or importer).
- Chemical identity.
- Signal Words (Danger, Warning).
- Warning pictograms, symbols (a red diamond with black on white text has been adopted as the standard symbol) or signal words ("Danger" or "Warning" have been adopted as signal words to emphasise hazard and levels of hazard). The hazard symbols in Fig. 1 are used in the GHS.

With the exception of the new serious health hazard symbol, the exclamation mark and the fish and tree, they are part of the standard symbol set used in the UN Recommendations on the Transport of Dangerous Goods (The GHS has deleted the St. Andrews Cross (a feature of the EC classification system) as a pictogram.):

- Hazard statements (standardised and linked with signal words and hazard symbols).

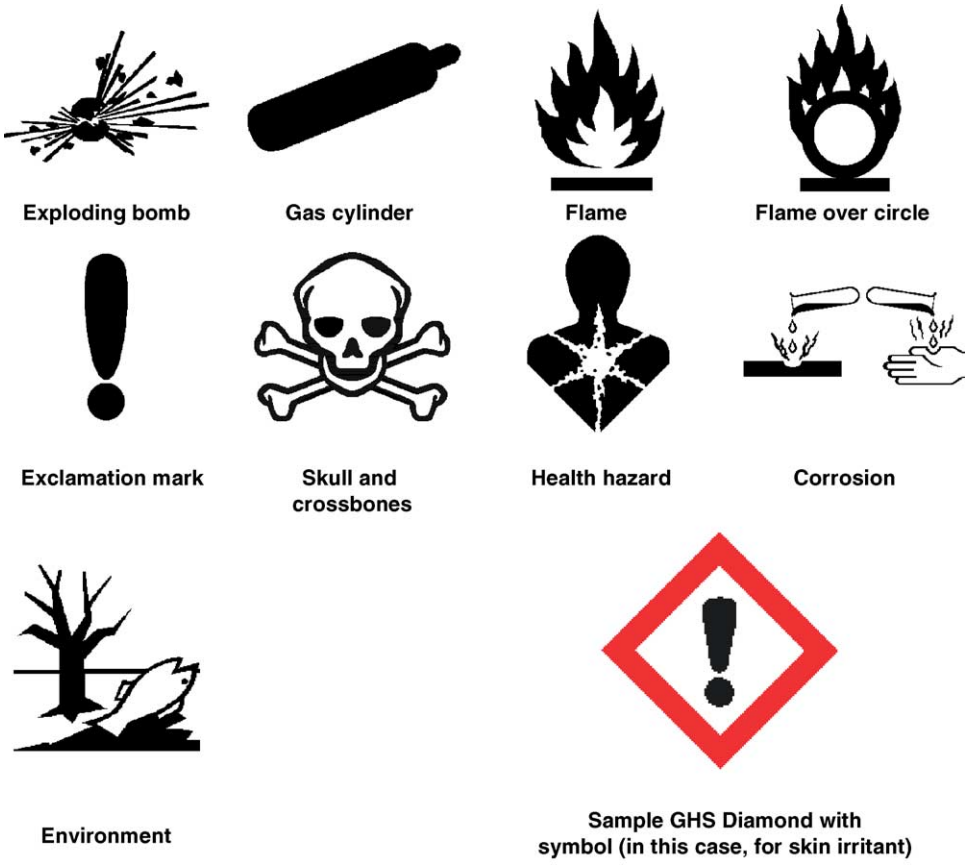


Fig. 1. Symbols for the GHS.

Table 20
Agreed entries for the 16 headers GHS SDS

| | |
|---|---|
| 1 | Identification of the material supplier |
| 2 | Hazard(s) identification |
| 3 | Composition/information on ingredients |
| 4 | First aid measures. |
| 5 | Fire-fighting measures. |
| 6 | Accidental release measures. |
| 7 | Handling and storage |
| 8 | Exposure controls and 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 | Additional information not otherwise covered |

- Precautionary statements (a standardised set of statements is being developed).

The safety data sheet (The GHS has dropped the word "material" from material safety data sheet. It will now be called the safety data sheet or SDS) is specifically aimed at use in the workplace. It should provide comprehensive information about the chemical product that to allows employers and workers to obtain concise, relevant and accurate information that can be put in perspective with regard to the hazards, uses and risk management of the chemical product in the workplace. Key safety data sheet elements include:

- A safety data sheet must be prepared for any chemical product that meets the harmonised criteria.
- A safety data sheet must be prepared using the standardised sixteen header format (see Table 20).

This format shown is consistent with the requirements of the NOHSC revised Code of Practice for MSDS, which comes into effect in 2006, is acceptable under Australian legislation, and is common to other international standards such as the ILO standard under Chemicals Recommendation 177, ISO 11014-1, and the US ANSI Standard Z400.1

- A safety data sheet must be freely available in the workplace to all users of a chemical product.
- A safety data sheet must be revised whenever new information become s available that impacts on the accuracy of the information in the safety data sheet, or at least every 5 years.

The development of the GHS is largely complete. The next phase is implementation. The Intergovernmental Forum for Chemical Safety recommends that all countries implement the GHS as soon as possible with a view to have the system fully operational by 2008. The Federal Government has given this commitment at the World Summit on Sustainable Development (WSSD) in 2002, and government agencies are now addressing GHS issues.

Ultimately, it is hoped that the GHS will provide all countries with a structure to classify and label hazardous chemicals, and ensure suitably understandable information is available for all manufactured, imported and exported chemicals. In this way, a system will be established that will form the basis of ONE international system for the sound worldwide management of chemicals.

## 11. GHS implementation in Australia

Consistent with the approach recommended by the UN, Australia is currently developing a national situation analysis for the GHS, aimed at providing a synopsis of how chemicals are classified and labelled across different sectors. This approach will allow Australian sectors to make an informed decision on GHS implementation, and to decide whether the GHS should be adopted, in whole or in part, across the various sectors.

This has application for areas such as consumer products and pesticides, where the existing poisons scheduling system has different classification and labelling requirements to the GHS. Agencies responsible for the labelling and classification of such chemicals are currently analysing the potential impact of the GHS, and whether or not to adopt the new system. Implementation of the GHS in most developed countries has ramifications for future chemicals classification and labelling activities especially in trade.

Some of the agencies that conduct hazard assessments on chemicals, including NOHSC, the Department of Health and Ageing, and the Department of the Environment and Heritage, have been trailing the GHS classification criteria to complement their existing assessments, so that the impact of GHS in the Australian chemical assessment process can be determined.

NOHSC recently agreed that the current regulations for workplace hazardous substances should be revised, and that there should be an integrated set of model regulations for chemical substances. This is so there can be a consistent approach to workplace chemicals regulation and risk assessments, to reduce the regulatory burden on industry and to improve health and safety outcomes for workers. As part of this new approach, workplace hazardous substances and Dangerous Goods are likely to be classified and labelled in a consistent manner, in line with the GHS. This review of the existing regulations will be conducted over the next few years, and with the GHS implementation target date firmly in mind.

## 12. Discussion

Taking a broad view of developments in OECD countries, Nichols and Crawford [15] outlined various phases of regulatory approach:

- the minimalist period of the pre 1960s,
- the fragmented approach of the late-1960s and early 1970s, in response to potential or actual damage to health or the environment. Governments reacted to known hazards in recognised situations, with the emphasis, in the main, on reactive, prescriptive and corrective methods. These tended to fit into existing institutional arrangements,
- the sectoral approach of the 1970s and 1980s of various agencies and government departments charged with the responsibility of a specific area, such as environment, workplace, public health or transport.

Development of chemicals management infrastructure worldwide have mirrored these phases. One further point should be noted. As noted above, chemicals control legislation has been introduced in discrete "waves" of the minimalist, fragmented, and sectoral approaches. This leads to the question, what is likely to be the next wave?

In many respects, criticism of the current regulatory system [4,16] is based on a misunderstanding of ministerial and legislative responsibilities and inter-jurisdictional demarcations. For chemicals, it makes little sense if a chemical exposure causes problems in one (or more than one) of the current jurisdictional sectors (environment, public health, occupational health and safety, transport, and so on). Perhaps what is needed next for consistent regulation of chemicals is a transectoral approach, where chemicals are regulated because they are chemicals, not because they are found in the environment or workplaces or anywhere else.

Chemicals assessment and control legislative systems in many countries are comprehensive, although some chemicals may be covered by more than one piece of legislation (for example, they may be used for both industrial and agricultural purposes). However, coordination systems are in place to avoid duplication of assessment work and conflicting application of controls.

The chemicals classification, labelling and packaging schemes around the world have been dominated by the UN Dangerous Goods System and the EC Hazardous Substances system. But having two (or more systems) is problematic, and this has lead to confusion, both in terms of industrial activity and trade, but also with regard to safety, health and environment.

The concept of a GHS is to be welcomed as a means of providing a unified chemical classification processes. However, identification of chemical hazard is only one part of the process. The focus of classification should be on safety, health and environment, not commerce and supply. Many chemical entities lack basic toxicity data to allow even a rudimentary assessment of risk, and steps should be taken to identify, assess and eliminate or better control chemical products containing such ingredients.

The GHS has the potential to clarify much of the complexity in chemicals classification, and could have immediate flow on effects for labelling and SDS, which communicate the hazard of chemicals to workers. The GHS may have long term flow on effects for improving workplace risk assessments, competency training and control of workplace hazards and risks. But in real terms, the GHS is a long way from the users of chemical products, and should not be seen as the solution to a number of existing and continuing problems.

A range of regulatory and administrative structures will need to be reformed to allow the GHS to clarify the existing complexity about classifying chemical hazards. Regulatory agencies must move to adopt the GHS to rationalise the current confusion with the existing multiple classification systems in their different sectors and across different agencies. In this way, existing systems could be rationalised by adoption of the GHS to allow a sensible, consistent approach to chemicals policy labels and MSDS for all chemicals in the workplace. To work properly, implementation of the GHS may need a "whole of Government" approach.

- Guidance or Codes will be required so that chemicals classifications are consistent.
- Industry-specific information will be required so that industry becomes aware of, and adopts, the new requirements.
- Plain English guidance will be required so that workers become better informed about chemical risks at work.

Along with policies, programs and administrative procedures, effective enforcement strategies will be required to realize the potential of the GHS and to ensure that deceptive classifications do not result in adverse health effects for workers and the public.

The call for a harmonized system at UNCED in 1992 is being taken up, and although if the 2000 date was somewhat ambitious, a harmonized system for classification and labelling of hazardous chemicals has been developed and is being implemented. When it is in place, the world will finally have one system for classification of chemical hazards.

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