



# **Survey for Review of Chemical Management Regulatory Systems Worldwide**

Committee on Trade and Investment (CTI)

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## I N T R O D U C T I O N

It's a well-known fact that the world is producing and using constantly increasing amounts of chemicals. This trend, in turn, not only affects the ecological footprint, but also increases the exposure of humans to hazardous chemicals. According to the World Health Organization (WHO), the chemical industry and the circulation of chemicals contribute to more than 25% of illnesses worldwide.

Therefore, the need for the state regulation of the chemicals' safety during their lifetime, including their production and handling, is primarily driven by a significant threat that chemicals pose to the human life and health, environment and property.

Because these problems are global and affect all countries to various extents, there is a particularly pressing need for the international regulation of the production and handling of chemicals.

International approaches to the regulation of safe handling of chemicals have been primarily incarnated in the UN Recommendations of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), OECD (Organization for Economic Cooperation and Development) guiding documents, various documents of the other organizations and fora, worldwide national regulations.

Since the previous release of the book ("The Comparative Analysis of the National and International Legislation on the Regulation of Chemical Products"), legislative systems in many countries have gone through major changes. In particular, the largest Asian countries (China, India, ) have mandated the application of the UN GHS Recommendations through a system of national standards and other legal instruments. Some other countries (such as Israel, Slovenia, Chile, Estonia) have joined the OECD and aligned their agenda with the resolutions and recommendations of this organization in the field of chemical safety.

Some of the most prominent results of the work performed by the international community include the development and adoption of Strategic Approach to International Chemicals Management (SAICM) in 2006. SAICM is a global policy framework that has been approved by the governments of the 175 countries and NGO to prevent harm to human health and ecosystems posed by chemicals.

In the end document "Overall orientation and guidance for achieving the 2020 goal of sound management of chemicals. The future we want for the sound management of chemicals" (endorsed at the 4<sup>th</sup> session of the International Conference on Chemicals Management (ICCM), 28 September to 2 October 2015) stakeholders have reaffirmed their commitment to the global approach to the sound management of chemicals on different levels. This approach enables stakeholders to address challenges in effective, harmonized and coordinated manner. The document also stated the essentiality of encouraging multi-sectoral and multi-stakeholder participation as well as strengthening SAICM.

World Summit on Sustainable Development also set an ambiguous aim of this process – achieving sound management of chemicals throughout their lifecycle by 2020 so "chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health" ("2020 goal"). Acceptance of these obligations were confirmed at the summit G20 in 2012.

SAICM enabled networking, coordination and participation of all the various groups of stakeholders within the question pool related to safety of chemicals.

Realization of SAICM to a big extend depends on the work of the public international organizations, especially the 9 participating organizations of the Inter-Organization Programme of the Sound Management of Chemicals (IOMC): Food and Agriculture Organization of the United Nations (FAO), International Labour Organization (ILO), United Nations Development Programme (UNDP), United Nations Environment Programme (UNEP), United Nations Industrial Development Organization (UNIDO), United Nations Institute for Training and Research (UNITAR), World Health Organization (WHO), World Bank and Organisation for Economic Cooperation and Development (OECD).

## Introduction

IOMC is focused on the particular issues in the area of sound management of chemicals as well as facilitation and coordination of international efforts in this area. Among areas of work: Pollutant Release and Transfer Registers (PRTR), classification and labelling issues, risk assessment of chemicals in terms of their impact on human health and environment, risk assessment methodology elaboration and harmonization, global chemical portals' development and administration, facilitation of inclusion of chemical handling issues into national development plans, obsolete pesticides management, emergency response preparedness and response.

At ICCM4 there were adopted 11 basic elements, critical to be addressed at the national, regional and international levels in order to achieve 2020 goal. They include the need to develop legal frameworks that address the entire life cycle of chemicals and waste.

The essence of the modern approach to solving the problems of sustainable development lies in the simultaneous solution of two issues and achievement of double win – both in the socioeconomic and ecologic areas. It means that socioeconomic projects should foresee the solution of ecological issues and ecological projects should provide for positive socioeconomic effect. This approach is the outcome of the lessons learnt while the realization of sustainable development ideas in the previous period. It became obvious that viable development route resides in accommodation of different issues, not in their contraposition. Such approach enables involvement of stakeholders from civil society. Without its participation substantial advancement towards sustainable development does not seem possible.

Up-to-date requirements of sustainable development may be viewed as voluntary limitations for developed economies for one part. For the other part they provide for new opportunities for developing economies in identifying routes of development towards «green» economy. They also provide for resource conservation and augmentation by means of their capitalization and support of international community. Worldwide support for the green growth determines the path forward to reduce poverty.

Issues regarding regulation of chemicals handling appear in the agendas of strategic and policy papers on advancement of chemical regulation in the Russian Federation with the increasing frequency. It does not only arise from the modern trends and motivation to comply with international requirements in order to strengthen national export potential, elimination of technical trade barriers, provide for safe transportation of chemicals and attract investments into national chemical industry.

Recently Russian Federation has been actively working on the advancement of the chemical regulation taking into account international experience. Regulators and reform ideologists face challenges on the creation of legal norms and infrastructure in order to perform notification of new chemicals, registration of new and existing chemicals as well as establishment of national lists of new and existing chemicals.

The publication contains information on the 13 chemical management systems and facts about the work of international organizations on the issue concerned. Description of chemical management systems is structured in identical blocks for every economy reviewed. These blocks correspond to the main elements of the regulatory model of a chemical management system, proposed by the Russian party. The model was discussed and received approval within the Virtual Working Group on Regulatory Convergence of Chemical Dialogue APEC in 2014 and Chemical Dialogue APEC itself. The information analyzed on every economy concerned is structured under standardized blocks, that simplifies comparison of different blocks in various economies. Such benchmarking enables to identify best practices and solutions in the sphere of chemical management in different chemical management frameworks and, most importantly, to approach common problems in a coherent manner.

International practice of interactions at various venues is indicative of the raising number of stakeholders involved in the processes connected to regulation of chemicals worldwide, in order to facilitate trade, minimize risks for human health and environment, that are associated with chemicals.

## Introduction

Russian regulators take note of the increased interest in the processes of harmonization and implementation of best regulatory practices. In line with that authors of this publication have made an attempt to trace progress in development of chemical management frameworks utilizing the original regulatory model. Use of analyzed data provided in this publication may be helpful to facilitate the intensification of the trade flows, perform actions to reduce risks for human health and environment posed by chemicals.

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**I n t e r n a t i o n a l r e g u l a t o r y f r a m e w o r k  
f o r s a f e h a n d l i n g o f c h e m i c a l p r o d u c t s**

## International regulatory framework for safe handling of chemical products

This chapter describes a global agenda in the area of the technical regulation and standardization of chemical products. The existing international and foreign legal instruments and mechanisms of the technical regulation and standardization of chemical products are reviewed and assessed to identify ways for their implementation at the national level.

### **1.1. Safe management of chemicals in the globalization context**

*Modern trends in chemical regulation dictate the need to study the global agenda that influences the regulation of chemicals. In the context of globalization and free trade, safe handling of chemicals is increasingly perceived as a common challenge for many countries.*

*Current national legislative systems that regulate safe handling of chemicals are based on the application of rules and laws within the global political framework in this area. They come as a result of the implementation of existing international treaties, conventions, and protocols.*

Human activities are inseparably linked to the production and use of various chemicals, most of which have become an integral part of our daily life. Chemicals play an important role in many sectors of the world economy, including agriculture, manufacturing, construction, transportation, medicine, household chemical goods, food and light industry. The international terms "chemical substance" or "chemical" has been used in its broad sense to denote pesticides, fertilizers, and other agricultural chemicals; the substances that are used in industrial processes; petroleum products, commercially available chemical goods for household consumers, pharmaceuticals, cosmetics, food additives, etc.

However, despite impressive benefits, chemicals may have hazardous physical and chemical properties — corrosive aggressiveness, explosiveness, flammability, and oxidizing capacity, to name just a few. Moreover, there is clear and ample evidence of potential risks to the health and environment, which can be caused by chemicals in various phases of their life cycle from production and import to waste disposal.

Some of such problems are industrial pollution, misuse and improper storage of chemicals, traffic accidents, industrial accidents, occupational diseases, and environmental impacts due to the use of chemicals.

Uncontrolled exposure to certain chemicals may be disastrous to the human health and may cause carcinogenic, teratogenic, and mutagenic effects. It may also have adverse effects on the reproductive, endocrine, immune, and nervous systems. It is an axiom today that the handling of chemicals should be properly regulated in order to ensure a sustainable agricultural and industrial development and to efficiently protect the environment and human health.

Technological solutions of the modern chemical industry can positively affect the overall course of economic development in terms of efficient use and saving of resources, energy, water and reducing the negative impact on humans and the environment.

On the world stage, various states face similar challenges that ultimately boil down to ensuring the sustainable development of their economies. The most effective way to solve common problems and tasks of the state is to achieve the goal of sustainable development by consolidating the efforts of the world community. Therefore, representatives of various economies of the world meet at the fora of APEC, OECD, UN to search for effective ways and ensure their uniform solution of goals and objectives in the field of chemicals management, harmonization of requirements, reducing the negative burden on human health and the environment, increasing the competitiveness of chemical products through the transition to new resources and energy-efficient production technologies, ensuring an adequate level of safety and welfare of the population. Their goal is to develop common goals and objectives in ensuring an effective safe and uniform approach to the management of chemicals and chemical products in all countries. The requirements or recommendations adopted by the international

## International regulatory framework for safe handling of chemical products

community on the management of chemicals will affect the trade in chemicals in the world community. The more economies will implement these requirements and ensure a unified approach to their implementation in national regulatory models, the more it will guarantee uniform requirements for chemicals in countries. Therefore, it will reduce the additional burden on manufacturers and suppliers of chemicals in the framework of ensure compliance with these requirements in the course of import and export of chemicals and reduce barriers to trade.

The increase of the global trade in products that contain chemicals and the global awareness of the high "cross-border mobility" of pollutants have recently pushed governments in many countries to take a more active stance in the global management of chemicals. The global agenda with regard to safe management of chemicals greatly affects relevant national legislative systems. The current national legislative systems that regulate safe handling of chemicals are based on the application of rules and laws in line with the global agenda in this area. They come as a result of the implementation of existing international treaties, conventions, and protocols.

One of the important tasks on the global agenda with regard to the management of chemicals is to harmonize certain laws and rules, which, once developed and reconciled at the international level, have high chances to be later implemented by individual countries.

This chapter provides an overview of priorities of the global agenda on safe management of chemicals for the protection of the human health and environment.

### **1.2. Basic principles of the global agenda on safe management of chemicals**

Fundamental principles of the global agenda on safe management of chemicals are important factors behind creating, developing, and implementing a regulatory framework. The fundamental principles that complement general maxims, such as "state sovereignty" and "collaboration and cooperation", are listed below.

#### *The "Polluter Pays" principle*

The "Polluter Pays" principle obliges the causer to indemnify for the incurred environmental damage. This approach was first established by the Organization for Economic Cooperation and Development (OECD). It is intended to prevent environmental pollution and remunerate monitoring techniques in the member countries in order to promote a sustainable use of natural resources and harmonization of international trade and investment.

This approach has been embodied in many international environmental agreements and formulated in the Rio Declaration on Environment and Development (Principle 16): "National authorities should promote the internalization of environmental costs and should use economic instruments by taking into account the approach that obliges the polluter to bear the total cost of depollution with due regard of the public interests and in line with the rules of international trade and investment".

"Polluter Pays" approach is viewed rather as a recommendation on the reimbursement of costs that are associated with environmental damage indemnification and industrial monitoring than as a strict legal principle. The polluter may use one of the following compensation options: it may either obtain a special license or a permit that imply the payment of certain fees or it may pay taxes for a certain amount of polluting emissions.

This principle has sped up the development of alternative technologies and products in industries, including the technology of waste minimization, and has enabled industrial enterprises to avoid such charges and associated loss of reputation.

#### *Sustainable development*

## International regulatory framework for safe handling of chemical products

Sustainable development is one of the key principles of the current international policy. This principle was first formulated in the Report of the World Commission on Environment and Development (WCED, the Brundtland Commission) in 1987 as the "development that meets the current needs without compromising the ability of the future generations to meet their own needs".

The report set forth the following critical targets of the international policy with regard to the environment and development:

- *ensure recoverable growth;*
- *change the quality of growth;*
- *meet the demand for work, food, energy, water,*
- *and sanitation;*
- *guarantee a stable level of population;*
- *maintain and enhance the resource base;*
- *reorient technologies and manage risks;*
- *merge the environment and economy in decision-making*

The Rio Declaration on Environment and Development (Principle 4) states that "in order to ensure a sustainable development, the environmental protection should become an integral part of the development process and should not be considered in isolation".

This principle provides the basis for the integrated approach that was presented at the World Summit on Sustainable Development in 2002 and that embraces social, economic, and environmental components.

### *Trans-sectoral approach*

The transition from the concept of protection of individual environmental sectors (e. g. marine environment, inland water, air or land) to the concept of the regulation of potential sources of environmental damage is one of the important stages of the evolution of the international environmental policy.

Many products (e. g. toxic substances) and processes may threaten various environmental sectors. When they have been recognized as potential sources of pollution, their regulatory control will be more effective.

Toxic or potentially hazardous substances should be regulated throughout their life cycle. This approach is known as the "cradle-to-grave" approach.

### *The "cradle-to-grave" approach*

This approach means that the handling of toxic and potentially hazardous chemicals should be regulated and controlled throughout the life cycle of these substances, which spans the production, transportation, marketing, use, and disposal both of the substances and the accommodating products.

This regulation is a highly technical task that we can accomplish by using various monitoring techniques and applying them to various product types.

### *Integrated pollution prevention and control*

The OECD Council Recommendation set the following targets of the integrated approach to the pollution prevention and control: to prevent or minimize the risk of the environmental damage as a whole, acknowledging the environment as an integrated phenomenon and taking into account the impact of substances and the human activity on all environmental media (air, water, soil).

## International regulatory framework for safe handling of chemical products

The approach is implemented in the following steps.

- *The "cradle-to-grave" analysis of substances and products.*
- *The anticipation of impacts from substances and activities on all environmental media.*
- *The minimization of the amount of waste and associated hazards.*
- *The use of common means (e. g. for the risk assessment) to identify environmental issues.*
- *Additional use of targets and limits.*
- *Strategies of the integrated approach:*
- *Sustainable development.*
- *Waste reduction.*
- *Cleaner technologies.*
- *Precautionary measures.*
- *Public information and public engagement.*
- *Consistent and effective implementation.*

The regulation of chemicals that are potentially hazardous to the human health and environment has resulted in the internationalization and globalization of the environmental protection.

### *The principle of regulation of potentially hazardous substances and application of special rules to substances of high concern*

Some toxic substances and types of waste are regulated by certain harmonized international norms, standards, and restrictions. The countries' obligations with regard to such substances may include the adaptation of international norms and standards to national legislative systems or international demands for the prohibition of production, use of, and trade in certain toxic materials or waste.

In such cases, countries commit themselves to taking special steps with respect to these substances in compliance with internationally agreed resolutions.

### *The analysis of hazard and risk*

The concept of hazard and risk in relation to chemicals is a fundamental concept in safe management of chemicals.

Throughout our lives, we contact with a huge number of natural occurring or synthetic chemicals that can be found in our food, water, environment, homes, workplaces, and surrounding air. These chemicals may have local effects, when they contact with our skin, eyes, the respiratory or gastrointestinal tract. When they are absorbed, they may also cause systemic effects. Depending on the dose and potentially hazardous properties, the chemical may either have no visible adverse effects or trigger a variety of effects, which range from minimum local alterations and discomfort to grave or fatal systemic effects.

The concept of chemical safety relies on the key statement that each substance can be used safely, even if some situations may require the highest degree of control.

### *The principle of involvement of multi-stakeholders*

Safe management of toxic and potentially hazardous substances has been recognized to be a global issue. Therefore, international cooperation in the area of the planning and development of

## International regulatory framework for safe handling of chemical products

management strategies affects not only the industry and government, but also all the stakeholders who come into contact with chemicals throughout their entire life cycle from production to waste disposal. These stakeholders are industrial and agricultural workers, trade-union organizations, health experts, government agencies, and environmental non-governmental organizations.

Although producers, distributors, and users of chemicals are primarily responsible for safe management, intergovernmental organizations, agencies, industry associations and community groups should be able to take part in decision-making on the chemical safety issues.

This principle has been internationally acknowledged in the Rio Declaration (Principle 10): "Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided."

### *The precautionary principle*

The precautionary principle is one of the most significant and innovative highlights of the Rio Declaration (Principle 15): "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The precautionary principle is currently used in the environmental management and is an integral part of legislative systems and technical regulations that pertain to the environment and human health.

### *The international principle of "best environmental practice/best available technique"*

The principle of the best available technique should be employed in the current international policy in the field of the environmental protection. In order to determine if the technology in use is really the "best-in-its-class" technology, one needs to look at a lot of factors, which include the nature and scope of pollution as well as the economic feasibility of the technology. The application of the best available technique is an exercise that consists of an optimum combination of environmental monitoring steps and strategies.

### *The principle of the freedom of access to the environmental information*

This principle is also known as the "Public's Right to Know". Information exchange and increased public awareness of the hazards and risks that are associated with harmful chemicals are important indicators of the evolution of the global agenda on safe management of chemicals.

Although this principle has been at least partially represented in all international agreements in the field of the environmental protection, it has been employed to the fullest in the document that has been created as part of the activity of the UN Economic Commission for Europe and adopted in Europe. This document is the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters.

The Aarhus Convention obliges the member countries to collect and publicly disseminate information, as well as to respond to official inquiries. The parties must prepare and publish national reports on the state of environment every 3–4 years.

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### 1.3. International policies for the technical regulation of chemical products

In order to prevent the environmental damage, special measures of technical regulation are required. Many international agreements demand that states adopt laws, rules, and technical regulations in combination with special measures of regulation of chemicals. The following are the international policies for the technical regulation of chemical products.

#### *Development of standards (for production processes, products, emissions; quality standards)*

International agreements may demand that the member countries establish standards for the products and processes that may produce an environmental impact. Alternatively, an international agreement may represent a certain standard. Standards are preset norms that apply to products or processes or restrict the amounts of pollutants or emissions. The categories of international standards are described in detail below.

#### Process standards

These standards contain the requirements for certain production processes. For example, the national legislation may prescribe the installation of treatment and filtration systems at production facilities. International process standards include the requirements of the incineration of certain types of hazardous waste or the requirements of the hermeticity of certain hazardous operations (for example, in biotechnology).

Process standards are often used to regulate the operations that are associated with accident risks or other hazards. For example, the Montreal Protocol on Ozone Layer encourages the member countries to determine the viability of prohibition or restriction of the import of the products from non-member countries that have been produced by using the chemicals that deplete the ozone layer, but do not contain such chemicals.

The European Directive 82/501/EEC lists the categories of hazardous processes and encourages the member countries to take all required measures and to demand that all producers involved in these hazardous processes submit the proof of identification of all existing accident risks, complete all industrial safety procedures, and provide industrial workers with the required safety information, safety training, and safety equipment. In addition, producers must notify the relevant competent authorities of the hazardous substances that are listed in the Annex to the Directive, if these substances are used or produced in any form in the industrial processes.

#### Product standards

Product standards are introduced for the products that are designed or produced for distribution to the end user. These standards can regulate the following parameters.

- *The physical and chemical composition of a product. For example, they may include the technical regulations that control the content of sulfur in fuel or blacklisted substances for certain products (e. g. mercury in pesticides).*
- *The technical implementation of a product (e. g. allowed emission rates and levels of noise in vehicles).*
- *The product appearance, product handling and packaging procedures, especially in relation to toxic products. Regulatory and technical requirements for packaging may also be extended to include the waste minimization and the product safety. The labeling requirements for products should guarantee the communication of information on the product content and product uses to*

## International regulatory framework for safe handling of chemical products

*consumers. The labeling requirements are often meant to avoid environmental damage through the misuse, spillage, or improper disposal of products.*

### Emission standards

The emission standards establish the allowed amounts or concentrations of pollutants in environmental releases from a particular source. The emission standards are most often regulated by international agreements and protocols.

The emission standards typically apply to fixed sources such as factories or buildings. Mobile sources of pollution are normally regulated by product standards.

### Quality standards

The quality standards establish the maximum allowed levels of environmental pollution. The quality standards may prescribe certain levels of concentration of chemicals in the air, river water, drinking water, soil, etc. Alternatively, they may specify maximum levels of noise in residential areas. The quality standards may vary depending on the resource use. For example, there are various water quality standards for drinking water, the water for agricultural or industrial purposes, and for the water that is used for bathing or fishing.

The World Health Organization (WHO) is continuously developing international quality standards for the air and for the drinking and recreational water.

### *The restriction or prohibition of the production, import, export, marketing, and use of chemicals*

If a particular activity, product, or process exposes the environment to risks, more stringent measures may be taken in order to avoid environmental damage. If the risk probability is extremely high, these measures may imply a total prohibition of such product or process. In international practice, such measures are typically applied to certain hazardous chemicals and waste. Such restraints and restrictions are formalized in international regulatory documents, some of which are listed below. The Vienna Convention and the Montreal Protocol on the Ozone Layer, the Convention on the Prevention of Marine Pollution by Dumping of Waste, the Rio Declaration on Environment and Development (Principle 14), and the Sofia Protocol to the Convention of 1979 on Remote Transboundary Air Pollution in relation to the emissions of nitrogen oxide.

The substances or activities that are regulated by these regulatory instruments are usually listed in the annexes to international documents.

The Basel Convention of 1989 on the Transboundary Movement of Hazardous Waste regulates the transportation and dumping of toxic and hazardous chemical waste. In particular, it prescribes prior authorization of the countries that are affected by such movement.

### *Prior informed consent to import and export*

The procedure of prior import and export authorization of hazardous substances is used in the international practice to avoid conflicts and reduce the risk of environmental damage. The import of certain chemicals should be authorized in advance by the importing countries. The authorization is requested for the hazardous goods that contain restricted or prohibited substances and follows the submission of full details on the hazard level of the substances to the authorizing country.

The importance of prior authorization for the global agenda on safe management of chemicals was first recognized in 1983 in the Resolution of the UN General Assembly. According to this resolution, "the products that are prohibited for use or sale on domestic markets because of the potential hazards to the environment and the public health may be sold overseas by companies, corporations, or individuals, only if the request for the supply of such products has been obtained from

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the importing country or if the use of such products has been officially allowed in the importing country".

The Food and Agriculture Organization of the United Nations (FAO) has applied this principle in its International Code of Conduct on the Distribution and Use of Pesticides. Listed below are the global agreements that are based on the procedure of prior authorization. The Basel Convention of 1989 on the Transboundary Movement of Hazardous Waste and the Rotterdam Convention of 1998 on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

### *The requirements for the classification, labeling, and packaging of chemical products*

The global agenda on safe management of chemicals establishes certain requirements for the classification, labeling, and packaging of chemical products. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) is an internationally harmonized system, which has been developed by the countries to ensure safe handling of chemicals.

### *Environmental Impact Assessment*

The assessment of the environmental impact is the procedure that reliably provides the relevant information on the potential environmental impact of a specific activity, on feasible trade-offs, and on the steps to reduce the environmental impact. This procedure stipulates that a developer or a business owner submit a written document to special agencies or decision-making authorities with the specification of the potential environmental impact that would result from the intended business activity. This procedure can be integrated into the licensing scheme.

The requirement of the assessment of the environmental impact has been incorporated in many international agreements. For example, according to the Principle 17 of the Rio Declaration on Environment and Development, "the assessment of the environmental impact is an instrument of the national policy that should be applied to the activity that is most likely to have substantial damaging effects on the environment and that is subject to the authorization by the relevant national authority".

The International Espoo Convention (the Convention on Environmental Impact Assessment in a Transboundary Context) was adopted by the countries in Espoo, Finland, on February 25, 1991. This Convention sets out the obligations of the parties in relation to the assessment of the environmental impact in early phases of business-activity planning. It also contains general obligations of the states to notify and consult each other on all major projects under consideration that could have a significant transboundary impact on the environment.

The Espoo Convention defines the "impact" as any effect of the intended activity on the environment, the human health and safety, flora, fauna, soil, air, water, climate, landscape, historical monuments, and other tangible objects as well as the interrelation between these factors. The impact also includes the effects on the population or on the social and economic conditions that result from the modification of these factors.

The list of business activities and production facilities that are subject to the impact assessment under the Espoo Convention includes:

- *Oil refineries (except for the businesses that produce only lubricants from crude oil) and coal or bituminous shale gasifiers and liquefiers with the daily capacity of 500 t and above.*
- *Thermal power stations or other combustion installations with the capacity of 300 MW and above, as well as nuclear power plants and nuclear reactors (except for research plants for the production and conversion of fissile and fertile materials, whose maximum capacity does not exceed 1 kW of the continuous thermal load).*

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- *The installations that are intended solely for the production or enrichment of nuclear fuel, reprocessing of irradiated nuclear fuel or for the storage, disposal, and processing of radioactive waste.*
- *Major blast furnaces, open hearth furnaces, and non-ferrous smelters.*
- *The installations for the extraction, processing, and conversion of asbestos and the products containing asbestos. The above is true for asbestos-cement products with an annual output of more than 20,000 t, for friction materials with an annual output of more than 50 t, and for other applications of asbestos with an annual utilization rate of more than 200 t.*
- *Chemical plants.*
- *The construction of motorways, highways, long-distance railways, and airports with the length of the main runway 2,100 m and above.*
- *Oil and gas pipelines with large-diameter pipes.*
- *Commercial ports, inland waterways, and ports for inland waterway traffic designed for the vessels of more than 1,350 t.*
- *Waste-disposal facilities for the incineration, chemical treatment, or landfilling of toxic and hazardous waste.*
- *Large dams and water storage basins.*
- *Ground water intake activity, if the annual intake volume has reached or exceeded 10 million m<sup>3</sup>.*
- *Pulp and paper production with a daily air-dried output of 200 t and above.*
- *Large-scale mining, extraction, and on-site beneficiation of metal ores and coal.*
- *Hydrocarbon production on the continental shelf.*
- *Large storage facilities for petroleum, petrochemical, and chemical products.*
- *Deforestation of large areas.*

The Espoo Convention specifies in detail all requirements for the procedure for the environmental impact assessment.

### *Licensing and issue of permits*

The licensing and issue of permits and certificates by competent authorities is the most common international practice for the prevention of the environmental damage. Any activity that has been identified or listed as an environmentally hazardous activity is subject to licensing.

The purpose of licensing is typically not to ensure total depollution, but rather to control major pollutions. Potentially hazardous chemical products (e. g. industrial chemicals, pesticides, or pharmaceuticals) may be subject to licensing by competent authorities in each phase of their life cycle from production, marketing to import, export, and use.

### *Industry initiatives*

The international norms that regulate safe handling of chemicals may be developed not only by governments, but also by private organizations or associations. The International Organization for Standardization (ISO) is one such example. It is a federation of more than 100 national standardization bodies. It was founded in 1946 to harmonize existing technical norms and standards.

International standards are developed in the relevant ISO Technical Committees. Final standards are adopted at international meetings. The standards that regulate the environmental protection and safe management of chemicals are developed in the following ISO Technical Committees (TC):

- *TC 94: Personal Safety — protective clothing and equipment*
- *TC 122: Packaging*
- *TC 146: Air Quality*

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- *TC 147: Water Quality*
- *TC 207: Environmental Management*
- *TC 243: Project Committee: Consumer product safety.*

Safe handling of chemicals is also supported by industrial enterprises, which commit themselves to ensuring the compliance with international initiatives such as ISO standards, technical norms, and rules developed by international organizations. They also engage in special programs (e. g. eco-labeling or Responsible Care®) developed by the associations of chemical manufacturers.

Responsible Care® is a global initiative of the chemical industry to drive its performance enacted in Canada in 1985. In terms of Responsible Care® national chemical companies and organizations take obligations to follow Responsible Care® Core Principles.

- *Continuously improve the environmental, health and safety knowledge and performance of technologies, processes and products over their life cycles so as to avoid harm to people and the environment.*
- *Use resources efficiently and minimise waste.*
- *Report openly on performance, achievements and shortcomings.*
- *Listen, engage and work with people to understand and address their concerns and expectations.*
- *Cooperate with governments and organisations in the development and implementation of effective regulations and standards, and to meet or go beyond them.*
- *Provide help and advice to foster the responsible management of chemicals by all those who manage and use them along the product chain.*

Responsible Care Global Charter encourages national associations to implement enhanced product stewardship commitments consistent with the International Council of the Chemical Associations (ICCA) Global Product Strategy (GPS). GPS, launched at the first International Conference on Chemicals Management (ICCM1) in 2006, builds on and extends industry's product stewardship efforts and is pivotal to industry's implementation of SAICM. Different components of GPS are aimed at progress in 4 key aspects of Responsible Care®, including ways of communication between the industry and users, performance monitoring and information sharing with public, enhancing cooperation and communication with various stakeholders.

One of the key Responsible Care® components is reporting of participating organizations on their effectiveness. Results are used for monitoring purposes and in order to summarize, analyze and compare achievements of the chemical industry on the global scale. Reporting process also facilitates best practices exchange. Global Charter also foresees reporting on the set of performance indicators of that contain environmental, health and safety indicators. Among them are emissions metrics (greenhouse gas emissions, NO<sub>x</sub> and SO<sub>x</sub> emissions), releases into water, energy and water consumption, number of incidents. Core set of indicators may be extended to include safety metrics.

By the end of 2015 more than 60 chemical associations were committed to Responsible Care in more than 60 countries around the globe. These chemical associations are in charge of Responsible Care® implementation in their corresponding countries. Program's development, implementation and coordination is conducted by Responsible Care Leadership Group, RCLG of ICCA. Process of implementation differs in various countries. In 2016 Vietnam and Egypt have started to implement Responsible Care®. Ghana, Kenya, Tanzania and Croatia are expected to adhere to the Program in the near future.

### **1.4. International agreements and conventions that form the bedrock of the modern system of safe management of chemicals**

The increase of the global trade in products that contain chemicals and the global awareness of the high "cross-border mobility" of contaminants have recently pushed governments in many countries

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to take a more active stance in the global management of chemicals. The focus of this work was defined at the UN Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992.

### *The United Nations Conference on Environment and Development (the Rio Conference)*

In 1992, the United Nations Conference on Environment and Development (the Rio Conference) set a goal of a sustainable economic development in line with contemporary needs and without compromising the needs of future generations.

The Heads of State and Government of more than 150 UN members adopted the Agenda for the XXI Century, which is a comprehensive document that reflects the commitment of states to a sustainable development.

Chapter 19 of the Agenda for the XXI Century of the Rio Declaration on Environment and Development, which is entitled "Environmentally Sound Management of Toxic Chemicals and Prevention of Illegal International Transportation of Toxic and Hazardous Products", describes an international strategy of the sound management of chemicals throughout their life cycle. This chapter, in particular, encourages countries to speed up international activities on the risk assessment of chemicals, to harmonize classification systems and labeling of potentially hazardous chemicals, to set up international programs for the reduction of risks that are associated with chemicals, and to strengthen national capabilities and capacities for the management of chemicals.

All countries that were represented at the Rio Conference agreed on the goal to ensure safe management of chemicals by 2000.

### *Intergovernmental Forum on Chemical Safety (IFCS)*

In 1994, the International Conference on Chemical Safety (Stockholm, Sweden) gathered top ranking representatives from more than 100 countries to identify the priorities in the implementation of Chapter 19 of the Agenda for the XXI Century of the Rio Declaration and to set up mechanisms for the implementation of its recommendations. The Stockholm Conference established the Intergovernmental Forum on Chemical Safety (IFCS), which enabled countries to regularly discuss activities and priorities in safe management of chemicals. At the first IFCS meeting, the Stockholm Conference adopted the "Priorities for Action" in order to facilitate the implementation of the recommendations in Chapter 19 of the Agenda for the XXI Century.

The IFCS meetings are held approximately every three years and are open for representatives from all over the world and delegates of international and non-governmental organizations. At the forum sessions and working sessions of regional offices, forum participants discuss important aspects of the management and safety of chemicals and develop basic recommendations for the national and international activities.

The Forum III, which was held in Brazil in 2000, identified several key recommendations also known as "Priorities for Action Beyond 2000".

- *By 2002, most countries will have developed a National Profile on the Management of Chemicals in consultation with stakeholders and will have achieved the coordination of the sound management of chemicals at the national level.*
- *By 2005, at least five countries in each IFCS region will have completed all steps required for the information exchange on potentially hazardous chemicals.*

The Forum IV that was held in Bangkok (Thailand) between November 1 and November 7, 2003 assessed the progress that had been made since the Forum III and recommended several necessary steps:

- *Ensure that countries have guaranteed capabilities and necessary capacities for the sound management of chemicals throughout their life cycle.*

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- *Engage in a dialog with international institutions for the support of development in order to integrate chemical safety issues into the poverty eradication and the sustainable development policies.*
  - *Take into account all available resources (e. g. those that were identified during the development of the National Profile) in dealing with the chemical safety issues.*
  - *Engage in a national dialog to support the integration of chemicals management.*
- After adoption of SAICM in 2006 at the ICCM1 Forum has viewed its input in the SAICM implementation as one of its main priorities.

### *Inter-Organization Program for the Sound Management of Chemicals (IOMC)*

In 1995, the Food and Agriculture Organization of the United Nations (FAO), the Organization for Economic Cooperation and Development (OECD), the International Labor Organization (ILO), the United Nations Industrial Development Organization (UNIDO), the United Nations Environment Program (UNEP), and the World Health Organization (WHO) established the Inter-Organization Program for the Sound Management of Chemicals (IOMC) as a joint agreement to coordinate activities in the field of chemicals management at the international level. In 1998, the UN Training and Research Institute (UNITAR) officially joined the Inter-Organization Program for the IOMC.

The IOMC aims to promote and coordinate the efforts of the program members towards the sound management of chemicals in relation to the human health and the environmental protection. The Coordination Committee has been established to enhance the interaction among 7 international organizations. This committee holds meetings twice a year to discuss important issues and exchange the information on current programs. Complex technical issues are handled by expert groups that meet and work to globally harmonize the System of Classification and Labeling of Chemicals, to assess existing industrial chemicals and environmental pollutants, to review accidents and the preparedness for emergencies that involve chemicals, to monitor registers of chemical pollutants and the transfer of potentially hazardous chemicals.

### *The World Summit on Sustainable Development (WSSD)*

The World Summit on Sustainable Development (WSSD) that took place between August 26 and September 4, 2002 in Johannesburg (South Africa) approved a plan and a political declaration (the Johannesburg Declaration on Sustainable Development), which are based on the progress that has been made since the Rio Conference of 1992. The summit also set new commitments with regard to the management of chemicals and their waste, as listed below.

- *The commitment set out in the Agenda for the XXI Century towards the sound management of chemicals throughout the entire life cycle of chemicals and hazardous chemical waste for a sustainable development and the protection of human health and environment. This intention is also geared towards the minimization of express negative impacts on the human health and environment by 2020 that result from the production and use of chemicals.*
- *The commitment to facilitate the ratification and implementation of international instruments for handling chemicals and hazardous chemical waste.*
- *The commitment to continue to develop a strategic approach to international management of chemicals on the basis of the Bahia Declaration on Chemical Safety and the "Priorities for Action Beyond 2000" adopted at the Intergovernmental Forum III on the Chemical Safety (IFCS).*
- *The commitment to promote partnership in the sound management of chemicals and hazardous chemical waste.*

### *Strategic Approach to the International Chemicals Management (SAICM)*

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At the first session of the International Conference on Chemicals Management in Dubai (UAE) in February 2006 the countries approved and adopted by a majority vote a global program entitled "Strategic Approach to International Chemicals Management". More information on SAICM is available under 1.7.

### *Other international agreements that pertain to the regulation of chemicals*

In addition to the above international structures and institutions, countries are increasingly bound by the obligations under international agreements and conventions to which they are parties. Below is the list of the international agreements that complement Chapter 19 of the Agenda for the XXI Century. Please note that many of them have been finalized only recently. The Stockholm Convention on Persistent Organic Pollutants, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal, the Convention on the Prohibition of Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction; the Convention on Chemicals No. 170 of the International Labor Organization dated 1990, the Convention on Major Industrial Accidents No. 174 of the International Labor Organization dated 1993, the Vienna Convention on the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, the UN Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention).

In addition to legally binding instruments, several framework agreements have been adopted at the international level, which provide important regulatory guidance in order to develop the potential for the management of chemicals. These are the following agreements: The FAO International Code of Conduct on the Distribution and Use of Pesticides (revised version), the UN Globally Harmonized System of the classification and labeling of chemicals, the Bahia Declaration on Chemical Safety adopted at the Intergovernmental Forum III on Chemical Safety.

Such international agreements are developed and finalized under the auspices of various international organizations, including UNEP, FAO, and ILO. After the ratification at the national level, they are implemented in the cooperation of national departments with respective international organizations. For example, national departments of the environment play a leading role in the implementation of the agreement that has been developed and finalized as part of the United Nations Environment Program (UNEP).

### **1.5. International statutory regulation of chemicals in various industrial sectors**

#### *Industrial chemicals*

As the amount of chemicals and chemical products is approaching global levels, the management of chemicals is becoming increasingly important both at the national and international levels. Risk management in relation to chemicals currently spans their entire life cycle from production to use and waste disposal.

The exposure to chemicals became the focus of scientific study on the international level in the 70-s of the past century. In 1971, the Chemicals Group was founded as part of the OECD, and at the UN Conference on the Human Environment in 1972 chemicals gained international recognition. This event triggered several initiatives: the permanent Environmental Health Criteria Program as part of the World Health Organization (WHO), the UNEP's International Register of Potentially Toxic Chemicals as part of the United Nations Environment Program (UNEP), and the ILO's International Program for

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the Improvement of Working Conditions and Environment as part of the International Labor Organization (ILO).

In 1980, the International Program on Chemical Safety (IPCS) was launched, which studies the risks to the human health and environment associated with the exposure to chemicals and publishes papers on toxicology and risk assessment of chemicals.

### *Chemicals in the workplace*

The international management of risks that are associated with the exposure to chemicals in the workplace is becoming increasingly important. The International Convention No 170 that has been developed in the context of the ILO activities and that pertains to the safety of chemicals use in the workplace (ILO, 1990) along with the accessory Chemical Recommendations No 177 (ILO, 1990) has formed the backbone of the international policy for the management and use of chemicals in the workplace.

In addition, the ILO has published a regulatory document entitled "Code of Practice on Safety in the Use of Chemicals" (ILO, 1993) and a training manual "Safety and Health in the Use of Chemicals in Work" (ILO, 1993), which provide guidelines for the application of Convention No 170.

The focus is laid on the application of special monitoring principles, such as the classification and labeling of chemicals, the provision of safety data sheets for chemicals, the reduction of the workers' contact with chemicals, the briefing and training of workers, and guaranteed cooperation among all stakeholders, including government agencies, trade unions, and employers.

### *Pesticides and chemicals in agriculture*

The Food and Agriculture Organization of the United Nations (FAO) developed and adopted the FAO International Code of Conduct on the Distribution and Use of Pesticides at the 23rd session in 1985. The revised and updated version of this document was adopted in 2002. It sets standards and rules for the use of pesticides in order to reduce the risks for the human health and environment.

### *Transportation of potentially hazardous chemicals*

The document entitled "Recommendations on the Transport of Dangerous Goods. Model Regulations" has been developed by the Committee of Experts in the Transport of Dangerous Goods of the UN Economic and Social Council. This document applies to the transportation of potentially hazardous chemicals. It is intended for the governments and international organizations that are involved in the regulation of the transportation of dangerous goods. These international recommendations have been structured as "Model Regulations on the Transport of Dangerous Goods" and take into account the technical advance, emergence of new substances and materials, the needs of modern transport systems and, above all, the need for the safety of people, property, and environment.

### *Chemicals in food*

The Codex Alimentarius Commission that has been established as part of the Joint FAO/WHO Food Standards Programme is an international body that harmonizes food standards worldwide.

The Joint FAO/WHO Expert Committee on Food Additives' (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues' (JMPR) are the expert bodies of the Codex Alimentarius Commission.

The Codex Alimentarius specifies allowable concentrations of pesticides in food (Maximum Residue Levels or MRL). The purpose of the MRL is to protect consumers from the harmful effects of pesticides by setting allowable limits for the concentration of chemicals that may be safely taken in with food.

## **1.6. International norms and standards that govern safe management of chemicals**

## International regulatory framework for safe handling of chemical products

International agreements for the safe regulation of chemicals describe in detail the technical norms and standards that have been harmonized and recommended for adoption at the national level. The most notable regulatory instruments are described below.

### *Globally Harmonized System of Classification and Labeling of Chemicals (GHS)*

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) is a result of the work that took more than 10 years to complete. The GHS is the fruit of joint efforts of many experts from different countries, international organizations, and stakeholders. In their work, they drew on extensive scientific knowledge and expertise ranging from toxicology to fire protection.

The point of departure was the need to harmonize the existing systems of hazard classification and to develop a single and globally harmonized system that would span the classification of chemicals, labeling, and safety data sheets.

Although the existing laws and regulations are quite similar in many countries, there are still significant differences, which translate into inconsistencies in the labeling of the same product and in the information that is included in safety data sheets across countries. The differences in the definitions of hazard classes may lead to inconsistent interpretations of substance properties (e. g. when the same substance is considered flammable or toxic in one country and not in the other). As a result, the requirements for the information on labels and in safety data sheets may differ considerably across countries. These inconsistencies may hamper international trade and compromise the measures taken to ensure the safety of chemical products.

Given the vast size of the international market for chemical products and the need for national programs to ensure their safe use, transportation, and disposal, it has been recognized that a globally harmonized approach to the classification and labeling would provide a good starting point for the development of such programs. It is expected that as soon as the countries have consistent and reliable information about the chemical products that they import or produce, they will be able to set up a generic structure for the monitoring of the exposure to chemicals and for the protection of the population and environment.

The current 6th version of the GHS text adopted in 2015 is accessible at the United Nations Economic Commission for Europe (UNECE) website.

### *The UN Recommendations on the safe transport of potentially hazardous chemical products*

The international rules of safe transport of potentially hazardous chemicals have been summarized in the "Recommendations on the Transport of Dangerous Goods. Model Regulations, 19th Revised Edition" — the document that was published by the United Nations in 2015.

The Model Regulations provide a clear outline of basic provisions that enable consistent development of national and international regulations for the control of transport by various vehicles. At the same time, these regulations are flexible enough to accommodate any special requirements that may need to be met. It is expected that governments, intergovernmental organizations, and other international organizations will go by the principles set out in the Model Regulations in revising or developing regulations within their area of competence. This, in turn, will help harmonize these regulations on a global scale. In addition, following the rules as closely as possible will speed up solving the problems that are faced by supervisory bodies and reduce the administrative burden. Although the Model Regulations are only advisory in nature, they are designed as mandatory provisions (e. g. instead of the verb "should" an affirmative form is used throughout the text that is a standard in regulatory instruments). This approach facilitates direct use of the Model Regulations as a basis for national and international transport regulations.

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The Model Regulations should be useful to everyone who is directly or indirectly related to the transport of dangerous goods. Among other things, the Model Regulations cover such issues as the principles of classification and definition of classes, master lists of dangerous goods, general packaging requirements, testing procedures, labeling, warning signs or placards, and transport documents. In addition, they include special requirements for specific classes of cargo. The universal application of the classification system, lists of goods, packaging requirements, labeling, warning signs, placards, and documentation that are envisaged by the Model Regulations should facilitate the work of carriers, shippers, and inspection bodies by simplifying transport operations, handling and monitoring, as well as by reducing time-consuming formal procedures. It will generally simplify their job and reduce barriers to the international transportation of such goods. At the same time, the advantages of this system will surface with a steady expansion of trade in goods that belong to the category of "dangerous goods".

### *Standards on the concentration of chemicals in food*

In order to develop international food standards, FAO and WHO have established a Joint Program on Food Standards.

The Codex Alimentarius Commission is an intergovernmental body that has been established as part of the Joint FAO/WHO Program on Food Standards for the development of food standards. The Codex Alimentarius is a set of food standards adopted by the Commission.

The Codex Alimentarius or Food Code is a worldwide directory of consumers, producers, food sellers, and national food quality control units. "Codex Alimentarius" is a Latin term that means "a food code".

The Codex Alimentarius Commission has provided states and the international community with a unique opportunity to jointly develop, harmonize, and enforce food standards.

The Commission's mandate is to develop international food standards in order to protect the health of consumers and to ensure fair practices in food trade, as well as to coordinate the standardization of food products that is carried out by international governmental and non-governmental organizations.

The Codex Alimentarius is a collection of ready-to-use standards that can be easily adapted to local conditions, if necessary.

By using the standards and documents of the Codex Alimentarius, states can achieve significant savings in time and financial resources that are required to assess risks and take appropriate action.

### *Standards of the health and safety in the workplace*

The General Conference of the International Labor Organization that was convened in Geneva by the Governing Body of the International Labor Office and that was held on June 6, 1990 (Session 77), taking into account the respective international conventions and recommendations, in particular: the Convention and Recommendation of 1971 on Benzene; the Convention and Recommendation of 1974 on the Occupational Cancer; the Convention and Recommendation of 1977 on the Production Environment (air pollution, noise, and vibration); the Convention and Recommendation of 1981 on the Occupational Safety and Health; the Convention and Recommendation of 1985 on Occupational Health Services; the Convention and Recommendation of 1986 on Asbestos and the List of Occupational Diseases as revised in 1980 and annexed to the Convention of 1964 on Benefits in Cases of Occupational Injuries; noting that the protection of workers from the harmful exposure to chemicals also enhances the protection of the entire population and environment;

pointing to the workers' need for the information on the chemicals that they use at work and to their right for such information; believing that it's critically important to prevent and reduce the number of illnesses and injuries caused by the use of chemicals at work by:

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- *the compulsory assessment of all chemicals in order to identify associated hazards;*
- *providing employers with a mechanism to obtain information about the chemicals used at work from suppliers for them to effectively implement programs to protect workers from chemical hazards;*
- *providing workers with the information on the use of chemicals at work and on the appropriate precautions for them to effectively participate in protection programs;*
- *establishing the principles of such programs in order to ensure safe use of chemicals, taking into account the need for cooperation under the International Program on Chemical Safety between the International Labor Organization, the United Nations Environment Program, and the World Health Organization, as well as with the Food and Agriculture Organization of the United Nations, and the UN Industrial Development Organization; and taking into account the respective acts, codes, and guidelines released by these organizations; having enacted several proposals for safe use of chemicals at work, which is the fifth item on the Session agenda; and having assigned the status of the international convention to these proposals, adopted the Convention on June 25, 1990 under the title "The Chemicals Convention of 1990".*

### **1.7. The Strategic Approach to International Chemicals Management (SAICM) and priority issues of the international and national policy for the technical regulation of chemical products**

SAICM was adopted at the first session of the International Conference on Chemicals Management (ICCM) in Dubai in February 2006. SAICM is a policy framework to provide for chemical safety around the globe.

The primary aim of the Strategic Approach is to facilitate the achievement of the 2020 Goal “to achieve the sound management of chemicals throughout their life cycle so that by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health”. “2020 goal” was agreed at the World Summit on Sustainable Development in Johannesburg in 2002.

An important national objective of the SAICM is to promote the existing initiatives with regard to the handling of chemicals in different sectors and to enhance the coordination and coherence between different governmental initiatives and other stakeholders.

Another important objective is to link these activities to the planning of national development (e. g. the national strategies for sustainable development, the UN Development Assistance Framework, Poverty Reduction Strategies, etc.).

In order to achieve this goal, the SAICM Overarching Policy Strategy (OPS) has formulated the following tasks: "To maintain an integrated approach to the regulation of chemicals, each Government should take steps to implement the Strategic Approach on the interdepartmental and interagency basis, so as to take into account the interests of all relevant national agencies and stakeholders and to cover all main activity areas" (Article 23, SAICM OPS).

The development of the SAICM that was formally launched in 2003 with a series of sessions of preparatory committees (Prep Coms) consisted of several key stages:

- *UNEP Governing Council, February 2002*
- *World Summit on Sustainable Development, Johannesburg, September 2002*
- *World Health Assembly, May 2003*
- *International Labor Conference, May 2003*
- *World Summit, New York, September 2005*
- *SAICM Preparatory Committees 1, 2, and 3*

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SAICM is the result of joint efforts of many stakeholders, including representatives of governments, non-governmental organizations (NGOs), and intergovernmental organizations (IGOs) from agriculture, environment, health, industry sectors, and labor organizations. This process was initiated by UNEP, the Inter-Organization Program for the Sound Management of Chemicals (IOMC), and the Intergovernmental Forum on Chemical Safety (IFCS).

The basic outcome of the SAICM development process is reflected in three key documents listed below.

### *The Dubai Declaration on International Chemicals Management*

The Dubai Declaration, which was adopted by ministers, heads of delegations, and representatives of the civil society and private sector, provides a harmonized overview of the political commitments towards the implementation of SAICM. This declaration reflects their "firm commitment to the Strategic Approach and its implementation". In particular, the importance of the following aspects is emphasized: the correlation of the sound management of chemicals with a sustainable development and poverty eradication; the contribution of SAICM to meeting the Millennium Development Goals, the implementation of international agreements, the role of non-governmental actors, and the importance of partnership.

### *The Overarching Policy Strategy (OPS)*

The OPS provides the information on the scope of SAICM, identifies the needs for an effective implementation of SAICM, sets targets, principles, and financial arrangements. This document describes five categories of the SAICM objectives:

- *Risks reduction*
- *Knowledge and information*
- *Guidance*
- *Capacity building and technical cooperation*
- *Illegal international traffic*

### *Global Plan of Action (GPA)*

GPA is an elaborated document that describes the activity areas, types of activity, performers, time lines, targets, and progress indicators. GPA includes 36 activity areas and 273 activities that are structured in accordance with the five categories of the SAICM objectives set forth in the OPS. This plan is recommended for use and elaboration as a working tool and as a guideline for the stakeholders implementing SAICM. The implementation of the Strategic Approach at the national level (incl. the "initial phase") provides for the development of national plans for the implementation of SAICM.

According to the proposed global plan of action, the following major activity areas of SAICM can be identified:

- *The analysis of gaps in national chemicals management regimes and the identification of priorities*
- *Protection of the human health*
- *Children and the chemical safety*
- *Occupational safety and health*
- *Implementation of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)*
- *Highly toxic pesticides: risk management and reduction*
- *Pesticide programs*
- *Reduction of harmfulness of pesticides to the human health and environment*
- *Ecofriendly manufacturing*

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- *Decontamination of polluted areas*
- *Lead in fuel*
- *Sustainable agricultural practices*
- *Persistent, bioaccumulative, and toxic substances (PBTs); chemicals that are very persistent and bioaccumulative in very large amounts; chemicals that are carcinogens or mutagens; substances with adverse effects on the reproductive, endocrine, immune or nervous system; persistent organic pollutants (POPs).*
- *Mercury and other chemicals that are a subject of global concern, chemicals that are produced or used in large amounts, substances for extensive dispersive applications, and other chemicals that cause nationwide concern.*
- *Risk assessment, risk management, and risk reporting*
- *Sound waste management and waste minimization*
- *Development of preventive and responsive measures to mitigate the emergency impacts from chemicals on the environment and human health.*
- *Research, monitoring, and data*
- *Acquisition of data on hazardous properties and making this data available*
- *Promotion of the industry engagement and its committed approach*
- *Information processing and dissemination*
- *Life cycle*
- *Release and Transfer Registers (PRTR): creation of national and international registers*
- *Education and training (public awareness)*
- *Stakeholder participation*
- *Flexible implementation of comprehensive programs for the sound management of chemicals at the national level*
- *International agreements*
- *Social and economic considerations*
- *Legal, directive, and institutional aspects*
- *Liability and compensation*
- *Evaluation of progress*
- *Protected areas*
- *Prevention of illegal traffic in toxic and dangerous goods*
- *Trade and environment*
- *Engagement of the civil society and non-governmental organizations (NGOs) that defend public interest*
- *Capacity building to support national measures*

At the ICCM3 session in Nairobi (Kenya) that was held 17-21 September 2012 stakeholders have agreed to include new activities into the GPA including nanomaterials and electronics.

At the ICCM4 in Geneva (Switzerland) held during the period between 28 September till 2 October 2015 a question of chemicals in products and issues of sharing that information with consumers was also brought up. Knowledge in the use of chemicals, and control of that use, including of the chemicals which are contained in products, is fundamental to the protection of human health and the environment. The Chemicals in Products Programme (CiP) is a voluntary initiative designed to assist all stakeholders throughout the product life cycle who are seeking effective procedures for the exchange of information on chemicals in products. Stakeholders include businesses, governments, intergovernmental agencies, recyclers, waste management actors, non-governmental organizations and consumer groups. The goal of the Programme is that stakeholders have greater access to the information on chemicals in products that they need to enable them to make decisions and take appropriate action on chemical hazards, exposure, risks and management.

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### 1.8. International organizations and online resources on safe management of chemicals

The international agreements that pertain to the environmental protection often incorporate the requirement of mandatory provision of information to the public. This provision is a guarantee of the public engagement in environmental decision-making.

For example, Principle 10 of the Rio Declaration says: "Environmental issues are best addressed when all concerned citizens are engaged in the process". At the national level, each citizen should be able to freely access the environmental information that is made available by public services, including the information on hazardous and potentially hazardous chemicals, and to participate in decision-making. By making this information freely available, states should encourage the engagement of the public in these processes.

The international information on chemicals is available on the Internet and can be used for the technical regulation of chemical products.

Activities of the OECD Chemicals Committee are reviewed below. APEC Chemical Dialogue activities are discussed more precisely in the Chapter 2.

#### *Organization for Economic Cooperation and Development (OECD) work on the safe handling of chemicals*

##### OECD as an international organization

The Organization for Economic Cooperation and Development (OECD) is one of the leading international economic organizations that coordinate and develop a unified economic policy of developed countries along with aid programs for developing countries. This organization was founded in 1961 after the ratification of the OECD convention that was signed in 1960.

The OECD works towards the following objectives:

- *contributing to the growth of the world economy by ensuring an optimum economic situation, employment growth, and higher living standards while maintaining the financial stability of the member states,*
- *helping achieve the economic and social well-being in the OECD region by coordinating the policy of the member states,*
- *coordinating the aid provided by the OECD states to developing countries.*

The OECD member states are: Australia, Austria, Belgium, Great Britain, Hungary, Germany, Denmark, Greece, Ireland, Israel, Iceland, Spain, Italy, Canada, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, Slovenia, the USA, Turkey, Finland, France, the Czech Republic, Sweden, Switzerland, Estonia, South Korea, Japan, Chile, Israel, Slovenia and Estonia. Brazil, China, India, Indonesia, and South Africa were also invited to participate in the talks about the possible expansion of the OECD.

Among other things, OECD cooperates with several international organizations, including: WTO, ILO, WHO, UNESCO, World Bank, etc.

##### Goals and objectives of the OECD

The primary mission of the OECD is to support the economic growth of the member countries, to increase their contribution to the global economic growth and development, and to support poverty reduction in non-member countries.

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The primary aim of the OECD is to analyze the state of the economy of the member states and partner countries and to work out recommendations for the economic regulation on the macroeconomic and sectoral levels.

The ultimate goals of the organization that are enshrined in the founding OECD Convention are:

Ensure the highest and the most sustainable economic growth, employment, and standard of living in the member countries; maintain financial stability that is necessary for the growth of the world economy.

Facilitate multilateral world trade in compliance with international commitments.

To accomplish these tasks, the member states are committed to:

- *share the required information with each other and the organization,*
- *make sure that available resources are used properly,*
- *conduct regular consultations, research, and participate in joint projects,*
- *promote scientific research and education,*
- *strive for financial stability,*
- *take steps to reduce barriers to the movement of capital and trade in products and services,*
- *support developing countries through the provision of capital and technical assistance,*
- *collaborate and take agreed measures as needed.*

The OECD profile is not limited to economic issues, but expands to cover the following key areas:

- *food policy, agriculture, and fisheries;*
- *finance and business issues;*
- *trade;*
- *education;*
- *labor, employment, and social issues including health care;*
- *environmental protection;*
- *governance and regional development;*
- *science, technology (incl. nanotechnology and biotechnology), and the industry;*
- *information, communication, and computerization.*

The basic principle of the OECD is the need to provide all countries with access to the benefits of globalization and technological progress.

### The OECD legal documents that regulate safe handling of chemicals and chemical products

The OECD actively supports the member countries in the development and implementation of high-quality tools for the protection of the environment and human health. The system of safe management of chemicals and chemical products works to ensure a harmonized approach for the generation and sharing of information on potential hazardous effects of chemicals. The system of safe management of chemicals protects human health and environment, harmonizes the pertinent policy of the OECD members, and minimizes non-tariff barriers to the trade in chemicals.

It also develops and constantly improves the system of safe management of chemicals and chemical products. The OECD's work on chemical safety and biosafety is carried out under the Environment, Health and Safety (EHS) Programme. EHS Programme is overseen by the "Joint Meeting" which comprises the EPOC Working Party on Chemicals, Pesticides and Biotechnology and the Chemicals Committee. Chemicals Committee reports directly to the OECD Council. Together with the Working Party on Chemicals, Pesticides and Biotechnology they oversee 11 subsidiary expert

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groups that are aimed at various issues of the EHS. Outcomes of their work as well as the work of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology are documents on chemicals management: reviews, reports, assessments, surveys, guidance, test guidelines, OECD legal acts and etc.

The OECD legislation for safe management of chemicals consists of decisions, recommendations, and decision-recommendations of the OECD Council that are mandatory for the OECD members, as well as non-mandatory recommendations of the OECD Council.

To date, the OECD legal framework for safe handling of chemicals and chemical products (in the scope of the OECD Chemicals Committee) includes 21 instrument listed below.

- *C(96)42/FINAL: Declaration on Risk Reduction for Lead (19.02.96).*
- *C(73)172/FINAL: Recommendation of the Council on Measures to Reduce all Man-Made emissions of Mercury to the Environment (18.09.1973).*
- *C(71)83/FINAL: Recommendation of the Council of the Determination of the Biodegradability of Anionic Synthetic Surface Active Agents (13.07.1971).*
- *C(87)2/FINAL: Decision-Recommendation of the Council on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls (13.02.1987).*
- *C(81)30/FINAL: Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals (12.05.1981, as amended on 26.11.1997).*
- *C(89)87/FINAL: Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice (02.10.1989, as amended on 09.03.1995).*
- *C(97)114/FINAL: Decision of the Council concerning the Adherence of non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final) and C(89)87(Final)] (26.11.1997).*
- *C(87)90/FINAL: Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals (26.06.1987).*
- *C(2018)51 Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals (25.05.2018, replacing [C(90)163/FINAL]).*
- *C(74)215: Recommendation of the Council on the Assessment of the Potential Environmental Effects of Chemicals (14.11.1974).*
- *C(77)97/FINAL: Recommendation of the Council on establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment (07.07.1977).*
- *C(82)196/FINAL: Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals (08.12.1982).*
- *C(84)37/FINAL: Recommendation of the Council concerning Information Exchange related to Export of Banned or Severely Restricted Chemicals (04.04.1984).*
- *C(83)98/FINAL: Recommendation of the Council concerning the OECD List of Non-Confidential Data on Chemicals (26.06.1983).*
- *C(83)97/FINAL: Recommendation of the Council concerning the Exchange of Confidential Data on Chemicals (26.06.1983).*
- *C(83)96/FINAL: Recommendation of the Council concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals (26.06.1983).*
- *C(89)88/FINAL - Recommendation of the Council concerning the Application of the Polluter-Pays Principle to Accidental Pollution (07.07.1989).*
- *C(2003)221: Recommendation of the Council concerning Chemical Accident Prevention, Preparedness and Response (15.01.2004).*

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- *C(88)85/FINAL: Decision-Recommendation of the Council concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances (08.07.1988).*
- *C(88)84: Decision of the Council on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage (08.07.1988).*
- *C(2018)5 - Recommendation of the Council on Implementing Pollutant Release and Transfer Registers (PRTRs) (10.04.2018, replacing [C(96)41/FINAL] amended by [C(2003)87]).*
- *C(2013)107 - Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials (19.09.2013).*

### **The system of mutual acceptance of data in the assessment of chemicals (MAD). The legislation in the field of the assessment and research of chemicals.**

The system of mutual acceptance of data in the assessment of chemicals (MAD), which is an offspring of the OECD, plays a fundamental role in harmonizing and implementing the policy of chemicals management in the OECD countries.

The system of mutual acceptance of data is implemented by the following regulatory acts of the OECD Council:

- *C(81)30: Decision of the OECD Council on the mutual acceptance of data in the assessment of chemicals*
- *C(89)87: Decision-Recommendation of the OECD Council on the principles of Good Laboratory Practice, as amended by Decision C(95)8*
- *C(97)114: Decision of the OECD Council on accession of OECD non-members to the regulatory documents of the Council that pertain to the mutual acceptance of data in the assessment of chemicals [C(81)30(Final) and C(89)87(Final)]*

#### C(81)30: Decision of the Council on the mutual acceptance of data in the assessment of chemicals

According to the Decision C(81)30, the chemicals test data that is obtained in the OECD member country in compliance with the OECD Test Guidelines and the OECD Good Laboratory Practice (GLP) Principles is recognized in another OECD member country for assessment and other purposes related to the protection of people and environment.

The OECD Test Guidelines are a set of internationally recognized analysis methods that are used by states, industry, and independent laboratories to determine the level of safety of chemical substances and preparations, including pesticides and industrial chemicals. The OECD Guidelines include methods for determining physical and chemical properties of substances, examining the impact of substances on the human health and environment, and studying the processes of decomposition and accumulation of substances in the environment.

The Principles of Good Laboratory Practice (GLP) is a system for managing organizational processes in the laboratory. They establish a set of conditions that are required to conduct efficient non-clinical research of chemicals and log the results.

The GLP Principles contain the requirements for the lab organization and management; for the personnel, equipment, materials, and reagents. They cover the following specific procedures:

- *acceptance and installation of equipment;*
- *acceptance, handling, storage, and preparation of test samples;*
- *conducting research;*
- *preparation of research reports and storing the information.*

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The implementation of uniform test methods and the GLP principles contributes to an increase in quality and enables a simultaneous use of the acquired data by many countries. It also reduces the likelihood of experiment duplication.

The Principles of Good Laboratory Practice (GLP) are listed in Annex II to the Decision. The OECD Guidelines on Chemical Test Methods are available on the OECD official website at <http://www.oecd.org/> in the Online Library section.

C(89)87: Decision-Recommendation of the Council on the compliance with the principles of Good Laboratory Practice

The primary aim of this Decision was to ensure high quality and reliability of chemical test data and to exclude the duplication of chemical tests and the reduction of the number of experimental animals.

This Decision necessitates the development of national procedures for the monitoring of the GLP compliance that would be based on lab audits and monitoring of experiments.

To accomplish this task, the following guidelines are recommended for use by the OECD member countries: the "Guideline on Procedures for Monitoring Compliance with Good Laboratory Practice" and the "Guideline for Lab Inspections and Experiment Audits". These documents are described in Annexes I and II of the Decision.

C(97)114: Decision of the Council on accession of OECD non-members to the regulatory documents of the Council that pertain to the mutual acceptance of data in the assessment of chemicals [C(81)30(Final) and C(89)87(Final)]

This Decision of the OECD Council has enabled other countries to join the OECD guidelines on the mutual acceptance of data in the assessment of chemicals.

The OECD non-member countries that accede to the guidelines of the Council are entitled to join the OECD Program for the management of chemicals in the part that pertains to the mutual recognition of chemical test results. In doing so, they have the same rights and duties as the OECD member countries.

The Decision also specifies the procedure for the accession of the OECD non-members to the above programs.

### **Acts on chemicals investigation and information sharing**

C(87)90: Decision-Recommendation of the Council on the systematic investigation of existing chemicals

This Decision-Recommendation is based on the following factors:

- *Most existing chemicals have not been systematically analyzed for potential hazards to the human health and environment, and for most of these chemicals no relevant information is available that could be used in this type of research.*
- *The existing chemicals that may pose unidentified threats to the human health and environment should be identified, researched, and, if necessary, taken under control.*
- *The OECD member countries should work together to protect the population and environment against the exposure to chemicals. This is because individual countries have limited capacities, whereas the volumes of chemicals in use are quite large.*

The Annex 1 to this Decision-Recommendation "Chemicals with Insufficient Data. Selection Criteria for the Protection of the Human Health and Environment" defines the tokens and procedure for the selection of chemicals that require additional information. The properties of the substance (e. g. physical and chemical properties, environmental behavior, the impact on humans or animals) and

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parameters of use (e. g. the production output) can act as selection tokens. The Annex II to the Decision-Recommendation defines the procedure for the preparation of the overviews of chemicals, overview candidates (e. g. substance identifiers, physical and chemical properties, the impact on humans, animals, and environment). It also sets forth the approaches to the evaluation of the quality of data that is represented in the overview.

The Decision reveals a need for a mechanism of the information exchange on chemicals between the OECD members, which would also allow for the use of other OECD Decisions and Recommendations.

C(2018)51: Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals

It revises and replaces a 1991 Decision-Recommendation of the Council (C(90)163/FINAL). The Decision-Recommendation is composed of two parts.

The Decision section of the part A focuses on:

*development of harmonised hazard and exposure assessment methodologies for chemicals (including methodologies to prioritise chemicals for regulatory consideration),*

*collaborative assessments and elaboration of classification and labelling designations for these chemicals,*

*information dissemination with proper respect given to the CBI protection.*

It is recommended to share the burden of information generation; the use of the results of investigations, performed by other countries, adhering to this act, for the assessment purposes is encouraged.

The Decision section of the part the Part B focuses on:

*risk prevention and reduction including the establishment and strengthening of national risk reduction programmes,*

*implementation of the GHS.*

It is also recommended that countries, adhering to this legal act identify and undertake activities to prevent or reduce the risks of chemicals taking into account their entire life-cycle, as well as share the best regulatory and non-regulatory practices regarding risk management approaches (including socioeconomic assessment).

Countries, adhering to this legal act are encouraged, where one or more countries identify that a chemical may pose a hazard or risk, or implement risk reduction measures in relation to a chemical, to report on what similar activities they are engaged in in relation to that identified chemical and associated risk or hazard.

The previous 1991 Decision was mainly focused at the joint selection and research of mass-produced chemicals by the OECD members to reduce the risk of exposure of the human health and environment, as well as the compilation of a shared and consistent database on these substances.

C(74)215: Recommendation of the Council on the Assessment of the Potential Environmental Effects of Chemicals

This Recommendation aims to promote harmonized approaches of the OECD member countries to the prevention of inadvertent exposure of the environment to chemicals through a preliminary assessment of their potential impact.

For the purpose of the well-being of humans and environmental balance, this document recommends the OECD member countries to do whatever is necessary to ensure that

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- *the statistics on import, production, and sales of chemical substances and products is properly maintained;*
- *the OECD member countries define and develop the procedures that may be used to assess the potential impact of chemical substances or products on the environment;*
- *the potential impact of a chemical substance is assessed before it enters the market.*

C(77)97/FINAL: Recommendation of the Council on Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment

This Recommendation is meant to support the OECD member countries in the implementation of new procedures or in the expansion of the existing procedures to prevent the exposure of humans and the environment to chemicals.

Because the existing procedures for the assessment of chemicals are largely focused on the impact on the human health, and because new chemicals should be assessed systematically, this Recommendation sets forth a certain assessment scheme that takes into account the impact both on the human health and on the environment. The proposed scheme should facilitate the exchange of information on chemicals among the OECD member countries.

The scheme provides for a primary assessment of substances to identify the following substances:

- *The substances that may be at least a source of danger, but that do not necessitate further research;*
- *The substances that may be a source of danger and may be released into the environment in some cases, and that necessitate further research, particularly into the impact on the human health;*
- *The substances that are hazardous or not hazardous to the human health, but that are released into the environment and necessitate further detailed research into the environmental impact.*

An initial assessment is broken down into two steps. On step 1, the following targets should be achieved:

- *Determine the physical and chemical properties of the substance.*
- *Determine the potential impact on the human health (to protect workers and evaluate the need for further research).*
- *Determine the probability of the release of the substance into the environment (to identify the need for further assessment of the environmental impact).*

On step 2, the substances that may be released into the environment in the amounts that contribute to the manifestation of their toxicity and other properties are subject to the assessment of the potential environmental impact.

The information that is required to complete steps 1 and 2 of the chemical assessment can be found in Annex II to the Recommendation.

C(82)196: Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals

According to this Decision, before a new chemical enters the market, the OECD member countries should be able to access all the information on its properties that would be required to assess the potential impact of this chemical on the human health and environment. The information required to compile a minimum database before the chemical enters the market has been annexed to the Decision. This minimum database includes the following information:

- *Substance identification data.*
- *Application field, volume of production, etc.*

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- *Recommended precautions for safe handling of the substance.*
- *Methods of analytical determination.*
- *Physical and chemical properties.*
- *Acute toxicity data.*
- *Ecotoxicity data.*
- *Biodegradation and bioaccumulation characteristics.*

C(84)37(Final): Recommendation of the Council concerning Information Exchange related to Export of Banned or Severely Restricted Chemicals

This document stipulates that the country exporting a prohibited or severely restricted chemical (in the exporting country) should provide the importing country with the information on the exported chemical for the importing country to make a timely and informed decision on this chemical. In exchanging the information, the countries should stick to the Guidelines on the Information Exchange related to the Export of Prohibited or Severely Restricted Chemicals that have been specified in this Recommendation. These Guidelines are described below.

The country that exports prohibited or severely restricted chemicals should guarantee that it has taken all required steps to provide the importing country with the relevant information for hazard prevention. The precautionary information should at least include the following data:

- *chemical identification data;*
- *an overview of the control measures that are taken in the exporting country;*
- *a notice on the availability of additional information to the importing country on a separate request.*

By using these Guidelines, exporting and importing countries can develop procedures for the acquisition and use of information, for the provision of additional information, and for checking if such information needs to be requested, as well as the measures to protect the information privacy.

C(83)98/FINAL: Recommendation of the Council concerning the OECD List of Non-Confidential Data on Chemicals

This document defines the concept and the set of non-confidential data that may be freely exchanged and disclosed.

According to this Recommendation, the mandatory data that is relevant to the assessment of chemical hazards and is fit for other purposes associated with the human and environmental protection may be considered to be non-confidential.

The non-confidential information on a chemical includes the following data:

- *trade name or commonly used name;*
- *general application data;*
- *precautions during production, storage, transport, and use;*
- *recommended processing and disposal techniques;*
- *precautions in case of an emergency (accident);*
- *physical and chemical data, except for the data that enables the substance identification (e. g. spectral analysis data);*
- *the information on health effects, safe handling, and environmental impact with the exact values and their interpretation.*

The list of non-confidential data is not restricted and may be expanded, if necessary, by mutual agreement of the exchanging countries.

C(83)96(Final): Recommendation of the Council concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals

## International regulatory framework for safe handling of chemical products

Given the economic value of the information on chemicals, in particular the information on the health, safe handling, and environmental impact; and given the possible negative consequences of the disclosure of such information for the competitiveness of the business or individual who acquires such information, this Document recommends the agencies that are responsible for the notification of new chemicals:

- *to demand that each notifier submit the certificate of the right to use the information that has been obtained at the laboratory specified by the notifier.*

C(83)97(Final): Recommendation of the Council concerning the Exchange of Confidential Data on Chemicals

Given the need for the exchange of confidential information on chemicals among the OECD member countries to assess the impact of chemicals on the human health and environment, this Document recommends the OECD member countries to take steps for enabling the exchange of such information and for using the principles that have been set out in the Annex "Recommended Principles Governing the Exchange of Confidential Information and Information on Chemicals among the OECD Member Countries".

The recommended principles are based on the following provisions:

- *A competent authority of the country (requester of the confidential information) should do everything possible to obtain the information available in its country before submitting a request for confidential information to the competent authority of another country.*
- *All the information that has been made available to the competent authority of the requesting country should remain the property of the owning country even after the exchange with competent authorities in any other country to the extent that was initially determined by the legislation of the owning country.*
- *The exchange of confidential information should not interfere with or affect the competition.*

### **The principles of the exchange of confidential information**

#### Principle 1

The exchange of confidential information on chemicals between the competent authorities of different countries is intended only to facilitate the assessment of exposure risks and the protection of the human health and environment.

#### Principle 2

The country that has obtained the requested information under no circumstances should use this information for any purpose other than the assessment of exposure risks and protection of the human health and environment.

#### Principle 3

The country that requests the information on a chemical should justify this request by confirming the following:

- *the chemical is being distributed or will shortly be distributed on the domestic market of the requesting country;*
- *the requested information is needed to assess the exposure risks associated with the chemical and to protect the human health and environment.*

#### Principle 4

The requesting country:

## International regulatory framework for safe handling of chemical products

- *should obey the decision of the information-providing country with regard to the information confidentiality;*
- *should handle the provided information at least retaining the same level of its confidentiality as in the information-providing country;*
- *may provide access to the information to the national, regional, and local authorities only for the assessment of exposure risks or for the protection of the human health and environment providing that these authorities guarantee the same level of information confidentiality;*
- *should not pass the information to any third country.*

### Principle 5

The requesting country should not request the confidential information that it is not entitled to acquire and use under its legislation or as part of the normal work of its governmental bodies.

### Principle 6

The information-providing country should consult with the source of the confidential information before its transmittal.

### **Acts regarding emergencies that involve hazardous chemicals**

The OECD actively supports its member countries in the exchange of information and experience in responding to accidents and emergencies that involve chemicals. These efforts have ultimately materialized in the following decisions and recommendations on the emergency notification.

C(89)88/FINAL: Recommendation of the Council concerning the Application of the Polluter-Pays Principle to Accidental Pollution

Countries are recommended to apply the Polluter-Pays Principle in connection with accidents involving hazardous substances, taking into account the "Guiding Principles Relating to Accidental Pollution" set out in the Appendix to the Recommendation.

C(2003)221: The Recommendation of the Council on preparation, prevention, and mitigation of the consequences of accidents involving hazardous chemicals

This document defines steps for the OECD member countries to develop and enhance national programs on the preparation, prevention, and mitigation of the consequences of accidents involving hazardous chemicals.

In particular, it is recommended that the OECD member countries carry out the following activities:

- *Develop and implement monitoring systems to deal with all aspects of the accident prevention, minimization, consequence mitigation, and to follow up, taking into account the input of all stakeholders, in particular, of the workforce and population.*
- *Maintain and increase the engagement of all stakeholders, including industry, governmental bodies, and public organizations in efficient teamwork and cooperation.*
- *Monitor the level of safety of hazardous industrial facilities.*
- *Exchange the information on accidents by submitting reports to the Major Accident Report System (MARS).*
- *Take required steps for allocating hazardous facilities and preventing prohibited actions near the existing hazardous facilities in order to minimize eventual exposure to the impact of the accident with due regard of the potential transboundary damage.*

The OECD Council recommends its member countries while completing the above steps to take into account the OECD Guidelines on the preparation, prevention, and mitigation of the

## International regulatory framework for safe handling of chemical products

consequences of accidents involving chemicals and the OECD Guidelines on the indicators of safety assurance activities.

C(88)85/FINAL: The Decision-Recommendation of the Council concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances

This Decision-recommendation is intended to support the OECD member countries in the development of policies and programs for the provision of information to the population that may be affected by accidents at hazardous facilities, as well as to enable the public participation in the decision-making with regard to such facilities.

This Decision sets a procedure for the information provision and defines a set of information on hazardous facilities that should be made public at all times. In particular, the following information should be provided without a separate request:

- *information on the method and source of public notification in case of an accident;*
- *information on safety measures and actions of locals in case of an accident;*
- *information on the list and classification of hazardous substances that may cause an accident;*
- *information on the potential impact of these substances on the human health and environment, including property.*

In addition, the Decision defines a set of information that is provided to the public on a special request.

The document provides for the public participation in decision-making with regard to the construction and licensing of hazardous facilities as well as in accident prevention and accident recovery plans by voicing opinions and making suggestions.

C(88)84: Decision of the Council on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage

According to this Decision, the OECD member countries should exchange information and hold consultations to prevent accidents that may cause transboundary damage and to reduce the damage from such accidents.

The Decision sets a procedure for the exchange of information among the OECD member countries and defines a set of information on hazardous facilities during their construction (reconstruction) and in case of accidents and emergencies at these facilities. According to this Decision, a hazardous facility is any industrial facility that contains any hazardous substances in unacceptable amounts (a list of hazardous substances and their prohibitive amounts for the hazardous facility can be found in Annex III to the Decision) and that is used to produce, utilize, and store hazardous chemicals capable of causing serious damage to the human health and environment in case of an accident.

The member countries should take all practical steps to apply the provisions of the Decision at their will and on a reciprocal basis, to enter into agreements and make arrangements, as needed, in order to specify the procedures for the exchange of information with regard to the accidents capable of causing transboundary damage.

C(2018)5: Recommendation of the Council on Establishing and Implementing Pollutant Release and Transfer Registers (PRTRs)

This Recommendation of the OECD Council replaces the 1996 Recommendation on Implementing PRTRs in order to take into account accumulated knowledge and good practices that became available due to the wide-spread establishment and advancement of PRTRs. The revised Recommendation aims to provide a well-defined guidance for countries, wishing to adhere to its provisions (both OECD Member and non-Member countries). It contains especially valuable

## International regulatory framework for safe handling of chemical products

information for those establishing and revising their PRTRs, targeting at generation of high quality and compatible PRTR data across the world.

It contains the detailed provisions related to the goals and objectives of PRTRs, their establishment, implementation, as well as evaluation and revision. It also provides a reference to the series of OECD Guidance Documents on PRTRs.

### **The OECD activities that pertain to the regulation of chemicals**

Among other things, the OECD Council regulates the circulation of certain chemicals and compounds in the environment. The regulatory instruments in this area include the following documents:

- *C(96)42/FINAL: Declaration on Risk Reduction for Lead;*
- *C(87)2/FINAL: Decision-Recommendation of the Council on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls (PCD);*
- *C(73)172/FINAL: Recommendation of the Council on Measures to Reduce all Man-Made emissions of Mercury to the Environment;*
- *C(71)83/FINAL: Recommendation of the Council on the Determination of the Biodegradability of Anionic Synthetic Surface Active Agents.*

#### C(96)42/FINAL: Declaration on Risk Reduction for Lead

This Declaration reaffirms the preparedness of the OECD member countries to ensure the development and enhancement of national or international programs required to reduce the risks that are associated with the exposure to lead.

The Annex I of the Declaration includes the following measures intended to reduce the risks that are associated with the exposure to lead:

- *removal of lead and its compounds from the manufacture of children's products and food packaging;*
- *gradual removal of lead from the manufacture of paint and anticorrosion agents;*
- *development of public awareness programs to significantly reduce the exposure to lead in the domestic use of lead-containing materials.*

In addition, this Declaration declares the readiness of the OECD member countries to exchange the information on the impact of lead and the potential for the reduction of exposure risks with other countries, including OECD non-members. The OECD non-member countries are also encouraged to take into account the provisions of this Declaration, to join the Declaration, and to ensure the implementation of envisaged measures.

#### C(87)2/FINAL: Decision-Recommendation of the Council on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls (PCD)

This Decision obliges all OECD member countries to stop the production, import, export, and sales of PCD from January 1, 1989. It also applies to all goods, products, and equipment that contain PCD as well as to the equipment that is produced using PCD, except for the import and export of liquid and other wastes that contain PCD or are contaminated with PCD.

The Decision provides for the exchange of information among the OECD member countries on new developments that pertain to the monitoring of use, storage, transportation, and safe disposal of PCD.

#### C(73)172/FINAL: Recommendation of the Council on Measures to Reduce all Man-Made emissions of Mercury to the Environment

## International regulatory framework for safe handling of chemical products

This Recommendation specifies the need for the measures to reduce all man-made emissions of mercury to the environment, which should be developed and implemented by the OECD member countries. The following tasks should be prioritized:

- *taking all mercury-containing compounds out of all uses that may result in their release into the environment anyway;*
- *maximal reduction of mercury concentrations in the emissions and waste of all industrial enterprises that use or produce mercury-containing compounds.*

The OECD Council also suggests that all OECD member countries exchange the information on the total annual national consumption and use of mercury from 1 January, 1974 as part of the activities of the Committee on Environmental Protection.

C(71)83/FINAL: Recommendation of the Council of the Determination of the Biodegradability of Anionic Synthetic Surface Active Agents

This document recommends the OECD member countries to adopt and use the system for testing surfactants that has been developed by the OECD and is described in the OECD report on the determination of biodegradability of surfactants.

C(2013)107: Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials

This Recommendation encourages countries to manage the risks of manufactured nanomaterials, apply the existing international and national chemical regulatory frameworks or other management systems, adapted to take into account the specific properties of manufactured nanomaterials. For the purpose of such adaptation, countries are advised to use the tools in the documents listed in the Annex to the Recommendation. Testing of nanomaterials should be performed based on the OECD Test Guidelines, adapted as appropriate to take into account the specific properties of manufactured nanomaterials and using the tools listed in Section I of the Annex to the Recommendation, as well as the OECD Principles of Good Laboratory Practice.

### A Vision for the Future

Consequently, the OECD legislation spans hazard assessment and research of chemicals and chemical products, the exchange of information on hazardous chemicals and accidents that involve chemicals. It also regulates the handling of certain groups of substances.

The regulatory acts of the OECD Council are available for the accession and implementation by non-member countries. They are published on the OECD official website at <http://www.oecd.org/> in the "OECD Legal Instruments / Environment" section.

**H i s t o r y o f**  
**t h e A s i a - P a c i f i c E c o n o m i c C o o p e r a t i o n**  
**( A P E C )**  
**C h e m i c a l D i a l o g u e**

Composed by Australia

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

### 2.1. History and composition of APEC

The Asia Pacific Economic Cooperation (APEC) is a regional forum established in 1989 to leverage the growing interdependence of the Asia-Pacific. It aims to create greater prosperity for the people of the region by promoting balanced, inclusive, sustainable, innovative and secure growth and by accelerating regional economic integration.

The annual APEC Economic Leaders' Meeting is attended by heads of government of all APEC members except Chinese Taipei. The location of the meeting rotates annually among the member economies.

All member economies border the Pacific Rim. There are currently 21 APEC member economies (See Table 2.1.):

**Table 2.1. - APEC member economies**

APEC Members	Year of Joining	Current Leader
Australia	1989	Prime Minister Malcolm Turnbull
Brunei Darussalam	1989	Sultan Hassanal Bokiah
Canada	1989	Prime Minister Justin Trudeau
Republic of Chile	1994	President Michelle Bachelet
People's Republic of China	1991	President Xi Jinping
Hong Kong, China	1991	Chief Executive CY Leung
Indonesia	1989	President Joko Widodo
Japan	1989	Prime Minister Shinzo Abe
Republic of Korea	1989	Acting President Hwang Kyo-ahn
Malaysia	1989	Prime Minister Najib Razak
Mexico	1993	President Enrique Pena Nieto
New Zealand	1989	Prime Minister Bill English
Papua New Guinea	1993	Prime Minister Peter O'Neill
Peru	1998	President Pedro Pablo Kuczynski
The Philippines	1989	President Rodrigo Roa Duterte
Russia	1998	President Vladimir Putin
Singapore	1989	Prime Minister Lee Hsien Loong
Chinese Taipei	1991	Representative James Soong
Thailand	1989	Prime Minister Prayuth Chan-ocha
The United States	1989	President Donald Trump
Viet Nam	1998	President Tran Dai Quang

APEC ensures that goods, services, investment and people move easily across borders. Members facilitate this trade through faster customs procedures at borders; more favourable business climates behind the border; and aligning regulations and standards across the region. APEC's initiatives to synchronize regulatory systems is a key step to integrating the Asia-Pacific economy. A product can be more easily exported with just one set of common standards across all economies. APEC works to help all resident of the Asia-Pacific participate in the growing economy. The forum adapts to allow members to deal with important new challenges to the region's economic well-being including disaster resilience, pandemic planning and addressing terrorism.

APEC operates as a cooperative, multilateral economic and trade forum. Member economies participate on the basis of open dialogue and respect for views of all participants. All economies have an equal say and decision-making is reached by consensus. There are no binding commitments or

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

treaty obligations. Commitments are undertaken on a voluntary basis and capacity building projects help members implement APEC initiatives.

APEC has four core committees with their respective working groups providing strategic policy recommendations to APEC Leaders and Ministers who annually set the vision for overarching goals and initiatives. The working groups are then tasked with implementing these initiatives through a variety of APEC-funded projects. Members also take individual and collective actions to carry out APEC initiatives in their individual economies with the assistance of APEC capacity building projects. Capacity building generally takes through skills training and technological know-how.<sup>1</sup>

APEC conducts the following meetings each year.

- *APEC Economic Leaders' Meetings are held once a year in the APEC host economy. Declarations from these meetings set the policy agenda for APEC.*
- *Annual APEC Ministerial Meetings of foreign and economic/trade ministers are held immediately prior to APEC Economic Leaders' Meetings. Ministers consider the year's activities and provide recommendations for APEC Economic Leaders' consideration.*
- *Sectoral Ministerial Meetings are held regularly covering areas such as education, energy, environment and sustainable development, finance, human resource development, regional science and technology cooperation, small and medium enterprises, telecommunications and information industry, tourism, trade, transportation and women's affairs. Recommendations from these meetings are also provided to APEC Economic Leaders for their consideration.*
- *The ABAC provides APEC Economic Leaders with a business perspective on APEC issues through an annual meeting and a formal annual report. The annual report contains recommendations to improve the business and investment environment in the APEC region. ABAC also meets four times per year and a representative attends Ministerial Meetings.*
- *Senior Officials' Meetings are held three times annually. Officials work under direction from APEC Ministers and guide the activities of the Committees, Working Groups and Task Forces.*

The structure of APEC is shown in Figure 2.1.

APEC has grown to become a dynamic engine of economic growth and an important regional forum. Its member economies are home to around 2.8 billion people and represent approximately 59 per cent of world GDP and 49 per cent of world trade in 2015. Growth has soared in the region, with real GDP increasing from USD 16 trillion in 1989 to USD 20 trillion in 2015. Per capita income has risen by 74 per cent over the same period creating a growing middle class in just over two decades.

Bringing the region closer together, reducing trade barriers and smoothing out differences in regulations have boosted trade which, in turn, has led to increasing prosperity. Average tariffs in the region fell from 17 per cent in 1989 to 5.2 per cent in 2012. During that same time, the APEC region's total trade increased over seven times leading world growth. Two thirds of this trade has occurred between member economies.

APEC has concentrated on implementing its 2009 Ease of Doing Business Action Plan with the goal of making it cheaper, easier and faster to do business in the region. Significant improvements have taken place at the border with centralized export-import processing online. Connectivity and supply chain logistics have been key items along with encouraging green technologies across the region.

### **2.2. Establishment of the APEC Chemical Dialogue (CD)**

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<sup>1</sup> <http://www.apec.org/About-Us/About-APEC/History>

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

The chemical industry is a cross-cutting sector that contributes to most industrial and many non-industrial sectors - its products are widely traded across borders, and it is a key economic building block in APEC economies.<sup>2</sup> The CD was established in 2001 with the Terms of Reference (Attachment A) approved by the Committee on Trade and Investment (CTI). It operates with both a Government and Industry Co-Chair.

The CD serves as a forum for appropriate government officials and industry representatives to solve challenges facing the chemical industry and users of chemicals in the Asia-Pacific region. It reflects APEC members' recognition of the importance of engaging with the private sector and building public-private sector dialogue and cooperation for mutual benefit.

The CD provides a forum to openly discuss trade and trade-related regulatory issues affecting the competitiveness and sustainable development of the chemicals industry in the Asia-Pacific region.

The CD operates within APEC as one of five industry dialogues under the CTI. The issues which the CD addresses include chemical sector liberalization, chemical trade facilitation and capacity building. The CD also focuses on improving regulatory policies and practices: it seeks workable regulatory programmes which ensure that regulatory, safety, and environmental goals can be implemented by both governments and businesses.

### **2.3. Structure of the Chemical Dialogue**

The CD meets twice a year in the margins of the Senior Officials Meetings (SOM1 and SOM3 respectively). The first CD meeting of the year provides for planning and task setting with the second meeting providing for implementation and reporting. It effectively provides for an exchange of views in accordance with the APEC Ministerial mandate between private sector chemical industry representatives and appropriate government officials who are involved in developing trade and trade-related regulatory policy within APEC member economies. The CD work program has focused on non-tariff measures, trade facilitation and economic and technical cooperation related to the chemical industry in the Asia-Pacific region.

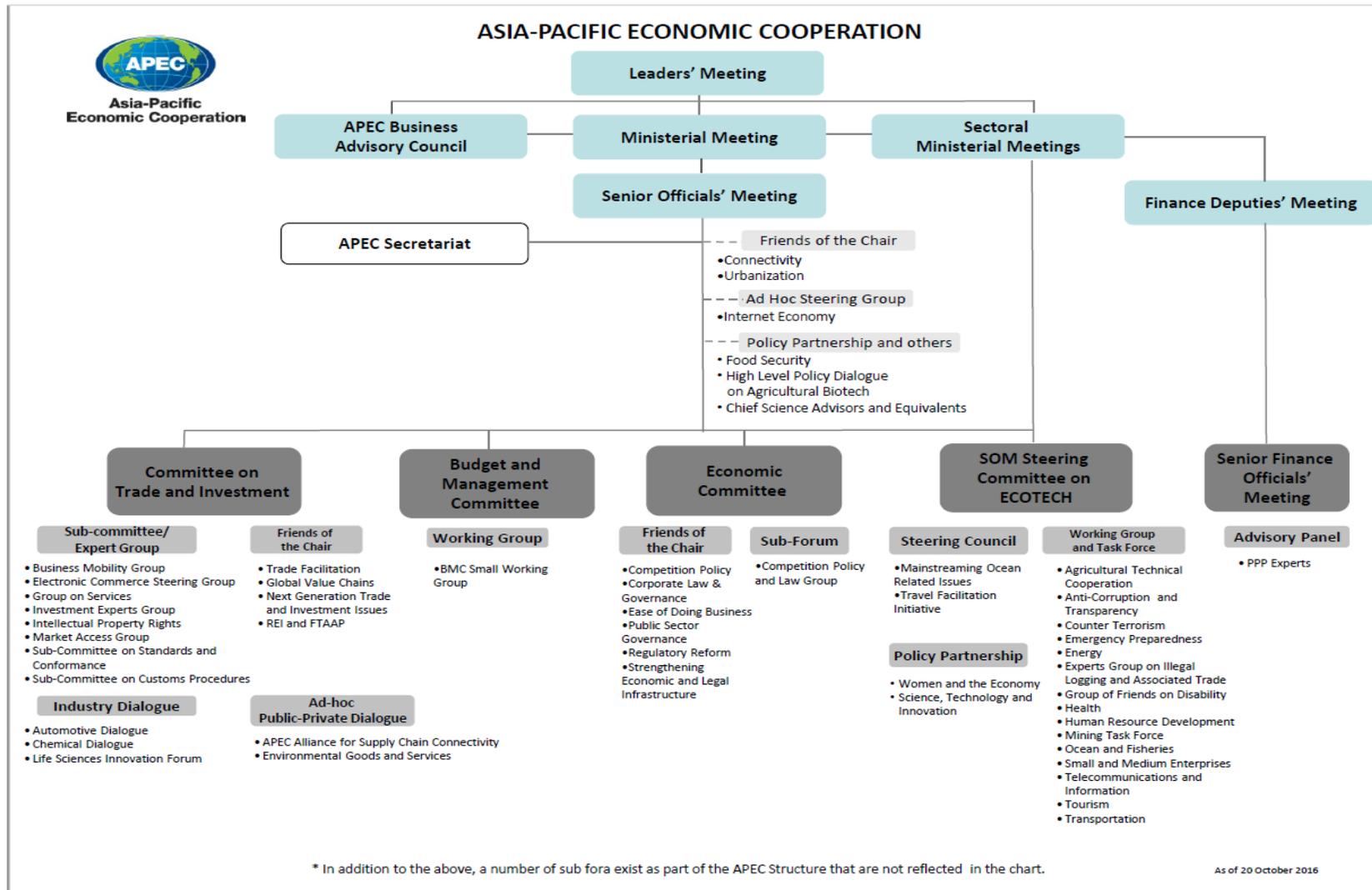
The CD reports to the CTI, reflecting the significance of the chemical industry to trade and investment, and, where appropriate, through the CTI to APEC Senior Officials, Ministers and Leaders.

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<sup>2</sup> <http://www.apec.org/Groups/Committee-on-Trade-and-Investment/Chemical-Dialogue>

# History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

Figure 2.1. - APEC structure<sup>3</sup>



<sup>3</sup> <http://www.apec.org/About-Us/How-APEC-Operates/Structure>

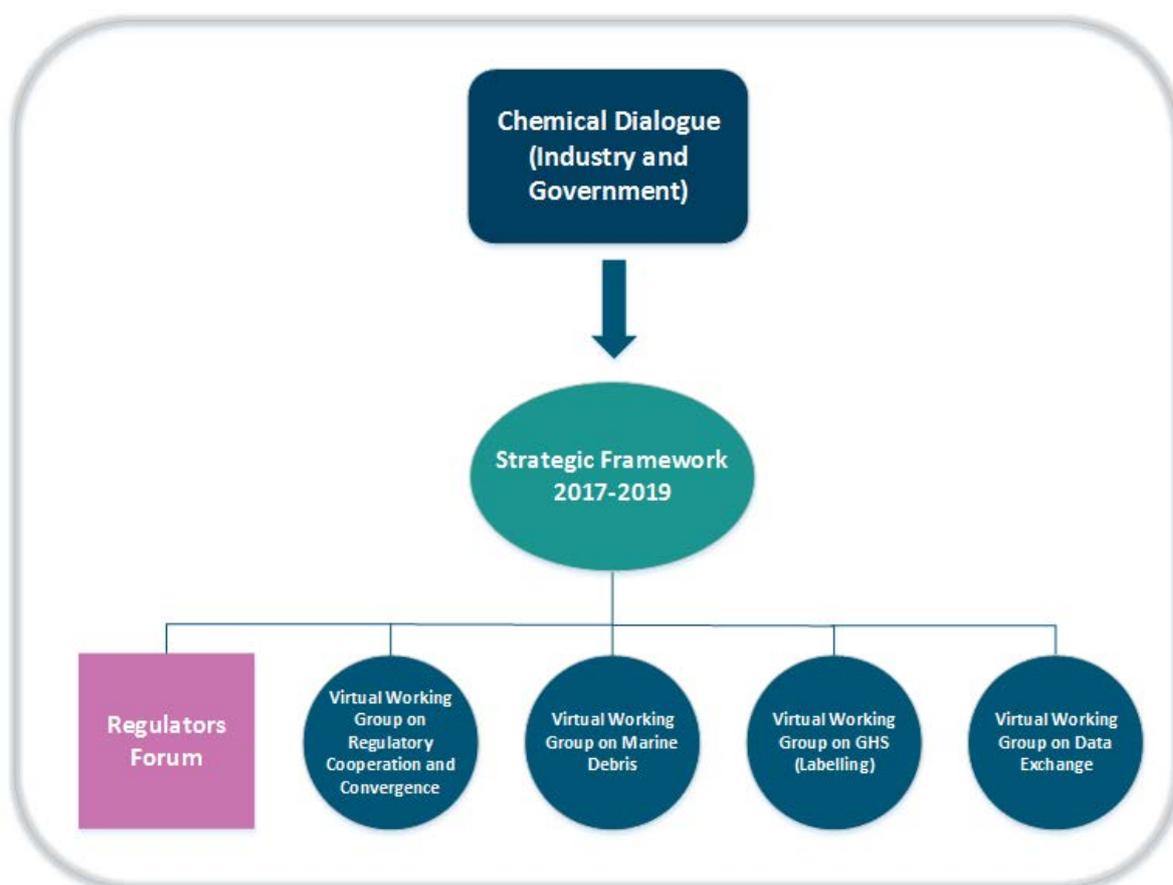
## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

Four virtual working groups report to the CD forum, with each group addressing a specific area of interest:

- a. *Regulatory Convergence and Cooperation*
- b. *Globally Harmonized System (GHS) of the Classification and Labelling of Chemicals*
- c. *Management of Marine Debris*
- d. *Data Exchange*

The virtual working groups of the CD usually have a Government and Industry Co-Chair in the same model as the Dialogue and varied economy membership. The terms of reference for each virtual working group and the regulators' forum are required to be approved by the CD.

**Figure 2.2. - APEC Chemical Dialogue Operational Overview**



### **2.4. Goals and Best Regulatory Practice of the Chemical Dialogue**

The Dialogue's primary goals are set out in its Strategic Framework 2017-2019, which builds on the original framework which was endorsed by APEC Ministers in 2011, (Attachment B). The three Shared Goals around which the Framework and the Dialogue's work are organized are:

1. *Expand and support cooperation and mutual recognition among chemical regulators in the region to facilitate trade.*
2. *Enhance understanding of the chemical industry's role as an innovative solutions industry.*
3. *Encourage chemical product stewardship, safe use and sustainability.*

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

The five overarching strategic objectives for the CD are:

- *To facilitate alignment of the Leaders' goals for sustainable economic growth and regulation.*
- *To promote regulatory capacity to facilitate trade while supporting environmental and health protection.*
- *To enhance chemical management and product stewardship over the life cycle and in cooperation with other initiatives and institutions where appropriate e.g. the OECD, UN, SAICM, WHO.*
- *To identify barriers to utilizing chemicals, products and processes to achieve sustainable and innovative solutions in the APEC region.*
- *To strengthen the positioning of the sector globally as an enabler of technological change and innovation as part of meeting challenges across the three key areas of focus for APEC – trade and investment liberalization, business facilitation; and economic and technical cooperation.*

The CD continues to discuss ways to contribute to APEC's overarching goals of trade liberalisation and business facilitation.

The CD program of work focuses on the challenges imposed by different approaches to regulation, including the difficulty in balancing the protection of trade secrets and confidential information with the need for transparency, facilitating data exchange, and the varying regulatory approaches to the treatment of chemicals in articles. The CD also continues to emphasize the integration of its work with the international chemicals agenda, including the UN's Strategic Approach to International Chemicals Management (SAICM).

Currently, regulatory cooperation and the promotion of best regulatory practices is the top priority of the CD, with the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals viewed as a significant contribution.

### *Principles for Best Practice Regulation*

The 2008 production of the Principles for Best Practice Regulation (Attachment C) is a guiding document which examines why chemicals are regulated and sets out the agreed nine principles and features that provide for best practice chemical regulation.<sup>4</sup>

APEC has also shown regional leadership by contributing the ground-breaking APEC Best Practice for chemical Regulation to the SAICM. The guidelines were formulated by APEC officials and industry representatives and endorsed by APEC Ministers.

Representatives of the CD presented the Best Practices for Chemical Regulation and the GHS Virtual Working Group reports to the second session of the International Conference on Chemicals Management in Geneva, Switzerland in May 2009.

### *The Principles*

Principle 1: CHEMICAL REGULATIONS SHOULD BE THE MINIMUM REQUIRED TO ACHIEVE THEIR STATED OBJECTIVES

Principle 2: CHEMICAL REGULATIONS SHOULD ADOPT A RISK MANAGEMENT APPROACH TO DEVELOPING AND ADMINISTERING REGULATION

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<sup>4</sup> <http://www.apec.org/web-search?q=CD+Best+Practice+Regulation>.

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

Principle 3: CHEMICAL REGULATIONS SHOULD MINIMIZE THE IMPACT ON COMPETITION

Principle 4: CHEMICALS REGULATORS SHOULD UTILIZE RELEVANT INTERNATIONAL STANDARDS WHEREVER POSSIBLE

Principle 5: CHEMICAL REGULATIONS SHOULD NOT RESTRICT INTERNATIONAL TRADE FLOWS

Principle 6: CHEMICAL REGULATIONS SHOULD BE DEVELOPED IN CONSULTATION WITH STAKEHOLDERS, SUBJECT TO PUBLIC

Principle 7: CHEMICAL REGULATIONS SHOULD BE FLEXIBLE, NOT PRESCRIPTIVE, AND BE COMPATIBLE WITH THE BUSINESS OPERATING ENVIRONMENT

Principle 8: CHEMICAL REGULATIONS SHOULD BE SCIENCE-BASED

Principle 9: CHEMICAL REGULATIONS SHOULD HAVE A CLEAR DELINEATION OF REGULATORY RESPONSIBILITIES AND EFFECTIVE AND TRANSPARENT ACCOUNTABILITY MECHANISMS

Further work was undertaken in 2016 to introduce a policy tool for improving the application of the best regulatory principles through the application of a regulatory checklist. The regulations and decisions by their administering bodies should:

- *Be the minimum required to achieve their stated objectives.*
- *Adopt a risk management approach to developing and administering regulation.*
- *Minimize unnecessary impact on competition.*
- *Utilize international standards as appropriate.*
- *Not restrict international trade flows.*
- *Be developed in consultation with stakeholders, subject to public review and comment and periodic review.*
- *Be flexible, not prescriptive, and be compatible with the business operating environment;*
- *Be science based.*
- *Have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms.*

The press release and document can be found at: [http://www.apec.org/Press/News-Releases/2016/1110\\_CD](http://www.apec.org/Press/News-Releases/2016/1110_CD).

### **2.5. The Regulators' Forum**

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

To support and complement its work, a Chemical Dialogue Regulators' Forum, which operates as a sub-forum of the CD, was established in 2009. The objectives of the Forum are to:

1. *Facilitate risk reduction and the sound management of chemicals across the APEC region and as an APEC contribution to broader implementation by the UN's Strategic Approach to International Chemicals Management (SAICM).*
2. *Share information and knowledge on chemicals management more broadly in the region with the increased and direct involvement of regulators.*
3. *Bridge principles and practice - sharing tools and experience with best practices and plan opportunities for collaboration to address common concerns.*
4. *Discuss the nexus between chemicals management and competitiveness (including for small and medium enterprises), with a view to facilitating trade while protecting human health and the environment.*

The operation of the Regulators' Forum was formalised in 2015. It has its own work plan (Attachment D), and its membership is similar to that of the CD but with greater representation from regulatory agencies and a separate Chair.

The Regulators' Forum meets once per year and coordinates its activities with and reports regularly to the CD generally through the VWG on RCC.

In 2015 the Regulators' Forum held the Risk Assessment Training on Metals and Metal Compounds Workshop. This was a one and a half day workshop held at SOM3 in the Philippines to build, with facilitation from governments, the capacity of the APEC regulatory community in the scientifically sound risk assessment of metals and metal compounds. It was used to document and discuss risk assessment approaches developed by APEC economies and non-APEC entities, illustrated by case studies. In addition to this, on-going training materials were provided over the remainder of 2015 and early-2016 to maintain the sustainability of capacity building beyond the training workshop.

The Regulators' Forum is also undertaking ongoing work on the Chemical Inventory proposal from Vietnam, the Risk Assessment and Chemicals management methodologies for perfluorinated carbons and brominated flame retardants from China.

With the increasing focus of developing regional regulatory cooperation to enhance trade outcomes, the Regulators' Forum will continue to play an important role in progressing APEC outcomes.

### **2.6. Funding Opportunities within the Chemical Dialogue**

APEC funding is a very competitive process. The CD has successfully secured APEC funding for a number of projects. A regulatory cooperation workshop was supported in Beijing 2014 to identify the next steps forward. The project was jointly funded by APEC and the US Government.

The Regulators' Forum provided a workshop on the assessment of metals in the Philippines in 2015 that was fully self-funded, largely by industry. In 2015 the United States proposed a self-funded project entitled: Addressing Marine Debris through Pilot Projects to Design Economically Sustainable Waste Management Infrastructure. This project is jointly endorsed by the CD and Oceans and Fisheries Working Group (OFWG). The project is currently being implemented.

APEC-funded projects are a vital part of the APEC process. Projects cover a range of beneficial activities for the region, from establishing channels for information exchange to assist business with trade and investment, to providing information technology training in developing economies.

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

APEC actively encourages the involvement of the private sector, universities and government in the Asia-Pacific Region in APEC projects. Self-funded projects are an increasingly important component operating within the CD.

APEC administers two project approval sessions per year. APEC member economies can apply for project funding during these two project approval sessions. Funding is approved by APEC's Budget and Management Committee (BMC).

Project sessions are very competitive, with many more applications than there is funding available. Members are required to have a well-developed proposal based on outcomes and to have consulted widely and obtained support from colleagues and other member economies.

Details of the project application process can be found at:  
<http://www.apec.org/Projects/Applying-for-Funds>

### **2.7. The Economic Importance of Chemicals and Manufacturing Shift to the APEC Region**

The chemical industry makes a considerable contribution to the economy and is one of the world's largest industrial sectors with many chemicals produced and traded internationally. It is composed of small, medium and large domestic and international companies.

Global sales in 2000 amounted to over \$US3.5 trillion, with exports approximately \$US1.5 trillion. It is a highly transformative industry and a key economic building block in APEC economies.

World chemical exports for 2014 were valued at US\$1112 billion with the Asian countries contributing 23per cent of the total exports, North America 13per cent and China 6.5 per cent.

The APEC share of global chemical exports has been increasing over the last several years. This demonstrates the increasing contribution of chemicals in APEC economies exports of manufactured goods and the economic growth and industry importance to the APEC region and economies.

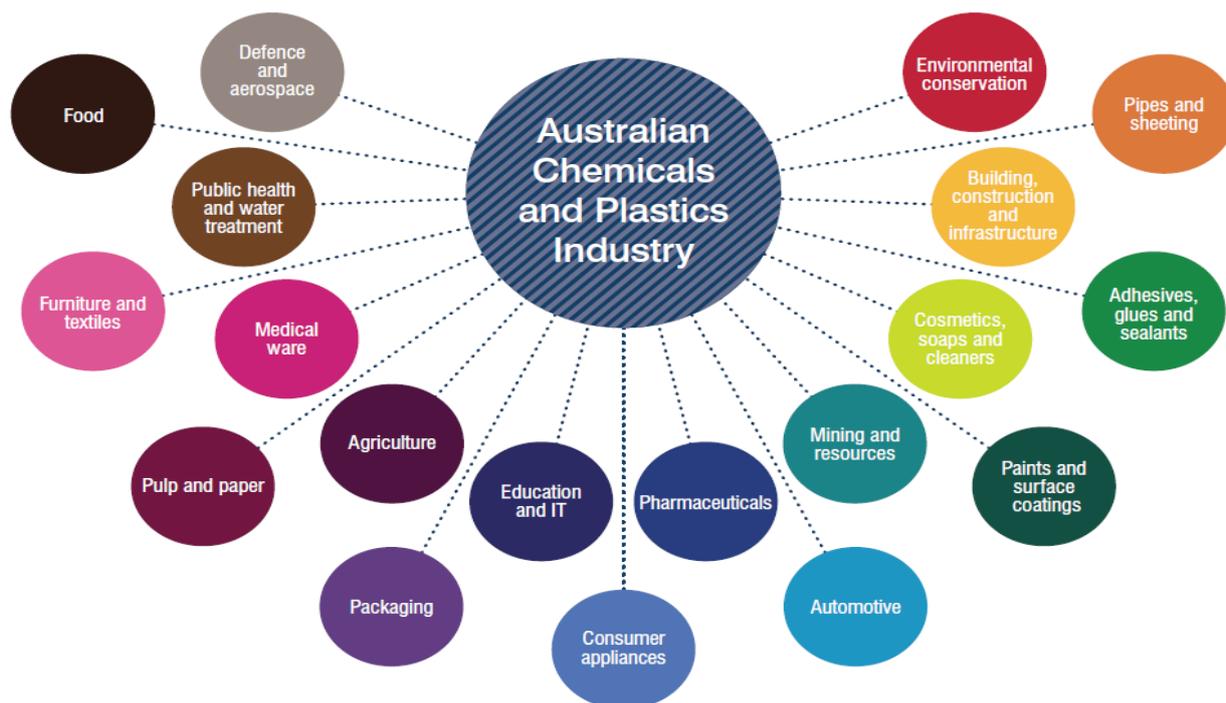
The chemical industry is a cross-cutting sector that contributes to almost all industrial and many non-industrial sectors. In terms of value of material inputs into other sectors, estimates suggest that chemistry contributions are significant.

The chemical industry is extremely diverse. Its products and services are fundamental to the economic and social wellbeing of member economies. The global chemical industry is intensely competitive and needs a level playing field in APEC economies to enable it to compete effectively in the global economy. Thousands of new chemical products enter the global market every year in an environment of increasing technical complexity.

The chemical industry continues to contribute to the development of innovative products and services and healthier and safer options from small improvements in everyday life to fundamental advancements in science and technology. Chemistry is synonymous with innovation and innovative business practices. From medicine to energy to computing to transport and many industries beyond, the chemicals and plastics industry has provided the products and services that increasingly continue to shape the world. The reach of chemicals in many different industries is shown in the figure 2.3.

**Figure 2.3. - Chemical involvement in different industries (PACIA, 2014)**

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue



The chemical industry's contribution to global productivity is of a significant magnitude having grown at a brisk pace for more than five decades. The bulk of the world's chemical output is accounted for by only a small number of industrialised nations with the bulk of the industry concentrated in three areas of the world- Western Europe, North America and Japan. The more recent growth in global chemical production can be attributed to accelerating rates in Asia and strong contributions from China.

APEC member economies are proving to be a growing source of influence in the global trade of chemicals as Table 2.2. below shows. This is consistent with the Asian Century trends experienced in other sectors. The APEC share in world chemical production is increasing as non-OECD economies, particularly Russia, India, Indonesia, China, South Africa and Brazil expand their capacity.

**Table 2.2. - APEC Chemical Industry figures (All figures are for 2015, except some employment figures. Sources: UNIDO, CEFIC, ACC, FERI, and IHS Economic)**

Economies	Shipments (US\$b)	Exports (US\$b)	Imports (US\$b)	Domestic Sales (US\$b)	Employment (US\$b)
Australia	20.6	\$9.8	\$22.9	\$33.7	41
Brunei	n/a	n/a	0.4	0.4	n/a
Canada	47.7	30.2	45.2	62.7	98
Chile	26.5	2.8	5.8	29.4	57
China	1920.6	135.3	184.7	1970	8669
Hong Kong	2.0	9.2	11.4	4.2	6
Indonesia	40.4	12.3	17.3	45.4	255
Japan	253.5	100.6	57.9	210.8	346
Malaysia	24.0	14.4	14.7	24.3	97
Mexico	57.9	15.8	38.4	80.5	153
New Zealand	3.2	1.6	3.3	4.9	10
Papua New Guinea	n/a	n/a	0.4	0.4	n/a
Peru	5.8	1.1	3.9	8.6	37

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Economies	Shipments (US\$b)	Exports (US\$b)	Imports (US\$b)	Domestic Sales (US\$b)	Employment (US\$b)
Philippines	11.5	1.7	6.2	16.0	97
Russia	49.2	23.8	26.8	52.2	423
Singapore	59.2	43.5	27.1	42.8	19
South Korea	169.1	53.9	59.3	174.5	143
Taiwan	83.4	53.7	32.5	62.2	90
Thailand	19.7	18.9	18.2	19.0	175
United States	797.1	183.8	205.0	818.3	810
Vietnam	17.6	4.0	14.3	27.9	151
Subtotal - APEC	3609	716	796	3688	11 677
World Total	5226	1960	1960	5226	17775
APEC/World	69%	37%	41%	71%	66%

Production of basic industrial chemicals, such as petrochemicals, organic intermediates, and inorganic chemicals is approximately 22 per cent of the combined US\$3.6 trillion APEC chemical industry output. Another 16 per cent of the region's output is in synthetic materials (plastic resins, synthetic rubber, and manufactured fibres). Specialty chemicals account for a fifth of output while agricultural chemicals and consumer products account for 9 per cent and 8 per cent, respectively. The remaining 25 per cent of output is in pharmaceuticals. A world leader in chemical production, APEC countries account for four-fifths of the world's production of basic industrial chemicals and three quarters of its plastic resins, synthetic rubber, and manufactured fibers. Two-thirds of the world's agricultural chemicals are produced in APEC countries.

World trade is an important element of globalization in the business of chemistry. The APEC chemical industry annually exports US\$716 billion in chemistry, about 37 per cent of the global total. Moreover, exports as a share of shipments are gaining. For that matter, imports as a share of apparent consumption are gaining.

### 2.8. CD Major Achievements

The CD has made a steady contribution to achieving APEC goals. Important CD activities include:

#### *Globally Harmonized System of Classification and Labelling of Chemicals*

The GHS is an internationally agreed-upon system, created by the United Nations. It is designed to replace the various classification and labelling standards used in different economies by using consistent criteria for classification and labelling on a global level. At the CD meeting in Ningbo, China in February 2014, it was agreed that the CD involvement in GHS activities would be analysed with a view to achieving a coordinated and cohesive approach to the CD GHS work and future activities. Led by Australia, CD members will work together to update on the status of implementing GHS in their economies.

#### *Clearinghouse Website for GHS Labelling*

Responding to the needs of industry, the CD created a GHS Reference Exchange and Tool (GREAT) clearinghouse website in 2010 that collects and provides GHS standardised labelling elements in local languages. Authorities and the chemical industry can find translations of labelling

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

terms for hazard communication and international trade purposes. Industry and interested users will also be able to search elements on the website and prepare their own labelling in different local languages.

As of January 2014, GHS labelling elements in different languages provided on the website continues to grow up to 34 languages from 11 member economies including Australia, Chile, China, Indonesia, Japan, Republic of Korea, Malaysia, Philippines, Russia, Thailand and Chinese Taipei, and 23 languages from EU members. The latest updates include Indonesian language version in Bahasa Indonesia and simplified Chinese. The website has received over 60 000 visits, predominately for viewing and applying the labelling elements in different languages.

### *Virtual Working Group (VWG) on Regulatory Convergence and Cooperation*

At the Chemical Dialogue meeting in Kazan, May 2012, members agreed to establish a VWG on Regulatory Convergence and Cooperation. The main aim of the VWG is to examine how the work of the CD could contribute to the broader APEC agenda for regulatory cooperation. The VWG has been exploring areas of collaboration with the APEC Sub-Committee on Standards and Conformance and their work on green buildings and good regulatory practices. The VWG is also undertaking a study to identify potential areas for further cooperation on regulatory work at the OECD, ASEAN and ERIA. In addition, the Russian Federation is undertaking comparative international regulatory system work and the Philippines and US progressing a project on sharing regulatory information.

### *Virtual Working Group (VWG) on Global Harmonised System (GHS) for the Labelling and Classification of Chemicals*

This group builds upon the GHS work progressed by the CD and has moved into evaluating the implementation of GHS in different economies and sectors. Divergences in GHS implementation are being examined looking into:

1. *building block implementation*
2. *GHS mixture cut-off values*
3. *classification of key products*
4. *adoption of difference versions of the GHS*
5. *Adoption of the GHS in different sectors (industrial, customer and agricultural)*

### *Virtual Working Group (VWG) on Data Exchange*

The VWG on Data Exchange was established in 2012 in order to facilitate the CD's contribution to the APEC Agenda through information sharing, fostering cooperation between business and governments on voluntary initiatives, enhancing synergy and complementarities with other regional and international institutions and fora on the issues of mutual concern. The VWG on Data Exchange undertake activities within three work streams:

- *Information sharing - information and knowledge sharing on chemical management practices;*
- *Voluntary initiatives - enabling cooperation between business and governments to improve chemical product stewardship and safe use (voluntary initiatives promotion);*

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

- *Cooperation with international fora - cooperation and coordination with other international and regional organizations on the issues of mutual concern (e.g. OECD, UN, SAICM etc.).*

### *Virtual Working Group on Marine Debris*

This group was established in 2015 as a joint VWG with the APEC OFWG to develop strategies for mitigating the increase amount of marine debris. A range of efforts have been undertaken including:

- *Supporting a pilot project initiative in the Philippines and Indonesia to demonstrate the feasibility of interventions to address marine litter.*
- *Contributing to a high level meeting hosted in Tokyo focused on building political will and developing an investment coalition to support waste management entrepreneurs.*
- *Drafting a set of policy and practice recommendations of the APEC High-level Meeting on Overcoming Barriers to Financing Waste Management Systems to Prevent Marine Litter in the Asia Pacific Region.*

## **2.9. CD Future Priorities and Direction**

Regulatory cooperation and convergence is a key priority for the CD, with activities focused on implementing regulatory best practice and improving alignment of regulatory requirements. Further developing collaborative regulatory chemical management approaches and expanding interest into other internationally operating mechanisms through sister fora such as the OECD/UN are important future activities. The overall aim is to move to convergent chemical management activities and information sharing to assist in regional trade promotion.

There is further scope to make use of good regulatory practice and information sharing through increased interaction with the Economic Committee and SCSC within the APEC umbrella.

Chemical labelling and classification remains an area of ongoing interest for the CD. The UN has made significant progress in rolling out the GHS system and is currently developing a voluntary classification listing to assist business in transitional activities. The CD reports annually to Trade Ministers on member progress in GHS implementation and maintains the GREAT website to assist business by providing information on GHS in multiple languages.

The CD also more recently established a virtual working group on marine debris in 2014 in collaboration with the OFWG. It is designed to promote innovative solutions to the issue of marine debris with a particular focus on innovations in land-based solid waste management to prevent debris from ever entering the ocean.

The VWG's terms of reference identify six objectives:

1. *promote plastics recycling*
2. *pilot innovative technologies*
3. *advance education and information sharing*
4. *build on existing public-private partnerships*
5. *share existing and develop new best practices*
6. *create partnerships, including with other regional organizations as appropriate.*

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

The work of the Regulators Forum will be a key contributor to advancing commonalities in regulatory practice and information sharing and promoting and practicing the best regulatory principles which have been outlined and established by the Forum.

The trade in chemicals has become increasingly important to the APEC region and the role of the CD in identifying issues and promoting best regulatory management remains highly relevant. It is a unique structure which continues to service as a forum for regulatory officials and industry representatives to find solutions to challenges facing the chemical industry and users of chemicals in the Asia-Pacific region. It reflects APEC members' recognition of the importance of engaging with the private sector and building public-private sector dialogue and cooperation for mutual benefit.

### 2.10. Contact Details

#### Chair

**Bryant P. Trick (Mr.)**

Deputy Assistant U.S. Trade Representative  
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#### Co-Chair

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#### Secretariat (based in Singapore)

**David WU (Mr.)**

Program Director

APEC Secretariat

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### 2.11. APEC Chemical Dialogue Terms of Reference

#### 1. The Mandate for the Dialogue

At the November 2000 Joint Ministerial Meeting in Brunei, Ministers “welcomed the initiative to establish a Chemical Dialogue comprising government and industry representatives” and said that “such public-private sector dialogues were important for improving the mutual understanding of key imperatives for the development of future policy and for enhancing the competitiveness of the industry.”

#### 2. The Purpose of the Dialogue

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

2.1. The Chemical Dialogue is an exchange of views (conducted at a series of meetings) in accordance with the Ministerial mandate between private sector chemical industry representatives and appropriate government officials who are involved in developing trade and trade-related regulatory policy within APEC member economies. Accordingly, the Dialogue will discuss trade and trade-related regulatory issues affecting the competitiveness and sustainable development of the industry in the Asia-Pacific region. The Dialogue will progressively develop a work program according to priorities identified by industry and officials in the course of their joint discussions, which may focus on non-tariff measures, trade facilitation, and economic and technical cooperation related to the chemical industry in the Asia-Pacific region.

2.2. Based on these discussions, the Dialogue will develop recommendations to facilitate trade in the chemicals sector and enhance the competitiveness and sustainable development of the industry in the region. Some APEC Member Economies may choose to move more quickly than others in terms of implementing recommendations as is consistent with APEC's flexible, voluntary and consensus oriented approach to trade facilitation and economic and technical cooperation.

### *3. The Structure of the Dialogue*

3.1. The Dialogue will be held annually. The work program and outcomes of the Dialogue will be reported to the CTI and, where appropriate, through the CTI to APEC Senior Officials, Ministers and Leaders. The work program and outcomes may also be conveyed to the APEC Business Advisory Council (ABAC) and other relevant APEC fora.

3.2. The Dialogue will meet twice a year, with the precise schedule determined each year to allow flexibility. The proposed schedule of meetings in any one year, including the annual Dialogue meetings, will be agreed and deposited with the APEC Secretariat in a timely manner for inclusion in the APEC calendar.

3.3. The annual Dialogue meetings will involve appropriate representatives of the chemical sector and of APEC member economies.

3.4. The Dialogue will be supported by a Regulators' Forum which will operate as a sub-forum of the Dialogue. The Forum will serve to bring together chemical regulators from APEC economies to share information and knowledge on chemical management practices, and promote opportunities for collaboration to address issues of mutual concern. The Forum's work will be governed by a terms of reference approved by the Dialogue and its work program and outcomes will be submitted to the Dialogue and will form a core component of the Dialogue's work for potential reporting to the CTI. Consistent with the public-private nature of the Dialogue, industry will participate in, and contribute to, the work of the Forum.

### *4. Administration of the Dialogue*

4.1. The Dialogue will be Co-Chaired by a representative of the chemical industry and a representative from the public sector to coordinate private sector views and public sector positions. Co-Chairs would be selected by the Dialogue from a list of nominees to serve for a term of up to two years, which can be extended by the Dialogue's agreement.

4.2. To facilitate the work of the Co-Chairs of the Dialogue each member economy is invited to designate up to two contact points to coordinate that member economy's participation in the Dialogue.

4.3. The names of the Co-Chairs and contact details, as well as the two contact points from each economy, will be deposited with the APEC Secretariat by the Dialogue coordinator. The Dialogue's Program Director from the Secretariat will be responsible for ensuring that these contact points remain current and that each economy has a minimum of one current lead contact.

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

4.4. The Dialogue will regularly review and revise its terms of reference to ensure they continue to guide its ongoing work.

4.5. The Dialogue's sub-fora, including the Forum as well as any virtual working groups approved by the Dialogue, will agree on terms of reference to govern their work which will be approved by the Dialogue. The sub-fora will regularly review and revise these terms of reference to ensure they remain relevant.

### **2.12. Strategic Framework for Chemicals in the Asia-Pacific Region 2017-2019**

#### **Promoting Sustainability and Innovation through Chemistry**

##### *Preamble*

##### *Committee on Trade and Investment*

Trade and investment liberalisation and facilitation are the cornerstones of APEC's mission and activities. The Committee on Trade and Investment (CTI) is the coordinating body for all of APEC's work in these areas.

The CTI provides a forum for APEC's member economies to deliberate trade and policy issues. It works to reduce impediments to business activity, with the objective of helping APEC economies achieve free and open trade and investment. The CTI oversees:

Eight sub-groups:

- Business Mobility Group (BMG)
- Electronic Commerce Steering Group (ECSG)
- Group on Services (GOS)
- Intellectual Property Experts' Group (IPEG)
- Investment Experts' Group (IEG)
- Market Access Group (MAG)
- Sub-Committee on Customs Procedures (SCCP)
- Sub-Committee on Standards Conformance (SCSC)

Three industry dialogues:

- Automotive Dialogue (AD)
- Life Sciences Innovation Forum (LSIF)
- Chemical Dialogue (CD)

The CTI was established in November 1993 by the Declaration of an APEC Trade and Investment Framework. APEC Leaders and Ministers direct its work and APEC Senior Officials provide guidance. The scope of the CTI's work was expanded and further clarified by the Osaka Action Agenda in 1995.

##### *Chemical Dialogue*

The APEC Chemical Dialogue serves as a forum for government officials and industry representatives to find solutions to challenges facing the chemical industry and users of chemicals in the Asia-Pacific region. It reflects APEC member economies' recognition of the importance of engaging with the private sector and building public-private sector dialogue and cooperation for mutual benefit.

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

Issues addressed by the Chemical Dialogue include chemical sector liberalisation, chemical trade facilitation, capacity building and product stewardship. The Chemical Dialogue also focuses on improving regulatory policies and business practices with a view to reducing trade barriers and to protect public health and safety and the environment.

The Chemical Dialogue has developed this Strategic Framework to guide its work, to achieve its objectives, and to help position the industry as a strategic contributor to the economy, sustainable innovation and trade in the region.

The APEC Chemical Strategic Framework for 2017-2019 has been developed in line with the APEC Chemical Dialogue Terms of Reference and reflects broader APEC strategic objectives such as: strengthening regional economic integration and expanding trade; promoting green growth; and expanding regulatory cooperation and advancing regulatory convergence.

This framework is designed to guide the strategic priorities and actions that the Chemical Dialogue will undertake in the years 2017 – 2019. Following the review of CTI sub fora during the Chinese host year (2014), this document also complements the review by the APEC secretariat into the action plans and terms of reference of the contributing virtual working groups. These include:

- *Virtual Working Group on Regulatory Cooperation and Convergence*
- *Virtual Working Group on the Globally Harmonised System (GHS) for Chemical Labelling*
- *Virtual Working Group on Data Exchange*
- *Virtual Working Group on Marine Debris*

### *The importance of the chemical industry for APEC*

The chemical industry makes a considerable contribution to the economy and is one of the world's largest industrial sectors, with many chemicals produced and traded internationally. It is composed of small, medium and large domestic and international companies. Global sales in 2015 amounted to over \$US5.2 trillion, with nearly \$US2.0 trillion in exports. It is a transformative industry and a key economic building block in APEC economies. World chemical exports for 2015 were valued at US\$1.96 trillion with the Asia-Pacific region contributing 27 per cent of the total exports—25 per cent of which is China— North America contributing 12 per cent and half of the world's exports originated in Western Europe.<sup>5</sup> The APEC share of global chemical exports has grown significantly over the last several years. This demonstrates the increasing contribution of chemicals in APEC economies' exports of manufactured goods and the economic growth and industry importance to the APEC region and economies.

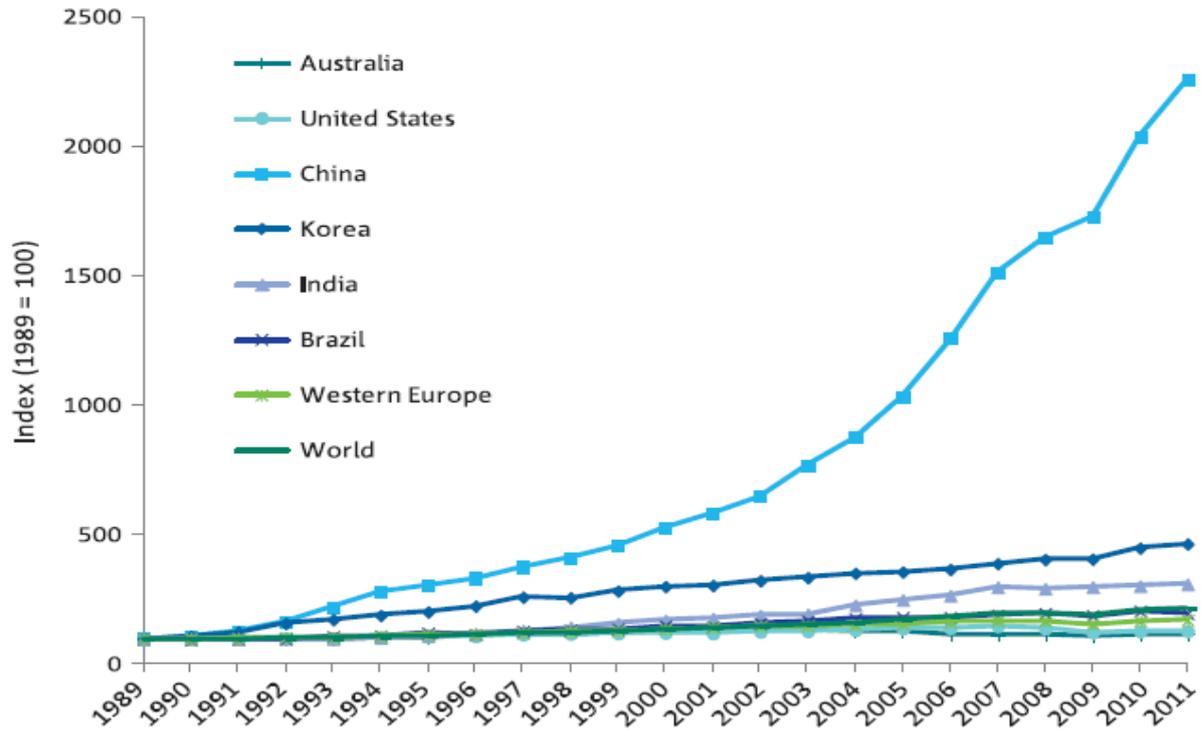
**Figure 2.4. - The ACC Global Chemical Production Regional Index, 1989-2011, selected countries and world output<sup>6</sup>**

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<sup>5</sup> American Chemistry Council, Business of Chemistry 2016 (Annual Data).

<sup>6</sup> ACC. (2012). 2012 Guide to the Business of Chemistry. Washington D.C.: American Chemistry Council.

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

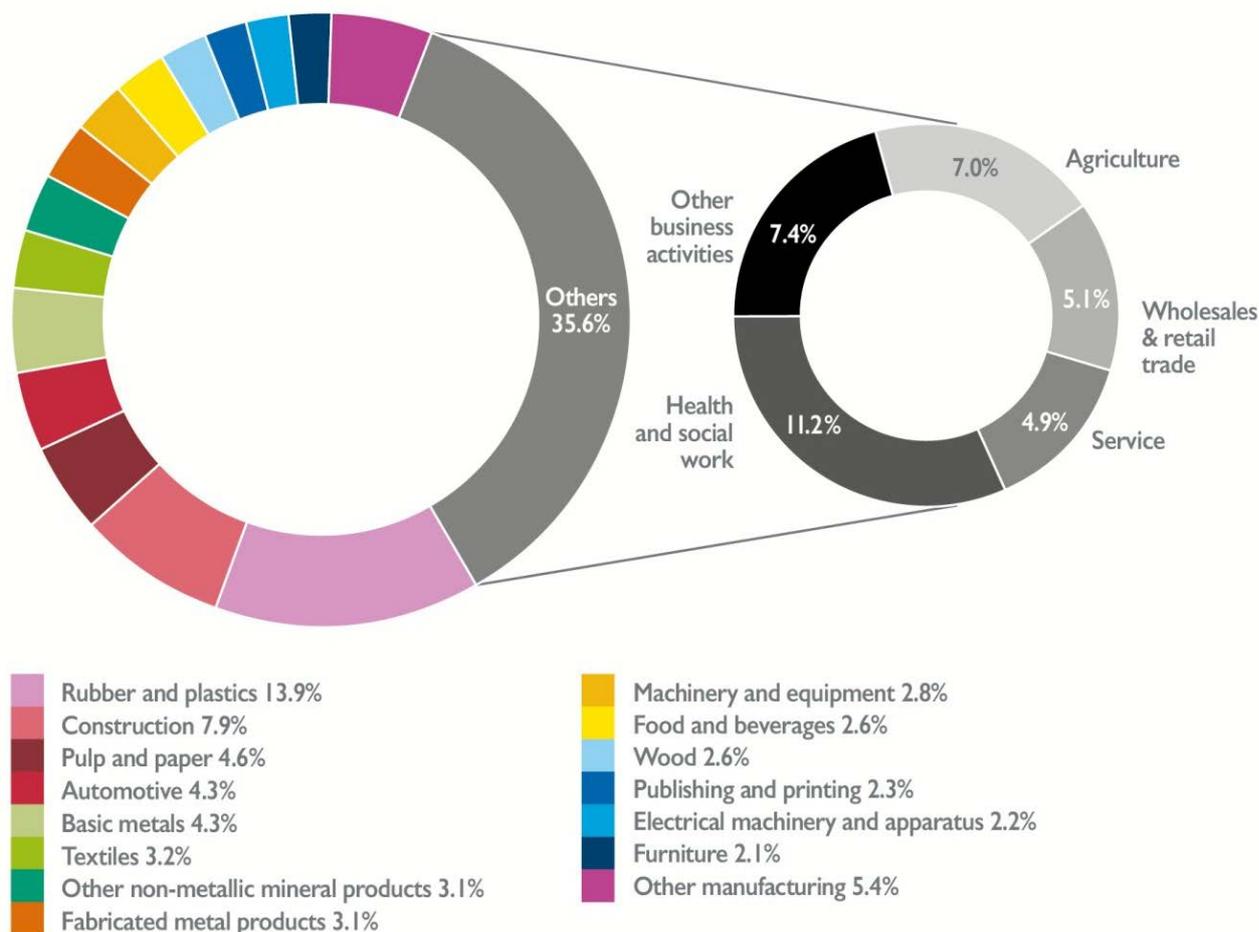


The chemical industry contributes in many ways to the products and services that consumers and industries use in their day-to-day activities. The industry is a cross cutting sector that contributes to almost all industrial and many non-industrial sectors. Almost every industry purchases some products and services of chemistry and, therefore, depends on the business of chemistry. Indeed, more than 96 per cent of manufactured goods are directly touched by chemistry. As an example of the role chemical industry plays in other aspects of the economy, Figure 2.5. demonstrates the contribution of chemical industries to other sectors in Europe.

**Figure 2.5. - Contribution of the chemical industry to the EU economy<sup>7</sup>**

<sup>7</sup> Cefic: Chemical Industry Profile 2014 – Eurostat and Cefic Analysis

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue



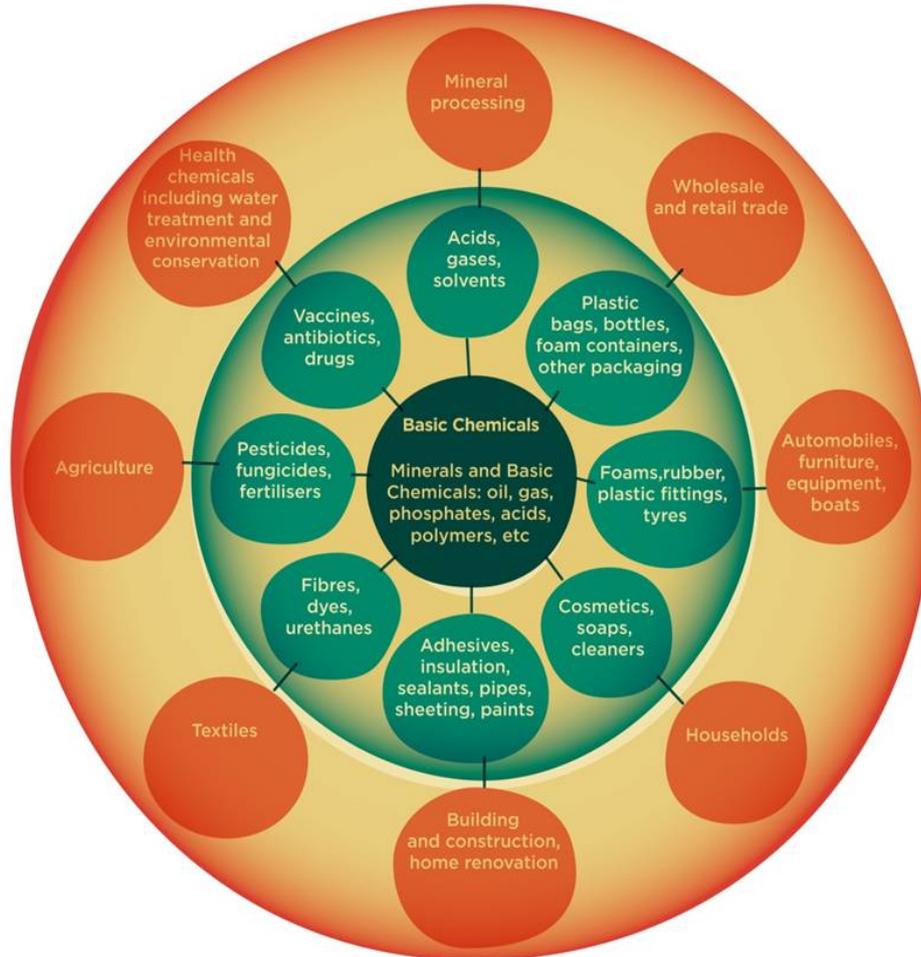
The chemical industry is extremely diverse. Its products and services are fundamental to the economic and social wellbeing of member economies. The global chemical industry is intensely competitive and needs a level playing field in APEC economies to enable it to compete effectively in the global economy. Thousands of new chemical products enter the global market every year in an environment of increasing technical complexity.

The chemical industry continues to contribute to the development of innovative products and services that make people's lives better, healthier and safer - from small improvements in everyday life to fundamental advancements in science and technology. Chemistry is synonymous with innovation and innovative business practices. From medicine to energy to computing to transport and many more industries beyond, the chemicals and plastics industry has provided the products and services that increasingly continue to shape the world. The industry's social license to operate is based on it ensuring worker, consumer and environmental safety.

**Figure 2.6. - Linkages between the chemicals and plastics industry and other industries<sup>8</sup>**

<sup>8</sup> Source: Plastics and Chemicals Industries Association *Workshop Forum: Key Themes and Directions*, 22 April 2010

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue



The chemical industry’s contribution to global productivity is of a significant magnitude having grown at a brisk pace for more than five decades. In 2015, China accounted for 37per cent of total global chemical production – more than North America and Western Europe combined. This compares to only 11 per cent a decade ago. More recent growth in global chemical production can be attributed to accelerating rates in Asia.

APEC member economies are a growing source of influence in the global trade of chemicals as the tables below show. This is consistent with the “Asian Century” trends experienced in other sectors. The APEC share in world chemical production is increasing as non-OECD economies, particularly Russia, India, Indonesia, China, South Africa and Brazil, expand their capacity. The APEC share of world chemical exports has increased some 3per cent over the last 2 years, particularly with the increasing export base of China and Indonesia. Chemical imports to the APEC region have also increased commensurately, 6per cent over the last 2 year period.

**Table 2.3. - Chemical Exports to the World (Millions, US Dollars, current prices),  
Chemical Exports as a Percent of Manufacturing Exports<sup>9</sup>**

	2010	2011	2012	2013	2014	2000	2014
<b>Australia</b>	7,200	8,090	8,659	7,515	6,617	18%	23%
<b>Brunei</b>							
<b>Darussalam</b>	2	3	250	92	472	NA	66%
<b>Canada</b>	33,153	39,432	37,043	37,870	37,993	8%	18%

<sup>9</sup> Source: World Trade Organization Trade Profile Time Series Data 2016

History of the Asia-Pacific Economic Cooperation (APEC)  
Chemical Dialogue

<b>Chile</b>	2,850	3,508	3,850	3,582	3,390	37%	33%
<b>China</b>	87,519	114,723	113,516	119,560	134,481	6%	6%
<b>Hong Kong, China</b>	18,424	19,986	19,523	18,778	17,789	5%	4%
<b>Indonesia</b>	8,164	11,568	10,599	10,979	10,105	9%	14%
<b>Japan</b>	78,419	84,505	78,954	75,822	72,245	8%	12%
<b>Korea, Republic of</b>	48,948	60,704	61,282	66,161	66,972	9%	14%
<b>Malaysia</b>	12,664	15,102	14,923	15,128	15,853	5%	11%
<b>Mexico</b>	11,853	14,187	15,396	15,590	15,726	4%	5%
<b>New Zealand</b>	1,360	1,652	1,865	1,921	2,091	27%	25%
<b>Papua New Guinea</b>	NA	38	220	NA	NA	0%	NA
<b>Peru</b>	1,018	1,372	1,328	1,185	1,204	14%	25%
<b>Philippines</b>	1,554	1,874	1,927	2,469	2,212	1%	5%
<b>Russian Federation</b>	24,614	31,247	31,544	29,092	32,336	28%	31%
<b>Singapore</b>	39,711	51,510	53,975	50,084	52,936	8%	18%
<b>Taiwan (Chinese Taipei)</b>	35,516	40,640	37,971	39,120	37,851	7%	14%
<b>Thailand</b>	16,932	22,788	23,125	24,363	24,716	8%	15%
<b>United States</b>	189,101	207,248	206,579	208,525	211,683	12%	18%
<b>Viet Nam</b>	1,876	2,869	3,745	3,829	4,364	2%	4%
<b>APEC Total</b>	620,877	733,049	726,274	731,665	751,035	9%	11%
<b>World</b>	1,707,664	2,002,238	1,958,865	1,993,991	2,053,848	13%	17%
<b>APEC per cent of World</b>	36%	37%	37%	37%	37%		

**Table 2.4. - Chemical Imports to the World (Millions, US Dollars, current prices), Chemical Imports as a Percent of Manufacturing Imports<sup>10</sup>**

	2010	2011	2012	2013	2014	2000	2014
<b>Australia</b>	20,133	24,648	24,923	22,846	22,406	14%	14%
<b>Brunei Darussalam</b>	257	245	242	288	304	NA	12%
<b>Canada</b>	41,598	45,802	46,888	47,864	48,494	10%	14%
<b>Chile</b>	5,976	7,442	8,055	8,179	7,867	18%	16%
<b>China</b>	149,417	180,542	178,567	189,635	191,841	18%	16%
<b>Hong Kong, China</b>	23,206	24,471	23,455	22,267	21,907	7%	4%
<b>Indonesia</b>	16,678	22,208	23,639	23,556	23,754	19%	23%
<b>Japan</b>	60,831	75,677	73,413	65,622	64,272	12%	16%
<b>Korea, Republic of</b>	40,961	47,969	47,091	46,665	47,195	14%	17%
<b>Malaysia</b>	14,981	17,598	17,648	18,623	19,728	9%	14%
<b>Mexico</b>	34,057	39,547	41,780	43,120	45,544	10%	14%
<b>New Zealand</b>	3,536	4,169	4,252	4,292	4,419	16%	15%
<b>Papua New Guinea</b>	NA	306	310	NA	NA	12%	NA

<sup>10</sup> Source: World Trade Organization Trade Profile Time Series Data 2016

## History of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue

<b>Peru</b>	4,403	5,465	5,865	6,105	6,057	22%	20%
<b>Philippines</b>	5,585	6,761	6,712	6,491	7,453	10%	17%
<b>Russian Federation</b>	30,416	37,186	38,307	40,166	37,374	21%	17%
<b>Singapore</b>	20,732	25,278	25,718	25,209	25,513	7%	11%
<b>Taiwan (Chinese Taipei)</b>	34,442	39,920	35,768	35,570	35,148	14%	21%
<b>Thailand</b>	19,896	23,762	23,898	23,592	23,455	15%	16%
<b>United States</b>	177,007	202,081	199,684	199,962	211,880	8%	12%
<b>Viet Nam</b>	12,475	15,528	16,140	18,178	20,551	0%	18%
<b>APEC Total</b>	716,585	846,607	842,353	848,232	865,162	10%	14%
<b>World</b>	1,752,247	2,053,997	2,008,889	2,060,006	2,116,212	13%	17%
<b>APEC per cent of World</b>	41%	41%	42%	41%	41%		

### *APEC Context*

APEC Leaders have identified sustainable growth and innovation as key aspects of the APEC agenda for the near term, and have committed to accelerating work on regional economic integration issues such as regulatory convergence and cooperation, border controls, improved regulatory frameworks and rules of origin. APEC Leaders have also encouraged inclusive growth, ensuring that small and medium enterprises benefit from regulatory reform and innovation.

The Chemical Dialogue developed this Strategic Framework to better direct its work, particularly in light of the increased focus by APEC member economies on chemical regulatory systems. It links the broader APEC policy objectives to activities being undertaken in the Chemical Dialogue arena. The original 2011-13 Framework was evaluated in 2013, with economies agreeing that it was valuable in guiding the work of the Chemical Dialogue. This document is the third Framework covering 2017-19.

The Regulator's Forum reports to the Chemical Dialogue and provides an opportunity for member economies' regulators to discuss emerging issues and share best practices. Activities include capacity building for risk assessment on metals and metal compounds and increased collaboration with the OECD Clearing House on New Chemicals. The Regulators Forum provides applied regulatory advice and knowledge of how member economy regulatory systems interact to meet Chemical Dialogue aims.

### *Global Context*

Chemicals management will remain high on the international agenda over the next three years. Continued cooperation between international forums is essential to encourage information sharing and the development of sound chemicals management and sustainable development. Significant joint efforts continue in the implementation of the Globally Harmonized System (GHS) for the Labelling of Chemicals. The 2017-2019 period will also be critical for the United Nations (UN) Strategic Approach to International Chemicals Management (SAICM), whose current mandate expires in 2020. The adoption, in 2015, of the UN Sustainable Development Goals (SDGs) will bring a greater focus on the economic, social and environmental pillars of sustainable development as part of the 2030 Development Agenda.

Significant changes have occurred in the EU in the last decade through the introduction of REACH legislation. The Organization for Economic Cooperation and Development (OECD) continues

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to participate in chemical management issues hosting its Joint Meeting of the Chemicals Committee and Working Party of Chemicals, Pesticides and Biotechnology.

Product stewardship, corporate responsibility and responsible management of the whole lifecycle of chemical products are areas of promotion and interest to both Government and Industry members of the Chemical Dialogue.

The APEC region continues to expand as a chemical producer, exporter and importer. The increasing re-distribution of chemical manufacturing industries from advanced economies to developing APEC economies is increasing the need for greater alignment in regulation to open markets and increase trade flows.

### *Challenges and Opportunities*

Over the next three years, APEC meetings will be hosted by Vietnam, Papua New Guinea and Chile. The CD will seek to address issues related not only to the business of chemistry, but also to the role of chemistry as an innovative solutions industry that promotes energy efficiency, greenhouse gas reductions, and technology breakthroughs in electronics, aerospace, medicine and other industries.

Governments are becoming increasingly committed to facilitating innovation and trade. The global chemical regulatory environment is undergoing change. Rightly, nation states determine their own chemical regulatory systems, resulting in varying regulatory approaches. To assist trade, the challenge is to identify commonalities between systems that may reduce the cost on industry.

The Chemical Dialogue has already advanced the pace and intensity of discussions and outcomes on chemical-related issues. The Dialogue is seeking to extend this work, including through the activities of the Regulators Forum, and the CD Virtual Working Group on Regulatory Cooperation, to facilitate risk reduction and the sound management of chemicals and bridge principles to practice by sharing tools and experiences on sound regulatory practices among member economies. It provides for capacity-building and information sharing and identifies issues of common interest to the diverse APEC membership. The Forum assists in promotion of best chemicals management approaches and provides a technical and regulatory resource network for the region.

There are substantial challenges facing the APEC region's chemical sector. As APEC members search for ways to improve the lives of their citizens in a responsible manner, the chemicals sector needs to position itself as an enabler of innovation. The globalisation of chemical trade has placed a new desire for innovation and sustainable chemistry within products and processes. Markets are demanding products that create less environmental impacts or that can be recycled or managed at the end of their lifecycle. The desire by nations to reduce the volume of plastic waste in landfill and in our oceans is also a concern that can be assisted by the development of new chemistry.

An interconnected system which leverages the regulatory needs of different nations allows chemicals to be more easily traded. The need to balance regulatory controls with the inherent risks of a chemical product needs to be communicated clearly to reduce harm and educate users of the beneficial uses of chemistry. As markets become more interconnected the role of chemical regulators will be to ensure that public and environmental safety is preserved while reducing unnecessary barriers to market entry.

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Challenges	Opportunities
<ul style="list-style-type: none"><li>• The role of the chemical industries in combating plastic pollution and supporting sustainable economic and environmental development.</li><li>• Ensuring safety and confidence in chemical trade through the complex regulatory systems operating around the world.</li></ul>	<ul style="list-style-type: none"><li>• Expansion of larger chemical market's regulatory systems provides the impetus for members to focus on common regulatory practices to reduce industry burden and increase market access</li><li>• New “green” and “sustainable” chemistry products and practices position the chemical industry to be a driving force for innovation and environmental sustainability.</li></ul>

### *Strategic Objectives*

The Chemical Dialogue has agreed to the following overarching strategic objectives for *the APEC Chemical Strategic Framework 2017 – 2019*:

- *To facilitate alignment of the Leaders' goals for sustainable economic growth and regulation.*
- *To promote regulatory capacity to facilitate trade while supporting environmental and health protection.*
- *To enhance chemical management and product stewardship over the life cycle and in cooperation with other initiatives and institutions where appropriate, e.g., the OECD, UN, SAICM, WHO.*
- *To identify barriers to utilizing chemicals, products and processes to achieve sustainable and innovative solutions in the APEC region.*
- *To strengthen the positioning of the sector globally as an enabler of technological change and innovation as part of meeting challenges across the three key areas of focus for APEC – trade and investment liberalization; business facilitation; and economic and technical cooperation.*

### *Goals*

The goals and supporting actions identified below give effect to the strategic objectives of *the APEC Chemical Strategic Framework 2017 – 2019*:

**Shared Goal 1: To facilitate trade by expanding and supporting regulatory cooperation and mutual recognition in the region**

- Building support for and participation by chemical regulators in the Chemical Dialogue's Regulators' Forum to exchange information on best practices in the sound management of chemicals in order to lift the capability and capacity of developing economies.*
- Identifying opportunities to enhance regional economic integration in chemicals, in particular through regulatory convergence and cooperation.*
- Promoting alignment in GHS implementation, taking UN's recommendations and members' laws and policies into consideration, across member economies and sharing information on GHS implementation status.*

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- d. *Identifying specific opportunities to engage with key international fora working on chemicals-related issues such as the OECD, UN, WTO and WHO.*
- e. *Conducting outreach to include SMEs, and entities such as downstream users and article manufactures along the value chain in the sound management of chemicals, in order to promote common understanding, and facilitate regional economic integration.*
- f. *Continuing to serve as a forum to exchange information about chemical regulatory initiatives within and outside of the APEC region.*

**Shared Goal 2: To promote understanding of the chemical industry's role as a provider of innovative solutions for sustainable economic, environmental and social development**

- a. *Identifying barriers to and opportunities for the use of chemicals, products and processes to achieve the three pillars of sustainable development: economic, environmental and social.*
- b. *Highlighting the importance of products and technologies enabled by chemistry for advancing global sustainable development and facilitating progress towards achieving the UN Sustainable Development Goals.*
- c. *Encouraging the development of enabling policy and regulatory frameworks to facilitate the innovation and deployment of chemical technologies and solutions.*

**Shared Goal 3: To enable effective cooperation between industry and governments to improve chemical product stewardship and safe use**

- a. *Leveraging voluntary industry stewardship activities (e.g. industry's Responsible Care program, industry commitments to provide appropriate hazard, use and exposure information, and risk information and management).*
- b. *Taking into account the special needs of SMEs, develop specific tools that can enhance chemical management capabilities (e.g. life cycle assessment and risk assessment).*
- c. *Promoting chemical product stewardship and consumer information as components of the safe use of chemicals, in partnership with external stakeholder groups, where appropriate.*

### *Conclusions*

The shift to greater chemical production to the APEC region provides more influence in global practices but also a shift in greater responsibility. The Framework continues to call for greater outreach to international fora. Current efforts to lift the capability and capacity of developing economies and small and medium businesses should be maintained. Promoting best practices and sharing information between economies in relation to risk assessment and management is key to facilitate trade and protect health and the environment. The Framework also provides scope for the APEC chemical industry to position itself as a provider of sustainable and innovative global solutions to make people's lives better, healthier and safer. By progressing work that contributes to sustainable growth and responsible product stewardship the industry will build trust with the community.

## **2.13. Principles for Best Practice Chemical Regulation 2008**

### *PART 1: PREAMBLE*

#### 1.1 Why regulate chemicals?

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We use chemicals every day and they are an integral part of our lives. The global production, trade, use, recycling and disposal of chemicals continues to increase with demand. When appropriately managed, chemical products contribute to the social and economic wellbeing of Member Economies.

It is only through the sound management of chemicals in protecting human health and our environment that economies are able to enjoy the full benefits that the use of chemicals can offer.

The sound management of chemicals may be viewed as the application of managerial best practice to chemicals throughout their life-cycle, so as to minimise risks of health and environmental impacts from the production, use and disposal of chemicals.

The role of government is to provide a policy and regulatory framework to ensure the safe and sustainable use of chemicals and to deliver a business operating environment which stimulates growth, innovation and trade. Governments regulate chemicals to protect human health, worker safety and the environment.

The challenge is to deliver efficient and effective regulation without undue burden on those being regulated.

### 1.2 What is Chemical Regulation?

Chemical regulation can be defined as a government endorsed measure(s) or intervention(s) that influences the way chemicals are manufactured and used across the product life cycle by industry, the community and individuals.

The challenge is to design and implement regulation which is no more trade restrictive than necessary to achieve its stated objectives.

In practice, regulation is usually a blended approach of voluntary, co-regulatory and legislative mechanisms undertaken in partnership between government, industry and community.

### 1.3 Why Best Practice Regulation?

The controls imposed on the chemical industry are many and often arise from cross jurisdictional responsibilities that may result in duplication of regulatory effort by Member Economies. These pressure points create an unstable business environment which detracts from other investments in research and development and innovation designed to help increase the competitiveness, efficiency and safety of chemicals in the marketplace of our region.

Achieving good regulation involves the integration of a number of key factors including:

- *sound and credible science to identify the problem;*
- *an effective risk management framework that considers costs and benefits and socio-economic factors;*
- *regulations that are commensurate with the risk posed;*
- *flexibility in the application and type of measures to best deliver desired outcomes;*
- *the avoidance of duplication;*
- *transparent and consistent approaches and open decision making processes;*
- *public participation and engagement in partnership approaches; and*
- *The wide availability of chemical safety information tailored to stakeholders needs.*

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These factors are applicable to the consideration and development of full spectrum of regulatory measures including voluntary, co-regulatory and/or legislative mechanisms.

The Principles for Best Practice Chemical Regulation also provide Member Economies with a mechanism for the identification of areas that would benefit most from regulatory reform, as well as assisting with market reform and openness and the application of best practices where appropriate.

### *PART 2: PURPOSE OF PRINCIPLES FOR BEST PRACTICE CHEMICAL REGULATION*

#### 2.1 APEC Agreed Regulatory Principles

APEC Member Economies already recognize that regulatory reform is a central element in the promotion of open and competitive markets, and a key driver of economic efficiency and consumer wellbeing. This is reflected in the agreement for an APEC-OECD Co-operative Initiative on Regulatory Reform reached in June 2000 and endorsed at the APEC Ministerial Meeting on 12-13 November 2000 in Brunei Darussalam.

Many economies within APEC have individually embarked on ambitious programmes to reduce regulatory burdens and improve the quality and cost-effectiveness of regulations. Member Economies have collectively endorsed regulatory reform principles and policy recommendations at the highest political levels.<sup>11</sup>

#### 2.2 Benefits of Chemical Specific Best Practice Regulation Principles

Although there is no single model of regulatory reform, the development of a set of guiding principles for best practice chemical regulation aims to promote consistency and facilitate harmonised approaches for cooperation by Member Economies to the regulation of the chemical industry.

The value in Member Economies exploring the development of a best practice framework for chemical regulation lies in the opportunity to address the business uncertainties. This should result in greater innovation, safer technologies, enhanced trade at reduced business costs and is consistent with the objective for the safe and sustainable use of chemicals. Further, regulators in Member Economies benefit from the ability to cooperate on issues of mutual concern, exchange information, coordinate, share burdens associated with potential elements of risk assessment and facilitate risk management solutions where necessary.

#### 2.3 Guidelines and Practical Tools

This document is aimed at providing a suitable framework for Member Economies to use when developing and implementing regulatory measures. The framework is considered broad enough to be utilised by Member Economies regardless of social, political or economic environments or stage of development.

A compendium of case studies and practical experiences may help to promote greater opportunities for learning as well as for cooperation between Member Economies. This cooperation may come from enhanced information sharing/exchange, harmonisation or mutual recognition or through a work share program.

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<sup>11</sup> The 1999 APEC Economic Leader's Declaration, containing the APEC Principles to Enhance Competition and Regulatory Reform, The 1997 OECD Policy Recommendations on Regulatory Reform, and The 1995 OECD Recommendation on Improving the Quality of Government Regulation.

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*PART 3: PRINCIPLES FOR BEST PRACTICE CHEMICAL  
REGULATION*

According to the OECD and other experts, regulations that conform to best practice are characterised by the following nine principles and features:

**PRINCIPLE 1: CHEMICAL REGULATIONS SHOULD BE THE  
MINIMUM REQUIRED TO ACHIEVE THEIR STATED OBJECTIVES**

- *Minimum necessary to achieve objectives:*
  - Ensure overall benefits justify costs, and ensure that the regulatory approach chosen has higher net benefits than its feasible alternatives.
  - Keep simple to avoid unnecessary restrictions
  - Target at the problem to achieve the objectives
  - Do not impose an unnecessary burden on those affected
  - Do not restrict competition, unless demonstrated net benefit
- *Not unduly prescriptive*
  - Performance and outcomes focussed
  - General rather than specific
- *Accessible, transparent and accountable*
  - Readily accessible to the public
  - Easy to understand
  - Flexible enough to deal with special circumstances
  - Open to appeal and review
- *Integrated and consistent with other laws*
  - Address a specific market failure or other significant problem not addressed by other regulations
  - Recognise existing regulations so as to avoid overlap/duplication and international obligations
- *Recognise industry voluntary measures*
  - Voluntary industry programs such as Responsible Care and the Global Products Strategy provide effective tools to help manage the health, safety and environmental aspects of a chemical throughout its lifecycle
- *Communicated effectively*
  - Written in plain language
  - Clear and concise
- *Mindful of the compliance burden imposed*
  - Proportionate to the problem

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- Set at levels that avoid unnecessary costs
- *Enforceable*
  - Provides minimum incentives needed for reasonable compliance
  - Able to be monitored and policed effectively
  - Fairly and consistently enforced

### PRINCIPLE 2: CHEMICAL REGULATIONS SHOULD ADOPT A RISK MANAGEMENT APPROACH TO DEVELOPING AND ADMINISTERING REGULATION

The term ‘risk’ refers to the probability that a particular hazard will cause harm, or that it may lead to the occurrence of an undesirable event. The analysis of risk comprises an understanding of both hazards and exposure so that well-defined systems will enhance decision making by contributing to a greater insight into risks and their potential consequences.

It is through strategic analysis of the environment in which the regulatory body operates that those elements that may generate future risks will be identified and assessed. The objective of risk analysis is to develop efficient and effective risk management strategies through the analysis of data to assist in the identification, assessment and management of risk.

The benefits of prudent risk management are:

- *A more rigorous basis for strategic planning as a result of a structured consideration of the key elements of risk.*
- *No costly surprises or unintended consequences to industry.*
- *Better outcomes in terms of program effectiveness and efficiency, e.g., improved service and/or better use of resources.*
- *Greater openness and transparency in decision-making and ongoing management processes.*
- *A better preparedness for, and facilitation of, positive outcomes from subsequent internal/external review and audit processes.*

### PRINCIPLE 3: CHEMICAL REGULATIONS SHOULD MINIMIZE THE IMPACT ON COMPETITION

Regulation should be designed to have minimal impact on competition. Although it may be necessary, for example, to regulate some aspects of commercial practice, regulation should avoid imposing barriers to entry, exit, or innovation. Regulation should not restrict competition unless it can be demonstrated, in a fully transparent manner, that:

- *the benefits to the community from a restriction on competition outweigh the costs; and*
- *that the objectives of regulation can only be achieved by restricting competition.*

### PRINCIPLE 4: CHEMICALS REGULATORS SHOULD UTILIZE RELEVANT INTERNATIONAL STANDARDS WHEREVER POSSIBLE

The WTO Agreement on Technical Barriers to Trade (TBT) recognizes the important contribution that international standards make in furthering the objectives of the General Agreement on Tariffs and Trade (GATT) 1994 by improving efficiency of production and facilitating international commerce. The Agreement obliges WTO Members to use relevant international standards (if such standards exist or their completion is imminent), or the relevant parts thereof, as a basis for their technical regulations, except when such standards or their relevant parts would be an ineffective or inappropriate means for fulfilling the legitimate objectives pursued.

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Within APEC, Member Economies have committed to harmonizing their standards, for example:

- *with international standards, wherever possible, by the year 2010 in the case of industrialised economies and 2020 in the case of developing economies;*
- *for radios and their parts, televisions, video apparatus, refrigerators, air-conditioners, industrial robots, rubber surgical and examination gloves, rubber condoms and food labelling by the year 2000 in case of industrialised economies and the year 2005 in the case of developing economies; and*
- *for electrical safety and electromagnetic compatibility with the IEC 60335 and CISPR series of standards, respectively, by the year 2004 in the case of industrialised economies and the year 2008 in the case of developing economies.*

### PRINCIPLE 5: CHEMICAL REGULATIONS SHOULD NOT RESTRICT INTERNATIONAL TRADE FLOWS

There should be no discrimination in the way technical regulations, standards, and conformity assessment procedures are applied between domestic and imported products, nor between imports from different supplying economies. Regulations should not be applied in a way that creates unnecessary obstacles to international trade.

### PRINCIPLE 6: CHEMICAL REGULATIONS SHOULD BE DEVELOPED IN CONSULTATION WITH STAKEHOLDERS, SUBJECT TO PUBLIC REVIEW AND COMMENT AND PERIODIC REVIEW

Effective consultation is fundamental in ensuring that the optimal regulatory outcomes are achieved. Consultation ensures that both the regulator and the regulated understand the problems, have alternative options to address the problems, and can identify costs as well as enforcement and compliance mechanisms in administering the regulatory requirements. It also enables civil society to engage directly with government in identifying and addressing problems, leading to a more engaged and constructive dialogue with all parties involved. Consistent with APEC's Transparency Standards<sup>12</sup> as agreed by Leaders in 2002 and 2003, consultation should involve procedures that provide for advance notice of proposed rule-making; an adequate comment period; notice of final regulation, which should include a thorough response to comments received; and, adequate time for implementation.

The seven principles for best practice consultation are:

- *Continuity - Consultation should be a continuous process that starts early in the policy development process.*
- *Openness - Consultation should be widely based to ensure it captures the diversity of stakeholders affected by the proposed changes. This includes the affected industry, the general public; trading partners; and relevant departments and agencies at all levels of government.*
- *Appropriate timeliness - Consultation should start when policy objectives and options are being identified and comments can still be taken into account. Throughout the consultation*

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<sup>12</sup> APEC Transparency Standards available at:  
[http://www.apecsec.org.sg/apec/leaders\\_declarations/2003\\_leadersstmtimplapectranspstd.html](http://www.apecsec.org.sg/apec/leaders_declarations/2003_leadersstmtimplapectranspstd.html).

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*process, stakeholders and the general public should be given sufficient time to provide considered responses.*

- *Accessibility - Stakeholder groups and the general public should be informed of consultation through publication of proposed measures (preferably by electronic means), and be provided with information about proposals, via a range of means appropriate to those groups.*
- *Transparency - Policy agencies need to explain clearly the objectives of the consultation process and the regulation policy framework within which consultations will take place, and provide thorough feedback on how they have taken consultation responses into consideration, including providing a public response to the comments received.*
- *Consistency and flexibility - Consistent consultation procedures can make it easier for all interested stakeholders to participate.*
- *Evaluation and review - Policy agencies should evaluate consultation processes and continue to examine ways of making them more effective.*

### PRINCIPLE 7: CHEMICAL REGULATIONS SHOULD BE FLEXIBLE, NOT PRESCRIPTIVE, AND BE COMPATIBLE WITH THE BUSINESS OPERATING ENVIRONMENT

There are three main types of regulations:

- *Design based – which specify the means for attaining the specified outcome.*
- *Performance based – which specify the desired objective in precise terms but allow the regulated entity to determine its own technique for achieving the outcome. Within the performance-based approach to regulation, market-oriented mechanisms that use economic incentives such as marketable permits and offsets should be explored. A market approach can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms.*
- *Market based – which use economic incentives, such as fees, marketable, tradeable permits, or changes to liability or property rights, to achieve a regulatory goal.*

In general, regulatory instruments should at least be performance-based, that is, they should focus on outcomes rather than inputs. ‘Deemed to comply’ provisions may be used in instances where certainty is needed. In such cases, regulations might refer to a standard or a number of standards deemed to comply with the regulation. In addition, market-based approaches, where feasible, often can achieve even higher efficiency by focusing on overall outcomes, while allowing an industry to trade the regulatory obligation to the lowest cost producer.

### PRINCIPLE 8: CHEMICAL REGULATIONS SHOULD BE SCIENCE-BASED

Good regulation should attempt to standardise the exercise of bureaucratic discretion, so as to reduce discrepancies between government regulators, reduce uncertainty, and lower compliance costs. However, this should not preclude an appropriate degree of flexibility to permit regulators to deal quickly with exceptional or changing circumstances or recognise individual needs. Nor should it

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ignore the danger of administrative action effectively constituting regulation and thus avoiding disciplines of regulation review. There is a need for transparency and procedural fairness in regulation review, and administrative decisions should be science-based and subject to effective administrative review processes.

### PRINCIPLE 9: CHEMICAL REGULATIONS SHOULD HAVE A CLEAR DELINEATION OF REGULATORY RESPONSIBILITIES AND EFFECTIVE AND TRANSPARENT ACCOUNTABILITY MECHANISMS

Overlapping or inconsistent regulation within the jurisdictions of Member Economies can have significant adverse consequences for economic and regulatory efficiency. High level political support is critical for implementing successful regulatory reform initiatives. An integrated policy is essential in ensuring that policies and regulations for all concerned areas are mutually supportive and not duplicative. There is also a need for institutional mechanisms to monitor and enforce the integrated policy and to oversee the cost benefit and regulatory impact assessment processes established to introduce transparency and accountability into the regulation making processes.

The overarching institutional framework for the harmonisation of regulation should:

- *Encourage continuous dialogue with the regulated community and other stakeholders regarding conflicting or duplicative mandates to achieve greater regulatory efficiency within and among Member Economies;*
- *Encourage the timely development of consistent and preferably uniform regulations;*
- *Discourage regulatory agencies and standards setting bodies from adopting unduly stringent and poorly justified regulations;*
- *Promote compliance with decisions to rationalise and harmonise areas of regulation.*

#### 2.14. Regulators' Forum Action Plan 2016-2017

##### *Objectives for the Forum*

- *Facilitate risk reduction and the sound management of chemicals across the APEC region and as an APEC contribution to broader SAICM implementation;*
- *Share information and knowledge on chemicals management more broadly in the region with the increased and direct involvement of regulators;*
- *Bridge principles and practice – sharing tools and experience with best practices and plan opportunities for collaboration to address common concerns; and*
- *Discuss nexus between chemicals management and competitiveness, including SMEs, to help facilitate trade in concert with protecting human health and the environment.*

##### *Work Aspects*

- *Provide updates from economies on chemicals management and more detailed information exchanges on domestic, regional and international issues of interest.*
- *Engage in dialogue and on specific chemicals management topics or challenges to help share information, tools and approaches across the region more broadly, facilitate compatible approaches and facilitate trade.*
- *Conduct outreach and provide feedback across regulators, industry and other stakeholders.*
- *Help implement relevant chemicals management best practices and goals of the CD and identify priorities for cooperative action and capacity building.*

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- *Act as a technical and regulatory resource network in the region on specific topics or needs as identified or requested by participants.*
- *Develop and, where possible, support project proposals and other trainings, seminars and exchanges on regional and member economy chemicals management priorities and needs.*
- *Leverage and promote related activities in APEC and elsewhere toward common chemicals regulatory forum interests and objectives.*

### *Accomplishments*

- *Creation of a network of regulators from the member economies in APEC*
- *Identified technical and regulatory areas for information exchange and capacity building*
- *Good Regulatory Practices workshop in Japan, March 2010*
- *Inventories and chemicals information seminar in Washington, DC, February 2011*
- *Risk Assessment and Risk Management workshop in Bangkok, Thailand, November 2012*
- *Metals Risk Assessment Workshop, Cebu, Philippines, August 2015*

### *Opportunities for further work*

- *Surveys, studies and pilot projects to increase transparency in and foster mutual understanding of regulatory approaches in APEC economies*
- *Engagement of regulators in cooperative activities ensuring meaningful outcomes*
- *Stakeholder engagement activities*
- *Cooperation and information exchange on chemical assessment and risk management activities in the region*
- *Further coordination on pertinent international chemical issues*

### *Information Exchange/Best Practices /Capacity Building*

Additional Initiatives that will be further explored by economies:

- *Indonesia, China, Russia: interested in initiatives related to working with SMEs*
- *Australia: survey on practices of engagement of SMEs*
- *Malaysia and Philippines: regulatory compliance and capacity building activities related to compliance*
- *The Philippines is also interested to add concerns on GHS implementation with SMEs – related to Indonesia's initiatives? This is in relation to the current approval of our GHS policy in the Philippines under DENR AO 2015-009 dated May 2015)*
- *U.S. and Chinese Taipei: further implementation of GHS by adding specific GHS tools to existing G.R.E.A.T. website*
- *Indonesia: focus work on SMEs, including surveys, studies, pilot projects on chemicals and waste management and GHS implementation.*
- *U.S.: create a website that could be a repository of translations of new regulatory actions*
- *Russia: GHS implementation*
- *Other suggestions: work with trade associations to do outreach to SMEs*

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**I n f o r m a t i o n a l   s u r v e y   a n d   a n a l y s i s  
o f   c h e m i c a l   m a n a g e m e n t   s y s t e m s  
i n   v a r i o u s   e c o n o m i e s**

## Informational survey and analysis of chemical management systems in various economies

Survey is structured in line with regulatory elements that were suggested for use at the Chemical Dialogue meeting in Ningbo (Republic of China), 2014.

These regulatory elements are:

1. *Regulated objects*
2. *Participants of regulatory system*
- 3-4. *Influences: national priorities and international activities*
5. *Parameters of regulation*
6. *Key procedures for control of regulated objects*
7. *Non-regulatory mechanisms*
8. *Availability of data*
9. *Laboratory infrastructure*
10. *Information sharing*

Chapter 3 integrates information about 17 chemical management regulatory systems of the economies exporting/importing chemicals according to the survey structure available on the open sources:

1. *the Commonwealth of Australia*
2. *Canada*
3. *the Republic of Chile*
4. *the People's Republic of China*
5. *Japan*
6. *the Republic of Indonesia*
7. *the Republic of Korea*
8. *the Realm of New Zealand*
9. *the Republic of Peru*
10. *the Russian Federation*
11. *the Republic of Singapore*
12. *Chinese Taipei*
13. *the Kingdom of Thailand*
14. *the United States of America*
15. *the Argentine Republic*
16. *the European Union*
17. *the Republic of Turkey*

**T h e C o m m o n w e a l t h o f A u s t r a l i a**

Composed by Australia

## 1. Regulated object

Chemicals are regulated according to their use.

Australian Government (Commonwealth) legislation governs the supply of chemicals in Australia, and importers or manufacturers of chemicals or chemical products must comply.

Legislation covers assessing and registering chemicals by national chemicals schemes and – to minimise duplication or unnecessary regulatory burdens on industry – the schemes complement each other. They cover:

- *Industrial chemicals, including chemicals used domestically*
- *Agricultural and veterinary chemicals*
- *Medicines and pharmaceuticals*
- *Chemicals used in (or with) food, including additives, contaminants and natural toxicants.*

In addition, several chemicals regulation frameworks support chemicals management:

- *Poisons scheduling – protecting public health*
- *Maintaining safety in the workplace*
- *Transporting of dangerous goods*
- *Managing chemicals in the environment*
- *Chemicals of security concern*
- *Illicit drugs precursor chemicals.*

Other entities which also play a role include:

- *Agencies which oversee competition, fair trading and consumer protection laws*
- *The Departments of Defence and of Foreign Affairs which are also concerned with chemicals of security concern and precursor chemicals.*

There are three levels of government in Australia – Commonwealth, state or territory, and local – each with its own responsibilities.

### *Regulatory Definitions*

Chemical uses in Australia are defined under the Industrial Chemicals (Notification and Assessment) Act 1989 as follows:

#### 1. *Agricultural chemical product*[1]—

A substance or mixture of substances that is a means of directly or indirectly:

- (a) Destroying, stupefying, inhibiting, attracting or repelling a pest in relation to a plant, a place or a thing; or
- (b) Destroying a plant; or
- (c) Modifying the physiology of a plant so as to alter its natural development, productivity or reproductive capacity;
- (d) Modifying the effect of another agricultural chemical product

#### 2. *Veterinary chemical product*[2]—

A substance or mixture of substances that is:

- (a) A means of directly or indirectly:
  - (i) Preventing, diagnosing, curing or alleviating a disease or condition in an animal or an infestation of an animal by a pest in relation to that animal; or
  - (ii) Curing or alleviating an injury suffered by an animal; or
  - (iii) Modifying the physiology of an animal:
    - a. So as to alter its natural development, productivity or reproductive capacity; or
    - b. So as to make it more manageable; or

Prepared by a pharmacist or veterinary surgeon, in the course of the practice of his or her profession, to deal with a particular condition of a particular animal in a particular instance.

3. *Chemicals for therapeutic use*[3]—

Means use in, or in connection with:

- (a) Preventing, diagnosing, curing or alleviating diseases, ailments, defects or injuries in humans; or
- (b) Influencing, inhibiting or modifying physiological processes in humans; or
- (c) Testing the susceptibility of humans to diseases or ailments;

And, without limiting this, includes use in, or in connection with, testing for pregnancy, contraception, prosthetics or orthotics.

4. *Food additive*[4]—

Means a chemical whose inclusion in food as a food additive is permitted under the Australia New Zealand Food Standards Code.

5. *Industrial Chemical*[5]—

Means a chemical that has an industrial use, being a use that does not meet the definition of one of the other categories (categories 1-4 above), and so includes ingredients used in cosmetic products.

Note that the specified various uses do not preclude a chemical which has multiple uses. For example a chemical with an industrial use can also have a therapeutic use and fall under two regulatory frameworks.

## 2. Participants of the regulatory system

Each of the four groups of chemical uses are regulated within separate legal and regulatory frameworks. Chemical regulation in Australia involves over 19 agencies at the Commonwealth level, 34 agencies at the state/territory level and a large number of local councils. An overview of the chemical regulatory system is shown in Figure 3.1.1.

In addition to the regulatory agencies noted on the diagram, all chemicals that are used in a workplace also link to the work health and safety (WHS) classification and labelling requirements.

Information on chemical regulation in Australia can be found in the Chemicals Business Checklist.<sup>13</sup> The aim of this checklist is to enable businesses to better understand the regulatory landscape in Australia and to direct chemical businesses to relevant information to help them be compliant, safe and sustainable. Other useful information points include the key regulator websites – National Industrial Chemicals Notification and Assessment Scheme (NICNAS)<sup>14</sup>, the Australian Pesticides and Veterinary Medicines Authority (APVMA)<sup>15</sup>, Therapeutic Goods Administration (TGA)<sup>16</sup>, Food Standards Australia New Zealand (FSANZ)<sup>17</sup> and the Australian Competition and Consumer Commission (ACCC)<sup>18</sup>.

### *Commonwealth Government*

The Commonwealth Government is involved in:

- *Registration of chemicals, companies and products.*
- *Hazard and risk assessment.*

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<sup>13</sup> Australian Government Chemicals Business Checklist

<http://industry.gov.au/industry/industrysectors/chemicalsandplastics/RelatedLinks/ChemicalsBusinessChecklist/Pages/default.aspx>

<sup>14</sup> National Industrial Chemicals Notification and Assessment Scheme (NICNAS). <https://www.nicnas.gov.au/>

<sup>15</sup> the Australian Pesticides and Veterinary Medicines Authority (APVMA). <https://apvma.gov.au/>

<sup>16</sup> Therapeutic Goods Administration (TGA). <https://www.tga.gov.au/>

<sup>17</sup> Food Standards Australia New Zealand (FSANZ). [www.foodstandards.gov.au/](http://www.foodstandards.gov.au/)

<sup>18</sup> Australian Competition and Consumer Commission (ACCC). <https://www.accc.gov.au/>

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- *Standard setting for the management of risks associated with chemicals (work health and safety, poisons and medicines scheduling).*
- *Implementation of international agreements and regulation of international trade.*
- *Monitoring transport of dangerous goods by sea and air.*
- *Scheduling of medicines and poisons.*

Chemicals and chemical products are regulated across several Commonwealth portfolios. NICNAS, TGA and FSANZ are all within the Health portfolio and APVMA within the Agriculture portfolio.

Risk to the environment is an explicit consideration in the regulatory assessments of industrial chemicals (including cosmetic ingredients) under the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act) and pesticides and veterinary medicines under the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet code).

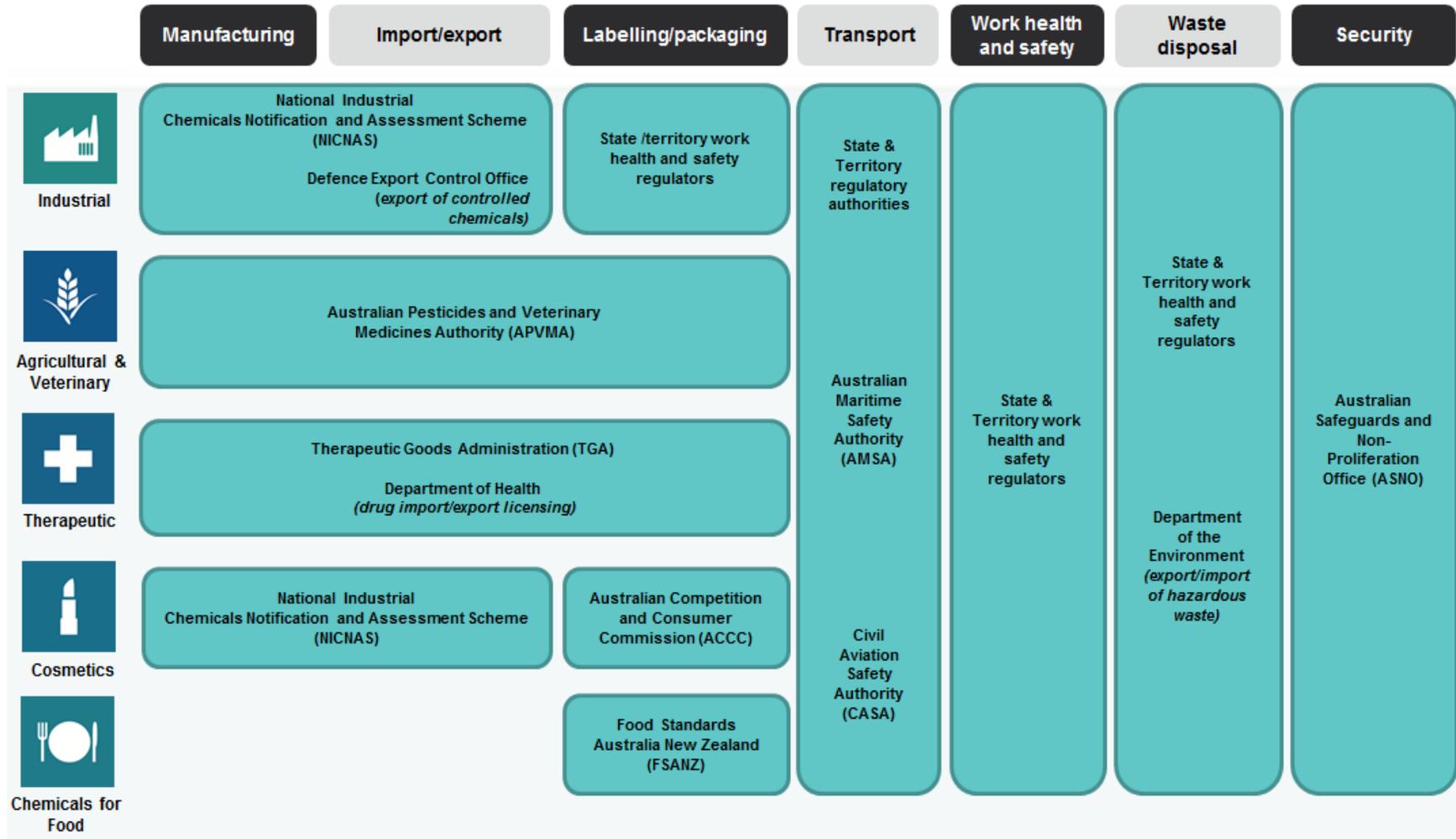
### *Office of Chemical Safety*

The Office of Chemical Safety (OCS) undertakes a number of regulatory functions in relation to chemicals. OCS administers the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which aids in the protection of the Australian people and the environment by assessing the risks of industrial chemicals. These assessments inform decisions made by a wide range of government agencies involved in regulating the control, use, release and disposal of industrial chemicals). OCS also provides human health risk assessment services on chemicals to other Commonwealth agencies – for example, chemicals used in coal seam gas extraction, oil dispersants and for setting drinking water guideline values.

NICNAS is a statutory scheme within the portfolio responsibilities of the Minister for Health, established under the ICNA Act and the Industrial Chemicals (Notification and Assessment) Regulations 1990 for managing the system for the introduction (by import or manufacture) of industrial chemicals in Australia. The scheme aids in the protection of the Australian people and the environment by assessing the risks of industrial chemicals, providing information and making recommendations to promote their safe use. Assessments undertaken under the ICNA Act are evidence-based evaluations of risk to public health, occupational health and safety and the environment of specified industrial chemicals.

The risk assessment reports include risk management recommendations to Commonwealth, state and territory and local government agencies. The risk managers are then responsible for considering the NICNAS recommendations and determining any necessary risk management conditions to control the use, release and disposal of industrial chemicals.

Figure 3.1.1. - The chemical regulatory system in Australia- chemical lifecycle



## The Commonwealth of Australia

NICNAS's functions include:

- *Assessing industrial chemicals both pre- and post-market (but not mixtures or products) for human health and/or environmental impacts.*
- *Registering introducers of industrial chemicals.*
- *Maintaining the Australian Inventory of Chemical Substances (AICS).*
- *Providing information on the human health and environmental impacts of industrial chemicals and making recommendations to risk managers (both at the Commonwealth and State/Territories level) on their safe use.*
- *Collating and analysis of information about the introduction of chemicals, audits companies for compliance, and undertakes relevant enforcement.*
- *Assisting in ensuring Australia meets its obligations under international agreements.*

### *Australian Pesticides and Veterinary Medicines Authority (APVMA)*

APVMA is the Australian Government regulator of agricultural and veterinary (Agvet) chemicals and products. APVMA evaluates, registers and regulates Agvet chemicals and products up to and including the point of retail sale. This includes:

- *Agricultural chemical products such as pesticides, herbicides, biocides, insecticides and seed treatments.*
- *Veterinary chemical products such as medicines, antibiotics, hormonal treatments and some stockfeeds and petfoods.*
- *Other chemical products such as insect repellents, garden sprays and pool chemicals.*

The APVMA regulates Agvet biotechnology products, and any Agvet product that contains either nanomaterials, a Genetically Modified Organism (GMO) or a product to be used in a Genetically Modified (GM) crop. APVMA permits cover the use of chemicals in GM crop trials however do not regulate the actual GM crops. APVMA liaises closely with the Office of the Gene Technology Regulator (OGTR) in the assessment of GMO products. The National Registration Scheme (NRS) for Agricultural and Veterinary Chemicals<sup>19</sup> is the regulatory framework for managing Agvet chemicals and products including vet medicines. Under this framework the APVMA is responsible for the regulation of Agvet chemicals and products and oversees the import and export of those chemicals, products including veterinary medicines. Before Agvet chemical products can be legally sold, supplied, promoted or used in Australia, the products must be registered with APVMA. APVMA monitors and enforces compliance in the marketplace, and helps manufacturers, importers and suppliers of Agvet chemicals to be aware and understand regulatory requirements. APVMA works with the Australian Customs and Border Protection Service to help stop the illegal importation of Agvet chemicals.[7]

The APVMA has these functions and powers conferred upon it by the Administration Act and by the Agvet Code of the participating territories. The Agvet Code makes provision for the evaluation, registration and control of agricultural and veterinary chemical products and for related matters. Mirror legislation is found in the states and territories of Australia, consistent with the arrangements set out in *the Agricultural and Veterinary Chemicals Act 1994*. [8]

### *Therapeutic Goods Administration (TGA)*

The TGA is part of the Health Products Regulation Group within the Department of Health. Under the Therapeutic Goods Act 1989 it is responsible for regulating the supply of therapeutic goods

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<sup>19</sup> The National Registration Scheme (NRS) for Agricultural and Veterinary Chemicals, <http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/regulation>

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in Australia. This includes prescription medicines, vaccines, vitamins, medical devices as well as blood and blood products.

The TGA also regulates the manufacturing and advertising of these products. Almost any product that makes therapeutic claims must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied or sold in Australia.<sup>20</sup>

The TGA takes a risk-based approach to regulation to ensure that, on balance, the benefits of therapeutic goods outweigh the risks. This means that goods are assessed based on the different levels of risk they pose to the person using them.

High risk medicines are assessed for quality, safety and efficacy, whereas low risk medicines are only assessed for quality and safety. Medical devices are assessed for quality, safety and performance against international standards. The TGA makes this assessment by applying scientific and clinical expertise to the decision-making process.

The TGA's monitoring and compliance processes include pre-market evaluation and approval of products, development, maintenance and monitoring of the systems for listing of medicines, licensing of manufacturers, post-market surveillance and assessment of medicines for export.[9]

The *Therapeutic Goods Act 1989* sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. It details the requirements for listing, registering or including medicines, medical devices and biological products on the ARTG, as well as many other aspects of the law including advertising, labelling, and product appearance.[10]

### *Advisory Committee on Chemicals Scheduling (ACCS)*

The ACCS was established to advise and make recommendations to the Secretary of the Department of Health (or delegate) on the level of access required for chemicals and in some instances medicines. Under revised scheduling arrangements, which took effect on 1 July 2010, the Secretary to the Department of Health (Health) (or the Secretary's delegate) superseded the National Drugs and Poisons Schedule Committee (NDPSC) as the decision maker for the scheduling of medicines and chemicals. Scheduling is a classification system that controls how medicines and chemicals are made accessible to consumers based on the substances contained within them. Substances are grouped into Schedules according to the appropriate level of regulatory control over their availability (e.g. Schedule 4 - medicines available only by prescription; Schedule 2 - medicines available over the counter in pharmacies).

### *Office of Drug Control (ODC)*

The Office of Drug Control is a newly established branch in the Health Products Regulation Group of the Department of Health set up to administer the Narcotic Drugs Act 1967 (ND Act), and parts of the Customs (Prohibited Imports) Regulations 1956 and the Customs (Prohibited Exports) Regulations 1958. The Office issues manufacturing licenses for narcotics as well as issuing import/export licenses and permissions that regulate the trade in controlled drugs.

In February 2016, the ND Act was amended to allow for the licensed cultivation of cannabis for medicinal purposes as well as make particular provisions relevant to the manufacture of medicinal cannabis product.

### *Australian Competition and Consumer Commission (ACCC)*

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<sup>20</sup> the Australian Register of Therapeutic Goods (ARTG), <https://www.tga.gov.au/searching-australian-register-therapeutic-goods-artg>

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The ACCC is an independent Australian Government statutory authority, currently under the portfolio responsibility of The Treasury, whose role is to enforce the Competition and Consumer Act 2010. The ACCC is also responsible for enforcing a range of additional legislation, promoting competition, fair trading and regulating national infrastructure.[11]

The ACCC's role is to improve consumer welfare, protect competition or stop anti-competitive or harmful conduct and promote the proper functioning of Australian markets. The priorities of the ACCC are reflected in four key goals:

- *Maintain and promote competition and remedy market failure.*
- *Protect the interests and safety of consumers and support fair trading markets.*
- *Promote the economically efficient operation of, use of and investment in monopoly infrastructure.*
- *Increase engagement with a broad range of groups affected by the work of the ACCC.*

The ACCC and state/territory consumer product safety regulators play an active role in:

- *Investigating potential chemical hazards in consumer products.*
- *Developing bans and mandatory standards where evidence shows a consumer product has or could cause injury, illness or death.*

### *Food Standards Australia New Zealand (FSANZ)*

FSANZ is an independent, bi-national statutory agency established by the Food Standards Australia New Zealand Act 1991 and is under the portfolio responsibilities of the Minister for Health. FSANZ develops and administers the Australia New Zealand Food Standards Code (the Code).[12]

FSANZ develops standards that regulate the use of food ingredients, processing aids, colourings, additives, vitamins and minerals. The Code lists requirements for foods such as additives, food safety, labelling and genetically modified foods. In Australia, enforcement and interpretation of the Code is the responsibility of state and territory departments and food agencies. Overarching food policy is set by the ministers who are responsible for food regulation in Australia and New Zealand. These ministers make up the Australia and New Zealand Ministerial Forum on Food Regulation. This forum develops food regulatory policy and policy guidelines that FSANZ must consider when setting food standards. The forum has general oversight of the implementation of standards, and has the capacity to adopt, amend or reject standards as well as ask FSANZ to review standards or create new ones.

### *Safe Work Australia and Work Health and Safety (WHS)*

Safe Work Australia is an independent Australian Government agency established by the *Safe Work Australia Act 2008*, with primary responsibility for leading the development of policy to improve work health and safety and workers' compensation arrangements across Australia. It is jointly funded by Commonwealth and state and territory governments through an Intergovernmental Agreement.

Safe Work Australia is responsible for making and maintaining model work health and safety laws, including a model Act, model regulations and model Codes of Practice. The objective of the model laws is to provide for a balanced and nationally consistent framework to secure the health and safety of workers and workplaces.

As a national policy body Safe Work Australia does not implement, regulate or enforce work health and safety laws. The Commonwealth and state/territory governments have responsibility for making WHS laws in each jurisdiction. Most jurisdictions, except Victoria and Western Australia, have enacted work health and safety laws in their jurisdiction that are based on the model laws. WHS

## The Commonwealth of Australia

laws are enforced by Comcare in the Commonwealth jurisdictions and by state/territory WHS regulators in each state and territory jurisdiction.

The model WHS Regulations, passed by most jurisdictions in 2012, provided a good lead in for GHS labelling, which became mandatory on 1 January 2017 (except in Victoria and Western Australia where it is accepted but not mandatory), referencing the 3rd Revised Edition of the GHS. A five year transitional period was provided to industry to prepare for the implementation of GHS labelling.[13]

### *Chemicals of Security Concern*

The Department of Home Affairs manages chemicals of security concern. A National Code of Practice for Chemicals of Security Concern has been developed to assist in handling products containing chemicals of security concern. The Code addresses 15 chemicals that are assessed as being particularly high-risk.

Australia is a signatory to the Chemical Weapons Convention (CWC); an international treaty that bans the development, production, possession and use of chemical weapons, and requires the destruction of existing weapons. Some chemicals produced or used for normal industrial, medical or research activities can also have applications in the manufacture of chemical weapons.

The chemical and biotechnology industries may be targeted as a source of materials for chemical and biological weapons programs. Some chemicals, chemical manufacturing facilities, equipment and components (including test, inspection or protective equipment) have a commercial use but may also be used in a chemical or biological weapons program. Defence Export Control (DEC) regulates the export of certain chemicals, chemical manufacturing facilities, equipment and components. Contact DEC for advice if you suspect your product or item is being used in a weapons program.

### *Illicit drug precursors*

Certain chemicals can be used in the manufacture of illicit drugs. These are generally known as 'precursors'. Possession, import and export of certain precursors is subject to Commonwealth, state and territory legislation. Chemistry Australia (formerly the Plastics and Chemicals Industries Association (PACIA)) and Science Industry Australia (SIA) have developed the Code of Practice for Supply Diversion into Illicit Drug Manufacture. The Code of Practice outlines procedures for secure storage, sales monitoring, record keeping and reporting around precursor chemicals. Certain narcotics, psychotropic and precursor substances are controlled under Customs legislations and require import or export licences from the Department of Health.

### *National Transport Commission (NTC)*

The Australian Dangerous Goods Code sets out the technical requirements for transporting dangerous goods by road or rail. The Code is given legal force in each Australian state and territory by each jurisdiction's dangerous goods transport laws. The NTC has ongoing responsibility for the maintaining the code. The NTC reviews the Australian Dangerous Goods Code every two years to help it meet international best-practice and evolving user needs in Australia.

Consultation on the draft Code for the Transport of Dangerous Goods by Road and Rail Edition 7.6, and the draft Competent Authority Panel Rules closed in February 2018. The next amendment package will adopt into the Code, where possible, the amendments that comprise the UN Recommendations on the Transport of Dangerous Goods Model Regulations Twentieth Revised Edition, as well as Australian-specific amendments. All issues are considered in consultation with the Transport of Dangerous Goods – Maintenance Advisory Group. In May 2018, the Transport and Infrastructure Council approved version 7.6 of the Code, with the changes effective from 1 July 2018

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and compulsory from 1 July 2019. States and territories have committed to amending their local laws to align with making the changes from version 7.6 of the Code for the Transport of Dangerous Goods by Road and Rail to their local laws.

### *Civil Aviation Safety Authority (CASA)*

The CASA was established on 6 July 1995 as an independent statutory authority. Under section 8 of the *Civil Aviation Act 1988*, CASA is a body corporate separate from the Commonwealth.

CASA's primary function is to conduct the safety regulation of civil air operations in Australia and the operation of Australian aircraft overseas. It is also required to provide comprehensive safety education and training programmes, cooperate with the Australian Transport Safety Bureau, and administer certain features of Part IVA of the *Civil Aviation (Carriers' Liability) Act 1959*.

The *Civil Aviation Regulations 1988* and the *Civil Aviation Safety Regulations 1998*, made under authority of the *Civil Aviation Act*, provide for general regulatory controls for the safety of air navigation.[14]

### *Australian Maritime Safety Authority (AMSA)*

The AMSA is a statutory authority established under the *Australian Maritime Safety Authority Act 1990* (the *AMSA Act*). They are Australia's national safety agency with a primary role in maritime safety, protection of the marine environment and aviation and maritime search and rescue.

AMSA's principal functions are:

- *Promoting maritime safety and protection of the marine environment.*
- *Preventing and combating ship-sourced pollution in the marine environment.*
- *Providing infrastructure to support safety of navigation in Australian waters.*
- *Providing a national search and rescue service to the maritime and aviation sectors.*

AMSA operates under the *AMSA Act* and as a Corporate Commonwealth Entity is also subject to the *Public Governance, Performance and Accountability Act 2013*. [15]

### *State/Territory Governments*

The eight state/territory governments are involved in, and have significant carriage of, risk management activities such as:

- *Control of use of agricultural and veterinary chemicals.*
- *Protection of public health.*
- *Work health and safety.*
- *Transport (by road and rail) and storage of dangerous goods.*
- *Managing environmental impacts (emission and disposal).*

The Australian Constitution specifies that the states/territories are responsible for matters such as conservation and environmental conservation and management. However the Commonwealth does have powers to initiate and consider new environmental regulations.

### *Environmental Protection Authority (EPA)*

Each state/territory has the responsibility for prevention and relevant response to environmental risks. The EPA is an environmental regulator that operates at a state/territory government level. Some

functions include providing advice on the environmental impacts of development proposals, policy advice, and regulatory services to provide for effective waste management, pollution control and sustainable practices.[16]

### *Local Councils*

There are approximately 560 local councils who are responsible for regional planning and waste disposal, including asbestos management, as outlined in WHS Regulations 2011. The powers for planning and waste disposal are given to local governments by the relevant state or territory.

## **3 - 4 . I n f l u e n c e s : N a t i o n a l P r i o r i t i e s a n d I n t e r n a t i o n a l A c t i v i t i e s**

### **N a t i o n a l p r i o r i t i e s**

#### *Reforms to NICNAS*

The Australian Government announced reforms to NICNAS in 2015, which will streamline the assessment process for industrial chemicals to reduce the regulatory burden on the sector, while also maintaining Australia's robust safety standards. The reforms will ensure that the level of assessment of industrial chemicals is proportionate to the potential risk they pose. Changes are expected to be in place by 1 July 2019. [17]

As part of these reforms, NICNAS will upgrade its current Information Technology system to:

- *Streamline notification and assessment processes.*
- *Include an integrated payments system.*
- *Create both internal and external portals for users to access the system.*
- *Provide a platform to better enable targeted and risk-based assessments and compliance activity.*
- *Enhance NICNAS' assessment and reporting capacity.*
- *Reduce administration burden.*
- *Integrate with other systems such as Department of Health and NICNAS websites.[18]*

The reform also introduces a ban on the use of animal test data for cosmetic ingredients.

### *National Standard for Environmental Risk Management of Industrial Chemicals*

Environment Ministers from the Commonwealth, state and territory governments met in July 2015 and agreed to establish a National Standard for the environmental risk management of industrial chemicals.

The National Standard will streamline regulation of industrial chemicals, enabling a more consistent, efficient and effective approach to environmental risk management of industrial chemicals across all jurisdictions.

The Standard will be established by the Commonwealth and implemented by each state and territory. The Standard is intended to be in full operation in all jurisdictions by 2018.[19] Further information is available electronically here: <https://www.environment.gov.au/protection/chemicals-management/national-standard>.

### *Agricultural Competitiveness White Paper*

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The White Paper outlines the initiatives and commitments by the Australian Government for each of our five priority areas for action.[20]

Priority 1 addresses better regulation, with the committal to reduce red tape from the economy. \$20.4 million has been allocated to further streamline agricultural and veterinary chemicals approvals. Farmers will get access to new farm chemicals more quickly, reducing the cost of doing business.

The Australian Government intends to further streamline the approval of agricultural and veterinary chemicals. This will reduce industry and user cost and improve the timely access to productivity-enhancing chemicals, while still ensuring appropriate safeguards are maintained.

Additionally, on 1 July 2015, reforms commenced as part of the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013 to:

- *Improve the efficiency and effectiveness of assessment processes for applications and reconsiderations.*
- *Enhance the consistency and transparency of assessments and reconsiderations.*
- *Improve the ability of the regulator to enforce compliance.*
- *Encourage industry to provide data to support ongoing registration of Agvet chemicals and permit applications.*

### *International Standards and Risk Assessments*

The Australian Government has adopted an approach to reduce regulatory burden and remove trade barriers.[21] If a system, service or product has been approved under a trusted international standard or risk assessment, no additional requirements should be imposed unless there is a demonstrable reason to do so.

## **I n t e r n a t i o n a l   A c t i v i t i e s**

### *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*

Australia has implemented the GHS for workplace hazardous chemicals (substances, mixtures and articles) since 1 January 2017. The model WHS laws introduced the GHS to ensure that chemical users are provided with practical, reliable and easy to understand information on chemical hazards and can take the appropriate preventive and protective measures for their health and safety.

The GHS is expected to provide significant trade benefits to industry as well as improved health and safety outcomes by introducing internationally consistent assessment criteria, labels and safety data sheets (SDS) for hazardous chemicals.

The model WHS Regulations impose a duty on manufacturers and importers of chemicals to determine whether the chemicals are hazardous and to correctly classify the chemical. Manufacturers and importers are also responsible for ensuring that correct GHS labels and SDS are prepared for hazardous chemicals. All workplace hazardous chemicals supplied from 1 January 2017 must have GHS compliant labels and SDS.

The states of Western Australia and Victoria (who have not implemented the model WHS laws) recognise GHS labels and SDS as compliant with their legislation.

Safe Work Australia has published a new database of GHS classification and labelling information called the Hazardous Chemicals Information System (HCIS). It contains information for over 4500 chemicals.

### *International Conventions*

## The Commonwealth of Australia

The table below outlines the current status of international chemical conventions in Australia.

**Table 3.1.1. - Conventions of which Australia is signed**

<b>Conventions</b>	<b>Status of ratification</b>	<b>Corresponding Acts and normative documents</b>
<b>Stockholm Convention on Persistent Organic Pollutants (POPs) 2001</b>	Signed 23/05/2001; ratified 20/05/2004	<i>National Implementation Plan (2006)</i>  <i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>  <i>Customs (Prohibited Imports) Regulations 1956</i>  <i>Customs (Prohibited Exports) Regulations 1958)</i>
<b>Vienna Convention</b> for the protection of the Ozone layer, 1985	Signed 22/03/1985; ratified 16/09/1987; accession 16/09/1987	<i>Ozone Protection Act 1989</i>  <i>Ozone Protection and Synthetic Greenhouse Gas Management Act 1989</i>
<b>Montreal Protocol</b> on Substances that Deplete the Ozone Layer, 1987	Signed 08/06/1988; ratified 19/05/1989	<i>Ozone Protection Act 1989</i>  <i>Ozone Protection and Synthetic Greenhouse Gas Management Act 1989</i>
<b>London Amendment</b> (1990): The amendment to the Montreal Protocol agreed by the Second Meeting of the Parties (London 27-29 June 1990)	Ratified 09/11/1992	
<b>Copenhagen Amendment</b> (1992): The amendment to the Montreal Protocol agreed by the Fourth Meeting of the Parties (Copenhagen, 23-25 November 1992)	Ratified 29/09/1994	

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Conventions	Status of ratification	Corresponding Acts and normative documents
<i>Montreal Amendment</i> (1997): The amendment to the Montreal Protocol agreed by the Ninth Meeting of the Parties (Montreal, 15-17 September 1997)	Ratified 10/11/1999	
<i>Beijing Amendment</i> (1999): The amendment to the Montreal Protocol agreed by the Eleventh Meeting of the Parties (Beijing, 29 November-3 December 1999)	Ratified 15/11/2005	
<b>Basel Convention</b> on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 1989	Signed 22/03/1989; ratified 05/05/1992; accession 05/02/1992	<i>Hazardous Waste (Regulation of Exports and Imports) Act 1989</i>
<b>Rotterdam Convention</b> on the Prior Informed Consent Procedure for Certain Hazardous and Pesticides in International Trade	Signed 10/09/1998; ratified 20/05/2004	<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>  <i>Customs (Prohibited Imports) Regulations 1956</i>  <i>Customs (Prohibited Exports) Regulations 1958)</i>
<b>Convention on the Organisation for Economic Co-Operation and Development (OECD), 1960</b>	Signed 14/12/1960; accession 07/06/1971	
<b>Convention for the Protection of the Natural Resources and Environment of the South Pacific Region (Noumea Convention), 1986</b>	Ratified 07/06/1971	
<b>Minamata Convention on Mercury</b>	Signed 10/10/2013	

## 5. Parameters of regulation

As outlined earlier, chemical regulatory controls in Australia operate at the Commonwealth, state and local government levels.

## 6. Key procedures for control of regulated objects

As noted earlier, Australia's system for industrial chemical regulation is established by the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act).

The ICNA Act covers chemicals that are not regulated and/or assessed under other legislation. Although the majority of chemicals available for use in Australia are industrial, the ICNA Act does not regulate or otherwise manage pesticides, therapeutics, or food additives, unless they have another industrial use in Australia.

### *New chemical substances*

An industrial chemical that is not listed on the AICS is defined as a new chemical. Unless exempt from notification, new industrial chemicals must be notified and assessed before being manufactured or imported into Australia. All chemicals that receive an assessment certificate are automatically added to the public list after five years. To list a chemical confidentially, the certificate holder must submit an application, including justification for requesting a confidential listing.[22] Manufacturers or importers of new industrial chemicals may need to notify NICNAS if the chemical is not listed on the AICS.

- *It is listed on the AICS with a condition of use, and its import/manufacture is proposed to be different.*
- *It is a new synthetic polymer, defined as:*
  - That which combines monomers and other reactive components, each representing at least 2 per cent by weight of the polymer, being a combination not listed in the AICS, or
  - One with weight at least 2 per cent of which is attributed to a monomer or other reactive component not listed in the AICS as a component of a synthetic polymer.

### *Existing chemical substances*

NICNAS does not need to be notified if the industrial chemical falls into any of the following categories.[23]

- a) *It is listed on the AICS and the proposed import and/or manufacture complies with any conditions of use.*
- b) *It is a reaction intermediate due to its transient existence and/or confinement to chemical reaction system.*
- c) *It is incidentally-produced as an impurity or by-product from a chemical reaction and does not have commercial value (information on these chemicals would be required if the parent chemical was subject to notification).*
- d) *It meets the legal definition of being naturally—occurring and thus is regarded as being on the AICS—although it is not specifically listed.*

e) *It is a polymer that does not fulfil the criteria for a new synthetic polymer.*

Examples of such chemicals include an existing synthetic polymer:

- Where only a change in monomer ratios has occurred- for example, if the ethylene-vinyl acetate ratio in an ethylene-vinyl acetate copolymer has changed from 70/30 per cent to 40/60 per cent.
- Containing one or more additional monomers or reactants, each at less than 2 per cent weight of the polymer.

## **7 . N o n - r e g u l a t o r y M e c h a n i s m s**

There are a number of non-regulatory mechanisms for industrial chemicals put in place by other industry groups such as the International Fragrance Association and Accord (the hygiene, cosmetic and specialty product industry association).

### *Responsible Care*

Responsible Care is an initiative of the international chemical industry to improve the health, safety and environmental performance of its operations and to increase community involvement and awareness of the industry.

Chemistry Australia Limited manages and oversees implementation of the program in Australia. The International Council of Chemical Associations (ICCA) manages Responsible Care at the global level.[24]

## **8 . I n f o r m a t i o n a l r e s o u r c e s**

### *Australian Inventory of Chemical Substances (AICS)*

AICS is the legal device that distinguishes new from existing chemicals. It is a database of chemicals (not products) and has a public and confidential section. Chemicals on the AICS can be imported or manufactured in Australia without notifying NICNAS, except chemicals that state 'Secondary Notification Conditions apply: 'Yes' and Conditions of Use: 'Yes'. These have mandatory requirements and NICNAS should be contacted before manufacturing or importing the chemical or chemical products containing the chemical.

### *Hazardous Chemical Information System (HCIS)*

Safe Work Australia has published a new chemicals database to make it easier for manufacturers, importers, suppliers and end-users of chemicals to meet the requirements of the GHS. The Hazardous Chemical Information System (HCIS) <sup>21</sup>provides information on over 4500 chemicals that have been classified in accordance with the GHS.

Manufacturers, importers and suppliers of hazardous workplace chemicals are responsible for ensuring that correct GHS labels and SDS are prepared for hazardous chemicals. And while users of chemicals aren't responsible for updating labels, they will need to be aware of the changes. Not all hazards are listed on the HCIS, and it is provided for guidance only.

### *The Poisons Standard (the SUSMP)*

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<sup>21</sup> The Hazardous Chemical Information System (HCIS), <http://hcis.safeworkaustralia.gov.au/>

## The Commonwealth of Australia

The Poisons Standard is a Legislative Instrument for the purposes of the Legislative Instruments Act 2003. The Poisons Standard consists of decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on medicines and chemicals.

The Poisons Standard has been presented with a view to promoting uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia. The Poisons Standard is the legal title of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Please note that rather than referring to the SUSMP edition number, publications will be named according to the month and year of publication on the Federal Register of Legislation (FRL) website. For example, SUSMP No.7 is known as Poisons Standard June 2015 on FRL.

The Poisons Standard is available in electronic form, free of charge, on the FRL website Poisons Standard June 2018 (SUSMP No. 21). The FRL is a repository and authoritative source of Commonwealth Acts, legislative and notifiable instruments, explanatory statements for legislative instruments, and other relevant documents and information.

### *Confidential Business Information (CBI) Protection*

Regulators and agencies involved in chemical registration in Australia have strict legal frameworks which protect confidential information from inappropriate disclosure or improper use by the agencies or their officers.

In carrying out its functions and duties under the Industrial Chemicals (Notification and Assessment) Act 1989 (the ICNA Act), NICNAS routinely receives sensitive commercial information which, if disclosed without authorisation, could cause harm to a person or organisation, or give an unfair advantage to another entity. NICNAS has measures in place to protect the confidentiality in the information it receives.

NICNAS considers trade secrets, usually information generated by a business entity about its own activities, to be confidential. This kind of information can include costs of production and pricing data; sales statistics; customer and supplier lists; sources of supply; market projections; and some chemical information.

NICNAS treats information about individuals as 'personal information' in accordance with the Privacy Act 1988. The Australian Government has in place legislation, policies and procedures designed to protect information it holds for official purposes. As a statutory scheme managed by the Commonwealth Department of Health, NICNAS complies with all relevant legislation, common law and departmental policies and procedures, when it gathers, uses and disseminates such information.

Any information received or collected by or on behalf of the Department of Health through employees or others acting on behalf of the Department is termed 'official information'. The Department will use official information only for the purposes for which it is obtained. Broad protection against disclosure of official information is provided for in the Crimes Act 1914, the Privacy Act 1988, the Archives Act 1983 and the Public Service Act 1999.

However, disclosure of official information may occur under the provisions of the Freedom of Information Act 1982, which provides a legislative right of access to government-held information, subject to a number of specific exemptions.

NICNAS has in place a series of controls including:

- *procedural controls: access, handling, use and transmission of different categories of official information are restricted to employees with appropriate security clearances;*
- *physical controls: access to work areas and document storage is restricted;*

- *technical controls: secure log-in, firewalls, encryption and antivirus software are used to protect the integrity of official information.*

NICNAS is responsible for official information once it has been received; it is the responsibility of the sender to ensure that information is not compromised before it reaches NICNAS.

## 9. Laboratory infrastructure

### *National Association of Testing Authorities (NATA) Australia*

NATA is the national organisation for conformity assessment of technical operations such as: laboratories, inspection bodies, proficiency testing scheme providers and reference material providers. By way of a Memorandum of Understanding, the Australian Government recognises NATA as the sole national accreditation body for establishing and maintaining competent laboratory practice. NATA also represents Australia in the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and on the OECD Working Group on Good Laboratory Practice.

NATA aims to:

- *Provide an accreditation service which meets the needs of stakeholders, and facilitate the recognition and acceptance of their products and services.*
- *Promote the science and practice of accreditation to enhance the acceptance of Australian products and services both in Australia and overseas.*

### *Good Laboratory Practice (GLP)*

Recognition is offered by NATA for compliance with the OECD Principles of GLP, which is available to any Australian facility undertaking non-clinical health and environmental safety studies. These studies would be required for the purpose of registering or licensing for use of pharmaceuticals, pesticides, veterinary drug products and similar products, and for the regulation of industrial chemicals. These studies fall into one of the following categories:

- *Physical-chemical*
- *Testing toxicity studies*
- *Mutagenicity studies*
- *Environmental toxicity, persistence and bioaccumulation studies*
- *Residue studies*
- *Studies on the effects of microcosm and natural ecosystem*
- *Target animal safety studies*
- *Worker exposure studies*
- *Analytical and clinical pathology and histology associated with GLP studies.*

The appropriate good laboratory practice standard for this testing is the International Organisation for Standardization: General Requirements for the Competence of Testing and Calibration laboratories (ISO/IEC 17025:2005). Accreditation to this standard demonstrates technical competence, therefore laboratories accredited to this standard demonstrated that they follow good laboratory practice and data they produce is technically valid.

## The Commonwealth of Australia

NATA has a number of overseas member facilities accredited to ISO/IEC 17025. This could be because there is no domestic accreditation body, the domestic accreditation body is not in a Mutual Recognition Agreement, or the body does not currently offer accreditation in the required field of testing. Other facilities may wish to be recognised as GLP compliant, however NATA is only obliged under OECD Mutual Acceptance of Data (MAD) directives to inspect Australian facilities. NATA would only inspect overseas facilities or sites if:

- *A request was received from the relevant Australian regulator.*
- *The facility or site was located in a country that does not have a GLP compliance monitoring authority adhering to MAD directives.*

There would be no obligation of overseas regulators to accept the outcome of a NATA inspection to these test sites.

### **10. Information sharing**

#### *Implementation of GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

Codes of practice and guidance materials relating to workplace chemicals have been developed or revised to reflect the requirements for hazardous chemicals including requirements for the classification, labelling and SDS of hazardous chemicals based on GHS documentation.

Safe Work Australia has a suite of training tools and information sheets about the GHS and the requirements under the model WHS Regulations.

As stated earlier, Safe Work Australia has published a new database of GHS classification and labelling information called the Hazardous Chemicals Information System (HCIS). It contains information for over 4500 chemicals.

#### *Response on emergency situations involving chemicals, including poisoning*

Response to emergency situations involving chemicals, such as spills, occurs at a state/territory level. Participants can include state/territory environment protection authorities (EPA), Safe Work Australia and fire authorities. Response on emergency situations involving poisoning includes the Poisons Information Centre.

##### **Fire Authorities**

State fire and rescue authorities respond to chemical spills and radiological and biological hazards under the appropriate Act, such as the Fire Brigades Act 1989 (NSW). State/territory fire and rescue authorities also respond to hazardous materials (Hazmat) incidents.[26]

##### **Fire Authorities**

The Poisons Information Hotline (13 11 26) is an Australian-wide telephone advice service for medical professionals and general public in cases of acute and chronic poisonings. The Poisons Information Centre also provides advice on poison prevention, drug information, first aid management of poisons and identification of toxic agents through this service.[27]

#### *OECD Mutual Acceptance of Data*

The testing of chemicals is labour intensive and expensive. Often the same chemicals are being tested and assessed in several countries. The OECD Council therefore adopted a Council Decision in 1981 – on Mutual Acceptance of Data (MAD) - stating that test data generated in any member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment.

A further Council Act was adopted in 1989 to provide assurance that the data are indeed developed in compliance with the Principles of Good Laboratory Practice. Australian regulators are legally bound to accept test data that has been generated in accordance with the OECD test guidelines by laboratories certified to Good Laboratory Practice standard.

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**C a n a d a**

Composed by Russian Federation  
Reviewed by Canada

## **I n t r o d u c t i o n**

Canadians depend on chemical substances each and every day for hundreds of things, from medicines to computers to fabrics to fuels. Some chemical substances are made deliberately and are used in manufacturing, while others are byproducts of chemical processes [1]. Canada's chemistry industry transforms raw materials like natural gas liquids, oil, minerals, electricity and biomass into the building blocks needed to manufacture some 70,000 products that are depended on every day. Vehicles, electronics, textiles, building materials, paper and pharmaceuticals all exist thanks to Canadian chemistry.

Canada's \$53-billion chemistry industry operates in every province, with key clusters in Ontario, Alberta and Quebec. It directly employs more than 87,000 Canadians and supports another 435,000 jobs in the Canadian automotive, aerospace, food and beverage, construction, forest products, plastics, computers and electronics sectors.

Canada's chemistry industry relies on feedstock from the oil and gas, electricity, mining and biomass sectors and adds five to 10 times the value to Canada's natural resources, through high-tech processes. It is the world's largest exporter of sodium chlorate and sulphuric acid, the second-largest exporter of ethylene glycol, the fourth-largest exporter of polyethylene, and is the nation's third-largest exporter of manufactured goods, exporting \$30 billion worth of products in 2012. It is a high-paying industry, with industrial chemical workers making an average salary of \$68,600. Lastly, the chemistry industry is Canada's second-most knowledge-intensive industry—34 per cent of the industry employees have a university degree [2].

According to the Chemistry Industry Association of Canada's "2016 Year-end Survey of Business", the following highlights in the field of industrial chemistry may be emphasized [3]:

- *2016 sales of industrial chemicals were expected to be approximately \$23 billion, a decline of 2% compared to 2015. Using constant dollar shipments as a proxy for output, volumes increased 3% compared to 2015. This indicates that on an aggregate basis, selling prices declined over the year, leading to the lower revenue estimate.*
- *Exports in dollar terms were expected to decrease by about 4% compared to 2015, to \$18.5 billion, reflecting a challenging trade environment.*
- *Operating profits were expected to fall about 9% for the year, dropping under \$3 billion for the first time since 2012. However, in 2016, the industry experienced its ninth consecutive year of high profits since the last recession.*
- *Capital expenditures in 2016 were projected to be just over \$1 billion, a decline of 7% compared to 2015. The large capital projects that were undertaken in the industry were essentially completed in 2016, and no new major projects were commenced.*
- *Imports of industrial chemicals in Canada in 2016 amount to \$18.6 billion.*

Additionally, the Chemistry Industry Association of Canada's "2016 Statistical Review of the Canadian Chemical Manufacturing Sector" showed that Canada's chemical industry is a significant contributor to the country's economy [4].

While chemicals provide benefits, they may also have harmful effects if not properly managed. The Government of Canada controls chemicals to protect human health and the environment using a variety of regulatory and non-regulatory measures. These range from providing information and guidance about proper use and disposal, to regulations that restrict or ban use. Strong science, assessment and monitoring, combined with a variety of control measures to manage the risks posed by chemicals form the risk-based approach to chemicals in Canada [1].

## **1 . R e g u l a t e d o b j e c t s**

The Canadian Environmental Protection Act, 1999 (CEPA 1999) is the main legislative tool used to assess and manage substances. CEPA 1999 defines a "substance" as any distinguishable kind of organic or inorganic matter, animate or inanimate, that can be released as a single substance, an effluent, waste or a mixture into the Canadian environment [5]. In addition to CEPA 1999, the risks from substances can also be regulated under other Acts, where they are best placed to do so, such as the Canada Consumer Product Safety Act, the Food & Drugs Act, the Pest Control Products Act, and the Fisheries Act.

CEPA 1999 grants the federal government extensive authority to assess and regulate toxic substances and products that contain them, and is active in addressing risks associated with toxic substances. It is jointly administered by the Minister of Environment and Climate Change and the Minister of Health. The Minister of Environment and Climate Change exercises powers, duties and functions related to risks posed by chemicals entering the environment, whereas the Minister of Health is responsible for addressing the risks posed by chemicals on human health.

Under CEPA 1999, over 50 regulations are designated for certain groups of chemicals. On the Government of Canada website, there is a list of regulations highlighting the certain groups of chemicals of concern, which become the object of regulation in Canada [6]. CEPA 1999 also established the following lists or inventories, which are amended regularly to include those substances deemed eligible following their assessment [7]:

- *Domestic substances list*
- *Export control list*
- *Non-domestic substances list*
- *Priority substances list*
- *Toxic substances list*
- *Virtual elimination list*
- *Matter that may be disposed of at sea*
- *Non-statutory list*
- *National pollutant release inventory (NPRI) [8]*

In 2006, the Government of Canada launched the Chemicals Management Plan (CMP) as a framework to assess environmental and health threats posed by chemical substances and to develop and implement risk management measures to deal with these substances, if required. The CMP builds on previous initiatives by assessing chemicals used in Canada and by taking action on chemicals found to be harmful to human health and/or the environment. The CMP is jointly delivered by Environment and Climate Change Canada and Health Canada [9].

## **2 . P a r t i c i p a n t s   o f   t h e   r e g u l a t o r y   s y s t e m**

In Canada, the federal, provincial, territorial, and municipal governments each have a role in protecting Canadians and their environment against risks from chemical substances. The federal government makes laws and develops guidelines and objectives that apply across Canada, conducts scientific research on human health and environmental issues, and collaborates with other countries on the assessment and effective management of chemicals [10].

Engaging stakeholders is central to Canada's Chemicals Management Plan (CMP). Stakeholders remain informed and contribute to the CMP through regular public information sessions and consultations [11]. The CMP Stakeholder Advisory Council is a multi-stakeholder group that contributes to the implementation of the CMP. The purpose of the Council is to provide stakeholders the opportunity to offer advice and input to Government on the implementation of the CMP, and to foster dialogue on issues pertaining to the CMP between stakeholders and government, and among

different stakeholder groups. Issues may include risk assessment, risk management, risk communications, monitoring, research, indicators of success, chemical policy, and other cross-cutting, integrated activities across the CMP.

The group holds a minimum of two meetings per year. Its current mandate is from April 2016 until March 31, 2021. Members represent national indigenous organizations, consumer groups, environmental non-governmental organizations, health non-governmental organizations and industry (including associations, producers, and users with a specific focus on downstream industry) [12].

### **3 - 4. Influences: National priorities and International activities**

The Government of Canada's goal is to safeguard the health of Canadians and the environment, while supporting economic growth—the essence of sustainable development [13]. Chemicals regulation in Canada is influenced by domestic priorities and international obligations. Canada supports the World Summit Sustainability Development 2020 goal for sound management of chemicals and waste domestically, through its legislative framework and the Chemicals Management Plan, and internationally, through work under multilateral environmental agreements and active participation in global initiatives [10, 14], which includes Strategic Approach to International Chemicals Management (SAICM), Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Organization for Economic Co-operation and Development (OECD), and World Health Organization (WHO).

Canada is party to several multilateral environmental agreements and is a contributor to a number of strategic programmes and activities in collaboration with other jurisdictions. While the Chemicals Management Plan is focused on achieving results in Canada, it is recognized that coordinated, global efforts are essential to provide effective management of chemical substances. The sharing of research, information (data) and knowledge among jurisdictions helps to increase efficiencies in the global management of chemicals, while supporting international trade [10] In addition, collaborative work toward global chemicals management has the potential to reduce regional impacts of certain chemicals subject to long-range transport, which results in effects in jurisdictions beyond the site of their release.

Table 3.3.1. provides a list of multilateral environmental agreements relevant to chemicals and waste management.

**Table 3.3.1. Multilateral environmental agreements (MEAs) relevant to chemicals and waste ratified by Canada and other relevant international initiatives**

<b>Name of the MEA</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Remark / source link</b>
The U.N. Framework on Climate Change	Yes	Yes	<a href="https://www.canada.ca/en/environment-climate-change/services/climate-change/united-nations-framework-convention.html">https://www.canada.ca/en/environment-climate-change/services/climate-change/united-nations-framework-convention.html</a>
The Rio Declaration on Environment and Development/Agenda 21	N/A	N/A	<a href="http://publications.gc.ca/Collection-R/LoPBdP/BP/prb0258-e.htm#implementingtxt">http://publications.gc.ca/Collection-R/LoPBdP/BP/prb0258-e.htm#implementingtxt</a>

## Canada

Name of the MEA	Status of ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Remark / source link
The Stockholm Convention on Persistent Organic Pollutants	Yes	23/05/2001	
The Montreal Protocol on Substances That Deplete the Ozone Layer	Yes	30/06/1988	
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	Yes	28/08/1992	
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	Yes	26/08/2002 (a)	
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Profile on Chemical Weapons and on their Destruction	Yes	26/09/1995	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Minamata Convention on Mercury	Yes	7/04/2017	<a href="http://www.mercuryconvention.org/Countries">http://www.mercuryconvention.org/Countries</a>
Vienna Convention for the Protection of the Ozone Layer	Yes	30/06/1988	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

### *Canada's Collaboration with International Partners to Advance the Strategic Approach to International Chemicals Management (SAICM)*

#### Multilateral Initiatives

Canada contributes to and benefits from collective efforts under the Organization for Economic Cooperation and Development (OECD) [15] and other international bodies to develop standards and guidelines that help avoid unnecessary duplication and accelerate the management of chemicals globally. Canadian scientists have contributed to a number of OECD initiatives, including the OECD Joint Meeting on of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology and the Working Party on Manufactured Nanomaterials.

Additionally, Canada participates in the six working groups of the Arctic Council, an intergovernmental forum that encourages Arctic States to take remedial and preventive actions related to contaminants and other releases of pollutants to reduce the associated risks [10]. The Arctic Council promotes cooperation, coordination and interaction in the Arctic region on issues of sustainable development and environmental protection. It helps advance Canadian priorities, including a renewed focus on multilateralism, strengthened relations with Indigenous peoples and addressing climate change. Canada played a key role in founding the Council and was the leading voice in ensuring that Indigenous peoples be a key part of this forum [16]. Canada is active in the Arctic Monitoring and Assessment Programme (AMAP), one of the Working Groups of the Arctic Council, which monitors

and assesses the human health and environmental status of the Arctic region with respect to pollution and climate change issues.

### North American Regional Initiatives

In 1994, Canada, along with the United States and Mexico signed the North American Agreement on Environmental Cooperation, which also established the Commission for Environmental Cooperation (CEC). In establishing the CEC [17], Canada, Mexico and the United States acknowledged the growing environmental, social and economic linkages, and agreed to promote sustainable development based on cooperation and mutually supportive policies. A Statement of Intent on North American Chemicals Cooperation signed in 2008 reaffirms the tri-partite intention to work collaboratively, and puts forward a framework for regulatory cooperation in the area of chemicals that outlines priorities and commitments. **Ошибка! Закладка не определена.**

Canada further engages with the United States through the Great Lakes Water Quality Agreement (GLWQA) to restore and maintain the chemical, physical and biological integrity of the waters of the Great Lakes. The GLWQA was signed in 1972 and most recently amended in 2012. Through the Agreement, Canada and the United States, in cooperation and consultation with other levels of government, Indigenous peoples, non-governmental entities and the public, work to restore and protect Great Lakes water quality and ecosystem health. Canada's collaboration and cooperation with the Government of Ontario, through the 2014 Canada-Ontario Agreement on Great Lakes Water Quality and Ecosystem Health, helps coordinate the activities of eight federal departments and three provincial ministries in order to support implementation of the 2012 GLWQA [18].

### Bilateral cooperation

The Consultations on Substance Management (COSM) between Canada and the United States are informal discussions to facilitate bilateral cooperation in the area of chemicals management, with the goal of strengthening national and regional risk-based chemical assessment and management efforts through increased sharing of resources and technical expertise [10].

In February 2011, the Governments of the United States (U.S.) and Canada launched the Canada-U.S. Regulatory Cooperation Council (RCC) to facilitate closer cooperation between Canada and the U.S. on the development of smarter and more effective approaches to regulation that strengthen the economy, enhance competitiveness, and protect public safety and welfare. In particular, Environment and Climate Change Canada, Health Canada, and the United States Environmental Protection Agency have department to department commitments and work plans on the topic of chemicals management [19].

The European Union is a strategic partner for Canada and the two share many common values [20]. Canada signed a Memorandum of Understanding (MOU) between the European Chemicals Agency and Environment and Climate Change Canada and Health Canada in 2010. The MOU has the objective of enhancing technical cooperation in order to share knowledge, exchange experience and best practice on matters of mutual interest related to chemicals management. Implementation of the MOU is achieved through a rolling work-plan, which is updated on an annual basis. The MOU has helped to developed networks of expertise and better understanding of regulatory issues with regards to chemicals as well as facilitated exchanges of information, the sharing of tools and methodologies for risk assessments, peer review of assessments, and on-going dialogue sharing information on respective regimes [21].

Further, Canada and Australia have concluded an arrangement relating to industrial chemicals - a Cooperative Arrangement between the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia, Health Canada, and Environment Canada. Signed in 2011, its objectives include achieving efficiencies of resources in new and existing industrial chemical reviews

as well as increasing knowledge of each other's risk assessment and management approaches and practices. This arrangement includes provisions for exchanging of information on new and existing industrial chemicals, working cooperatively through joint projects of mutual interest, sharing of assessment and management related expertise, and adopting (when desirable and where possible) consistent practices and regulatory approaches. Implementation is achieved through a cooperative work program, reviewed on an as-needed basis. As a result, Australian legislation has recognized Canada as a "Competent Authority" which allows sharing of new Canadian assessments on substances with Australia (NICNAS). Additionally, Australia serves as a peer-reviewer for Canadian assessment reports on new and existing industrial chemicals, as needed [22].

Canada is also engaged in a number of less formal bilateral initiatives and will continue to work with other countries to promote capacity building, sharing of technical expertise, information and data, as well as specific agreements regarding environmental considerations, product safety, and pharmaceuticals [10]. These activities often lead to the development of standards and guidelines such as those such as those involving food and plumbing for drinking water.

### **5 . P a r a m e t e r s   o f   r e g u l a t i o n**

CEPA 1999 enables Environment and Climate Change Canada and Health Canada to take action on a wide range of environmental and health risks posed by substances and waste. It provides a suite of tools that can be used to identify, assess and address these risks. In many cases, CEPA 1999 authorizes more than one possible approach to address a given risk. Some examples of risk management instruments are regulations, pollution prevention planning notices, guidelines, codes of practice, and Significant New Activity Notices [23].

The Government of Canada also has access to risk management tools outside of CEPA 1999 that can address CEPA-toxic or other chemical substances. A chemical substance is found toxic under CEPA 1999 if it is entering or may enter the environment in a quantity of concentration or under conditions that:

- *have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- *constitute or may constitute a danger to the environment on which life depends; or*
- *constitute or may constitute a danger in Canada to human life or health [5].*

Actions can be taken to develop instruments under other Acts, such as the *Canada Consumer Product Safety Act (CCPSA)*, the *Pest Control Products Act (PCPA)*, the *Fisheries Act*, and the *Food and Drugs Act (FDA)*. When making risk management decisions, consideration is given to which Act is best placed to manage the identified risks [24]. This allows the government to protect the environment and human health in cost-effective ways that reflect social, economic and technological factors.

For chemical substances that have been found CEPA-toxic following a screening assessment for risk, risk management:

- *includes development of objectives (human health/environment) based on risks identified, and*
- *requires the identification, evaluation, selection and implementation of appropriate actions to manage those identified risks, and to track progress to ensure actions are meeting the desired objectives.*

For tracking of the effectiveness of applied regulatory tools and enforcement activities, the performance indicators are enacted on the stage of regulatory Instrument Development for the dedicated chemical or chemical substances [25].

### **6 . K e y   p r o c e d u r e s   f o r   c o n t r o l   o f   t h e   r e g u l a t e d**

## o b j e c t s

### *Regime leading up to the Chemicals Management Plan*

Over the past 30 years, CEPA 1999 has been a key statute for Canada's work on chemicals management. First promulgated in 1988 ("1988 CEPA") and renewed in 1999, it provides the legislative framework for risk assessment and management of existing and new substances in Canada.

The Priority Substances Assessment Program was the first chemicals assessment program introduced under CEPA 1988 whereby chemical substances were identified on a priority basis by a Minister-appointed panel of experts, added to a Priority Substances List and then evaluated through a risk assessment to determine whether they were harmful to Canadians or the environment. The government was mandated by law to carry out and complete the risk assessments within a period of five years. The Priority Substances Assessment Program included two Priority Substances Lists (PSL), dating from PSL1 in 1989 through to PSL2 in 1995 covering 44 and 25 substances respectively over a ten year period.

In 1994, the Domestic Substances List (DSL) was established, identifying an inventory of existing substances that were reported to be in use or commerce in Canada from 1984-1986. With the establishment of the DSL, Canada also developed a set of regulations effectively launching the New Substances Program, which required every new substance manufactured or imported in Canada to be assessed for potential risks to human health and the environment before being allowed on the Canadian market.

When the Canadian Environmental Protection Act was updated in 1999 (CEPA 1999), it introduced new tools and approaches to address pollution prevention and chemicals management within Canada. A key initiative within the legislation was a mandatory provision requiring the Government to review all of the substances on the DSL (23,000 substances) to determine whether they had certain characteristics indicating that the government should further assess the risk associated with their continued use in Canada. Canada completed this exercise, called Categorization, in 2006, identifying 4,300 existing substances for further assessment [26].

### *The Launch of Canada's Chemicals Management Plan (CMP)*

The Government of Canada created the Chemicals Management Plan (CMP) in 2006 to protect human health and the environment by assessing chemicals used in Canada and by taking action on chemicals found to be harmful. Delivered jointly by Environment Canada and Health Canada, and through partnership and engagement with stakeholders, activities under the CMP help to protect Canadians and their environment from harmful effects of chemical substances.

The CMP accelerated timelines to assess environmental and human health risks posed by chemical substances, and develop and implement prevention, reduction, elimination and management measures to reduce these risks by using the most appropriate management tools among a full suite of federal laws.

Under the CMP, information is gathered on substances in use in Canada; assessments and, when necessary, risk management is conducted on these substances through regulatory and non-regulatory measures; the public is informed of any known risks; and the public and stakeholders are encouraged to participate. The government also engages in research, monitoring and surveillance, and participates in international activities [26].

Additionally, the 4,300 existing substances requiring further assessment have been divided into three groups of priorities for action between 2006 and 2020, so that the government could take accelerated and measured action on chemicals of greatest potential concern. During the first phase

(2006-2011) and the second phase (2011-2016), 1,100 and 1,650 chemicals were addressed, respectively. Approximately 1,550 are being addressed in the third phase (2016-2020) [27].

### *New Substances*

Under its New Substances program, the Government of Canada is responsible for administering the New Substances Notification Regulations (Chemicals and Polymers) and the New Substances Notification Regulations (Organisms) of CEPA 1999. These Regulations were created to ensure that any new substance (chemical, polymer or animate product of biotechnology) is subject to an assessment of potential risk to human health and/or the environment, and any appropriate control measures are taken. Under this program, the Government of Canada typically receives and evaluates approximately 500 notifications per year and takes action on 15 to 20 substances.

When a company or individual plans to import or manufacture a new substance, it must first submit a notification package. The data requirements and associated assessment period depend on the type of substance and quantities that the companies intend to import or manufacture. When the assessment identifies that a new substance may pose a risk to human health or the environment, CEPA 1999 empowers the Government of Canada to intervene prior to or during the earliest stages of its introduction into Canada. This ability to act early makes the New Substances program a unique and essential component of the federal management of toxic substances [26].

### *CMP: Phase One*

The first phase of the Chemicals Management Plan (CMP1) involved several important initiatives, built on a base of strong science, including the “Challenge initiative” for high priority substances, the Rapid Screening of lower priority substances, an approach for substances in the Petroleum Sector, establishment of key stakeholder initiatives, an update of the DSL Inventory as well as taking action on substances, with potential high hazard characteristics, deemed not to be in Canadian commerce.

- *The Challenge initiative focused on about 200 high-priority substances which were divided up into 12 batches. Each batch included mandatory information gathering, publication of draft assessments for public comment and publication of final assessment decisions with proposed risk management approaches as required.*
- *The Rapid Screening Approach was applied to approximately 1,100 substances which were identified as potential lower risk substances that were unlikely, given current evidence, to be harmful to the environment or human health. Government scientists expected that the substances, while meeting the categorization criteria, were not likely to pose a risk in the amounts at which they are found in Canada. An accelerated screening approach applied conservative scenarios to determine whether further assessment was necessary.*
- *The Petroleum Sector Stream Approach included approximately 160 substances identified as priorities for action through Categorization and were grouped to be addressed in a sectoral approach. A large portion of high priority petroleum substances are used or manufactured during petroleum refining or bitumen / heavy crude oil upgrading activities.*
- *Stakeholder bodies were also established, including the Stakeholder Advisory Council with the mandate to provide input on the implementation of the CMP. The Challenge Advisory Panel was established to review the application of precaution and weight of evidence in risk assessments and to provide third-party advice on approaches developed for risk assessments under the Challenge.*

Under CMP1, the Government of Canada was successful in taking decisive action to address substances of high concern, and reassured Canadians about substances that were of little concern. Canada demonstrated its commitment to assessing all of the substances that have been identified through categorization via successive rounds of assessment and, where necessary, taking action to

manage risks. Continuously improved information on the uses and effects of chemical substances through mandatory information collection helped establish future rounds of priorities moving beyond CMP1. CMP1 also recognized that managing chemicals safely relied on strong stewardship from Canadian industry. The federal government also worked to ensure that information about chemical substances (hazards and practices for safe management) was available to Canadians through a central website for the CMP [26].

### *CMP: Phase Two*

Canada renewed the Chemicals Management Plan in 2010-2011, for a further five years, with an updated approach, building upon lessons learned under the first phase of the CMP, and a continued commitment to strong science to start to address the remaining priorities. Key initiatives under the second phase include a groupings approach, whereby 500 substances would be addressed under nine substance groupings [26]. **Ошибка! Закладка не определена.** These substance groupings were selected for further action based on the categorization exercise completed in 2006 and new information received as part of the first phase of the Chemicals Management Plan.

The groupings were identified based on structural or functional similarities and were assembled based on considerations related to assessment efficiencies, management efficiencies, the ability to support informed substitution decisions, timing of international actions and stakeholder engagement. Final screening assessment decisions and proposed risk management approaches (when applicable) have been published or are being finalized. The initiative includes the following substance groupings [28]:

- *Aromatic Azo and Benzidine-based Substance Grouping*
- *Boron-Containing Substances*
- *Certain Organic Flame Retardants Substance Grouping*
- *Cobalt-Containing Substance Grouping*
- *Internationally Classified Substance Grouping*
- *Methylenediphenyl Diisocyanate and Diamine (MDI/MDA) Substance Grouping*
- *Phthalate Substance Grouping*
- *Selenium-containing Substance Grouping*
- *Substituted Diphenylamines Substance Grouping*

Canada is also undertaking an update of the Domestic Substances List (DSL) as well as a further rapid screening initiative for substances identified as no longer being in commerce, or used in low volumes, under the inventory updates. Stakeholder bodies were also modified: the Challenge Advisory Body was replaced with the CMP Science Committee. **Ошибка! Закладка не определена.** The CMP Science Committee was created in 2013 to contribute expertise pertaining to scientific considerations in the delivery of the CMP. The first 3-year term of the CMP Science Committee ended in the Fall of 2016. The committee for the second 3-year term consists of nine core members that will serve from Summer 2017 to Summer 2020 [29].

### *CMP: Phase Three*

The next phase of the CMP runs to 2021. Over five years, approximately 1,550 priority substances will be addressed. The government has announced measures for risk assessment, risk management and information-gathering for those substances [30]. A notice of intent for early stakeholder engagement was published in February 2016, and an announcement that applies to these substances was published in the Canada Gazette [31].

The approximate 1,550 priority substances to be addressed include those identified during categorization of the Domestic Substances List and the 2015 Review Identifying Risk Assessment Priorities. There will continue to be an emphasis in future assessments on selection of “fit-for-purpose”

approaches, so that efforts are focused on the substances of highest concern, and engagement of stakeholders is efficient, strategic and targeted. As the program continues to evolve, strong science remains a priority. Science approach documents will be published for substances that are expected to be of low concern for either human health or the environment. These documents will describe the assessment approach and results for substances identified as of low concern.

Management of risks from toxic chemicals will continue to involve the selection and application of tools appropriate to the level of risk identified, with the aim of achieving environmental and human health objectives on a sustained basis. For the 1,550 substances to be assessed during the next phase of the CMP, consultation on risk management actions will be initiated for those substances that are found harmful to human health or the environment. In addition, Canada will continue to actively engage in international discussions on the sound management of chemicals and waste beyond 2020, including under the various multilateral environmental agreements on chemicals and in the Strategic Approach to International Chemicals Management.

As of December 2017, the Government of Canada has addressed 3,331 of the 4,300 chemicals identified as priorities for attention by 2020-2021, including draft and final assessments. It has found 420 existing chemicals to be harmful to the environment and/or human health and implemented 80 risk management actions for existing chemicals (with additional tools in development). The Government of Canada has also received approximately 5,671 notifications for new substances prior to their introduction into the Canadian market. These notifications have been assessed and over 283 risk management actions have been taken, when necessary, to manage potential risks to Canadians and their environment [32].

## 7. Non-regulatory mechanisms

In the 1980s, pressures to regulate Canada's chemistry industry were growing, galvanized by spills, process safety, and transportation incidents in Canada and abroad. Canada's chemistry CEOs faced the facts: the public did not trust industry. Building public trust would require something above and beyond the law: a commitment to doing the right thing.

Between 1985 and 1988, members of the Chemistry Industry Association of Canada (then known as the Canadian Chemical Producers' Association) drafted the first Responsible Care® Codes – including stringent guidelines for the safe and environmentally sound management of chemicals. Those codes remained essentially unchanged for more than two decades.

But Responsible Care® did evolve. In 1992, CIAC members began voluntarily reporting their environmental emissions under Responsible Care®. A year later, CIAC introduced the Responsible Care® public verification process – inviting industry experts, public advocates and representatives from local communities to assess first-hand whether companies were living up to their commitments.

As Responsible Care® neared its silver anniversary in 2010, members began asking whether the initiative was equipped to address public concerns about health, climate change, resource conservation, and the industry's environmental footprint. CIAC's Board of Directors endorsed a new Responsible Care® Ethic and Principles for Sustainability, and the Responsible Care® Codes were completely rewritten to reflect the more exacting sustainability standards that CIAC companies would be expected to live up to [33].

The Responsible Care® initiative, developed in Canada and launched in 1985, has served as a model for chemical industries around the world to address public concerns about the manufacture, distribution, and use of chemicals. Since the adoption of Agenda 21 at the Rio Earth Summit in 1991, 52 countries have adopted Responsible Care® and tailored it to their operations [34].

## 8. Availability of data

Canada's approach to chemicals management promotes an open and transparent information exchange between parties. To keep Canadians and stakeholders apprised of the work being carried out under the Chemicals Management Plan, the Government of Canada maintains a website which provides up-to-date information on the progress being made, as well as links to key initiatives in related program areas. **Ошибка! Закладка не определена.** The CEPA Environmental Registry and Chemicals Management Plan websites provide searchable or downloadable lists of existing chemical substances, results of rapid screening and prioritization exercises, detailed substance assessments, and proposed risk management activities. This information is available for use by international parties and other jurisdictions across Canada to inform their chemicals assessment and risk management activities.

In addition, the Government of Canada has created a website on mercury and the environment to provide scientific background information and to outline current policies, programs, and practical guidance related to mercury [35]. As well, information submitted by facilities subject to Pollution Prevention Planning Notices under CEPA 1999 is made publicly available [36]. The federal government also maintains a list of substances that are restricted and prohibited in cosmetics called the Cosmetic Ingredients Hotlist [37]. This administrative list is intended to help manufacturers avoid these substances, in order to satisfy the requirements for sale in Canada.

The federal government works with key civil society organizations to strengthen their ability to fully participate in CMP-related consultative processes, and provides funding for the creation of stakeholder networks which are used to disseminate information. A CMP Stakeholder Advisory Council draws from multiple sectors, including Aboriginal organizations, consumer groups, environmental and health non-government organizations, industry, and labour. The involvement of stakeholders at key milestones has also helped to improve the accuracy of information and to improve data quality.

Environment and Climate Change Canada and Health Canada collect scientific data (e.g. toxicological studies) and commercial activity information (e.g. substance use and quantities) from a variety of sources and mechanisms, such as by working in collaboration with stakeholders and associations. Through the mandatory information gathering provisions under CEPA 1999, the Government of Canada regularly obtains updated information on the commercial status of substances. Several sections of CEPA 1999, such as sections 46, 70 and 71, allow the federal government to collect information from industry and other individuals regarding their activities with substances, as well as other available toxicological information that informs assessment. Under the CMP, the Government of Canada has used these authorities under CEPA 1999 to collect information on the commercial status of existing substances and certain other information required for risk assessments. For substances that are new to Canada, industry is required to provide specific information to the New Substances Program as required by the New Substances Notification Regulations under CEPA 1999 [38].

Under section 313 of CEPA 1999, any person who provides information to the government under CEPA may, at the same time, submit a written request that the information be treated as confidential. This feature ensures that Confidential Business Information (CBI) is protected from public disclosure. When the identity of a substance is claimed confidential, it is protected with a masked name, which is proposed by the submitter. Masking may be accomplished by disguising structurally distinctive elements of the explicit chemical name of the substance, while retaining the generic identity/molecular structure of the substance. In most cases, masking a single element of the explicit chemical name of the substance would be sufficient, although masking multiple elements of the substance is also accepted when needed with supporting justification. Masked names are reviewed upon submission; if the claim for confidentiality of the explicit chemical name is acceptable, the proposed masked name will be evaluated to determine whether or not it is consistent with the Masked Name Regulations [39]. In some instances, information submitted under CEPA 1999 to support risk assessments may be identified as CBI. CBI is considered in risk assessment decision-making but is

protected in public documents in order to maintain confidentiality. To allow the highest possible level of transparency to stakeholders and the public in risk assessment documents, CBI should only be claimed for information that is truly confidential [38].

CEPA 1999 provides the legislative basis for annual industrial reporting to Canada's National Pollutant Release Inventory (NPRI) on pollutant releases (to air, water and land), disposals and transfers for recycling by facilities that meet NPRI reporting requirements. NPRI data is made publicly available in a variety of formats, including an online query tool, downloadable databases, and map layers for use with Google Earth. The NPRI is a key resource for improving public understanding of releases to the environment, identifying priorities for action, encouraging voluntary action to reduce releases, tracking progress in reducing releases, supporting targeted regulatory initiatives, and supporting the development of other pollutant release inventories, such as the Air Pollutant Emissions Inventory, and related international reporting obligations.

Canada works proactively, with a number of industry sectors as well as with provincial and territorial governments, to enhance the consistency and accuracy of reporting. This work involves developing and providing online training modules for facilities along with sector specific guidance to improve the accuracy of the information reported. For 2016, the last reporting year for which information is available, over 7000 facilities reported to the NPRI on more than 300 listed substances.

Canada's Single Window is an online reporting system created by the federal government, which is also used by provincial government to collect environmental data from industry. This online system was developed in response to industry requests to streamline and simplify environmental reporting requirements, thus reducing the administrative cost and paperwork burden of regulatory compliance. Single Window provides a platform for federal and provincial governments to collect environmental information in a more timely, efficient and cost-effective manner, and to improve the quality and accuracy of data. The system was first launched in 2010 with an initial scope that addressed the data collection needs of the NPRI, Canada's Greenhouse Gas Emissions Reporting Program (GHGRP), and their provincial partners. The system has since expanded to support regulatory reporting for more than a dozen environmental programs.

A comprehensive information service related to prevention of hazardous workplace chemical exposures is provided by the Canadian Centre for Occupational Health and Safety (CCOHS), including a range of web-based chemical databases. CCOHS, in collaboration with the World Health Organization and the International Programme on Chemical Safety (IPCS), provides a software system used in poison centres around the world to support the collection, evaluation and reporting of human toxic exposure data. CCOHS also hosts the authoritative IPCS INCHEM data service which provides free public access to internationally peer-reviewed, chemical safety-related publications and database records via the eChemPortal [40] website.

On-going monitoring programs—such as the Canadian Health Measures Survey (CHMS), the Maternal-Infant Research on Environmental Chemicals (MIREC), the First Nations Biomonitoring Initiative (FNBI), the Arctic Monitoring and Assessment Program (AMAP), the Northern Contaminant Program, the Canadian Total Diet Study, and the National Air Pollutant Surveillance (NAPS) — provide data and trend information on levels of substances in humans and the environment.

## **9 . L a b o r a t o r y i n f r a s t r u c t u r e**

The OECD's Principles of Good Laboratory Practice (GLP) is a managerial concept covering the organizational process and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Non-clinical health and environmental safety studies covered by the principles of GLP include work conducted in the laboratory, in greenhouses and in the field.

A 1989 OECD Council Decision-Recommendation [C(89)87(Final)] [41] established that OECD Member countries, in which testing of chemicals for purposes of assessment related to the protection of human health and the environment being conducted pursuant to the principles of GLP, shall establish procedures for monitoring compliance with GLP based upon facility inspections and study audits.

In this regard, the Standards Council of Canada (SCC) has established a GLP Compliance Monitoring Authority (GLP MA) recognized by the OECD and functioning in accordance with the OECD document Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (1995).

Health Canada's Pest Management Regulatory Agency (PMRA) in its role as the regulatory authority for pesticide registration in Canada, the New Substances program administered by Environment Canada and Health Canada, and the Health Products and Food Branch of Health Canada (HPFB) have recognized the SCC as the GLP MA of facilities submitting human health and environmental safety studies.

The HPFB GLP policy directive applies to sponsors submitting non-clinical data in Clinical Trial Applications, New Drug Submissions or Drug Identification Number applications relating to pharmaceuticals, radiopharmaceuticals or biologic drugs for human use. Non-clinical studies include all in vitro and in vivo testing, not involving human subjects, performed to determine the safety of human drugs.

A comprehensive list of studies requiring compliance to the Principles of GLP is available from the respective receiving authorities.

A 1981 OECD council decision [C(81)30(Final)] [42] decided that data generated in an OECD Member country in accordance with the OECD Principles of GLP shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of human health and the environment; that is, the Mutual Acceptance of Data (MAD).

SCC GLP MA in-compliance recognition of domestic test facilities and test sites (including field sites) involved in pre-market non-clinical human health and environmental safety studies on pesticides and industrial chemicals meets the requirements of the OECD Decision on MAD, and facilitates acceptance of Canadian pesticide and industrial chemical GLP studies submitted to receiving authorities in other OECD Member countries.

## **10 . I n f o r m a t i o n   s h a r i n g**

### *The implementation of GHS in Canada*

Canada has worked with other countries to develop a single, Globally Harmonized System of Classification and Labelling of Chemicals (GHS), an integral component of SAICM. Canada is currently undertaking stakeholder consultations in order to implement the GHS.

Under the Food and Drugs Act, Canada's Cosmetic Regulations were amended in 2006 to require ingredient labelling on all cosmetic products. The Consumer Chemicals and Containers Regulations, 2001 under Canada's Hazardous Products Act require labelling using a criteria-based system by which products are regulated on the basis of the scientifically assessed hazards that they pose to users, such as toxicity, flammability, or corrosivity. Scientific data is used to identify the types of inherent hazards and the possible routes of exposure to the product in order to appropriately classify the product and determine if a child resistant container is required. These regulations address acute exposure situations resulting from reasonably foreseeable use of the product. After classification, the regulated products must display hazard symbols, warning statements, instructions, and first-aid

treatment(s), in both of Canada's official languages (English and French). The label must also disclose all hazardous ingredients when present at specified concentrations.

The Workplace Hazardous Materials Information System (WHMIS)[43] is the cornerstone of workers' right-to-know legislation in Canada, and mandates the provision of material safety data sheets (MSDSs), labelling, and the provision of worker education programs for hazardous chemicals intended for occupational use. The WHMIS requirements of the Hazardous Products Act and the Controlled Products Regulations do not restrict or otherwise limit the use of any chemicals in the workplace. Federal, provincial and territorial government partnerships have been established to protect Canadian workers, and an information service, including a web-based searchable collection of WHMIS hazard classification information is provided by the Canadian Centre for Occupational Health and Safety.

*Response on emergency situations involving chemicals, including poisoning*

Canada's Emergency Management Act, 2007 [44] sets out clear roles and responsibilities for all federal Ministers across the full spectrum of emergency management, including prevention/mitigation, preparedness, response and recovery. In preparation for emergencies, federal departments work in close partnership with other levels of government, industry, and communities to identify potential risks, to develop and exercise contingency plans and to train personnel. Transport Canada develops safety and security regulations, means of containment standards, provides oversight and expert advice on dangerous goods safety and security incidents to promote public safety in the transportation of dangerous goods by all modes of transport in Canada. Canada's National Environmental Emergencies Contingency Plan [45], provides a framework to identify a variety of environmental hazards and to guide appropriate responses to hazards and emergencies. When the need arises to access a wide variety of expertise and resources, a Regional Environmental Emergencies Team [46] can be activated. Canada's Health Portfolio Chemical Emergency Response Plan also provides an operational framework to support the provinces and territories in the event of chemical emergencies, including the provision of scientific advice and risk assessments regarding the public health impacts of exposure to chemicals, consequence management advice, analytical support, medical assistance and supplies, advisories, alerts and warnings to the Canadian public.

Canadian laws support the principle of polluter responsibility, which means industry is accountable for taking adequate preventive actions and for having effective response plans in place. For example, under the Transportation of Dangerous Goods Act, when a shipper transports dangerous goods that require an emergency response assistance plan (ERAP), the plan must be approved by Transport Canada prior to the shipment taking place. Under CEPA 1999, Environmental Emergency Regulations require facilities that manufacture, store, use or dispose of toxic or other hazardous materials in quantities beyond specified thresholds to prepare and implement environmental emergency plans.

The amount of hazardous and noxious substances (HNS) that are currently being transported in and around Canada has expanded rapidly in recent years. The related risks are managed under Canada's Marine Oil Spill Preparedness and Response Regime, which administers policies, regulations and programs to protect the marine environment, to mitigate the impact on the environment of marine pollution incidents in Canadian waters, and to protect the safety of the general public. This includes the development of a Hazardous and Noxious Substances Program for preparing and responding to marine HNS incidents. The National Aerial Surveillance Program serves to detect pollution violations in Canadian waters and to collect evidence for use in the prosecution of offenders.

Internationally, Canada works with several partners and in multi-lateral fora to advance and share knowledge in the area of emergency prevention, preparedness and response. Canada maintains a significant working relationship with organizations such as the Joint United Nations Environment

Programme (UNEP) /Office for the Coordination of Humanitarian Affairs (OCHA) Environment Unit. Canada has several agreements with the United States to deal with environmental disasters on common borders, including the Canada-United States Joint Inland Pollution Contingency Plan and the Canada-United States Joint Marine Pollution Contingency Plan. Canada is party to the International Maritime Organization's Convention on Oil Pollution Preparedness, Response and Cooperation (OPRC Convention) and the International Convention for the Prevention of Pollution from Ships (MarPol). Canada has implemented Annexes I, II and III which set carriage rules for oil, noxious liquid substances and packaged dangerous goods; this includes hull design, discharge controls, designs for transfer conduits and connections and operational procedures to promote safety and prevent pollution from spills and accidents. Canada is also an active member of the Arctic Council, a high-level forum for cooperation regarding the prevention, preparedness and response to environmental emergencies in the Arctic that are a result of human activities or natural disasters.

Canada's Food and Consumer Safety Action Plan, proposes measures to support better identification of risks in the food supply, the establishment of preventative risk mitigation approaches, and targeted oversight to verify that industry's preventative approaches are effective and that there is a rapid response when problems do occur. Canada has a long history of cooperation regarding food safety with international regulatory counterparts to leverage resources and knowledge, and to apply sound regulatory practices and standards which are consistent with international norms. Canada collaborates and coordinates many of its risk management efforts with key food regulatory partners in the United States, Europe, Australia, New Zealand, and Japan. Engagements range from informal information exchanges to multilateral harmonization initiatives through international organisations such as Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, and the World Health Organization (WHO).

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## **I n t r o d u c t i o n**

The chemicals are widely used in modern life in Chile. Chemicals are applied in almost every part of public and private life of human and society. The following factors, as high rates of economic and industry growth, growth in raw material and endproduct consumption, the establishment of trade agreements and thereof boost in exports and imports in Chile, international obligations, as well as the main provisions of the Constitution of the Republic of Chile on safety, health and environment made Chilean citizens work out the national chemical management policy.

The country's economic growth over the past 20 years has been a determining factor in the domestic chemical industry, mainly due to increased use of chemicals, in terms of both volume and diversity.

The Chilean chemical industry is made up of approximately 300 companies, which manufacture locally and distribute around 400 chemicals at national and international level. One should also consider companies such as Oil Refineries, as well as the Steel, Pulp and Paper, Petrochemical and Copper Mining Industries, among others.

The chemical industry is essential to the Chilean economy. It represents about 6% of national GPI and around 30% of the industrial GPI. Important raw materials are produced for other key industries mostly for export sectors such as: mining, fruit production, cellulose and paper, wood products, and salmon. Some chemicals are exported globally such as methanol, nitrates, iodine and lithium carbonate. Main export markets are EU (22%), USA, Asia, Aladi and Mercosur (15 % each), and others such as, GRULAC, Africa and Australia.

Chile has businesses aimed at foreign markets in the national chemical industry, which have adapted their products to the customer's specific requirements, for whom they have developed the necessary skills to compete in the international market. There are also companies specifically focused on the domestic market. Regarding international trade in chemicals, it is important to note that it has been strongly supported by bilateral and multilateral trade agreements, as well as some partnership and complementation agreements. Given the above, during 2013 Chile made imports totalling close to US\$12.180 million, while exports reached an amount close to US\$3.701 million.

### **1 . R e g u l a t e d o b j e c t s**

Chemicals and wastes, which can be defined as «hazardous substances» (under Part II, Section b, of Circular No. 2/C 152 (1982)) are regulated in Chile. To be hazardous means to possess the following characteristics: corrosivity, irritate, flammability or combustibility, explosivity as well as radioactivity, what means to represent a risk to the health, safety or well-being of humans or animals.

Among them are chemicals, agrochemicals and fertilizers, consumer products, drugs, foodstuff, medicinal products, cosmetics, household cleaning products, fuels (gasoline, kerosene, diesel oil, etc.), industrial gases (liquefied gas, oxygen, nitrogen, etc.), potassium nitrate, nitrate sodium potassium, lithium carbonate, molybdenum trioxide, detergents, paints, solvents, organic dyes, polyvinylchloride, triple superphosphate, herbicides, fungicides, insecticides, urea nitrate ammonium, inks [3].

There are also several chemicals of concern on international level that are being regulated as well. They are, for example, POP's (Stockholm Convention on Persistent Organic Pollutants) (Decree No. 38 / 2005/ MINREL), hazardous wastes (Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Decree No. 685/1992 / Ministry of Foreign Affairs - MINREL), mercury (Minamata Convention on Mercury, signed by Chile in 2013, but not yet ratified), hazardous chemicals and pesticides (Rotterdam Convention on the Prior Informed Consent

Procedure for Certain Hazardous Chemicals and Pesticides subject of an international trade I (Decree No. 37/2005 / MINREL).

## **2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m**

Several governmental bodies are involved in the regulatory processes, as well as non-governmental organizations:

1. *Ministry of Health and Health Services/ <http://web.minsal.cl/> - regulates all the stages of life cycle of hazardous substances;*
2. *Ministry of Agriculture/ <http://www.gob.cl/ministers/agricultura/>- controls the regulation aspects relating to agricultural pesticides;*
3. *Ministry of Labour/ <http://www.mintrab.gov.cl/>- governs the basic health and environmental conditions in the workplace;*
4. *Ministry of Economy/ <http://www.economia.gob.cl/>- promotes cleaner and efficient chemicals production management, as well as monitors laws, regulations, policies on generation, storage, transport, distribution of liquid fuels, gas and electricity;*
5. *Ministry of Environment/ <http://portal.mma.gob.cl/>- oversees the issues on risk assessment of chemicals, genetically modified organisms and other substances, that can affect the environment;*
6. *Ministry of Defence/ <http://www.defensa.cl/>- is responsible for supervision and control of weapons, explosives, fireworks and pyrotechnics. It establishes and updates national list of Explosives and chemicals used in manufacturing of explosives. Also, it administers and provides safely maritime activity on the coasts and waterways under Chilean jurisdiction;*
7. *Ministry of Transport and Telecommunications/ <http://www.mtt.gob.cl/>- administers transportation and distributions issues of chemical substances;*
8. *Ministry of Interior/ <http://www.interior.gob.cl/>- advices, guides, coordinates, evaluates and controls prevention and care of emergency situations caused by natural disasters or by human activities;*
9. *Ministry of Finance/ <http://www.hacienda.cl/> - the National Customs service under this ministry oversees imports of dangerous substances prior to the entry of the country;*
10. *Ministry of Foreign Affairs/ <http://www.minrel.gob.cl/minrel/site/edic/base/port/inicio.html>- performs negotiating role on the fora concerning international conventions related to environmental issues (import, export, management, transportation, use and disposal of chemicals of global concern);*
11. *Ministry of Mining/ <http://www.minmineria.gob.cl/>- monitors issues on hygiene and safety in the extractive mining industry, as well as monitors transport, handling of explosives and dangerous substances used in mining operations;*
12. *The National Emergency Office (ONEMI)/ <http://www.onemi.cl/>;*
13. *The Agricultural and Livestock Service, SAG/ <http://english.sag.gob.cl/areas-action/agricultural-forestry>;*
14. *Chile's National Environmental Commission (CONAMA);*
15. *The Chemical Industry Association of Chile (ASIQUM) / <http://www.asiquim.com/nwebq/>;*
16. *National Customs Service/ [http://www.aduana.cl/aduana\\_eng/site/edic/base/port/inicio.html](http://www.aduana.cl/aduana_eng/site/edic/base/port/inicio.html);*

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17. *The Ministry of Defense is the General Directorate of Territory Maritime and Merchant Marine (DIRECTEMAR);*
18. *National Standards Body: Instituto Nacional de Normalización;*
19. *National Metrology Institute: Instituto Nacional de Normalización;*
20. *Accreditation Bodies :Instituto Nacional de Normalización (INN)/ <http://www.inn.cl/>.*

### **3 - 4 . I n f l u e n c e s : n a t i o n a l p r i o r i t i e s a n d i n t e r n a t i o n a l a c t i v i t i e s**

Can be divided into three main parts:

1. *Constitution, National strategic documents, legislation on chemical regulations*
2. *UNASUR, MERCOSUR, Free trade agreements provisions (with EU, Panama, Japan, China, USA, Canada, Mexico, Korea, Federal Republic of Central America, European Free Trade Association (EFTA), Trans-Pacific Strategic Economic Partnership (P4) Agreement (New Zealand, Singapore, Brunei Darussalam, Chile), economic complementation agreement with Argentina, Bolivia, Colombia, Ecuador, Mercosur, Venezuela and Peru.*
3. *International Conventions*

#### *Constitution*

Constitution of the Republic of Chile, at section 19 No. 8, guarantees all persons the right to live in an unpolluted environment. It is mandatory for the state to ensure that this right is not affected and protects the preservation of nature. In this sense, statutory provisions may establish specific restrictions on the exercise of certain rights in order to protect the environment.

Also, Constitution of the Republic of Chile, at section 19 No. 9, guarantees all persons the right to protection of health.

#### *International Conventions*

Chile ratified several significant conventions on regulation of chemicals (see Table 3.15.1.).

**Table 3.15.1. – Conventions on chemicals regulation ratified by Chile**

<b>Conventions</b>	<b>Status of Ratification (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark/ source link</b>
The Stockholm Convention on Persistent Organic Pollutants	yes	20.01.2005	yes	<a href="http://chm.pops.int/Countries/StatusofRatifications/PartiesandSignatoires/tabid/4500/Default.aspx">http://chm.pops.int/Countries/StatusofRatifications/PartiesandSignatoires/tabid/4500/Default.aspx</a>
The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	18.01.1990	yes	<a href="http://ozone.unep.org/en/treaties.php">http://ozone.unep.org/en/treaties.php</a>
The Basel Convention on the Control of Transboundary	yes	11.08.1992	yes	<a href="http://www.basel.int/Countries/StatusofRatifications/tabid/1341/Default.as">http://www.basel.int/Countries/StatusofRatifications/tabid/1341/Default.as</a>

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Conventions	Status of Ratification (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark/ source link
Movements of Hazardous Wastes and their Disposal				<p><i>px</i></p> <p>Declaration: The Government of Chile considers that the provisions of this Convention [ . . . ] help to consolidate and expand the legal regime that Chile has established through various international instruments on the control of transboundary movements of hazardous wastes and their disposal, whose scope of application covers both the continental territory of the Republic and its area of jurisdiction situated south of latitude 60oS, in accordance with the provisions of article 4, paragraph 6, of the present Convention.</p>
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	yes	20.01.2005	yes	<a href="http://www.pic.int/Countries/Statusofratifications/tabid/1072/language/en-US/Default.aspx">http://www.pic.int/Countries/Statusofratifications/tabid/1072/language/en-US/Default.aspx</a>
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	12.07.1996	yes	<a href="https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mtdsg_no=XXVI-3&amp;chapter=26&amp;lang=en">https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mtdsg_no=XXVI-3&amp;chapter=26&amp;lang=en</a>
The Minamata Convention on Mercury	no		yes 10.10.2013	<a href="http://www.mercuryconvention.org/Countries/tabid/3428/Default.aspx">http://www.mercuryconvention.org/Countries/tabid/3428/Default.aspx</a>
ГАТТ/ВТО соглашения (касающиеся торговли химическими)	yes	16.03.1949	yes	<a href="https://www.wto.org/english/thewto_e/gattmem_e.htm">https://www.wto.org/english/thewto_e/gattmem_e.htm</a>

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Conventions	Status of Ratification (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark/ source link
веществами)				
Vienna Convention for the Protection of the Ozone Layer	yes	06.03.1990	yes	<a href="http://ozone.unep.org/en/treaties-and-decisions">http://ozone.unep.org/en/treaties-and-decisions</a>
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.	no		yes 19.12.1975	<a href="https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mtdsg_no=VI-18&amp;chapter=6&amp;lang=en">https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mtdsg_no=VI-18&amp;chapter=6&amp;lang=en</a>
United Nations Convention on Psychotropic Substances, 1971.	yes	18.05.1972	yes	<a href="https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mtdsg_no=VI-16&amp;chapter=6&amp;lang=en">https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mtdsg_no=VI-16&amp;chapter=6&amp;lang=en</a>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.	yes	13.03.1990	yes	<a href="https://treaties.un.org/pages/viewdetails.aspx?src=treaty&amp;mtdsg_no=vi-19&amp;chapter=6&amp;lang=en">https://treaties.un.org/pages/viewdetails.aspx?src=treaty&amp;mtdsg_no=vi-19&amp;chapter=6&amp;lang=en</a>
Convention on the Organisation for Economic Co-operation and Development	yes	07.05.2010	yes	<a href="http://www.oecd.org/chile/chilesaccessiontotheoecd.htm">http://www.oecd.org/chile/chilesaccessiontotheoecd.htm</a> Chile pledged its full dedication to achieving the Organisation's fundamental aims. Chile is the first South American country to join the OECD

### 5. Parameters of regulation

*Information from the open sources is not available.*

### 6. Key procedures for control of regulated objects

*Existing and New Chemicals, Registration, Permit*

Chile has no national inventory of existing chemical substances and no requirement for the notification of new substances.

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The Sanitary Code makes the Ministry of Health and Health Services accountable for the elimination or control of environmental factors affecting the health, safety and welfare of the inhabitants. Through this instrument it is empowered to control Health Sector activities related to chemicals and waste, including the manufacturing, importation, distribution, transportation, sale, possession and disposal. Articles 90 to 93 of the Code relate to the control of the stages of the life cycle of substances that are hazardous to health. Article 90, specifically, mentions that the regulation will set the conditions for production, import, dispensing, distribution, utilization, and disposal of toxic or hazardous substances. Also indicated by Article 90 is that the importation and manufacture of these substances requires the authorization of health services.

Law 18.164, published September 17, 1982 in the Official Gazette, establishes a requirement by customs in that toxic or dangerous substances, and substances used in food or cosmetics may not clear customs without presenting customs authorities with a certificate from the proper health authority indicating where the goods will be deposited and the route and condition of transport.

Law 18,164 on Customs Destinations gives instructions for the clearance of hazardous chemicals and pesticides and indicates that to process any customs destination involving toxic substances or those that are dangerous to health, among other national services, customs shall require a certificate from the respective health service in which the authorized locations will be for the deposit of said goods, the route and conditions of transport to be used or to transfer from the customs area to the specified location. Once the processing of documents of destination and the goods are removed from storage at customs, they are deposited under the responsibility of the consignee of same, who can not use, consume, sell, assign them under any title without obtaining authorization and prior approval required by law.

Exempt Resolution N° 408 of May 11, 2016 of Ministry of Health modified Exempt Resolution No. 714 of July 16, 2002 regarding the list of dangerous substances to health. This resolution provides the list of substances that are hazardous to health in application of Law 18.164 on customs destinations, and the application of import authorization established in articles 90 and 93 of the Sanitary Code, which must be granted by Health Services. This list includes chemicals, active ingredients and nonagricultural pesticide formulation.

As an aside, on 26 September 2012, the Chilean Department of Environmental Health began the process of expanding its online database of registered sanitary and domestic disinfectants to include pesticide product registration. Individuals and businesses can begin the registration process via the online system.

Supreme Decree N° 43 of March 29, 2015 of Ministry of Health, regulation of storage of dangerous substances, applicable to hazardous substances classified in Chilean Standard (NCh) N°382.

Exempt Resolution N° 1521 of December 26, 2016 of Ministry of Health, approves the facility declaration system that store dangerous substances, established in the supreme decree N° 43, of 2015, of the Ministry of Health.

Decree-Law No. 1 of November 8, 1989, sets activities listed requiring express sanitary authorization by Health Services for operation, which include the manufacture and importation of substances hazardous to health and the manufacture and importation of pesticides.

Decree No. 298 of February 11, 1995 on Transportation of Dangerous Cargo for Streets and Roads, establishes the conditions, rules and procedures applicable to streets and roads transport of substances or products which are, by their nature, dangerous or that represent health risks to people, public safety, or the environment. Radioactive materials and explosive products are excepted because these have their own regulations. For purposes of the application of this decree, hazardous substances are those found in Standard NCh 382/2004.

Decree No. 144, Organic Solvents Harmful to Health of May 10, 1985, as modified by Decree 650/88, published May 17 regulates the production, distribution, sale and use of pure organic, mixtures

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of these products and industrial or for domestic use that contain them. It also states that all organic solvents and products containing them must have the following legend printed on their label: "The prolonged inhalation of this product produces irreparable brain damage." The regulation prohibits the use of benzene as a solvent or diluent, or in the manufacture of common products that expose users to dermal contact, ingestion or inhalation of the vapors. The regulation only allows certain exceptions found in Article 10.

Decree No. 114 is Regulation on Safety of Toys of June 17, 2005 regulates toys so they do not compromise safety or health of users when used for their normal and intended use, considering the usual behavior of children.

Decree No. 157 is Regulation on Pesticide for Sanitary and Domestic Use of June 30, 2007. This decree regulates the conditions for registration, authorization, manufacture, import, storage, packaging, sale, possession, transport, distribution, promotion, advertising, application and disposal of pesticides for sanitary and domestic use, as well as in the manipulation of those that may affect human health.

### *Restricted, Prohibited, or Banned Chemicals*

Also restricted is the list of dangerous substances found in Annex A of NCh 382 of 2004.

- *Decree No. 374/97 promulgated August 25, 1997 on maximum lead in paints.*
- *Decree No. 754/98 of December 12, 1998 prohibiting Toluene in adhesives and glues.*
- *Decree N° 114/2005 regarding chemical substances in toys.*

As chemical use and application on all the stages of life cycle is very wide and diverse in Chilean day to day life, the issues on chemical safety in Chile are managed by different ministries and agencies depending on the scope of their jurisdiction, where chemicals are involved.

11 different ministries regulate production, import, export, transport, handling, usage, disposal of chemicals.

All chemicals, which handling or management may pose danger to environment and human, can be called «dangerous». They are regulated through the following instruments:

1. Dangerous chemicals generally	Chilean norm N°382
	Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
	Pollutant Release and Transfer Register (RETC) – Decree N°1/2013/MMA y Res. Ex. 1139/2004/MMA
	National Chemical Safety Policy (PNSQ)
1. Import	Customs Law (No. 18.164)
	List of Substances Hazardous to Health ( Res. 408/2016) – In process of being updated
	Authorisation from MINSAL (Minsitry of Health) (ASDigital)
2. Manufacturing	Health Code - D.F.L. No. 725/67
	Conditions in the Workplace - S.D. N° 594/1999
	Pesticide Regulation for Sanitary and Domestic Use (Decree N°157/2005)
3. Transport	Transport of Hazardous Substances (S.D. No. 298/1995) – In process of being updated
4. Storage	Storage of Hazardous Substances (S.D. No. 43/2015)
5. Usage	Agricultural Protection Provisions (LawNo. 3.557/2009)

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	Fixed Standards for Agricultural Pesticide Evaluation (Res. No. 3670/1999)
	Pesticide Regulation for Sanitary and Domestic Use (Decree N°157/2005)
6. Disposal	Hazardous Waste Disposal (S.D. No. 148/2004)
	Conditions in the Workplace - S.D. N° 594/1999

### *Studies and Others instruments*

#### PCBs

2005: National Inventory of PCBs. CONAMA.

2008: National Inventory of PCBs in other uses. CONAMA.

2009: Updating of the National Inventory of PCBs and Destruction Technologies. CONAMA.

2011: Tool for decision making in the management of PCBs. It was developed within the GEF / UNEP MSP Project: "Best Practices for PCB Management of the Mining Sector of South America(Chile and Peru)". Ministry of Environment.

#### POPs

2006-2010: National Implementation Plan for the Management of Persistent Organic Pollutants (POPs) - Phase I.

2012: Study of information collection about new persistent organic pollutants (POPs) in Chile.

#### Mercury

2009: Creation of the "National Plan for risk management of mercury in Chile". It is waiting definitions from Minamata Convention for its update. CONAMA.

#### Cadmium and Lead

2010: Study on the identification of the main national sources of cadmium and lead; national register of sites with potential presence of these metals and development of a methodological guide for estimating use, consumption and release of cadmium and lead.

#### Dioxins y Furans

2011: Register of sites with presence of dioxins and furans associated with the use of pentachlorophenol in sawmills, (phase II): confirmatory research and preliminary estimate of environmental risk. Ministry of Environment.

## 7. Non-regulatory mechanisms

The Chemical Industry Association of Chile (ASIQUM) represents around 120 companies. It covers manufacturers (about 62 % of members), dealers (13%) and specialized providers of services for chemical industry, such as Warehousing, Transportation, High Volume Terminals, Waste Management and others (25%). The mission of ASIQUM, can be sum up as follow. Its goal is to give support on information, technical matters and representation of its company members and maintain relations of mutual convenience with State Agencies, and national and international private

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institutions. Manage the Responsible Care implementation, to maintain standard practices in health, safe and environment issues, making sure the national communities are well aware of this process.

Last year authorities has request ASIQUIM, to participate in important legislations related to the chemical handling, such as storage and waste management, and the most important one, the "National Policy on Chemical Safety" which recognized ASIQUIM as an important player in the Chilean Chemical Sector, and most important, promote the implementation of Responsible Care in the Chilean Chemical Industry as a written actions in the shortcoming future.

The trademark of RC goes far beyond the "generality" of having a "responsible behavior" in the industrial action, but it is implementing an integrated management system to promote sustainable development.

ASIQUIM is responsible for implementation of the Responsible Care in Chile. It represents Chilean initiative on the national and international level. In this field ASIQUIM enters the net of following international organizations: the American Chemistry Council (ACC), the Business Federation of the Spanish Chemical Industry (EIQUE), the National Association of Chemical Industry in Brazil (ANIQ), Chemical Industry Association of Brazil (ABIQUIM). Solving the common tasks and sharing experiences on the field ASIQUIM created links between Asiquim AG and the 54 national associations of the chemical industries in the world.

Sharing of best practices how to implement Responsible Care with the purpose to improve performance of chemical industry, build trust and credibility between stakeholders involved in chemical production and handling, promote continuous improvement of health, safety, environment and social rates.

Responsible Care contributes to develop the close working links between the chemical industry and the government, particular regarding the issues on management of hazardous substances.

The Chilean initiative of product stewardship has been developed taking into account the expectations of national health, environmental authorities, interests of the Chilean trade association and the local chemicals producers.

### Product stewardship verification process

The second quarter of the year self-assessment questionnaire is being sent to the companies, taking part in stewardship program. The survey findings are published in an annual report. 2012 the On-line Web Response System was launched, where participating companies can learn about best practices and tools how to run sustainable chemical production In accordance with Chilean legislation and criteria of the Quality Management System (ISO 9001), Environmental Management System (ISO 14001) and Occupational Health and Safety Management Systems—Requirements (OHSAS 18001), Social Responsibility (ISO 26000). As well as companies are able to fulfill the questionnaire online to find out how they match the abovementioned criteria. If Companies don't have a certification confirming their activities are consistent with quality management criteria, the implementation of Responsible Care practices can advance the possible certification to these standards.

The following aspects of company activities are checked: community relations, Emergency Preparedness and Response,

Orient the verification process and certified companies, to the distinctive elements of Responsible Care include: community relations, Emergency Preparedness and Response, Product position in the value chain and other issues.

If the company implemented 80% of the Responsible care practices of or more, it will be invited to Responsible Care Check, it means company will undergo the verification process. This procedure involves a visit to the facility. The visit performs an independent verification team from ASIQUIM. This team interviews different areas of the company, as well as its partners (suppliers,

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customers, neighbors, emergency response agencies, etc.). Subsequently, the team issues a report where positive elements and opportunities for improvement are provided in detail.

At the end the verification process the Responsible Care certificate is handed, which is valid for three years. Upon expiration of three years the company must be reviewed.

The Responsible Care Management System and the process of verification are validated and recognized both nationally and internationally. This management system was incorporated in the National Policy on Chemical Safety Conama (Current Ministry of Environment) which was ratified by the council of ministers in 2008.

### 8. Availability of data

In Chile there are several inventories of dangerous prohibited or restricted substances (see the Table 3.15.2. below).

**Table 3.15.2. – Chemical inventories in Chile**

<b>Name of inventory</b>	<b>Short description</b>
List of Dangerous Substances to Health	This list contains the chemical substances identified as dangerous to health by the Government of Chile.
Occupational Exposure Limits-Biological Exposure Indices (BELs)	This list contains a list of substances for which the government of Chile has established biological exposure indices (BEIs).
Occupational Exposure Limits-Carcinogens	This list contains those substances considered carcinogenic by the Government of Chile.
Occupational Exposure Limits-Ceilings (LPAs)	This list contains those substances for which the Government of Chile has established a ceiling value. The ceiling is defined as the concentration that should not be exceeded during any part of the work exposure.
Occupational Exposure Limits-Skin Designations	This list identifies those substances which have shown potential for cutaneous absorption as identified by the Government of Chile.
Occupational Exposure Limits-STELs (LPTs)	This list contains those substances for which the Government of Chile has established short-term exposure limits (STELs).
Occupational Exposure Limits-Substances Prohibited for Use in the Workplace	This list contains those substances prohibited from the workplace by the Government of Chile except for the qualified cases made by the sanitary authority.
Occupational Exposure Limits-TWAs (LPPs)	This list contains those substances for which the Government of Chile has established 8-hour time-weighted average exposure limits (TWAs).

### 9. Laboratory infrastructure

Sub-Department of Inspection Section of the Institute of Public health services (under the Ministry of health and health services) is responsible for examination of laboratories complying with Good Manufacturing Practices and Good Laboratory Practices.

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There were worked out recommendations of laboratory practices performing by medical laboratories of different scope of research. These laboratories can undergo the conformity verification procedure and get the certificate acknowledging compliance status.

### **10. Response on emergency situations involving chemicals, including poisoning**

*GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

#### **Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)**

Chilean standard NCh No. 382:2013 is used for the general classification of dangerous substances. This standard concurs completely with the classification and numbers assigned to dangerous substances under the 2001 UN Model Regulation. In September 2013 INN published an update to the chemical classification standard under NCh 382:2013 based on the 17th Revision of the UN Transportation Model Regulation and the fourth Revision of the UN Purple Book.

NCh 2190 of 2003 (Decree 43, promulgated April 23, 2004 published in the Official Gazette of June 21, 2004) is the standard for transportation of dangerous goods, and hazardous identification of risks labeling.

Decree N° 43 promulgated July 2015 governs storage of dangerous chemicals. This regulations excludes explosives, liquid and gaseous fuels for energy use, alcoholic beverages, and cosmetic products, which are controlled under specific regulations. The regulation on storage of dangerous chemicals applies to labeling of all dangerous substances and is found in Title XIII under Labeling. Containers and packages are to be labeled in Spanish, legibly written with black lettering over a white background, placed horizontally when the container is in upright position.

Labels should include at the very least minimum information coinciding with the Safety Data Sheet (SDS). Dangerous substance should be identified with their chemical name and UN numbers. In case of mixtures, each one of the substances that contribute to the hazard or the dangerous mixture, or that substitute it, should be identified, in accordance with NCh 382. Also included should be the name of the provider, name, address, and telephone number of the manufacturer or importer, and safety indications, per the SDS. The substances should be labeled according to NCh 2190 of 2003. Substances for exportation in compliance with GHS labeling, should also have this labeling.

#### **Safety Data Sheet (SDS)**

Chile has implemented specific workplace safety requirements. The Chilean Ministry of Health Decree 594 as amended through November 10, 2003, now requires Safety Data Sheets to be maintained where hazardous substances are stored.

Chilean standard (NCh) No. 2245 of 2003 (Decree No. 254, published in the Official Gazette of November 26, 2003) of the Chilean National Standards Institute has established standards for the content and order of sections of Safety Data Sheets and hazard labels. These standards are consistent with International Standard Organization (ISO) 11014-1994 Safety Data Sheet for Chemical Products.

Part I, Content and Order of Sections is not equivalent to it since it has some major deviations, which are due to the need to make it compatible with Supreme Decree No. 298/1994 of November 25, 1994 regulating transport of dangerous cargo on the streets and roads from the Ministry of Transport.

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There are 16 Sections to be filled out in the Spanish language. The information must be clear and concise. Under the Decree 43/2015 y Decree 594/99, as modified in February 2018, both of Ministry of Health, there is a duty for employers to keep safety data sheets in locations where chemicals are stored and ensure basic sanitary and environmental protection for the health and well being of workers. Moreover, Decree No. 594/99 establishes occupational exposure limits. Law 16.744/68 of January 23, 1968 (published February 1, 1968), establishes reporting requirements and practices with regard to workplace accidents and illnesses.

In August 2015 NCh No. 2245 was updated under Rev.5 of the UN GHS and became mandatory in September 2015.

### *Emergency response*

On the web-site ASIQUIM Information about authorities related to emergencies can be found:

- *contacts of emergency consultants;*
- *authorities related to emergencies;*
- *technical information;*
- *security sheet.*

### *Emergency consultants*

Depending on the sort of chemicals hazardous properties, which may cause emergency situation, the Chilean citizens may call relevant emergency consultants.

### *Authorities related to emergencies*

Responsibility for emergency situations is divided among different ministries and other institutions relevant to emergency response actions.

### *Technical information*

In the paragraph Technical information can be found relevant technical information: regulations, chilean standards and so on, such as

- *Manual on storage of hazardous substances*
- *Emergency plan*
- *Signage in transport*
- *Health risks classification*
- *Hazardous products Classification*
- *Information on Decree 78*

### *Security sheet*

On the web-site the access to MSDS is available. MSDS were provided by the companies associated with ASIQUIM.

## **B I B L I O G R A P H Y & R E F E R E N C E S**

1. *Instituto de Salud Pública de Chile. [www.ispch.cl](http://www.ispch.cl)*
2. *CODIGO SANITARIO DECRETO CON FUERZA DE LEY N° 725. <http://www.leychile.cl/Navegar?idNorma=5595>*

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3. *World Guide to Standards Resources: CHILE.* <http://gsi.nist.gov/global/index.cfm/L1-3/L2-5/L3-21>
4. *Official translation of the original 1980 Constitution.* <http://confinder.richmond.edu/admin/docs/Chile.pdf>
5. *Política Nacional de Seguridad Química.* [http://www.sinia.cl/1292/articles-44404\\_PoliticaNacSegQuimica.pdf](http://www.sinia.cl/1292/articles-44404_PoliticaNacSegQuimica.pdf)
6. *LOLI cloud.* <https://lolicloud.chemadvisor.com/RDWeb/Pages/en-US/login.aspx>
7. *Asociación Gremial de Industriales Químicos de Chile ASIQUM A.G.* <http://www.asiquim.com/nwebq/>

## **T h e P e o p l e ' s R e p u b l i c o f C h i n a**

Composed by Russian Federation  
Reviewed by People's Republic of China

## The People's Republic of China

The major chemical industry sectors in China cover: oil and natural gas exploration and production, refinery, manufacturing of chemical fertilizer, pesticide, basic chemical materials, synthesized materials, paint and color products, special chemical products, rubber products, chemical mining, and special equipment.

### 1. Regulated objects

Industrial chemicals and chemical substances, substances used as ingredients or intermediates for pharmaceuticals, pesticides, cosmetics, food additives and feed additives are regulated in China. Regulated substances may be divided into different groups:

- *New Substances;*
- *Hazardous Chemicals;*
- *Explosives Precursors;*
- *Priority Controlled Chemicals for Environmental Management;*
- *Severely Restricted Chemicals;*
- *Drug Precursor Chemicals;*
- *Chemical Weapons Precursors;*

Each group has its own regulation procedures. Depending on the kind of the above listed groups chemicals may be referred to, they are regulated and controlled differently.

Besides, chemical substances that raise concern globally such as POPs, ozone depleting chemicals are regulated in China as well.

### 2. Participants of regulatory system

Chinese chemical regulatory system is very complex mainly because of too a large number of the authorities are involved. The following authorities are involved.

### 3 - 4. Influences: Economy priorities and International Activities

On one side, legislation in China is developed through planning and consensus building in accordance with priority growth areas in the country. The government itself has a long term view as signaled by its five year plans which are designed to build upon their predecessor. As with all legislation, the targets are set by governments and then regulators need to design a system that practically meets them.

On the other side, China ratified several significant conventions on regulation of chemicals and is obliged to provide for the realization of these international commitments (see Table 3.4.1).

**Table 3.4.1 – Conventions on chemicals regulation ratified by China**

Conventions	Status of Ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark / source link
The Stockholm	yes	13/08/2004	yes	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

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Conventions	Status of Ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark / source link
Convention on Persistent Organic Pollutants			23/05/2001	In 2007 China has developed a National Implementation Plan for the Stockholm Convention on Persistent Pollutants (NIP)
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	yes	22/03/2005	yes 24/08/1999	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Montreal Protocol on Substances That Deplete the Ozone Layer		14/06/1991 (a)	no	<a href="https://treaties.un.org/">https://treaties.un.org/</a> In 2013 China and USA has agreed on the joint activities on the gradual reduction of production and use of the ODS
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	25/04/1997	yes 13/01/1993	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Minamata Convention on Mercury	yes	31/08/2016	yes 10/10/2013	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
Vienna Convention for the Protection of the Ozone Layer		11/39/1989 (a)	no	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol	-	-	-	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
Convention on Psychotropic Substances, 1971		23/08/1985 (a)	no	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	25/10/1989	yes 20/12/1988	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

5. Parameters of regulation

*Information from the open sources is not available.*

## **6 . Key procedures for control of regulated objects**

In China, industrial chemicals are mainly regulated by the following regulations:

- *Decree 591 - Regulations on Safe Management of Hazardous Chemicals;*
- *Decree 677-Regulations on Pesticide Administration;*
- *MEP Order 7 - The Measures for Environmental Management of New Substances;*
- *SAWS Order 53 - The Measures for the Administration of Registration of Hazardous Chemicals;*

Dozens of other supporting regulations or national standards issued by various ministries.

There are other regulations for chemical weapon precursors and drug precursor chemicals.

### *Decree 591: Hazardous chemicals regulation*

Regulations on Safe Management of Hazardous Chemicals (Decree 591 of the State Council of China) was published by the State Council of China on 11 March 2011 and entered into force on 1 Dec 2011. Decree 591 is the highest chemical control law in China and it regulates hazardous chemicals through the entire supply chain, from manufacture, importation, distribution, storage to transportation and use.

Decree 591 is not a single law. It is supported by dozens of ministerial regulations (including MEP order 7) and numerous guidance documents. Many governmental bodies are responsible for implementation of the Decree.

Decree 591 require businesses who handle hazardous chemicals in China to apply for licenses to operate (“license system”) and submit HazChem registrations (“HazChem registration”). Decree 591 also implements GHS in China requiring companies to provide SDSs and labels prepared in accordance with relevant national standards.

In Decree 591, hazardous chemicals are defined as highly toxic chemicals and other chemicals which are toxic, corrosive, explosive, flammable and do harm to human body, facilities and environment. All chemicals meeting GHS hazard classification criteria may fall within its scope.

Among all hazardous chemicals placed on Chinese market, more than 2800 chemicals have been added to the Catalogue of Hazardous Chemicals. This Catalogue is an administrative license Catalogue. Businesses who handle hazardous chemicals in the Catalogue are subject to various license requirements.

It shall be noted that some hazardous chemicals in the Catalogue belong to highly toxic chemicals, explosives precursors are subject to more stringent requirements.

### *License System under Decree 591*

Any legal entity producing, importing, distributing or using hazardous chemicals in the Catalogue of Hazardous Chemicals in China shall obtain a license. There are three main types of licenses:

- *Production license for producers;*

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- *Operation license for importers, distributors, sellers, etc;*
- *Safe use license for certain downstream users*  
Safe use license is only required if the volume of certain hazardous chemicals used exceeds certain amount and the industry sector of the user is on the list of applicable industry sectors.

Detailed info about application of licenses can be found in the following supporting regulations.

- *SAWS Order 41 - Production License;*
- *SAWS Order 55 - Operation License;*
- *SAWS Order 57 - Safe Use License.*

### *HazChem Registrations with Ministry of Emergency Management (former SAWS)*

The article 66 and 67 of Decree 591 require domestic manufacturers and importers of hazardous chemicals to register hazardous chemicals prior to manufacturing or importation. Detailed registration requirements and procedure are outlined in SAWS's order 53 - The Measures for the Administration of Registration of Hazardous Chemicals.

It shall be noted that this HazChem registration is required for both hazardous substances and mixtures regardless of whether they are included in the Catalogue or not. There is no small volume exemption either.

### *Decree 591 and GHS Implementation in China*

Decree 591 is the most important law implementing GHS in China. Article 15 requires chemical manufacturers to provide SDSs and labels prepared in accordance with relevant national standards. Article 37 prohibits distributors from selling hazardous chemicals without SDSs or labels. Companies who fail to classify, label and package hazardous chemicals in accordance with those standards would face a maximum penalty or a ban.

### *China MEP Order 7: new chemical substances notification system*

The Measures for Environmental Management of New Chemical Substances (China MEP Order 7) was released in Jan 2010 by China MEP and came into force on 15 Oct 2010 to substitute previous regulation of 2003.

This regulation requires that manufacturers, importers submit new substance notifications and obtain approvals from the MEP prior to production or importation. A foreign exporter may appoint a legal Chinese representative to submit new substance notifications.

The notification requirement not only applies to new substance on its own, in preparation or articles intended to be released, but also applies to new substances used as ingredients or intermediates for pharmaceuticals, pesticides, cosmetics, food additives and feed additives, etc.

New substance is defined as a substance other than those listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). China has a pre-market notification system for new substances.

There are 4 types of new substance notifications which depend on the use and volume of a new substance: scientific research record, simplified notification – special conditions, simplified notification – general conditions and regular notification.

There is no small volume exemption under China MEP Order 7 although new substances in small volume (<1t/y) qualify for reduced notification requirements.

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In January 2013, former China MEP published the updated version of IECSC. There are 42342 substances in IECSC (last updated in 2013) in the non-confidential part and 3270 substances in the confidential part of the list.

If a substance cannot be found in above list, you may submit a formal enquiry to MEE to check the confidential section to confirm whether your substance is a new substance.

Notified new substances may be added to this inventory 5 years since the date of the first commencement of manufacturing or importation. For a polymer, even if all monomers are listed, polymer notification is required if the polymer itself is not listed.

If one substance is listed on China IECSC that does not mean that it is free of any production or import and export control in China. For example, if it is a hazardous chemical, a drug precursor chemical or chemical weapons precursor, it will be subject to stringent license and registration requirements.

### *MEP Order 7 Exemptions*

The following substances are exempt from MEP Order 7:

- *Chemical substances subject to other existing laws and regulations (pharmaceuticals, pesticides, cosmetics, biotic substances, food additives, etc.);*
- *Naturally occurring substances;*
- *Substances of noncommercial purpose or unintentionally produced (including impurities (content of a single impurity <10%w/w, total content of all impurities<20%w/w), waste or by-products);*
- *Special categories such as glass, cement, alloys, non-isolated intermediates, articles.*

On-site isolated intermediate is regarded as non-isolated intermediate in China and thus exempt.

**Table 3.4.2 – MEP Order 7 - Data Requirements and Estimated Duration**

Regular Notification	Four levels: 1-10t/y, 10-100t/y, 100-1000t/y, 1000t/y+
	Minimum data requirement increases with tonnage band
	Risk assessment report required for all levels
Simplified Notification – General Conditions	Minimum physio-chemical data: melting point, partition coefficient n-octanol/water and water solubility
	1 of the following 3 eco-toxicology studies must be conducted in China : ready biodegradability or acute toxicity study with Chinese fish or acute toxicity test with earthworms
Simplified Notification – Special Conditions	No minimum data requirement
	Simplified notification form and supporting document required
Scientific Research Record	Test data not required
	Only application form needs to be submitted

### *Mandatory Local Ecotoxicological Studies*

For simplified notification under general conditions and regular notification, some ecotoxicology studies must be done. The figure below shows which eco-toxicology studies must be conducted in China and the estimated duration of such studies in China.

*Joint Submission possibility*

Joint submission of new substance notification under China MEP Order 7 is possible and not mandatory. However, if several registrants notify a new substance jointly or share test reports, their manufactured or imported amount should be added to determine the right level of notification.

*Post-notification obligations*

Getting a registration certificate is not the end. Certificate-holders have to fulfill post-notification obligations based on the category of management stated on the certificate. New substances will be categorized as general new chemical substances or hazardous new chemical substances based on their hazard properties. Hazardous new chemical substances possessing persistent, bioaccumulative properties or are harmful to ecological environment and human health will be further classified as priority hazardous new chemical substances for environmental management and subject to additional post-notification requirements (Table 3.4.3.).

**Table 3.4.3. – Main post-notification obligations associated with different category of new substances**

Category	Post-notification Obligations
General new substances(1-6)	<ol style="list-style-type: none"> <li>1. Communicate SDSs;</li> <li>2. Implement risk management measures;</li> <li>3. Submit a letter of commencement of M/I;</li> <li>4. Keep documents on file for over 10 years;</li> <li>5. Do not sell substances to downstream users who are not capable of implementing risk management measures;</li> <li>6. Submit updates if a new hazard arises;</li> </ol>
Hazardous new substances (1-8)	<ol style="list-style-type: none"> <li>7. Submit annual report (for previous year);</li> <li>8. Comply with other requirements specified by Decree 591;</li> </ol>
Priority hazardous new substances (1-11)	<ol style="list-style-type: none"> <li>9. Submit report on disposal information;</li> <li>10. Submit substance circulation info;</li> <li>11. Submit annual plan (for next year);</li> </ol>
Simplified notification (1-2)	<ol style="list-style-type: none"> <li>1. Submit annual report (for previous year);</li> <li>2. Keep documents on file for over 10 years;</li> </ol>
Scientific research record (1-2)	<ol style="list-style-type: none"> <li>1. Shall be used in special facilities and under the direction of professional personnel;</li> <li>2. Can only be used for R&amp;D</li> </ol>

**7. Non-regulatory mechanisms**

*Responsible Care®*

Many international companies have been locating their production in China in the past few decades, they were the first in the country who started implement Responsible care program. These international companies produce 10-15% of the chemical products manufactured in China. They are members of Association of International Chemical Manufacturers (AICM). Total number of participating international chemical company members amounts to 50. They implement Responsible Care principles at their own operations and support Chinese companies introducing Responsible Care.

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AICM became the one voice for multinational chemical companies in China, the members have developed a shared vision.

In 2007, China Petroleum and Chemical Industry Federation (CPCIF) launched the campaign for promoting "Responsible Care" in Beijing on behalf of China Petroleum and Chemical Industry.

CPCIF, located in Beijing, China, is a nonprofit-distributing social group of self-discipline, consisting of sectional associations, local associations, key enterprises and institutions as well as chemical industrial parks in the petrochemical industry on the basis of voluntary union, which covers all fields and sectors and represents more than 70% of China petroleum and chemical industry.

CPCIF began to explore Responsible Care in China in the mid-2000s and became a member (observer) of ICCA in 2000. Activities to date have included development of Guidelines for Implementation of Responsible Care (industrial standard) and the engagement and training of chemical companies. The 2011 Guidelines, which reinforces the importance of relevant government regulations and standards, include six codes that pertain to product stewardship (including risk characterization, risk management and communication), process safety, occupational health and safety, pollution prevention and control, storage and transport safety, community awareness, and emergency response.

Companies in China are showing an increased commitment to chemical risk management, as 300 CEOs have signed the Responsible Care charter on September 2015, according to ICCA.

### 8. Availability of data

MEP administers the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) which contains 45 612 chemicals (as of 2013). For more information on IECSC please see sub-section China MEP Order 7.

In 2015 regulators have published a revised version of the Catalogue of Hazardous Chemicals, containing 2,828 entries on hazardous chemicals and a few mixtures. For chemicals listed in the Catalogue of Hazardous Chemicals importers, manufacturers and foreign sellers will be required to get a license under the Decree 591.

### 9. Laboratory infrastructure

#### *Background*

China has been following developments on the MAD system and GLP Principles of the OECD since 2003 and promoting GLP for adhering to the MAD system since its first participation in the annual meetings of the OECD Working Group on GLP as an ad hoc observer in 2005. The Chinese delegation reported the progress on implementing GLP in China and expressed its interest in adhering to the MAD system at the 22nd meeting of the OECD Working Group on GLP in 2008. In the same year, the Certification and Accreditation Administration of China (CNCA) issued a series of GLP-related regulations and guidance documents in line with the MAD requirements, which became effective on April 1, 2009, and the laboratory accreditation body of China, China National Accreditation Service for Conformity Assessment (CNAS), included the GLP accreditation into its evaluation system.

#### *Current GLP Status of China*

The establishment of the GLP system in China has significantly progressed over the past decade. The CNCA was created with the approval of the China State Council in 2001, which granted the CNCA the mandate to manage, oversee, and coordinate the certification and accreditation of

laboratories and inspection institutes nationwide. The CNAS was authorized to be the laboratory accreditation body by the CNCA.

In the past decade, several series of GLP-related regulations and guidance documents were issued in China, which include Good Laboratory Practices for Non-Clinical Studies of Pharmaceuticals in 2003, Good Laboratory Practices for Toxicity Studies of Pesticides (NY/T 718-2003) and Good Laboratory Practices for Physical and Chemical Testing of Pesticides (NY/T 1386-2007).

The Notice on Standard Management of Chemical Testing Institutions (No.85, 2016) release by the MEP in 2016.

## **10. Information sharing**

### *10.1. The implementation of GHS in China*

China is one of many countries that have agreed to implement GHS.

Decree 591 is the most important regulation implementing GHS in China.

Chinese government has published several compulsory national standards (starting with GB) and recommended national standards (starting with GB/T) between 2008 and 2013.

Companies selling chemicals to China and chemical companies in China are required to adopt these standards to classify, label and package chemicals as well as prepare safety data sheets in accordance with the requirements of GHS as from 1 May 2011.

#### **Classification Standards**

In 2013 SAC issued 28 mandatory chemical classification standards (GB 30000.2-2013 to GB 30000.29-2013 Safety rules for classification and labelling of chemicals) and each standard corresponds to one hazard class under GHS rev.4. The standards come into force on 1 Nov 2014.

Compulsory GHS classifications for chemical substances are provided in the Catalogue of Hazardous Chemicals.

#### **Labeling and Packaging Standards**

China released 3 national standards related to the labeling and packaging of chemical products in line with GHS in 2008 and 2009.

The first mandatory national labeling standard (GB 15258-2009) – “General rules for preparation of precautionary label for chemicals” came into force on 1 May 2010. Examples of precautionary labels, transport symbols, and precautionary statements for different categories of chemicals are given in this compulsory standard. This standard introduces GHS labelling elements, but also some additional requirements to provide to 24 emergency response number, etc.

The second mandatory national standard (GB 190-2009) - “Packaging symbol of Dangerous goods” is based on the 15th revised edition of the UN recommendations on the Transport of Dangerous Goods. This standard specifies the requirements of pictogram, label size, colour and packaging of hazardous goods. This standard also came into force on 1 May 2010.

A new recommendatory standard GB/T 32374-2015 “Phrase and codification of chemical hazard statements” enters into force since 1 January 2017. It is based on the GHS rev.4 and specifies the chemical pictograms, hazard statements, precautionary statements and the code phrase.

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### Safety Data Sheet Standards

The most important national standard related to Safety Data Sheet (SDS) in China is "Safety data sheet for chemical products: Content and order of sections" (GB/T 16483 -2008). This recommended standard was published in June 2008 and entered into force in February 2009. It specifies the structure, content and format of Safety Data Sheet in line with China GHS.

The other important standard is GB/T 17519-2013 "Guidance on the compilation of safety data sheet for chemical products", which came into force on 31st Jan 2014. This recommended standard provides detailed guidelines for SDS authoring in China.

SDS consists of 16 standard sections, all SDS and labelling should be provided in Chinese, 24h emergency telephone number is required for the SDSs and labels of hazardous chemicals.

### GHS Labelling for Consumer Products in China

Most of the consumer products (excluding cosmetics) containing chemicals may not only be subject to main Chinese chemical control laws and GHS requirements, but also be subject to relevant product specific national standards and additional labeling requirements(format, content, font size etc).

Example of those consumer products include detergents, paints, fuel additives, lubricants, air fresheners, adhesives, aerosol products, disinfectants and pesticides for households, etc.

Some of those product specific national standards include:

- *GB/T 25322-2010 Safety Label of Consumer Product*
- *QB/T 2952-2008 Requirements for detergent marks and packaging*
- *GB 5296.3-2008 Instruction for use of consumer products-General labeling for cosmetics*
- *SH 0164-1992 Rules for the Packing, Storage, Transportation and Inspection upon Delivery of Petroleum products (applicable to Lubricants, industrial oils and related products)*
- *BB/T 0005-2010 Labelling, classification and terms of aerosol products*
- *GBT 18419-2009 Domestic sanitary insecticidal-Aerosols*

GB 13690-2009 "General Rule for Classification and Hazard Communication of Chemicals" clearly says that the standard applies to both workplace chemicals and consumer products.

However, GHS labelling for consumer products has become a trend as more countries or regions have adopted or recommended GHS labelling for consumer products (for example, EU and Japan).

### Transportation of Dangerous Goods (TDG)

China's national standards have linked TDG with UN GHS. In Oct 2011, China has released two revised national standards for dangerous goods. Those two standards are consistent with the 16th revised edition of the <UN Recommendations on the Transport of Dangerous Goods>.

Those two standards are:

GB 6944-2012, Classification and code of dangerous goods

GB 12268-2015, List of dangerous goods.

In accordance with the Ministry of Transport Order No.36 (2016) SDS and labels are required for dangerous goods that also listed in the Catalogue of Hazardous Chemical. According to the AQSIQ Announcement No. 30 (2012), Chinese label and SDS are required for imported chemicals, whilst for export, during road transport SDS, Label and equivalent Chinese translations are required.

### 10.2. Emergency response

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The key regulations that define the requirements for emergency response in China are:

- *Regulation on the Safe Management of Hazardous Chemicals in China (Decree 591)*
- *Work Safety Law of the People's Republic of China (2014 Amendment)*
- *Emergency Response Law of the People's Republic of China*

Alongside the laws at the highest level are state council and ministry laws, as well as national standards, which may be mandatory or voluntary.

National Registration Centre for Chemicals of China (NRCC) provides chemical emergency response line in China. It provides emergency consulting services for enterprises and institutions, social public, as well as providing technical support to the Public Sectors.

Supporting NRCC's chemical emergency response line are many other organizations that provide assistance when incidents happen, such as:

1. *Firefighting service (A force with 2700 units nationwide);*
2. *National Poison Control Centre, under the Centre for Disease Control (CDC) of China (A medical system with 18 regional rescue centres/hospitals nationwide). The map in the slide shows the location of the CDCs.*
3. *Engineering rescue team (an engineering rescue system, with 8 regional centres nationwide including; Shanghai, Qingdao and Dalian).*
4. *Local hospitals and response team(s) from the enterprise(s) involved*
5. *Police forces*
6. *If necessary, with order or approval of the Ministry of Defence, armed forces can be also involved.*

Emergency Response law of PRC is the key regulation to follow from a Response perspective. SAWS operates at a National level but with regional/municipality nuances and management i.e. If a local regulatory branch thinks it is needed, they develop local regulations under state law to suit their local conditions.

The requirements for undertaking first response in China:

- *Provision of a local (+86) emergency contact number*
- *Helpline must be manned at all times (24/7/365)*
- *Responses in the local language (Mandarin)*
- *Person providing response must have expertise in chemical emergency response procedures and immediate access to substance information (the SDS)*
- *Ability to adequately respond to test from authorities (two strikes rule)*
- *Foreign companies cannot provide their own ER service*

Future developments

Ministry of Transport project to track all DG shipments/ transport within China via GNSS and consignment information managed on a central DB.

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**J a p a n**

Composed by Russian Federation  
Reviewed by Japan

## **I n t r o d u c t i o n**

The Japanese chemical industry is the second largest industry in the country and the world's third largest in the terms of shipment.

The industry can be divided into four general areas of production:

- *Base chemicals that include petrochemicals, their derivatives and basic inorganics. Produced in large volumes, they are sold as commodities to manufactures in the chemical industry or to the other industries.*
- *Specialty and fine chemicals that are intended for specialized use and produced in lower volumes than base chemicals, including ingredients used in adhesives, additives, plastics, coatings, paints and inks, crop protection, dyes and pigments. The Japanese chemical industry is a key supplier of fine chemicals to manufacturers of electrical appliances worldwide.*
- *Pharmaceuticals including both basic pharmaceutical products and pharmaceutical preparations.*
- *Agricultural chemicals, in particular pesticides and chemical growth agents such as synthetic fertilizers and hormones.*

## **1 . R e g u l a t e d o b j e c t s**

Several laws and regulations for managing chemical substances are put in force in Japan for respective rationales, for example:

- *poisonous and deleterious substances are regulated by the Poisonous and Deleterious Substances Control Act (PDSCA) from the viewpoint of health and hygiene;*
- *chemicals at workplace are regulated by Industrial Safety and Health Law (ISHL) for ensuring the safety and health of workers;*
- *new and existing industrial chemical substances are regulated by Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (so called Chemical Substance Control Law, CSCL) from the viewpoint of prevention of environmental pollution that poses a risk of impairing human health or of interfering with the population and/or growth of flora and fauna;*
- *chemical substances released and transferred in waste are regulated by the PRTR system and Promotion of Chemical Management.*

## **2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m**

Three ministries share the responsibility for implementation of the above mentioned laws:

- *the Ministry of the Environment (MOE);*
- *the Ministry of Economy, Trade and Industry (METI);*
- *the Ministry of Health, Labor and Welfare (MHLW).*

Besides, the National Institute of Technology and Evaluation (NITE), working under METI and cooperating with other relative ministries, supports for functioning of the CSCL and the PRTR system, etc. from a technical aspect.

## **3 - 4 . I n f l u e n c e s : N a t i o n a l p r i o r i t i e s a n d I n t e r n a t i o n a l a c t i v i t i e s**

Japan legislation in a field of chemical safety historically developed in response to the social problems. In particular, it means that main laws, CSCL and ISHL, were enforced as a response to

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serious pollution cases which took place in Japan in 1960's. Thereafter, the amendments to existing laws and introduction of new regulations (for example, PRTR and SDS Law) were the reflection of progress in international chemical management. So, with a view to achieve WSSD 2020 goals the latest changes were brought into CSCL in 2009 and entered into force in 2011/2012. These amendments introduced «Comprehensive Assessment» which consists of the obligatory reporting of substantially all chemicals and prioritization on basis of stepwise risk assessment. Now, this system continues to develop.

### *International Conventions*

**Table 3.5.1 – Conventions on chemicals regulation ratified by Japan**

Name of the Convention	Status of ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark / source link
The Stockholm Convention on Persistent Organic Pollutants	yes	2002 (a)		POPs, in particular PCBs, are managed by CSCL (ban), the Waste Disposal and Public Cleaning Law, and the Law for the Promotion of Environmentally Sound Destruction of PCB waste <a href="http://chm.pops.int/">http://chm.pops.int/</a>
The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	1988 (A)	1987	Implemented by the Act on the Protection of the Ozone Layer through the Control of Specified Substances and Other Measures (Ozone Layer Protection Law), 1988
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	1993 (a)		Implemented by the Act for the Control of Export, Import and Others of Specified Hazardous Wastes and Other Wastes, 1992 <a href="http://www.basel.int/">http://www.basel.int/</a>
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	yes	2004	1999	<a href="http://www.pic.int/">http://www.pic.int/</a>
Convention on the Prohibition of the Development, Production,	yes	1998 (A)	1997	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

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Stockpiling and Use of Chemical Weapons and on their Destruction				
The Minamata Convention on Mercury	yes	2016 (A)	2013	<a href="http://www.mercuryconvention.org/Countries">http://www.mercuryconvention.org/Countries</a>
The Vienna Convention for the Protection of the Ozone Layer	yes	1988 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol			1973	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention on Psychotropic Substances, 1971	yes	1990	1971	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	1992	1989	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

### 5. Parameters of regulation

*Information from the open sources is not available.*

### 6. Key procedures for control of regulated objects

Japan's chemical management legislation consists of many laws and regulatory acts. Industrial chemicals are mainly regulated by the following laws:

- *The Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substance Control Law, CSCL);*
- *Industrial Safety and Health Law (ISHL);*
- *The Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (PRTR and SDS Law) and Promotion of Chemical Management;*
- *Poisonous and Deleterious Substances Control Act (PDSCA).*

Poisonous and Deleterious Substances Control Act was the first act aimed at control of poisonous and deleterious substances from the view point of health and hygiene and was implemented in 1950. This law imposes a license requirement on manufacturers, importers and sellers of Poisonous Substances or Deleterious Substances. It also requires that persons engaged in relevant businesses meet

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prescribed standards for the transportation, storage or disposal of Poisonous Substances or Deleterious Substances and comply with specific requirements on storing, labeling or transferring.

Two main laws regarding regulation of chemical substances – ISHL and CSCL – were firstly enacted in 1972 and 1973, respectively.

ISHL's role is to ensure the safety and health of workers, so it regulates chemicals at workplaces. ISHL designates substances that are prohibited to manufacture or import, substances requiring permission and chemical substances requiring safety data sheets and labels. ISHL also controls new substances and requires manufacturers and importers to notify them prior to production and importation.

CSCL controls both new and existing industrial chemical substances from the viewpoint of prevention of chemical pollution. For new substances, a strict pre-marketing evaluation system is implemented. For existing chemical substances, manufacturers or importers are required to report their quantity and uses annually if the volume of manufacture or importation exceeds certain amount. CSCL also designates substances subject to priority risk assessment and prohibits some substances from manufacture or importation.

It should be noted that food, food additives, package, pesticides, fertilizers, feed and feed additives, medicine, cosmetics and medical devices, radioactive materials and drugs are out of CSCL and ISHL scopes and subject of regulation by other relevant laws.

PRTR and SDS Law was enacted in 1999 with a purpose of promoting voluntary improvement and management, and introduced two systems; the one is PRTR system which requires to report the amounts of release and transfer of the specified chemical substances (see more info in section 10.2 of the chapter) and the other is SDS system which provides information concerning the properties and the handling of the specified chemical substances by business operators.

Moreover, some Japanese laws, such as ISHL, PRTR and SDS Law and PDSCL have been amended to introduce GHS (pictograms, SDS, etc.) in Japan (see more in section 10 of the chapter).

In accordance with CSCL chemical substances are divided into several categories subject to special regulatory procedures. Assignment to the categories is presented in table 3.17.2.

**Table 3.5.2 – Requirements for regulation of chemical substances under CSCL**

Category	Definition and Requirements
New Substances	Definition: A substance that is not listed in the Inventory of Chemical Substances Control Law (CSCL inventory); Requirement: Approval required prior to manufacture/importation.
General Chemical Substances	Definition: All substances other than Priority Assessment Chemicals (PACs), Class I/II Specified Substances, Monitoring Substances; Requirement: Annual report if the volume of M/I is $\geq 1\text{t/y}$ .
Exempt Substances	Definition: Substances that are confirmed to be substances with no concern and announced by authorities; Requirement: No need of annual report.
Priority Assessment Chemical Substances (PACs)	Definition: Substances prioritized for assessment due to their potential risks of long-term toxicity to human health or the environment; Requirements: Annual report if the volume of M/I is $\geq 1\text{t/y}$ ; manufacturers and importers may be requested to provide more hazard data.

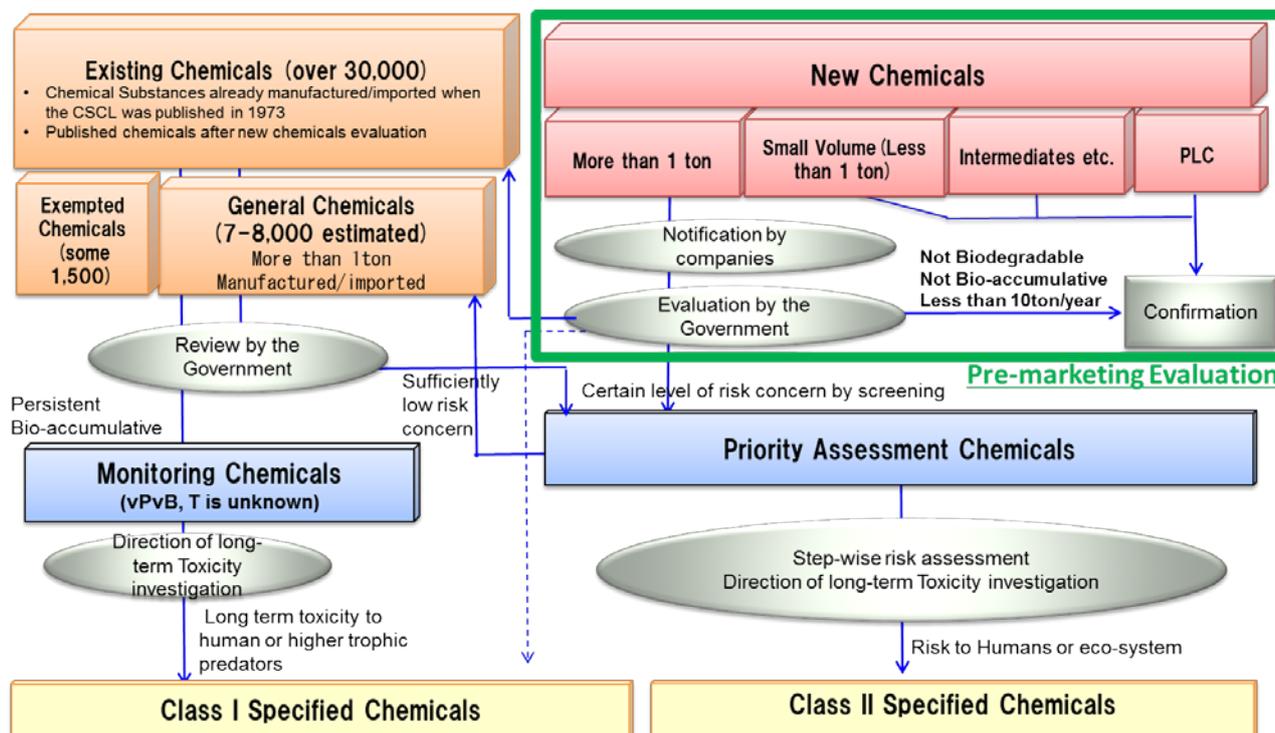
## Japan

Category	Definition and Requirements
Monitoring Chemical Substances	<p>Definition: Existing chemical substances that are confirmed to be persistent and highly bio-accumulative (however, long-toxicity is unknown);</p> <p>Requirements: Annual report if the volume of M/I is &gt;1kg/y; authority may order manufacturers and importers to investigate long-term toxicity for humans or for predator animals at higher trophic level.</p>
Class II Specified Chemical Substances	<p>Definition: Substances which have a risk of long-term toxicity for humans or for the environment;</p> <p>Requirements: Notification of planned M/I quantity prior to M/I and actual amounts after M/I; government may issue orders to change the planned manufacture and import amounts; technical guidelines and recommendations will be given for the products containing those substances by cabinet order.</p>
Class I Specified Chemical Substances	<p>Definition: Persistent, highly bio-accumulative , and substances which have a risk of long-term toxicity for humans or for predator animals at higher trophic level;</p> <p>Requirements: Prior permission is required for manufacture and/or import (virtually prohibited except essential uses); the import of certain products containing such substances is prohibited.</p>

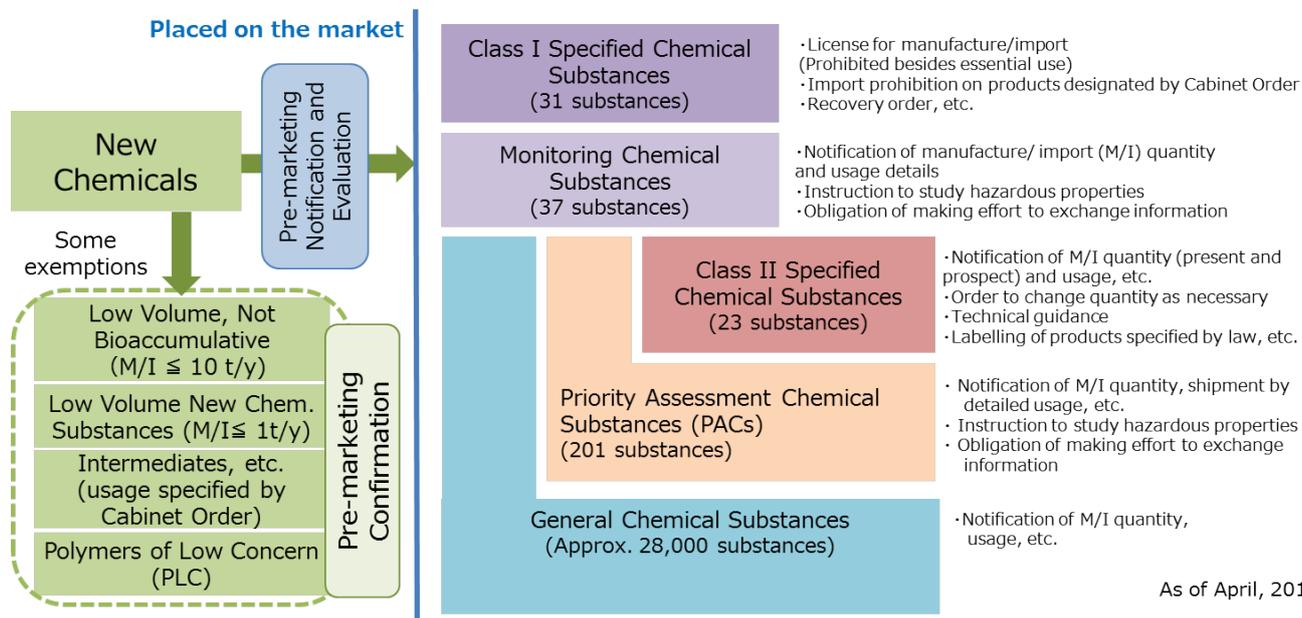
When chemical substances are designated as Class I Specified Chemical Substances under CSCL, manufacturers and importer of the substances are required to receive permission in advance. Moreover, such substances are prohibited against any use other than permitted uses. In addition, the Government of Japan imposes certain measures on products that use chemical substances designated as Class I Specified Chemical Substances, including an import ban on certain articles or preparations containing those substances. Outline of CSCL is presented on schemes 3.5.1 and 3.5.2.

### Scheme 3.5.1 - Outline of CSCL

## Japan



**Scheme 3.5.2. – Outline of CSCL. Data on quantity of substances per group is indicated in accordance with CSCL inventory**



As stated in Table 3.5.2. annual report is obligatory for general chemical substances, Priority Assessment Chemical Substances (PACs) and monitoring chemical substances. The main purpose of annual reporting is to provide the Japanese government with the information on the volume and uses of existing chemical substances placed on Japanese market. Based on the info received and available knowledge on chemical hazards, the Japanese government may take further regulatory actions against those existing substances by adding them onto different regulatory lists such as the list of priority assessment chemicals or the list of specified chemical substances.

Annual report shall be submitted to the Ministry of Economy, Trade and Industry (METI) between April 1 and June 30. The following substances are exempt from annual report:

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- *substances in products that are sold to general consumers;*
- *substances that are manufactured and imported with a total amount less than 1 t/y;*
- *substances for testing & research purpose;*
- *substances that have been confirmed as intermediate, PLCs or low production;*
- *substances that are announced as exempt due to their low concern.*

Procedures of notification and risk assessment involve testing using OECD Test Guidelines for testing of chemicals.

ISHL aims at control of chemicals at the workplace. Table 3.5.3 summarizes how different categories of chemicals are regulated under ISHL.

**Table 3.5.3 – Requirements for regulation of chemical substances under ISHL**

Category	Requirements
New Substances	Definition: A substance that is not listed the Industrial Safety and Health Law list (ISHL list); Requirement: Approval required prior to production/importation.
Harmful substances to be prohibited	8 substances in accordance with ISHL list; Requirement: prohibited from manufacturing or importation.
Harmful substances to be permitted	7 substances in accordance with ISHL list; Requirement: permission required prior to manufacturing or importation.
Harmful substances to be indicated	663 substances in accordance with ISHL list; Requirement: shall be indicated on labels.
Notifiable substances to be delivered SDSs	663 substances in accordance with ISHL list; Requirement: shall possess GHS SDSs.

Both Chemical Substance Control Law (CSCL) and Industrial Safety and Health Law

(ISHL) require a new substance to be notified prior to its production and importation. There are many differences between notifying a new substance under CSCL and notifying a new substance under ISHL. Table 3.5.4 summarizes the main differences between CSCL notification and ISHL notification.

**Table 3.5.4 – Requirement for notification of new substances under CSCL and ISHL**

Items	CSCL	ISHL
Existing Substance Inventory	CSCL inventory	ISHL list
Applicant	Manufacturer and importer (domestic and foreign company)	Domestic manufacturer or importer only
Type of notification	Standard notification, Low volume notification (<10t/y), Confirmation	Standard notification, Low Volume Notification(<100kg/y), Confirmation
Standard Notification: Hazard Data	Designated biodegradability, bioaccumulation, toxicology and eco-toxicology data	AMES test or carcinogenicity test
Responsible authority (ies)	METI, MHLW and MOE.	MHLW

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Process of standard pre-marketing notification under CSCL includes submission of hazard data (biodegradability study; bioaccumulation study (or partition coefficient); AMES study; chromosomal aberration study; 28-days repeated dose study; acute daphnia/fish study, algae growth inhibition study) to METI, MHLW, and MOE.

For the substances of the following conditions, a part or all of the tests can be omitted;

- *Substances being biodegradable and not bio-accumulative with total M/I amount in Japan  $\leq$  10t/y, which are subject to Low volume notification, require only biodegradability and bio-accumulation studies.*
- *The following substances, which are subject to prior confirmation, do not require hazard data.*
  - i) Substances with total M/I amount in Japan  $\leq$  1t/y, which are subject to Small volume confirmation;*
  - ii) Intermediates used in closed system;*
  - iii) Polymers of low concern.*

Total M/I amount means the sum of all manufactured and imported volume of the same substance in Japan, not the volume manufactured or imported by each legal entity.

The following substances are exempt from new substance notification under CSCL:

- *impurities (less than 1%w/w);*
- *products;*
- *naturally occurring substances;*
- *substances for R&D purposes;*
- *chemical substances regulated by other laws (i.e, pharmaceuticals, cosmetics, pesticides, food additives, etc.).*

Under ISHL there are two types of notification: standard notification and small volume notification. For standard notification, the information required is test (AMES test (mostly) or carcinogenicity test (rarely)) and other information such as manufacturing process, reaction formula, etc. For low volume notification (<100kg/y), no test data is required.

New substances notified with standard notification under CSCL will be added onto CSCL inventory 5 years after its notification. New substances notified with standard notification under ISHL will be generally added to ISHL list within 1 year.

## 7. Non-regulatory mechanisms

Japan is one of the leading members of ICCA, it is represented by the Japan Chemical Industry Association (JCIA). The JCIA was established almost 70 years ago, and now includes about 180 member companies and 80 organizations. The JCIA has undertaken activities to fulfil its mission of promoting the healthy development of the chemical industry through the research and study of production, distribution and consumption of materials related to the Chemical Industry. JCIA also focuses on the research and study of various issues relating to technology, labor, environment and chemical safety of the industry, and on planning appropriate measures and actions to the economic prosperity of Japan and the betterment of the national standard of living.

Within its activity in ICCA the JCIA is proactively tackling three priority issues of Chemical Policy and Health, Energy and Climate Change, and Responsible Care. In Asia, in particular, the JCIA conducts various activities such as promoting implementation of Responsible Care and technology transfer to address important issues such as process safety.

The JCIA has been a member of Responsible Care Leadership Group since 1990.

## 8. Availability of data

Japan has two inventories of existing chemicals – the Inventory of Chemical Substances Control Law (CSCL inventory) and the Industrial Safety and Health Law list (ISHL list) under ISHL.

The Japan CSCL inventory consists of two parts:

- *existing chemical substances placed on Japanese market before October 16, 1973 (approximately 20,600 substances);*
- *new chemical substances that have been notified and determined under the CSCL, and published on government Gazette (approximately 8,000 substances).*
- *ISHL list contains about 60,000 substances and consists of two parts as well:*
- *existing chemical substances under CSCL and chemical substances notified to MOL, before enacted new substance notification under ISHL;*
- *new substances notified under ISHL and published on government Gazette.*

A substance that is listed on CSCL inventory (excluding substance listed on the inventory before enacted new substance notification under ISHL) but not listed on ISHL list is also subject to new substance notification under ISHL.

Moreover, in order to enhance transparency and reduce compliance risk on the chemical safety through sharing and disclosure of national regulatory information of the Member Countries of ASEAN, ASEAN-Japan chemical safety database (AJCSD) started its full operation in April 2016 operated by the National Institute of Technology and Evaluation of Japan (NITE). Database contains Regulatory information of ASEAN countries and Japan, hazard and risk information, GHS classification results and sample SDSs. AJCSD is available free of charge at <http://www.ajcsd.org/>.

## 9. Laboratory infrastructure

Japan has adopted OECD's Mutual acceptance of data system and GLP principles and guidance. National entity responsible for Good Laboratory Practice program in Japan is the Japan Society of Quality Assurance (JSQA).

## 10. Information sharing

### *10.1. Implementation of GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

Introduction of GHS is led by the inter-ministerial committee since 2001. Before the global adoption of GHS, several laws relating labeling of chemicals have already been implemented. Due to this circumstance, authorities decided to introduce GHS into these existing laws. Thus no central law to implement GHS exists in Japan. On the other hand, to ensure consistency among these laws Japan adopted JISs (Japan Industrial Standards) as tool to implement GHS. Now two JISs exist and mentioned by laws:

- *JIS Z7252 (Latest Version JIS7252-2014) providing chemical classification criteria;*
  - *JIS Z7253 (Latest Version JIS7253-2012) stipulating format and content of SDSs and labels. The latest version entered into force on June 1st, 2012, but as the transition period, the old version of JIS Z7253 had also been effective until the end of December 2016.*
- Both standards are based on 4th revised edition of GHS.

## Japan

It should be noted that SDSs are mandatory and labels are mandatory or mandatory to make an effort by the following laws:

- 663 (SDS) and 663 (label) substances under ISHL;
- 562 substances under PRTR and SDS Law;
- other substances under Poisonous and Deleterious Substances Control Law (PDSCL).

For other chemicals, SDSs and labels are recommended, more exactly it is «obligatory to make effort to comply» with mentioned JISs.

According to JISs SDS and labels should be prepared in Japanese. For SDS 16 standard headings are required and relevant information is to be entered for each of the 16 headings. If the information is not available, the reason should be stated.

Substance name and its concentration or concentration range shall be indicated in SDSs if it is present above concentration limit and contributes to the classification of a product. However, the following substances must be disclosed even if their content is below concentration limit.

- respiratory sensitizing or skin sensitizing substance > 0.1%w/w;
- carcinogenic cat. 2 substance > 0.1%w/w;
- reproductive toxicant cat. 1 or cat. 2 > 0.1%w/w;
- STOT cat. 2 substance > 1%w/w.

Japanese labels are usually more complex than in other countries. Other items required for display in accordance with domestic regulations (e.g., fire service laws, PDSCL) should also be added. When a hazard class and hazard category are assigned for the substances or the mixtures in accordance with JIS 7252, a label is to be produced using pictograms, signal words, hazard statements, precautionary statements, handling/storage and supplier's information allocated for each. For small packages on which labels are not easily affixed, the label elements other than those required by domestic regulations may be displayed using a tag that is tied to the containers or packages. The generic name may be printed on label in order to protect confidential business information provided that the general name would not pose a risk to the health and safety of the receiver, or to environmental protection.

Moreover, with a view to help companies to prepare SDSs and labels METI has released “ the GHS Mixture Classification System,” a free tool for classifying mixtures according to 4th revised edition of GHS, available on the official site at [http://www.meti.go.jp/policy/chemical\\_management/int/ghs\\_auto\\_classification\\_tool\\_ver4\\_EG.html](http://www.meti.go.jp/policy/chemical_management/int/ghs_auto_classification_tool_ver4_EG.html). And MHLW and MOE have conducted GHS classifications on hundreds of substances. The classifications can be downloaded via site of the National Institute of Technology and Evaluation(NITE).

### *10.2. Response on emergency situations involving chemicals, including poisoning*

Japan has an integrated system of chemical disaster response that involves local fire and police services, local emergency medical services (EMS), local hospitals, Japanese Self-Defense Forces and the Japanese Poison Information Center (JPIC). The Japan Poison Information Center was founded in 1986 as a result of co-operation between the Ministry of Health, Labor and Welfare, the Japanese Association for Acute Medicine, the Japan Pediatric Society and other related medical organizations. The JPIC is the only poison information center admitted by the Ministry of Health, Labor and Welfare to provide toxicological information to medical personnel and the general public.

### *10.3. Promotion of chemical management*

## Japan

Japan has a comprehensive system of accounting of the amounts of chemical substances released and transferred in waste as a result of industrial operations – the PRTR system acting under PRTR law.

The PRTR system requires businesses operators handling the specified chemical substances under the special condition mentioned below to estimate the amounts of chemical substances released and transferred in waste and to report the data to their local governments. Local governments transfer the data to national government that compiles data submitted and makes the results public.

Special conditions for the business operators are as follows:

- *business operators whose operations fall under the 24 types of business operations specified in the government ordinance; or*
- *business operators who employ over 21 employees during their regular business operations; or*
- *business operators who annually handle one ton or more of any chemical substance specified in the «Class I Designated Chemical Substances» (or 0.5 ton or more of the Specific Class I Designated Chemical Substances) –*  
are obliged to confirm and notify the amount of release (into atmosphere, public water bodies, soil within the place of business concerned) and the amount of transfer as wastes (outside of place of business concerned).

Class I Designated Chemical Substances includes 462 substances. Specified Class I Designated Chemical Substances consists of 15 substances selected from Class I due to their carcinogenic properties.

PRTR data provided are disclosed by public announcement by the Government as well as being disclosed on request. The data from individual business facilities as well as national and prefectural aggregate data are disclosed on the PRTR website maintained by National Institute of Technology and Evaluation (NITE). The PRTR system aims to establish the common background of risk communication among the government, the business operators and the public by providing data about releases of chemical substances to the environment. These data also help the business operators to manage their own amount of releases and to reduce the environmental risks from chemical substances and will be useful for risk communication with the people living in the surrounding area of the facility.

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## **T h e R e p u b l i c o f I n d o n e s i a**

Composed by Russian Federation  
NOT reviewed by Indonesia

## **I n t r o d u c t i o n**

Although Indonesia is mostly an agricultural country, manufacturing sector has become the main contributor to gross domestic product for the last ten years. For the period 2015 – 2025, the industrial sector is expected to grow 10%/year, to account for 35 – 40% of national output. One of ten core industry clusters is petrochemical production. Other main sectors of chemical cluster are cement, ceramics, fertilizer, resin and plastics.

Key regions for development of the petrochemical industry are Banten, East Java and East Kalimantan. Capacity utilization of the petrochemical industry is still below installed capacity, and the government is driving for better integration with raw material supplies. Petrochemical industry growth achieved 3,89% in 2014, yet it is predicted to increase in the next years.

### **1 . R e g u l a t o r y o b j e c t s**

Hazardous and toxic substances are regulated in Indonesia by Government Regulation No. 74 Year 2001 «On hazardous and toxic substance management». According to it «hazardous and toxic substance» means a substance or material that by its nature and or its concentration and or its quantity, may, either directly or indirectly, contaminates and or damages the living environment, and or may harm the living environment, health, human survival and other living creatures. Hazardous and toxic substances known as Bahan Berbahaya dan Beracun in Indonesia are abbreviated as B3.

Hazardous and toxic chemicals are divided into three groups, in particular:

- *usable hazardous and toxic substances (209 substances according to Annex I of Regulation No. 74 Year 2001) which needs registration in case of production and import. Registration means a registration and numbering of B3 available within the territory of the Republic of Indonesia.*
- *limited use of hazardous and toxic substances (10 substances according to Annex II of Regulation No. 74 Year 2001) which needs notification permit and registration number in case of import. Notification for import means a prior notice from the exporter country authority to responsible authority of the Republic of Indonesia in the event of import or when a cross border transit will be made for limited use B3 and or in case any other B3 is imported for the first time.*
- *banned/prohibited hazardous and toxic substances (10 substances according to Annex II of Regulation No. 74 Year 2001) which are banned for import and use. In the listed of prohibited B3 are aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex, toxaphene, HCB and PCBs.*

It should be noted that the following substances and materials are exempted from the scope of Government Regulation No. 74 Year 2001:

- *radioactive materials;*
- *explosives;*
- *food, beverages and other food additives;*
- *household medical supplies;*
- *cosmetics;*
- *pharmaceutical ingredients;*
- *narcotics, psychotropic substances and precursors as well as other addictive substances;*
- *chemical and biological weapons.*

More detailed description on the provisions of the Government Regulation No. 74 Year 2001 «On hazardous and toxic substance management» is provided under the section 6. Key procedures for control of regulated objects of the chapter.

## 2. Participants of the regulatory system

The following governmental bodies are involved into the regulation process:

- *Ministry of Environment and Forestry (Directorate General of Solid Waste, Hazardous Waste and Hazardous Toxic Chemical Substances Management is responsible for Government Regulation No. 74 Year 2001 «On hazardous and toxic substance management»);*
- *Ministry of Trade;*
- *Ministry of Health;*
- *Ministry of Agriculture;*
- *Ministry of Industry;*
- *Food and Drugs Inspection Agency;*
- *Customs Authority.*

In addition, the Coordinating Agency of the Chemical Industry (BKS-INKIM) and the Indonesian Chemical Industry Club (ICIC) in 2008 formed a new organization: Federasi Industri Kimia Indonesia (Federation of the Indonesian Chemical Industry) – FIKI. A key objective of the organization is «to lead efforts to develop the chemical industry in Indonesia in ways that benefit communities, nation and state». FIKI is coordinating the activities of leading chemicals-related associations in relation to government, society and international / global parties; assisting with policy-making of the national industry; acting as a facilitator in business promotion, investment and trading; and offering networking for related legal business.

## 3 - 4. Influences: National priorities and International activities

The priorities of chemical regulation system of the Republic of Indonesia are revision of the abovementioned Government Regulation No. 74 Year 2001 «On hazardous and toxic substance management» with the view of requirements of international agreements and initiatives (Stockholm Convention, Rotterdam Convention, SAICM), progressive implementation of GHS and creation of simple database of chemicals summarizing the results of registration and notification processes.

### *International Conventions*

**Table 3.6.1. – Conventions on chemicals regulation ratified by Indonesia**

<b>Name of the Convention</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark / source link</b>
The Stockholm Convention on Persistent Organic Pollutants	yes	2009, ratification	2001	Act No. 19 year 2009 on ratification of the Stockholm Convention

<b>Name of the Convention</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark / source link</b>
The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	1992, ratification	1992	Ministries of Environment, Health, Trade, Industry, Agriculture, etc) released various regulations in compliance with Environmental Management Law 23/1997 and the Montreal Protocol to control and prohibit the import/use of certain ODS
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	1993, ratification	1993	Indonesia is the part of Indonesian-Swiss Country-led Initiative on an informal process to improve the effectiveness of the Basel Convention
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	yes	2013, ratification	1998	Act No. 10 year 2013 regarding ratification of the Rotterdam Convention
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	1998, ratification	1993	In accordance with its CWC obligations, Indonesia controls chemicals listed within the treaty and additionally, enacted the Law of the Republic of Indonesia on the Use of Chemical Materials and the Prohibition of Chemical Materials as Chemical Weapons in 2008
The Minamata Convention on Mercury	no		2013	<a href="http://www.mercuryconvention.org/Countries">http://www.mercuryconvention.org/Countries</a>
Vienna Convention for the Protection of the Ozone Layer	yes	1992 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Single Convention on Narcotic Drugs, 1961, as amended	no		1976	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

Name of the Convention	Status of ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark / source link
by the 1972 Protocol				
United Nations Convention on Psychotropic Substances, 1971	yes	1996 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	1999, ratification	1989	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

## 5. Parameters of regulation

*Information from the open sources is not available.*

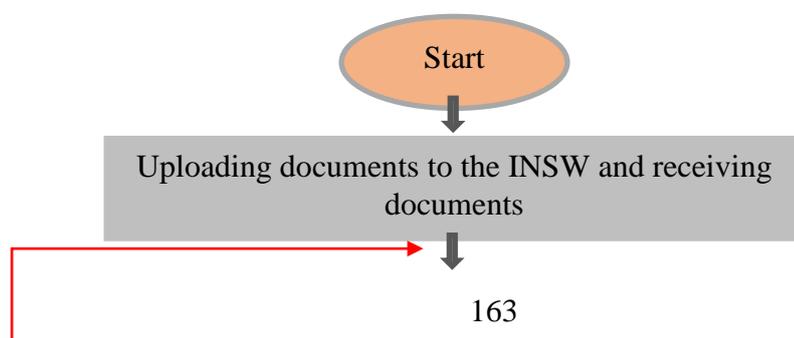
## 6. Key procedures for control of regulated objects

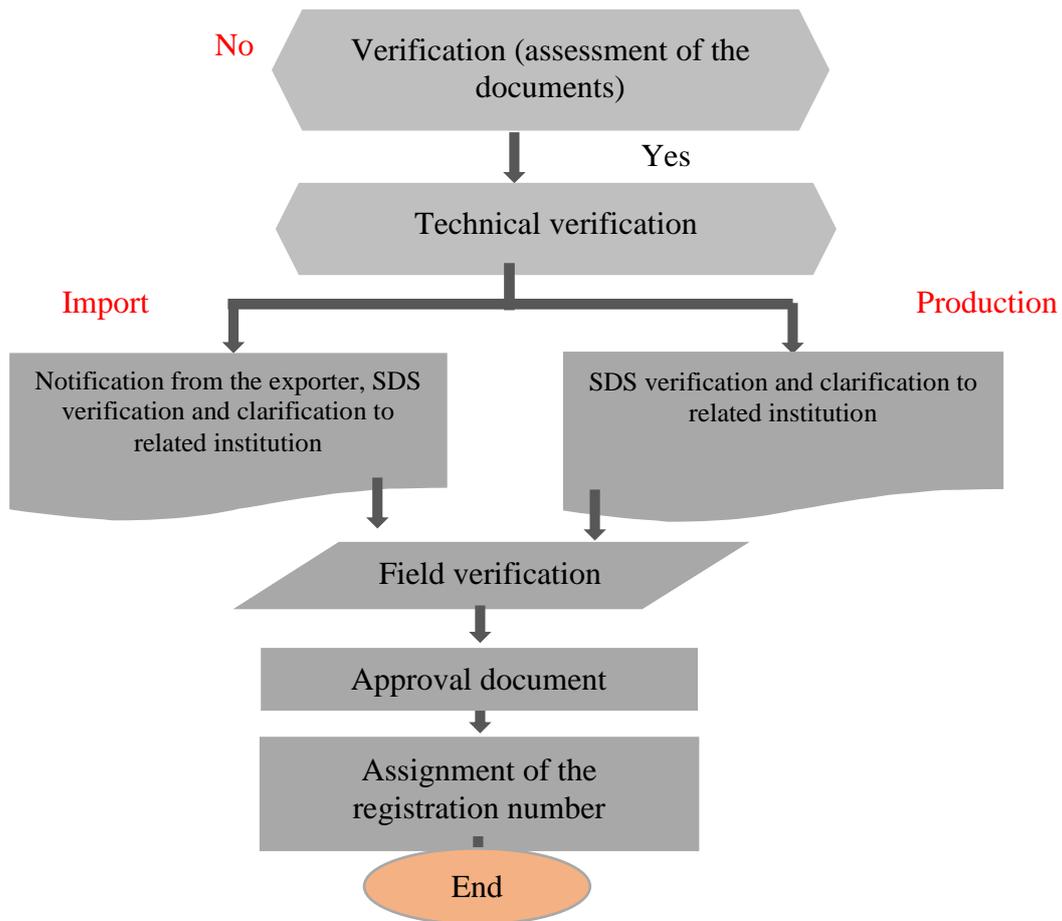
In accordance with Government Regulation No. 74 Year 2001 (is under revision now) following procedures are required in the management of B3: registration procedure, notification procedure and labeling requirements.

Registration for B3 is stated by Article 6 of the abovementioned Regulation and reflects responsibility of producers and consumers regarding protection on human health and environment from the impact of hazardous properties of B3. Registration procedure is expected to help the relevant institutions to exchange information so that all institutions can make use of the matters pertaining to hazardous properties of chemicals produced and imported for the first time so that the decision makers can restrict or prohibit the distribution of the corresponding B3. Information regarding the prohibited B3 and B3 that has been registered to certain entity must be regularly passed to other relevant entity such as importers, producers, and consumers of B3.

The process of registration is carried out under the Indonesia National Single Window (INSW) in accordance with the scheme 3.6.1. below:

### Scheme 3.6.1. – Registration process

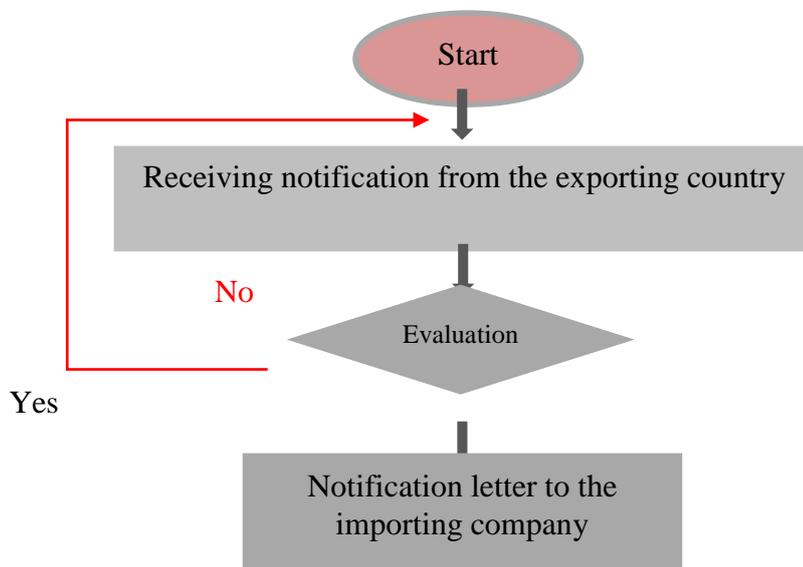


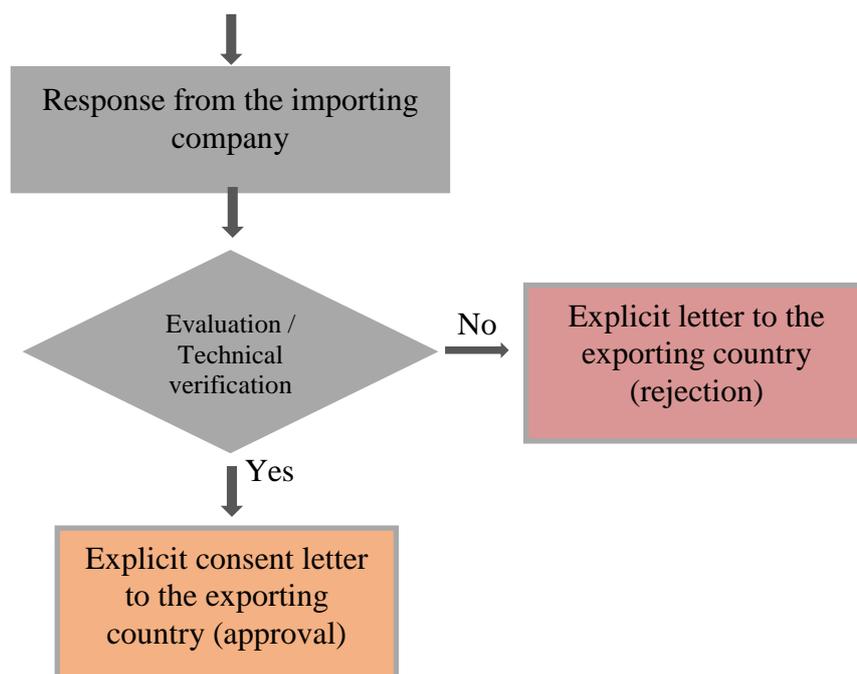


Notification for B3 is stated by Article 7 of the abovementioned Regulation. It is prior notice from the exporter country authority to responsible authority of the Republic of Indonesia in the event of import or when a cross border transit will be made for limited use B3 and or in case any other B3 is imported for the first time (regulated in the PIC – Prior Informed Consent of the Rotterdam Convention).

The process of registration is carried out in accordance with the scheme 3.6.2. below

**Scheme 3.6.2. – Notification process**





If it is necessary to consider new chemical substances, i.e. substances not included in annexes to Regulation No. 74 Year 2001, the responsible authority (Ministry of environment and forestry) makes the decision on registration or notification procedures after conducting individual consultations with the manufacturer or supplier.

Procedure for providing symbols and labels on B3 in accordance with GHS implementing Decrees (see section implementation of the GHS for more details).

The regulation is under review at the moment. Several changes are anticipated, including the change in the definition of the B3 taking into account GHS provisions, the lists of B3 in the Annexes will be updated. Such issues as public access to information, harmonization with existing laws on chemicals management are also awaited.

## 7. Non-regulatory mechanisms

Indonesia is a member of Responsible Care® program. First, the program was introduced to the members of the Indonesian Chemical Industry Club (ICIC), the business community as well as other industries (non ICIC) in 1994.

It has moved ahead with the formation of Committee National Responsible Care® Indonesia (KN-RCI) to promote the initiative. This organization was formally established in January 1997 and endorsed by 25 chemical industry associations (making up FIKI). After consultation made with the Government authorities of Indonesia have led to a decision to encourage the implementation of the Responsible Care® and it has been supported by the Directorate General of Chemical, Agriculture and Forestry Based Industries at the Ministry of Industry and Trade.

Indonesia is only a member of Responsible Care Leadership Group, neither full no observer member of ICCA.

## 8. Availability of data

There is no national database of chemicals but it is being planned by the participants of the regulatory system to create a simple database summarizing the results of registration and notification processes.

## **9 . L a b o r a t o r y   i n f r a s t r u c t u r e**

Indonesia is not adherent to the OECD System for Mutual Acceptance of Chemical Safety Data (MAD), and now is only on its way on implementing of good laboratory practice principles.

## **1 0 . I n f o r m a t i o n   s h a r i n g**

### *10.1.Implementation of GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

Ministry of Industry is responsible for implementation of GHS. Particularly, with a view of implementation the following legislative acts were issued:

- *Decree of Minister of Industry No. 87/M-IND/PER/9/2009 regarding Globally Harmonized System of Classification and Labeling of Chemicals;*
- *Decree of Minister of Industry No. 23/M-IND/PER/4/2013 regarding the Revision of Decree of Minister of Industry No. 87/M-IND/PER/9/2009 regarding Globally Harmonized System of Classification and Labeling of Chemicals (implementing 4th edition of UN GHS Purple book);*
- *Decree of Director General of Agrochemical No. 21/IAK/PER/4/2010 regarding Technical Training of GHS Implementation for Classification and Labelling on Chemicals.*

In accordance with Decree of Minister of Industry No. 23/M-IND/PER/4/2013 single substance chemicals both for domestic consumption and import are compulsory and required to implement GHS ever since March 24, 2010 and chemical mixtures are voluntarily required to implement GHS. However, after December 31, 2016, mixtures for both domestic production/ consumption and import are compulsory and required to implement GHS. There is an exemption for SMEs.

Chemical substances are obliged to be tagged with label and to own Safety Data Sheet (SDS), which is object for periodical review and revise (at least every 5 years). Requirements for SDS and labelling are fully harmonized with 4th edition of GHS. SDS and labelling should be prepared on Bahasa Indonesian language which can be accompanied by any UN language (for instance, English).

### *10.2.Response on emergency situations involving chemicals, including poisoning*

Accident and emergency management is also regulated by Government Regulation No. 74 Year 2001 «On hazardous and toxic substance management». In particular, in accordance with Article 25 of the abovementioned Regulation in event any accident and/or emergency occurs as a result of B3, then any person who conducts management activities is obliged to take the following steps :

- To secure (isolate) the accident scene;*
- To manage the accident in accordance with the definitive procedures of accident management;*
- To report the accident and or emergency to the apparatus of local municipal government; and*
- To provide information, assistance, and to evacuate the community surrounding the scene.*

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10. *The Minamata Convention on Mercury.* <http://www.mercuryconvention.org/>
11. *11.Responsible Care® Indonesia.* <http://www.responsiblecare-indonesia.or.id/>

## **The Republic of Korea**

Composed by Russian Federation  
NOT Reviewed by Korea

## Introduction

The chemical industry is the South Korea's major industry and the third largest industry in the manufacturing sector of the country. According to the American Chemistry Council, Korea ranked 6th in terms of production of the chemical industry behind countries like the USA, China, Japan, Germany and Brazil.

South Korea produces fine chemicals (pharmaceuticals, dyes, agricultural chemicals, pigments, perfumes, surfactants and catalysts), petrochemicals and fertilizers.

### 1. Regulated objects

Both new and existing substances are regulated in the South Korea. Hazardous chemicals used at workplaces are additionally regulated.

Since February 2nd, 1991, most chemicals have been categorized (in particular, new chemicals, toxic chemicals, observational chemicals and restricted or banned chemicals) and regulated by the Toxic Chemicals Control Act (TCCA) of the Ministry of Environment.

On January 1st, 2015, two regulatory schemes splitting the abovementioned act – the Act on the Registration and Evaluation, ect. of Chemicals (or AREC as it called in South Korea or K-REACH as it called by the world chemical community), and the Chemical Control Act (CCA) – came into force. Provisions related to the registration and evaluation of new and existing substances now fall under the umbrella of K-REACH, and CCA activities focus principally on the control of hazardous substances and response to chemical accidents.

Thus, in accordance with K-REACH manufacturers or importers in Korea shall register the following substances:

- *new chemical substances;*
- *existing substances (designated by the Ministry of Environment) manufactured, imported or sold more than 1 ton per year.*

«Existing chemical substance» means a chemical substance falls under one of followings:

Chemical substances published by the Minister of Environment through the consultation with the Minister of Employment and Labor as chemical substances distributed for commercial uses in the country prior to February 2nd, 1991.

Chemical substances published by the Minister of Environment as the substances cleared of the new chemical notification under the previous Toxic Chemicals Control Act after February 2nd, 1991.

«New chemical substance» means any other chemical substance.

«Existing chemicals subject to registration» means the substances published by the Minister of Environment among existing chemical substances as necessary to register for Hazard Evaluation or Risk Assessment in accordance with K-REACH.

It is necessary to note that the scope of K-REACH does not embrace:

- *radioactive substances (regulated by the Atomic Energy Act);*
- *pharmaceuticals and non-pharmaceutical drugs (regulated by the Pharmaceutical Affairs Act);*
- *narcotics (regulated by the Act on the Control of Narcotics);*
- *cosmetics and similar materials (regulated by the Cosmetics Act);*
- *ingredients and agrochemicals (regulated by the Agrochemicals Control Act);*
- *fertilizers (regulated by the Fertilizer Control Act);*
- *food, food additives, tools, containers and package (regulated by the Food Sanitization Act);*

## The Republic of Korea

- *livestock feeds (regulated by the Act on Control of Livestock and Fish Feeds);*
- *ammunitions (regulated by the Act on the Control of Firearms, Swords, Explosives);*
- *military supplies (regulated by the Act on the Management of Military Supplies and of the Defense Acquisition Program Act with exception of commercial goods under Article 3 of the Act on the Management of Military Supplies);*
- *health functional food (regulated by the Health Functional Food Act);*
- *medical devices (regulated by of the Medical Device Act).*

Moreover, K-REACH also has special provisions for products. «Product» means an item used by end user or its component or part with a possibility to cause consumers to be exposed to a chemical substance and the product could be a preparation or an article. K-REACH sets two obligatory procedures for products: Product Notification and Risk Assessment.

Hazardous chemicals used at workplaces are additionally regulated by the Occupational Safety and Health Act (OSHA), 1990, by the Ministry of Labor.

Household chemical products and biocidal products might be regulated under the new separate regulation proposed by the Ministry of Environment (at the moment they are managed under the K-REACH).

## 2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m

Seven ministries of South Korea are involved in managing chemicals in order to protect human health or the environment from possible hazards. They are:

- *Ministry of Environment (Chemical Policy and Chemical Safety Divisions under Environmental Policy Office), MOE;*
- *Ministry of Employment and Labor (Occupational Health and Occupational Safety Divisions under Industrial Accident Prevention and Compensation Bureau);*
- *Ministry of Trade, Industry and Energy (Climate Change and Industrial Environment Division, CCIED), MOTIE. CCIED is in charge of issues related to the climate change and industrial environmentally friendly projects.*
- *Ministry of Health and Welfare;*
- *Ministry of the Interior;*
- *Ministry of Agriculture, Food and Rural Affairs;*
- *Ministry of Science, ICT and Future Planning.*

Besides, the National Institute of Environmental Research (Environmental Health Research Department of the Ministry of Environment) leads environmental investigations in support of governmental policy and the National Institute of Chemical Safety (affiliated agency under the Ministry of Environment) is in charge of chemical accident prevention and response.

## 3 - 4 . I n f l u e n c e s : N a t i o n a l p r i o r i t i e s a n d I n t e r n a t i o n a l a c t i v i t i e s

Currently, South Korea's chemical industry is in the process of a major transformation from a large-scale commodity industry to an industry in which new challenges are arising. In 2010, the South Korean government launched a nationwide project to address worldwide initiatives in green chemistry and clean energy, establishing an investment plan called «Material and Component Technology 2012». The objective of this plan is to develop 100 core technologies for new materials and components in areas as light-emitting diodes (LEDs), solar power, green cars and new renewable energy. The plan involves:

## The Republic of Korea

- *investment in promising composite materials for driving «green growth» business;*
- *investment during 2010 to 2018 in the development of 10 new materials (e.g., plastics for flexible displays and multifunctional polymers), with the goal of claiming 30% of world market share;*
- *development of 20 core basic materials (e.g., coatings for electronic-paper technology used in electronic reading devices, and epoxy resin for high-end epoxy molding compounds), the demand for which is expected to sharply increase in the world market.*

So now South Korea's chemical industry is mainly aimed at research and manufacturing of new, environment-friendly materials of high functionality.

As with many countries, South Korea is pursuing a chemicals management approach that ensures substances being placed on its market are assessed for risk potential based on its planned application.

### *International Conventions*

**Table 3.7.1. – Conventions on chemicals regulation ratified by South Korea**

<b>Name of the Convention</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark / source link</b>
The Stockholm Convention on Persistent Organic Pollutants	yes	2007, ratification	2001	«Persistent Organic Pollutants Control Act», 2008, establishes strategy for a systematic management of POPs at the governmental level
The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	1992 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	1993 (a)		«Act Relating to Transboundary Movement of Wastes and their Disposal», 1994
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	yes	2003, ratification	1999	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

## The Republic of Korea

Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	1997, ratification	1993	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Minamata Convention on Mercury			2014	<a href="http://www.mercuryconvention.org/Countries">http://www.mercuryconvention.org/Countries</a>
Vienna Convention for the Protection of the Ozone Layer	yes	1992 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol	yes	1973, ratification	1973	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention on Psychotropic Substances, 1971	yes	1978 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	1998 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>

### 5. Parameters of regulation

*Information from the open sources is not available.*

### 6. Key procedures for control of regulated objects

#### *K-REACH*

Under K-REACH, any person who intends to manufacture or import a new chemical substance or at least one ton per year of a designated existing chemical substance shall register the chemical substance before manufacturing or importing («registration»). K-REACH also sets out requirements for companies to report the volume and uses of substances they manufacture/import («annual report») and notify products containing hazardous chemicals substances («product notification»). Foreign manufacturers who export chemical substances to South Korea may appoint a Korea-based only representative to submit annual report or registrations or product notifications.

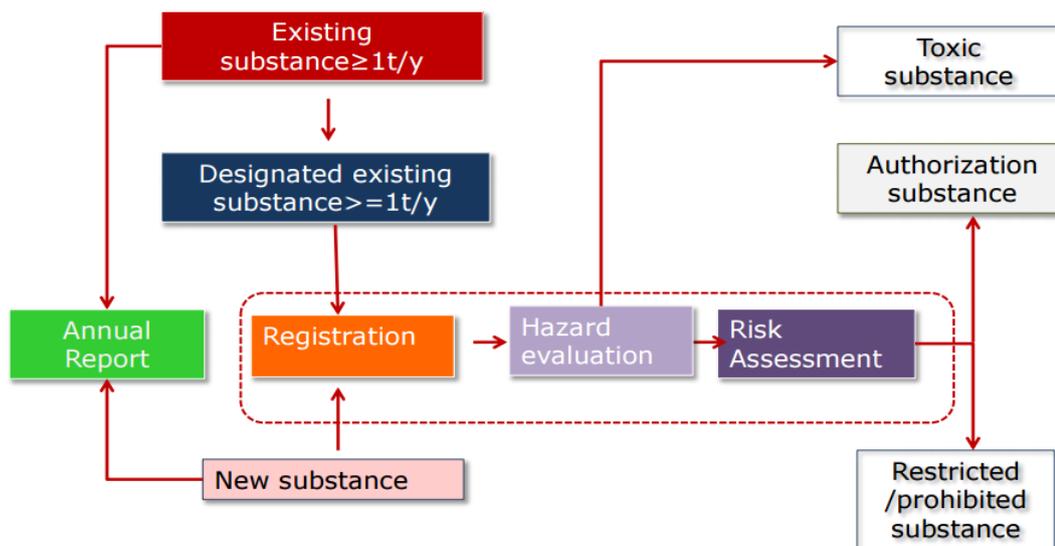
Annual report system will be abolished according to the amendments to the K-REACH. A new pre-registration scheme will be introduced to all existing substances manufactured or imported in the volumes more than 1 t/y enabling joint registrations.

Amendments were also made to the product notification procedure. It will be required that only products containing substance of risk concerns like carcinogenic or mutagenic properties should be notified when the substance is contained more than 0.1% in product.

Overview of K-REACH relating to chemicals is shown on the figure 3.7.1.

As stated in Article 10 of K-REACH any person who intends to register new or existing chemical substance should apply for registration to the Minister of Environment. The details of the process of registration is subject to special Ministerial Decree.

**Figure 3.7.1. – K-REACH outline**



In accordance with Article 14 of K-REACH under the framework of application the following data (or Registration Dossier) should be submitted:

- *name, location and company representative who intends to manufacture or import substance under consideration;*
- *chemical identity information: chemical name, molecular formula or structure, etc.;*
- *information on ways of application of substance;*
- *classification and labeling of chemical substance;*
- *physical and chemical properties of chemical substance;*
- *hazard information of chemical substance;*
- *risk information, including exposure scenario describing handling measures, exposure control or management process through the lifecycle of chemical substance (this shall apply only to chemical substance to be manufactured or imported ≥ 10 tons per year);*
- *guidance data for safe use (protective equipment, emergency measures for explosion, fire, release, etc.);*
- *other data prescribed by special Ministerial Decree or Presidential Decree.*

It should be noted that according to Article 14 paragraph 2 and Article 22 data on physical and chemical properties and hazard information should be gained strongly by domestic testing laboratories designated by the Minister of Environment or Foreign testing laboratories which are confirmed to comply with OECD Good Laboratory Practice.

The Ministry of Environment is also responsible for the evaluation of registration data received («hazard evaluation»). Based on the result of hazard evaluation and risk assessment, substances may be put into the following categories:

## The Republic of Korea

- *Toxic substance: designated by the Ministry of Environment after hazard evaluation;*
- *Authorization substance: means a chemical substance listed by the Ministry of Environment after consultation with the head of the relevant central authority and deliberation by the Chemical Substance Assessment Committee as one potentially hazardous and thus requiring permission from the Minister before its manufacture, import or use;*
- *Restricted substance: means a chemical substance as listed by the Ministry of Environment after consultation with the head of the relevant central authority and deliberation by the Chemical Substance Assessment Committee as one deemed highly hazardous if used for a specific purpose and thus required to be banned from its manufacture, import, sales, stocking, storage, transport or use for that purpose;*
- *Prohibition substance: means a chemical substance as listed by the Ministry of Environment after consultation with the head of the relevant central authority and the deliberation by the Chemical Substance Assessment Committee as one deemed highly hazardous and thus required to be banned from its manufacture, import, sales, stocking, storage, transport or use for any purpose.*

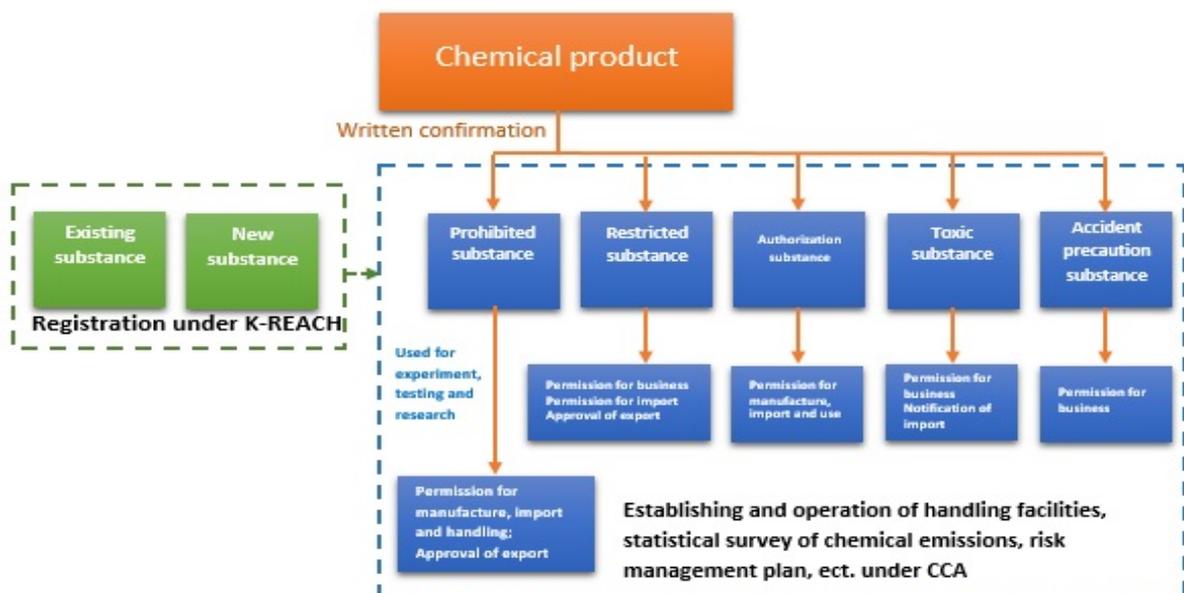
Hazardous substances under K-REACH include all above substances and other substances with hazards or risks.

K-REACH has a grace period for registration of designated existing chemicals of max 8 years (in particular, designated existing chemicals are being divided into 3 groups with grace periods of 2, 5 and 8 years). It means that any person who intends to manufacture or import an existing chemical substance to be registered will be allowed to manufacture or import without registration during the above grace period.

After categorization substances become subject of regulation by the Chemical Control Act (CCA).

Overview of CCA is presented on the figure 3.7.2.

**Figure 3.7.2. – Chemical Control Act (CCA) outline.**



So according to CCA after categorization substances are managed in the following ways:

- *Toxic substance: Any person who intends to import toxic substances should notify the type and usage information;*

## The Republic of Korea

- *Authorization substance: Any person who intends to manufacture, import or use these substances should obtain permission in advance;*
- *Restricted substance: Any person who intends to import restricted substances should pay attention to the restricted usages and apply for permission in advance;*
- *Prohibited substance: In principle, no one can handle prohibited substances, however, for those manufactured, imported or sold for use in experiment, testing and research, handling is provisionally permitted provided permission is obtained.*

Additionally, CCA allocates «Accident precaution substances» group consisting of 69 chemicals with designated usage level thresholds (Chapter V of CCA). CCA requires that any person who handles accident precaution chemicals, once such threshold is exceeded, should prepare and submit the risk management plan every five years.

Also according to the Article 9 of CCA, manufacturers or importers of chemicals shall submit «Witten Confirmation of Details for Chemical Product» to the Ministry of Environment (or designated entity) prior to manufacture or import after careful self-evaluation whether it contains any regulated chemical.

As it is mentioned in section 1 K-REACH states additional regulation for products (see definition in section 1), particularly «product notification» and «risk assessment».

In accordance with Chapter 6 «Management of risk-concerned products, etc.» of K-REACH anyone who manufactures or imports a product containing a hazardous substance to the extent of one ton or more per year shall notify to the Ministry of Environment the name and content of the substance, the type of hazard and its uses before starting manufacturing or importing the product.

Any product may be produced or imported as set out in the Environment Ministerial Decree without reporting in cases when:

- *exposure to human beings or environment can be avoided under normal conditions of use;*
- *considered chemical substance has been already registered for that use.*

However, an application of exemption needs to be submitted to the Ministry of Environment for above two cases.

According to Article 33 of K-REACH risk assessment is performed on risk-concerned products by institutions or experts appointed by the Ministry of Environment. «Risk-concerned product» means the one published by the Ministry of Environment in consultation with the head of relevant central administrative agency as it is concerned to pose risks to public health or environment among followings:

- Product used mainly as household items by general consumers, such as Cleaner, Perfumery, Adhesives, Polish, Deodorizing agent, Synthetic detergents, Bleaching agent, Fabric softener, etc. (also called «consumer product»);*
- Products used to kill the harmful creatures, except human and animals, such as insect repellents, disinfectants, preservatives, or inhibit or interfere with the biological activity (also called «biocidal product»).*

After risk assessment, the Ministry of Environment shall establish safety and labelling standards for risk-concerned products. The safety and labelling standards shall specify, for example, hazardous chemical substances that cannot be used in a certain product and the content, yield or evaporation of hazardous chemical substances contained in the product. Once safety and marking standards have been published, the Ministry of Environment can take actions (sales ban or recall) against:

- *any product not compliant with the safety and labelling standards.*
- *any product with no such standards in place and thus deemed likely to cause damage to people or environment.*

## 7. Non-regulatory mechanisms

Until 2005, there was no single association that represented the entire Korean chemical industry. In 2005, 10 sector groups came together to establish Korea Chemical Industry Council (KOCIC) as the official representative of the country's chemical industry. KOCIC members include Korea Chemicals Management Association, Korea Chlor-Alkali Industry Association, Korea Cosmetic Association, Korea Crop Protection Association, Korea Fertilizer Industry Association, Korea Petrochemical Industry Association, Korea Pharmaceutical Manufacturers Association, Korea Responsible Care Council, Korea Soap & Detergent Association and Korea Specialty Chemical Industry Association. KOCIC has three special committees participating in different worldwide initiatives: Energy & Climate Change Committee, Chemical Policy & Health Committee and Responsible Care Committee.

Organization being in charge of implementation of Responsible Care® program is the Korea Responsible Care Council, a member of Leadership Group since 2000.

Since 2007, the Korea Chemical Industry Council has been a full member of ICCA.

## 8. Availability of data

South Korea possesses the Korea Existing Chemicals Inventory (KECI) which is available via National Chemicals Information System (NCIS) (<http://ncis.nier.go.kr/main/Main.jsp>). KECI was issued jointly by the Ministry of Environment and the Ministry of Employment and Labor and includes information about 42 600 chemical substances.

Currently, KECI consists of three parts:

- *chemical substances which were placed on Korean market before February 2nd, 1991, and notified by the Ministry of Environment (about 35 600 chemical substances);*
- *chemical substances which were notified after hazard review by the Ministry of Environment, after February 2nd, 1991 (more than 3 600 chemical substances);*
- *chemical substances which were notified by the President of the National Institute of Environmental Research (NIER) (more than 1360 substances).*

The National Chemicals Information System offers search by CAS number, NIER number, chemical name and divides all chemicals into groups in accordance with K-REACH, CCA and international conventions (in particular, Stockholm and Rotterdam). In future, it is planning to update KECI by including data from other inventories such as OECD SIDS, EPA and EU risk reports.

## 9. Laboratory infrastructure

In 2011, South Korea's Good Laboratory Practice (GLP) program has achieved compliance with the OECD's GLP principles and guidance. National entity responsible for Good Laboratory Practice program in South Korea is the National Institute of Environmental Research (NIER). In 2006 there were 14 certified GLP laboratories in the South Korea.

## 10. Information sharing

*10.1. Implementation of GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

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South Korea has fully implemented GHS for both substances and mixtures since July 1st, 2013. Suppliers of hazardous chemicals should classify their chemicals according to GHS classification criteria, prepare safety data sheets (SDS) and label for the containers or packages of hazardous chemicals according to relevant national standards.

The most important national GHS standard is Public Notice No. 2013-37 «The Standard for Classification, Labelling of Chemical Substance and Material Safety Data Sheet» by the Ministry of Employment and Labor. It stipulates chemical classification criteria, the content of SDSs/labelling, and phrases for various hazard and precautionary statements in Korean.

In order to implement GHS the following laws also were developed and updated:

- *the Chemical Control Act (by the Ministry of Environment);*
- *the Occupational Health and Safety Act (by the Ministry of Employment and Labor);*
- *the Hazardous Material Act (by the National Emergency Management Agency).*

Requirements for SDS and labelling according to national legislation are quite standard and consistent with GHS but have some national specialties.

South Korea has adopted standard 16-section SDS. SDS should be prepared in Korean in general, but proper nouns such as chemical name, the name of foreign entities, etc., may be written in English; SDS prepared in foreign language may not need to be translated into Korean if it is for a reagent which is used solely for test and research in laboratories. In section 3 composition/information, the concentration of ingredients may be indicated in the form of ranges (by using the lower limit and the upper limit) within  $\pm 5\%$  of the contents. In this case, if the contents are less than 5%, the lower limit shall be indicated as « $\geq 1\%$ » (0,1% for carcinogens and germ cell mutagens, 0,2% for respiratory sensitizers [gases only], and 0,3% for reproductive toxicants). In section 14, Korean regulations should be provided. Confidential business information such as substance name, CAS or content can be hidden, but hazards must be fully disclosed.

Korean GHS label is standard GHS label and it usually contains the following elements: chemical name, pictogram (up to 4 pictograms if there are 5 or more pictograms), signal words, hazard statements (repeated statements can be omitted and similar statements can be combined), precautionary statements (up to 6 p-statements if there are 7 or more p-statements) and information of the supplier (the contact info of Korean legal entity needs to be given). Labelling should be given in Korean language excluding for chemicals only for lab use and research.

According to the new foreseen amendments hazardous chemical information such as name, hazard, risk and safe use information regardless of quantity, content (if contained in a mixture) and registration status shall be provided to downstream users (revision of article 29 of K-REACH).

For toxic chemicals there are also additional requirements stated by the Ministry of Environment (it is mandatory to disclose information on toxic chemical content for mixtures and display on labelling all available pictograms published by the National Institute of Environmental Research).

### *10.2. Response on emergency situations involving chemicals, including poisoning*

Response and prevention of chemical accidents is regulated by Chapter V of the CCA «Preparation for and countermeasures against chemical accidents».

In accordance with CCA, all enterprises intending to install and operate handling facilities for hazardous chemicals shall prepare an off-site impact analysis report that evaluates the impact of potential chemical accidents on the surrounding environment and population and, in case of use of «Accident precaution chemicals» prepare risk management plan (see section *Key procedures for*

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*control of regulated objects*). Risk management plan should be updated every 5 years and include chemical accident leakage scenarios, emergency action plans and damage restoration.

In every case of chemical accident, the responsible enterprise should manage it by taking emergency action according to risk management plan and immediately reporting to the associated institution (designated by the Ministry of Environment). The Ministry of Environment is in sole charge of all chemical accidents and institutions which can be assigned to accident sites to provide accident recovery and other assistance.

In 2013, the Ministry of Environment established the National Institute of Chemical Safety (NICS) as a specialized institution to be in charge of chemical accident prevention and responses. The main tasks of NICS is to maintain an accident response information system, revise accident response manuals, provide assistance for accident site response and recovery and offer professional training for chemical handling and response staff. Since July 15th, 2015 NICS also operates Chemistry Safety Clearing-house – a database containing information of previous chemical accidents by period of occurrence, place, type of accident, cause, damage and type of industry.

In South Korea also exists the Chemical Accidents Response Information System (CARIS). The main objective of CARIS is to track and predict the dispersion of hazardous chemicals in the case of an accident or terrorist attack involving chemical companies and to facilitate an efficient emergency response to hazardous chemical accidents by rapidly providing key information in the decision-making process. CARIS is also operated by NICS.

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**T h e R e a l m o f N e w Z e a l a n d**

Composed by Russian Federation  
Reviewed by New Zealand

## **I n t r o d u c t i o n**

Chemical industry in New Zealand is represented by national and international companies and includes manufacturing of industrial chemicals and consumer products, such as agrichemicals, disinfectants, various organic chemicals.

### **1 . R e g u l a t e d o b j e c t**

Regulated object – chemicals and substances, and, particularly, hazardous substances (explosives, pesticides, and industrial chemicals).

To better understand the legislative system that regulates the handling of hazardous substances in New Zealand, some definitions are given below.

Group standard means an approval for a group of hazardous substances of a similar type, nature or having a similar circumstance of use.

Chemical means any element or compound in its natural state or obtained by any production process, including any impurities and any additive necessary to preserve the stability of the chemical, but excluding any solvent which may be separated without affecting the stability of the chemical or change its composition.

Substance, according to the definition of the term in Hazardous Substance and New Organisms (HSNO) Act, the main chemical management regulation in New Zealand, means —

- (a) *any element, defined mixture of elements, compounds, or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof;*
- (b) *any isotope, allotrope, isomer, congener, radical, or ion of an element or compound which has been declared by the Authority, by notice in the Gazette, to be a different substance from that element or compound;*
- (c) *any mixtures or combinations of any of the above;*
- (d) *any manufactured article containing, incorporating, or including any hazardous substance with explosive properties.*

Hazardous substance unless expressly provided otherwise by regulations or an EPA Notice, means any substance –

- (a) *with one or more of the following intrinsic properties (which meet the criteria prescribed in the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017):*
  - (i) *Explosiveness;*
  - (ii) *Flammability;*
  - (iii) *A capacity to oxidise;*
  - (iv) *Corrosiveness;*
  - (v) *Toxicity (including chronic toxicity);*
  - (vi) *Ecotoxicity, with or without bioaccumulation; or*
- (b) *which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (a) of this definition.*

### **2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m**

EPA (Environmental Protection Authority) sets rules and conditions for importing and manufacturing hazardous substances. The EPA's role under the HSNO Act is to approve hazardous substances in New Zealand and to set controls to protect people and the environment.

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Many types of hazardous substances are regulated under the HSNO Act, for example explosives, pesticides, veterinary medicines, dangerous goods including fuels, household products. More than 100,000 hazardous substances are regulated, many under a group standard approval.

According to the Environmental Protection Authority Act 2011, the objective of the EPA is to undertake its functions in a way that:

- (a) *contributes to the efficient, effective, and transparent management of New Zealand's environment and natural and physical resources; and*
- (b) *enables New Zealand to meet its international obligations.*

The functions of the EPA are —

- (a) *to advise the Minister on any matter relating to its functions under the Environmental Protection Authority Act 2011 or an environmental Act;*
- (b) *to exercise the powers, and carry out the functions and duties, conferred on it by or under the Environmental Protection Authority Act 2011 or an environmental Act;*
- (c) *if requested by the Minister, —*
  - (i) *to provide technical advice to the Government and Crown entities on any matter related to its functions under an environmental Act;*
  - (ii) *to provide administrative assistance (including secretarial services) to a person or group of people appointed by the Minister to provide advice or report on any matter related to its functions under an environmental Act;*
  - (iii) *to contribute to and cooperate with international forums and carry out international obligations related to its functions under an environmental Act.*

Until June 2011, new organisms and hazardous substances in New Zealand were regulated by the *Environmental Risk Management Authority New Zealand* (ERMA NZ). ERMA NZ was established by section 14 of the Hazardous Substances and New Organisms Act 1996. ERMA consisted of two parts: the authority which made decisions on applications, such as whether or not some hazardous substances or new organisms would be allowed to come into New Zealand, and the agency which gathered and collated information on environmental issues from experts and the wider community. In June 2011 ERMA NZ was disestablished and its functions were incorporated into the new Environmental Protection Authority (EPA).

*Ministry of Business Innovation and Employment* (MBIE) together with WorkSafe New Zealand (WorkSafe NZ) provide leadership on workplace health and safety across government, administering Health and Safety at Work Act.

### *WorkSafe New Zealand*

WorkSafe NZ (established in December 2013) is the workplace health and safety regulator, promoting good workplace health and safety practices, and administering the requirements (controls) that apply to the use of hazardous substances in places of work. It performs proactive website assessments and onsite investigations of harm at the workplaces and enforces the Health and Safety at Work Act.

On 1 December 2017, many requirements for managing hazardous substances in workplaces moved out of HSNO and into the new Health and Safety at Work (Hazardous Substances) Regulations 2017. These regulations bring together workplace requirements for hazardous substances (other than for ecotoxic substances and for disposal) into a single place. The regulations sit under the Health and Safety at Work Act 2015. Previously these requirements were set in regulations, group standards, transfer notices and individual substances approvals under the HSNO Act. Most HSNO Act workplace requirements transferred directly to the HSW HS Regulations with only minor changes.

*Ministry of Environment* is the Government's principal advisor on the environment. A key aspect of this role is effective monitoring of chemical and biological risk to the health and safety of New Zealand's people and environment. As part of this, the Ministry also oversees the international

environmental agreements, ratified by New Zealand. For the indicative list of such agreements, that relate to chemicals see Table 1.

### 3 - 4 . Influences : National Priorities and International activities

Section 6 of the HSNO Act requires that New Zealand’s international obligations are taken into account when making decisions on hazardous substance applications. New Zealand engages with the global community through a number of international agreements and conventions that are concerned with the protection of the natural, social and cultural environment; protection of human health and safety; and trade. These obligations are met by the EPA and other agencies participating in a number of international forums and ensuring that international best-practice standards are adhered to.

Significant international hazardous substance related forums that New Zealand authorities have participated in include the UN SCE GHS, Stockholm and Rotterdam Conventions, the OECD, APEC and the SAICM fora.

Involvement in these allows engagement in the global knowledge-sharing process which adds value to the way chemicals are used and regulated.

Recent changes in workplace safety area, including situations involving handling with hazardous chemicals, were triggered by the Government intention to improve significantly workplace injury and death rates. The Health and Safety at Work Act and supporting regulations are part of the Government’s Working Safer package of reforms (“Working Safer: a blueprint for health and safety at work”) which aims to reduce New Zealand’s workplace serious injury and death toll by 25 per cent by 2020. The need for reform was triggered by the Pike River Coal Mine Tragedy, explosion at the Pike River coal mine resulted in death of 29 men.

**Table 3.8.1. – Conventions which New Zealand is signee to**

<b>Name of the Convention</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark / source link</b>
The Stockholm Convention on Persistent Organic Pollutants	yes	24/09/2004	23/05/2001	Entered into force for NZ on 23/12/2004; <a href="https://treaties.un.org/">https://treaties.un.org/</a> Hazardous Substances and New Organisms Act 1996 Imports and Exports (Restrictions) Prohibition Order (No 2) 2004
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	20/12/1994		Imports and Exports (Restrictions) Prohibition Order (No 2) 2004
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous	yes	23/09/2003	11/09/1998	Entry into force: 22/12/2003 <a href="https://treaties.un.org/">https://treaties.un.org/</a> Imports and Exports (Restrictions) Prohibition Order

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Chemicals and Pesticides in International Trade				(No 2) 2004
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	15/06/1996	14/01/1993	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Minamata Convention on Mercury	no		10/10/2013	<a href="http://www.mercuryconvention.org/">http://www.mercuryconvention.org/</a>
Vienna Convention for the Protection of the Ozone Layer	yes	02/06/1987	21/03/1986	Entered into force on 22/09/1988  Ozone Layer Protection Act 1996 <a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	21/07/1988	16/09/1987	entered into force on 01/01/1989  Ozone Layer Protection Act 1996;  Ozone Layer Protection Regulations 1996 <a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol	yes	26/03/1963	30/03/1961	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention on Psychotropic Substances, 1971	yes	07/06/1990	13/09/1971	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	16/12/1998	18/12/1989	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

The Stockholm Convention on Persistent Organic Pollutants (POPs), 2001 was adopted by the Conference of Plenipotentiaries on 22 May 2001 in Stockholm, Sweden. The Convention entered into force on 17 May 2004, and for New Zealand on 23 December 2004. The Convention obligations are implemented domestically through the HSNO Act and Imports and Exports (Restrictions) Prohibition

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Order (No 2) 2004. In addition, New Zealand's National Implementation Plan under the Stockholm Convention on POPs sets out how New Zealand proposes to meet convention obligations.

The Montreal Protocol on Substances that Deplete the Ozone Layer was signed in 1987. The Protocol sets targets for reducing the production and consumption of ozone-depleting substances. New Zealand's obligations under the Montreal Protocol are implemented through the Ozone Layer Protection Act 1996 and the Ozone Layer Protection Regulations 1996.

New Zealand has phased out the import of the following controlled ozone depleting substances in accordance with the Protocol:

- *halons by 1994*
- *chlorofluorocarbons (CFCs), other fully halogenated CFCs, carbon tetrachloride, methyl chloroform and hydrobromofluorocarbons by 1996*
- *methyl bromide for non-quarantine and pre-shipment purposes by 2007*
- *hydrochlorofluorocarbons (HCFCs) by 2016.*

In addition, New Zealand intends to ratify the Kigali Amendment to the Montreal Protocol, and begin phasing down hydrofluorocarbons (HFCs) from 1 January 2020.

Information on applying for import or export permits for ozone depleting substances is available on the Environmental Protection Authority website.

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 1989 aims to reduce the amount of waste produced by signatories and regulates the international traffic in hazardous wastes. It requires prior approval of hazardous waste imports and exports, and requires exporting countries to ensure that hazardous waste will be managed 'in an environmentally sound manner'. The Basel Convention also allows countries to enter into regional agreements with different requirements, provided that the agreements are no less environmentally sound. New Zealand has entered into two such agreements:

1. *The Convention to Ban the Importation into Forum Island Countries of Hazardous and Radioactive Wastes and to Control the Transboundary Movement and Management of Hazardous Wastes within the South Pacific Region (Waigani Convention), which regulates sending hazardous waste in the South Pacific.*
2. *Organisation for Economic Co-ordination and Development Decision C(2001)107/FINAL (OECD Hazardous Waste Decision), which regulates sending hazardous waste between OECD countries.*

New Zealand has implemented the Basel Convention, Waigani Convention, and OECD Hazardous Waste Decision in a number of ways. One of the main ways is through the Imports and Exports (Restrictions) Prohibition Order (No 2) 2004. This Order requires permits from the Environmental Protection Authority (EPA) to import or export waste in line with these agreements.

## 5. Parameters of regulation

*Information from the open sources is not available.*

## 6. Key procedures for control of regulated objects

Following the Working Safer reforms, New Zealand's system for managing hazardous substances has changed.

In August 2015 the health and safety reform legislation (the Health and Safety Reform Bill) was passed by Parliament.

The Health and Safety Reform Bill has made changes to the Hazardous Substances and New Organisms (HSNO) Act through the Hazardous Substances and New Organisms Amendment Act 2015;

replaced the Health and Safety in Employment Act with a new Health and Safety at Work Act, taking effect on 4 April 2016.

As a result, many controls on the management of hazardous substances in workplaces moved from the HSNO Act to the Health and Safety at Work (Hazardous Substances) Regulations in 2017, so that businesses can have one set of more simplified requirements covering all workplace hazards.

### *Hazardous Substances and New Organisms (HSNO) Act*

The purpose of this Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

The passing of the HSNO Act in June 1996 represented one of the most significant reforms of environmental legislation since the Resource Management Act. The Act came into force in two stages. Provisions relating to new organisms took effect in July 1998. The provisions relating to hazardous substances came into force on 2 July 2001.

The Act established the Environmental Risk Management Authority (ERMA New Zealand) to assess and decide on applications to introduce hazardous substances or new organisms into New Zealand. This includes genetic modification of plants, animals and other living things in New Zealand. In July 2011, ERMA became the Environmental Protection Authority (EPA).

Under HSNO, all hazardous substances require a HSNO approval, and it is an offence under the Act to import or manufacture a hazardous product that does not have one. There are two types of approvals: individual substance approvals and group standard approvals.

The HSNO system approves substances, not products (“substances” include individual substances and mixtures, i.e. formulated products). All explosives, fuels and pesticide products, as well as many single component chemicals are covered under individual substance approvals. Most other products are covered by group standards. A group standard is an approval for a group of hazardous substances of a similar, nature, type or use. Group standards set out conditions that enable the group of hazardous substances to be managed to minimize adverse effects. Some group standards exclude substances with certain hazards, for example substances with carcinogenic, mutagenic, or reproductive (CMR) classifications.

On or after December 2017, the EPA reissued its 208 group standards to reflect the movement of controls from HSNO to the new HSW legislation, and to incorporate other changes to the hazardous substance regime, including the issuing of EPA Notices.

Group standard categories include:

- *Active ingredients used for the manufacture of agricultural compounds*
- *Additives, process chemicals and raw materials*
- *Aerosols*
- *Agricultural compounds*
- *Animal nutritional and animal care products*
- *Class 4 substances*

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- *Cleaning products*
- *Compressed gas mixtures*
- *Construction products*
- *Corrosion inhibitors*
- *Cosmetic products*
- *Denatured ethanol*
- *Dental products*
- *Embalming products*
- *Fertilisers*
- *Fire fighting chemicals*
- *Food additives and fragrance materials*
- *Fuel additives*
- *Graphic materials*
- *Laboratory chemicals and reagent kits*
- *Leather and textile products*
- *Lubricants*
- *Metal industry products*
- *Not Otherwise Specified (N.O.S.) substances*
- *Oxidising substances (class 5.1.1) and organic peroxides (class 5.2)*
- *Pharmaceutical active ingredients*
- *Pheromone containing products*
- *Photographic chemicals*
- *Polymers*
- *Refining catalyst*
- *Solvents*
- *Surface coatings and colourants*
- *Tattoo inks*
- *Veterinary medicines*
- *Water treatment chemicals*

An up-to-date list of group standards is available at the EPA website <https://www.epa.govt.nz/industry-areas/hazardous-substances/group-standards/2017-group-standards/>.

A step-by-step process on how to assign a product to a group standard or individual substance approval is reflected in the EPA's website.

For the process on how to assign a product to a group standard, see <https://www.epa.govt.nz/industry-areas/hazardous-substances/group-standards/assign-your-product-to-a-group-standard/>.

For the process on how to assign a product to an individual approval, see <https://www.epa.govt.nz/industry-areas/hazardous-substances/guidance-for-importers-and-manufacturers/assigning-your-product-to-an-individual-approval/>.

When assigning a product to a group standard approval, a record must be kept. It also should be kept if assigning a product to an existing individual approval.

Before one can determine whether a specific product can be assigned to an existing approval, the substance must be classified for its hazardous properties. This includes any physical hazards, toxic and ecotoxic properties. The preferred approach to classification is to use hazard data on the product itself.

The thresholds for the HSNO hazardous properties are set out in the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017. These classifications typically align with the GHS classifications, but there are differences as well. For example, HSNO does not separate reversible eye effects into two sub-categories and does not specifically address the GHS category of transient target organ effects. Further details on the thresholds and classification systems are given in the User Guide to the HSNO Thresholds and Classifications, published by ERMA New Zealand in 2008, and re-published by the EPA in January 2012.

### *Health and Safety at Work Act*

A series of regulations were developed to support the Health and Safety at Work Act. These include: general risk and workplace management regulations, major hazard facilities (MHF) regulations, asbestos regulations, and hazardous substances regulations. Guidance on the HSW Act and regulations are available at the WorkSafe NZ's website.

The HSW Act is based on the Australian Model Work Health and Safety Law, which is performance-based legislation. The HSW legislation is administered by MBIE, and implemented by WorkSafe NZ. One of WorkSafe's key roles is enforcing the rules around using hazardous substances at work.

WorkSafe also took on most of the responsibility for approving compliance certifiers, who certify that other people are competent to handle high-risk substances, or that sites or equipment meet certain standards.

## **7. Non-regulatory mechanisms**

Responsible Care® NZ, RCNZ (formerly NZ Chemical Industry Council (NZCIC)) represents approximately 85% of New Zealand's major manufacturers and importers of hazardous substances. RCNZ members are diverse including multi-nationals and local chemical manufacturers and importers (suppliers), range of major chemical users including transport operators, retailers, waste disposal operators, the Armed Forces, energy suppliers, oil and gas exploration companies and local authorities. Partners include government agencies and the emergency services.

RCNZ adopted the Responsible Care Management System® (RCMS) - an integrated compendium of national EHS performance standards (codes of practice) incorporating an audit system enabling compliance with demanding national workplace EHS protection legislation and enforced by government agencies.

## **8. Availability of data**

### *NZIoC (New Zealand Inventory of Chemicals)*

The Inventory of Chemicals (NZIoC) is a database containing single component hazardous chemicals that can be used in products approved under group standards (with a few exceptions). Due to a lack of information on certain chemicals at the time the inventory was developed, some non-hazardous chemicals are also listed.

The NZIoC has two features which make it different from existing chemical inventories in other countries. They are:

1. *Non-hazardous substances are not required to be listed;*

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2. *NZIoC also lists approval status for a hazardous substance (i.e., whether a hazardous substance can be only used on its own or used as a component in a product covered by a group standard.)*

If it has an individual approval number (a number with HSR in front) then it can be used as a chemical in its own right. It should be noted that the HSR approval number assigned to a chemical would only be used for a "pure chemical" and in this case this number should appear on the safety data sheet (SDS). A group standard approval number can be used if there is an appropriate group standard. In this case, the approval number or the name of the group standard should appear on the SDS.

If a substance is imported into or manufactured in New Zealand after 30 June 2006, and contains a hazardous chemical that is not listed on the NZIoC, then the importer or manufacturer of the substance must supply the Authority with the following information:

- a. *the name of the substance;*
- b. *the HSNO approval number and/or title of the Group Standard under which the substance has a deemed approval;*
- c. *the name and CAS number of the chemical not listed on the Inventory of Chemicals that is present in the substance;*
- d. *the concentration of that chemical in the substance;*
- e. *the hazardous properties of the chemical, including the provision of the relevant hazard data used to assign the substance to the Group Standard;*
- f. *the proposed use of the substance.*

EPA updates the NZIoC regularly with new chemicals that have been notified and verified.

NZIoC is accessible at <https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/>

### *Approved Hazardous Substances with Controls database*

This database contains information on the classifications and controls for all approved hazardous substances.

In this database, each substance can be searched for by substance name, CAS number or its HSNO approval number. The database is maintained by the EPA and is accessible at <https://www.epa.govt.nz/database-search/approved-hazardous-substances-with-controls/>

### *CCID (Chemical Classification and Information Database)*

The CCID lists classifications of many single component HSNO-approved substances. It includes chemical identification information, supporting data for classifications (where available), including references and classification data itself. The information in the CCID is useful when classifying formulated products. It may also be useful for preparing labels and safety data sheets. The CCID is linked to the OECD's eChemPortal

Database search may be performed via chemical name or CAS number at <https://www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid/>

### *Hazard Substances Toolbox*

The Hazard Substances Toolbox is maintained by the WorkSafe NZ. It is aimed to raise awareness among stakeholders, help them to increase their compliance with the HSNO Act, providing a user friendly interface to learn about necessary steps to be performed in order to comply. The Toolbox is a multi-media package that provides both practical guidance, reference materials and tools that help to complete each step, regardless the hazardous substances being used.

It provides the information about using and storing hazardous substances safely, contains the explanations of the key HSNO controls, how to create an inventory for the chemicals at the workplace. WorkSafe also provides a free tool - the Hazardous Substances Calculator that is aimed to determine which HSNO controls have to be in place while using and storing chemicals at the workplace.

The Toolbox targets the category of workers managing chemicals at their workplaces, putting the emphasis on SMEs. It can be accessed at the WorkSafe New Zealand website (<https://www.hazardoussubstances.govt.nz/>).

## 9. Laboratory infrastructure

### *GLP (Good laboratory practice)*

International Accreditation New Zealand (IANZ) IANZ has been designated by the New Zealand Government as the Compliance Monitoring Authority for the OECD's programme for the Mutual Acceptance of Data ([www.ianz.govt.nz/](http://www.ianz.govt.nz/)).

Testing facilities are inspected for compliance with the OECD Principles of Good Laboratory Practice and related consensus documents. The primary criteria document against which all GLP Compliant test facilities are assessed is: OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring. Number 1. OECD Principles of Good Laboratory Practice (1998).

The scope of application of the OECD Principles is restricted to non-clinical safety testing of test items contained in: industrial chemicals, pesticide products, veterinary drugs and some others.

Typically, non-clinical safety tests fall into the following categories:

- *physical-chemical testing;*
- *toxicity studies;*
- *mutagenicity studies;*
- *environmental toxicity studies on aquatic and terrestrial organisms;*
- *studies on behaviour in water, soil and air;*
- *residue studies;*
- *studies on the effects on mesocosms and natural ecosystems;*
- *analytical and clinical chemistry testing*

## 10. Information sharing

### *10.1. Implementation of GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

The hazardous properties thresholds for the HSNO Act are set out in the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017.

The HSNO Classification system is unique to the country. The classification systems comprise:

- *numbered classes (for example, class 6), indicating the intrinsic hazardous property;*
- *numbered subclasses (for example, subclass 6.1), indicating the type of hazard; and*
- *lettered categories (for example, category A) indicating the degree of hazard.*
- *The nine classes for the hazardous properties are:*
- *class 1: explosiveness;*
- *class 2: flammability, gases;*
- *class 3: flammability, liquids;*
- *class 4: flammability, solids;*

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- *class 5: oxidising capacity;*
- *class 6: toxicity;*
- *class 8: corrosiveness; and*
- *class 9: ecotoxicity.*

The schemes of classification and determination of threshold values of potential explosiveness, flammability, and oxidation are based on the UN Model Regulations.

Classifications on toxicity and ecotoxicity generally align with the UN GHS classifications, but there are some differences. For example, HSNO does not separate reversible eye effects into two sub-categories and does not specifically address the GHS category of transient target organ effects.

EPA is currently working to update the current HSNO hazardous substances classification system to GHS Rev. 6 or later within the next three years.

### EPA Notices

The EPA can set hazardous substance rules under the HSNO Act. These are detailed in EPA Notices. EPA Notices are tertiary instruments, and are approved by the EPA Board rather than going through the Government process. This allows the notices to be updated quickly, allowing the EPA to keep up to date with international and technological changes. Although they are approved by the EPA Board, proposed EPA Notices must go through a public consultation period.

#### Hazardous Substances (Minimum Degrees of Hazard) Notice 2017

Prescribes the criteria that determines a substance is hazardous under HSNO.

Replaces the old Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001

#### Hazardous Substances (Classification) Notice 2017

Prescribes the criteria for each hazard classification.

Replaces the old Hazardous Substances (Classification) Regulations 2001

#### Hazardous Substances (Labelling) Notice 2017

The HSNO labelling requirements can be found in the following:

- *Hazardous Substance (Labelling) Notice 2017*
- *Some group standards have additional requirements or variations*  
There are also two labelling codes of practice which provide means of compliance:
- *“Labelling of Hazardous Substances”, Prepared by Responsible Care New Zealand*
- *“Product Labelling and Documentation Code for Agricultural Compounds and Veterinary Medicines”, prepared by AGCARM*

The Hazardous Substance (Labelling) Notice 2017 consolidates the generic labelling requirements in the previous regulations into one Notice. The Notice also incorporates some substance-specific variations. It requires the GHS pictograms, signal word, and hazard and precautionary statements to be on the label, which is a change from the previous requirements of the Hazardous Substances (Identification) Regulations 2001.

Labels for workplace chemicals (including pesticides) will have to be prepared in compliance with the GHS requirements.

Labels on consumer products must comply with the GHS. In addition, there are alternative compliance provisions, which allow the relevant laws from Australia, USA, Canada or EU to apply,

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for example, if the substance is scheduled under the Australian Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), the labelling requirements contained within that standard would apply.

Manufacturers, importers and suppliers of hazardous substances all have certain responsibilities under the Labelling Notice.

There are the following transition periods:

- *until 1 December 2021 for substances covered by group standards.*
- *2 – 4 years from the date of re-issue of approval for individual approvals approved before 1 December 2017.*

For the individual approvals approved after 1 December 2017, there is no transitional period and the compliance is required from the date of the approval.

### Hazardous Substances (Safety Data Sheets) Notice 2017

The Notice requires that all safety data sheets need to be in the 16-header format in line with the GHS provisions. Either the HSNO or GHS classification must be provided in Section 2 of the safety data sheet, along with the GHS signal word, and hazard and precautionary statements. The Notice includes more details on the specific information required in some sections of the safety data sheet. Importers and manufacturers would have the responsibility of ensuring their SDS comply with the requirements.

The Notice also allows GHS-compliant safety data sheets from Australia, EU, Canada, and USA, as long as some New Zealand specific information is also included.

A code of practice for SDS was prepared by Responsible Care New Zealand to provide aid on creating an SDS.

The SDS requirements that relate to availability of SDS in the workplace have transferred to the HSW legislation.

There are the following transition periods:

- *until 1 December 2021 for substances covered by group standards.*
- *2 – 4 years from the date of re-issue of approval for individual approvals approved before 1 December 2017.*

For the individual approvals approved after 1 December 2017, there is no transitional period and the compliance is required from the date of the approval.

### Hazardous Substances (Packaging) Notice 2017

This Notice sets the rules for the packaging of hazardous substances, including the rules for child-resistant packaging. This notice combines and updates rules previously set in the Hazardous Substances (Packaging) Regulations 2001 and group standards.

This Notice came into force on 1 December 2017. It aligns the hazardous substances packaging rules more closely to the United Nations (UN) Recommendations on the Transport of Dangerous Goods. The notice also updates the rules for the packaging of consumer products.

### Hazardous Substances (Disposal) Notice 2017

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This Notice sets the national minimum standard for the disposal of hazardous substances. It updates disposal provisions in the Hazardous Substances (Disposal) Regulations 2001 and group standards.

### *10.2. Response on emergency situations involving chemicals, including poisoning*

0800 CHEMCALL® emergency response service is provided by Responsible Care New Zealand.

Those importing, manufacturing, storing, transporting or disposing of hazardous substances or dangerous goods are legally required to protect employees, the community and the environment in accordance with the Health and Safety at Work Act 2015, the Land Transport Act 1998, Land Transport Rule: Dangerous Goods 2005, the Resource Management Act 1991, and the Hazardous Substances and New Organisms Act 1996.

0800 CHEMCALL® fulfils the legal obligation to provide a quick and effective response in the event of an accident or incident involving chemicals, providing a 24/7 emergency service phone number. It provides free technical advice and emergency response service to schools, hospitals, the emergency services and enforcement agencies.

## **B I B L I O G R A P H Y & R E F E R E N C E S**

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4. EPA, “New Zealand Inventory of Chemicals ( NZIoC ),” vol. 2007 March.
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6. E. Directorate, C. Group, and M. Committee, “OECD series on principles of good laboratory practice and compliance monitoring,” Ann. Ist. Super. Sanita, vol. 33, no. 1, pp. 1–172, 1997. Diderich, “ENV/JM ( 2014 ) 13 For Official Use,” vol. 33, pp. 1–42, 2014

## **T h e R e p u b l i c o f P e r u**

Composed by Russian Federation  
Reviewed by Peru

## **I n t r o d u c t i o n**

The chemical industry in Peru main sectors are industrial chemicals, oil refineries, petroleum products and coal, rubber products, plastic products and other chemicals.

The areas of greatest impact on the GDP are industrial chemicals and industrial cleaning sector items, hygiene and toilet.

### **1 . R e g u l a t e d o b j e c t s**

Prior to marketing some chemicals and chemical products are evaluated according to the criteria of health protection (they may be considered to be the regulatory objects):

- *pesticides for agricultural use;*
- *pesticides and disinfectants for home, industrial and public use;*
- *hygiene products for home use;*
- *medicines and cosmetics;*
- *toys and school suppliers;*
- *asbestos chrysotile (use, labeling, import, as well as the processes of removal, transport and final disposal).*

Handling of a number of substances that are considered to be precursors in the manufacture of illicit drugs used in household and artisan is regulated as well.

What is more, chemicals related to explosives and pyrotechnic products and chemicals susceptible to be used for the manufacture of chemical weapons are also regulated.

Generally the existing chemical substances legislation (use, prohibition or restriction of chemical substances) in Peru is covered over international conventions, which Peru signed or associated itself with.

POP's according the provisions of Stockholm Convention on Persistent Organic Pollutants, hazardous wastes according to Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, hazardous chemicals and pesticides - Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides and Pesticides and mercury according Minamata Convention, ODS according to the Montreal Protocol.

### **2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m**

Several governmental bodies and institutions are involved in the regulatory processes of the regulatory objects listed above:

- *Ministry of Health – MINSa / <http://www.gob.pe/minsa>*
- *Ministry of Environment – MINAM / <http://www.gob.pe/minam>*
- *Ministry of Interior – MININTER / <http://www.gob.pe/mininter>*
- *Ministry of Production – PRODUCE / <http://www.gob.pe/produce>*
- *Ministry of Energy and Mines – MINEM / <http://www.gob.pe/minem>*
- *Ministry of Agriculture and Irrigation – MINAGRI / <http://www.gob.pe/minagri>*
- *National Institute of Quality - INACAL (under the Ministry of Production)/ <https://www.inacal.gob.pe/principal/categoria/acerca-de-inacal>*

The use of hazardous chemicals may be banned or restricted by congress, industry and manufacturing sector, national, regional or local governments, agriculture sector as well.

### 3 - 4 . Influences : National priorities and International activities

May be divided into 3 main parts:

- *Constitution, National strategic documents (National Environmental Policy approved on 23 May 2009 by S.D.№ 012-2009-MINAM), legislation on chemical regulations.*

Constitution of the Republic of Peru, in articles 7 and 65 guarantees all persons the right to protection of his health. In article 67 it guarantees to protect the environment.

In Articles 192 item 7 and 195 item 8, regional governments and local governments oversee the issues on development and regulation of activities and/or services **regarding health, housing, sanitation, environment, sustainability of natural resources, public transportation, industry, agro-industry, energy, mining, roads, communications** and other activities according to law.

- *Andean Community (CAN), the Union of South American Nations (known in Spanish as UNASUR), the Southern Common Market (known in Spanish as MERCOSUR), Free trade agreements provisions (with China, Japan, USA, Canada, Mexico, South Korea, European Free Trade Association (EFTA), EU, Chile).*
- *International Conventions*  
Peru ratified several significant conventions on regulation of chemicals (see table 3.9.1).

**Table 3.9.1 – Conventions on chemicals regulation ratified by Peru**

Conventions	Status of Ratification (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark/ source link
The Stockholm Convention on Persistent Organic Pollutants	yes	14.09.2005	yes	<a href="http://chm.pops.int/Countries/StatusofRatifications/PartiesandSignatoires/tabid/4500/Default.aspx">http://chm.pops.int/Countries/StatusofRatifications/PartiesandSignatoires/tabid/4500/Default.aspx</a>
The Montreal Protocol on Substances That Deplete the Ozone Layer	no	31.03.1993 Accepted	yes	<a href="http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32508/4">http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32508/4</a>
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	no	23.11.1993 Accepted	yes	<a href="http://www.basel.int/Countries/StatusofRatifications/tabid/1341/Default.aspx">http://www.basel.int/Countries/StatusofRatifications/tabid/1341/Default.aspx</a>
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	yes	14.09.2005	yes	<a href="http://www.pic.int/Countries/Statusofratifications/tabid/1072/language/en-US/Default.aspx">http://www.pic.int/Countries/Statusofratifications/tabid/1072/language/en-US/Default.aspx</a>
Convention on the Prohibition of the	yes	14.01.1993	yes	<a href="https://treaties.un.org/Pages/ViewDetails.as">https://treaties.un.org/Pages/ViewDetails.as</a>

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<b>Conventions</b>	<b>Status of Ratification (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark/ source link</b>
Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction				<i>px?src=TREATY&amp;mt dsg_no=XXVI-3&amp;chapter=26&amp;lang=en</i>
The Minamata Convention on Mercury	yes	21.01.2016	yes 10.10.2013	<i>http://www.mercuryconvention.org/Countries/tabid/3428/Default.aspx</i>
ГАТТ/ВТО соглашения (касающиеся торговли химическими веществами)	yes	07.10.1951	yes	<i>https://www.wto.org/english/thewto_e/gattmem_e.htm</i>
Vienna Convention for the Protection of the Ozone Layer	yes	07.04.1989	yes	<i>http://ozone.unep.org/vienna-convention-protection-ozone-layer/46095/2205</i>
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.	no		yes 12.09.1977	<i>https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mt dsg_no=VI-18&amp;chapter=6&amp;lang=en</i>
United Nations Convention on Psychotropic Substances, 1971.	yes	28.01.1980 Accepted	yes	<i>https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&amp;mt dsg_no=VI-16&amp;chapter=6&amp;lang=en</i>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.	no	13.03.1990	yes	<i>https://treaties.un.org/pages/viewdetails.aspx?src=treaty&amp;mt dsg_no=vi-19&amp;chapter=6&amp;lang=en</i>

### 5. Parameters of regulation

*Information from the open sources is not available.*

### 6. Key procedures for control of regulated objects

*Existing and New Chemicals*

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Peru has no national inventory of existing chemicals substances and no requirement for the notification of new substances.

### *Registration, Permit*

*Raw chemical materials and other taxed products/Substances (considered precursors in the manufacture of illicit drugs) used in household and artisan*

The Government of Peru adopted Law No. 28305 (July 29, 2004), regulated through Supreme Decree No. 053-2005-PCM, which controls some raw chemical materials and other taxed products that can be used in the production of illicit drugs derived from coca leaves, poppies, and other precursor materials.

In August 2012 the notice was published that under Article 6 of the Law No. 28305 companies are obliged to register their use of sodium cyanide, potassium cyanide and mercury in order to monitor that these companies are in line with all the corresponding national regulations. The Law also foresees provisions to monitor the distribution, transportation, and marketing of such chemical products to prevent their use in illegal mining.

The law regulates the complete commercial chain: imports, production, manufacture, preparation, packaging, re-packaging, retail, transport, storage, distribution, transformation, use, and services related to these substances.

There are several Government divisions involved in the enforcement of the Law, particularly the Interior Ministry (MININTER), the Special Attorney for Illicit Drug Trafficking, and the Specialized Anti-Drug Units from the Peruvian National Police (DIRANDRO). This last Government division can provide a "User's Certificate" that allows for the use of the products registered in a "Unified Registry" database, implemented by the Ministry of Production (PRODUCE). The User's Certificate is valid for 2 years, and can be renewed by the user. If the company has more than one production site using these regulated substances, it should request a certificate for each location. If the company decides not to renew the Certificate, it can not just let it lapse, but has to present a request for cancellation.

When the Certificate is in effect, the company must keep special records and present monthly statements on all activities performed with the substances. Additionally, there may be regular police inspections to ensure compliance.

Fines are also defined in the Law, as well as reason to cancel the certificate.

There is a subset of these products that in small quantities are considered "For Household and Artisan Use," and commercialization is allowed without a User's Certificate when the amounts do not exceed the values described in the law. Under this subset it is also not necessary to register in the Unified Registry database, keep special records, or present monthly reports.

There is also a second subset, for bigger quantities in what is denominated "Zones Regulated by Special Regime."

In a third category of subset for bigger quantities in the denominated "Special Regime Zones," a Small Retailer User's Certificate might be required, and reports needed if sales are above a certain threshold that varies per substance.

More information can be found at the website of the Ministry of Production (<https://www.gob.pe/produce>) or in the legal section of the Official Gazette "El Peruano" (<https://elperuano.pe/>).

Peru's **Ministry of Health** (MINSa) under Supreme Decree No 015-2005-SA of July 6, 2005 and Article 2, interjection 22 and Article 7 of the Political Constitution of Peru states that "The Ministry has the obligation to dictate the necessary measures for the protection of the health of workers

against the risks of exposure to chemical substances in the workplace in accordance with Preliminary Title Law No. 26842". Please see the lists short descriptions in the section 8 "Availability of data".

## 7. Non-regulatory mechanisms

Peru is a full member of ICCA. The Chemical Industry Committee of the National Industries Society (known in Spanish as Comité de la Industria Química de la Sociedad Nacional de Industrias - CIQ-SNI) is a body responsible for implementation of the stewardship program in Peru. CIQ-SNI adopted Responsible Care in 1996.

## 8. Availability of data

In Peru there are several inventories of dangerous prohibited or restricted substances (see table 3.9.2 below).

**Table 3.9.2 – Chemical inventories in Peru**

Control of Chemical Raw Materials and Supervised Product	This list includes controlled raw chemical materials and other taxed products that are used in the production of illicit drugs
Control of Chemical Raw Materials and Supervised Product-Household and Artisan Use	This list includes controlled substances considered precursors in the manufacture of illicit drugs that may be commercialized with less control when in smaller amounts, for household and artisan use
Occupational Exposure Limits-Carcinogens	This list contains the substances designated as carcinogens by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Occupational Exposure Limits-Ceilings	This list contains the ceiling exposure limits for substances as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Occupational Exposure Limits-Respiratory Sensitizers	This list contains respiratory sensitizers as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Occupational Exposure Limits-Simple Asphyxiants	This list contains substances that have been identified as simple Asphyxiants as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Occupational Exposure Limits-Skin Designations	This list contains the substances given the skin designation as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Occupational Exposure Limits-Skin Sensitizers	This list contains skin sensitizers as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Occupational Exposure Limits-STELs	This list contains the short-term exposure limits (STELs) for substances as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace

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Occupational Exposure Limits-Toxic for Reproduction	This list contains substances considered toxic for reproduction as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Occupational Exposure Limits--TWAs	This list contains the time-weighted average (TWA) exposure limits for substances as established by Peru's Regulation of Occupational Exposure Limits of Chemicals in the Workplace
Prohibited Carcinogenic Substances	This list contains the prohibited carcinogenic substances as established by Peru's Regulation of Occupational Exposure Limits of Chemicals
Prevention and Control of Occupational Cancer	This list contains the carcinogenic substances with which contact or exposure should be avoided / limited

### 9. Laboratory infrastructure

#### *Accreditation of medical laboratories and GLP*

The General Directorate of Medicines, Supplies and Drugs (known in Spanish as Dirección General de Medicamentos, Insumos y Drogas - DIGEMID), is the technical-regulatory body (under the Ministry of Health - MINSA) responsible for authorization of pharmaceuticals, medical devices and certification, control and monitoring of the processes related to the production, importation, distribution, storage, marketing, promotion, advertising and sale of the pharmaceuticals and medical devices, as well providing of equitable access to medical products that are much-in-demand in Peru.

Recommendations for good laboratory practices, good manufacturing practices, good storage practices are specified in Ministerial Resolution Nº485-2013/MINSA approved by the Ministry of Health.

The Peruvian National Quality Institute of Standardization, Metrology and Accreditation (INACAL) under the Ministry of Production (PRODUCE), carries out accreditation of Conformity Assessment Body (the laboratories of tests, calibration and clinics, the certification bodies of products, systems and people, and the inspection bodies), after being submitted to an audit to demonstrate that it complies with the internationally recognized standards and guidelines as ISO/IEC International Technical Standards, which have been adopted as NTP Peruvian Technical Standards.

### 10. Information sharing

#### *10.1.GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

The Peruvian government has expressed a desire to implement GHS, but has acknowledged that it lacks the necessary support for training and development to create an effective program. There is currently no regulation in force for the creation and management of SDS, or for the labelling of hazardous chemicals. However there are regulations in the mining, production, transport and agriculture sectors which establish the use of SDS for chemicals used by companies under their control.

In addition, there are some unique regulations related to specific chemical types:

Technical Standard No. G50 (primarily used in the construction industry) requires SDS for all chemical substances and their derivatives;

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It also requires storage and project personnel must be trained on handling.

The Peruvian Ministry of Environment (MINAM) will accept any version of the GHS for SDS which are used in the country.

With regard to transport of dangerous goods the Andean Community (CAN) have developed draft regulations based on the 13th revised edition of the UN Model regulations, the ADR 2005 and the RID 2005, which are still under consideration.

### *10.2. Emergency response*

According to the "National Environmental Health Policy 2011 - 2020" The Ministry of Health (MINSa) is responsible for care of emergencies and disaster. The General Directorate of Disaster Risk Management and National Defense in Health (known in Spanish as Dirección de Gestión del Riesgo de Desastres y Defensa Nacional en Salud - DIGERD) of the Ministry of Health is dealing with the risks to public health, which appear due to long-term exposure of chemicals containing in wastewater, industrial or hospital hazardous hard wastes, products (toys, stationery, school supplies), and caused by atmospheric emissions from industries, other economic activities, traffic accidents.

Chronic poisoning occurrences are registered in Peru from the following chemicals: lead, mercury, arsenic, copper and aluminum.

The General Directorate of Disaster Risk Management and National Defense in Health (DIGERD) develops, organizes, maintains an emergency response on the national, regional and local level.

Beyond that, it is worth mentioning that the Ministry of Environment is responsible for declaring environmental emergencies in coordination with the competent authorities.

## **B I B L I O G R A P H Y & R E F E R E N C E S**

1. Ministry of Health - MINSa / <http://www.gob.pe/minsa>
2. Ministry of Environment – MINAM / <http://www.gob.pe/minam>
3. Ministry of Interior – MININTER / <http://www.gob.pe/mininter>
4. Ministry of Production – PRODUCE / <http://www.gob.pe/produce>
5. Ministry of Energy and Mines – MINEM / <http://www.gob.pe/minem>
6. Ministry of Agriculture and Irrigation – MINAGRI / <http://www.gob.pe/minagri>
7. National Institute of Quality – INACAL (under the Ministry of Production)/ <https://www.inacal.gob.pe/principal/categoria/acerca-de-inacal>
8. [Chemical Legislation, Regulation and Data Tools in Peru/2012/CTI2/FOR/003](#)
9. Constitution of Peru/  
[http://www.congreso.gob.pe/Docs/files/CONSTITUTION\\_27\\_11\\_2012\\_ENG.pdf](http://www.congreso.gob.pe/Docs/files/CONSTITUTION_27_11_2012_ENG.pdf)

**T h e R u s s i a n F e d e r a t i o n**

Composed by Russian Federation

## Introduction

Chemical industry is a key branch of economy. In accordance with the classification of industrial production adopted in the Russian Federation [1], the industrial chemistry includes two enlarged types of economic activity: chemical production (70%) and production of rubber and plastic products (30%).

The share of the chemical industry in the structure of industrial production of the Russian Federation at the end of 2016 was 9.3% (in 2014 it was 6%), yielding to extraction of mineral resources, engineering industry, production of electricity, gas and water, along with metallurgical and food production.

There was an increase in the following main sub-sectors of the chemical industry in 2016:

- *manufacture of chemical crop protection products – 95,6 thousand tons (+59,6%);*
- *manufacture of dyes and pigments – 30,04 thousand tons (+18,5%);*
- *manufacture of chemical fibers and yarns – 173,6 thousand tons (+10,5%);*
- *manufacture of lacquers and paints – 1296,7 thousand tons (+8,8%);*
- *manufacture of passenger, truck and agricultural vehicle tyre – 50,1 million items (+8,3%);*
- *manufacture of plastics articles – 4730 thousand tons (+6,5%);*
- *manufacture of sodium carbonate – 3233,6 thousand tons (+5,1%);*
- *manufacture of sodium hydroxide – 1152,8 thousand tons (+3,4%);*
- *manufacture of Mineral fertilizers (on primary nutrient basis) – 20,7 million tons (+2,7%) [1].*

The core markets for the Russian chemical products export in 2016 were the CIS countries, Brazil, the USA, China, Finland, India and the Republic of Turkey [3].

## 1. Regulated objects

In the Russian Federation the definitions of the terms “chemical substance”, “chemical product” and “mixture” are established in the technical regulation “On the safety of chemical products” [4] as follows:

“chemical substance” – chemical elements and (or) their compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process of manufacturing chemical products, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (chemical substances include chemical products, in which a chemical substance is present at a concentration of 80 percent (by weight) or more, with the remaining 20 percent (by weight) or less are considered to be impurities, and (or) additives);

“chemical product” – a chemical substance or mixture;

“mixture” – composed of two or more substances a mixture or solution in which these substances do not react with each other.

Also according to the interstate standard GOST 30333-2007 [5] the following terms and their definitions are used:

“article” – a product which has passed all the technological stages of manufacture and is usable for the satisfaction of human needs or for production in the form in which it is manufactured by the manufacturer, without further modification;

“material” – a product of industrial processing of a chemical substance or mixture, intended for the manufacture (production) of other materials, products and articles, and also used for the products operation.

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For regulatory purposes the chemical substances and products can relate to some group or category, depending on the following characteristics [4,6,7,8,9]:

1. *the substance status: allowed, restricted or prohibited for release into circulation within the territory of the Russian Federation;*
2. *the need for special control:*
  - persistent organic pollutants;
  - perfluorinated chemicals;
  - heavy metals, etc.;
3. *the ultimate goal of using the products:*
  - products for professional (industrial) use;
  - products intended for use in everyday life;
  - products used for research and development and for laboratory study;
4. *the stage of product life cycle:*
  - raw material;
  - intermediate product;
  - finished product/article;
  - production and consumption wastes;
5. *the nature of hazards:*
  - chemicals that pose hazard due to their physical-chemical properties, e.g. explosives, flammable gases, flammable liquid, etc.;
  - chemicals that pose health hazard, e.g. via acute toxicity, by causing damage (necrosis) /skin irritation or affecting the reproduction function, etc.;
  - chemicals that pose environmental hazards, including those with acute and / or chronic aquatic toxicity;
  - chemicals that pose hazard to soils, etc.;
6. *the main purpose/function:*
  - pesticides and agrochemicals;
  - lubricating oils;
  - perfumery and cosmetic products;
  - polymer materials;
  - paint and varnish products, etc.

In the sphere of foreign trade of the Russian Federation, the classification of goods by codes of the commodity nomenclature of foreign economic activity (TN VED) was widely used, according to which the products of the chemical and related industries are assigned to 28-38 groups [10].

## 2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m

Regulation of the chemicals handling in the Russian Federation has a multi-sectoral character, which includes, among other things, the delineation of powers between federal executive authority [11]. In particular, functions of providing access to the markets of goods and services are carried out by the Ministry of Industry and Trade of the Russian Federation [12]; Rospotrebnadzor conducts an assessment of the quality and safety of products imported for the first time into the territory of the Russian Federation [13], etc. Spheres of responsibility of the federal executive authority, involved in the key chemicals regulation processes in Russia are presented in table 3.10.1. below.

**Table 3.10.1. - Sphere of responsibility of the federal executive authority, involved in the regulation of chemicals in the Russian Federation**

Federal executive authority	Sphere of responsibility
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## The Russian Federation

<b>Federal executive authority</b>	<b>Sphere of responsibility</b>
Ministry of industry and trade of the Russian Federation (Minpromtorg of Russia) <a href="http://www.minpromtorg.gov.ru">www.minpromtorg.gov.ru</a>	Regulation in the field of industrial sector; functions of providing access to the markets of goods and services; chemicals import and export control; ensuring the security of critically important chemical facilities in order to minimize or completely eliminate the danger of the negative impact of their technological processes, products and production wastes on human health and the environment; issuance of licenses and other permits for the export-import operations with certain types of goods, etc.[12].
Ministry of Natural Resources and Environment of the Russian Federation (Minprirody of Russia) <a href="http://www.mnr.gov.ru">www.mnr.gov.ru</a>	Regulation in the field of use, renewal, and conservation of natural resources; functions of environmental monitoring and pollution control; production and consumption waste management; formation and maintenance of a list of methods for calculating the emission of harmful (polluting) substances into the atmospheric air by stationary sources [14]; state accounting of the ozone-depleting substances circulation, etc. [15].
The Ministry of Foreign Affairs of the Russian Federation (MFA of Russia) <a href="http://www.mid.ru">www.mid.ru</a>	Coordination of the international activities of the Russian Federation including in the field of protecting human health and the environment from the adverse effect of chemicals; formulation of proposals for aligning of the legislation of the Russian Federation with its international legal obligations; ensuring the protection of the foreign policy interests of the Russian Federation in the course of international cooperation, etc. [16].
Ministry of Economic Development of the Russian Federation (MEDT of Russia) <a href="http://www.economy.gov.ru">www.economy.gov.ru</a>	Licensing, accreditation of certification bodies and testing laboratories (centers) performing work on conformity assessment (through the activity of the subordinate Federal Service for Accreditation); formation of targeted programs, including those related to chemical products, etc. [17].
The Ministry of agriculture of the Russian Federation (Minselkhoz of Russia) <a href="http://www.mcx.ru">www.mcx.ru</a>	Regulation in the field of agroindustrial sector; organization of examination of regulations on application and state registration of pesticides and agrochemicals; issuing of conclusions on the rationale for importing into the Russian Federation of samples of unregistered plant protection products (pesticides) for registration and production tests, as well as the adoption of a decision on the admissibility of the import of plant protection products (pesticides), etc. [18].
The Ministry of health of the Russian Federation (Minzdrav of Russia) <a href="http://www.rosminzdrav.ru">www.rosminzdrav.ru</a>	Regulation in the field of sanitary and epidemiological welfare of the population; health service support of workers of particular branches of economic activity with especially dangerous working conditions, functions of medical and biological assessment of the impact on the human health of especially dangerous factors of chemical nature; formation of a list of harmful and (or) dangerous workplace factors and processes during which the mandatory pre-medical examinations are carried out before employment as well as periodic medical examinations

## The Russian Federation

Federal executive authority	Sphere of responsibility
	during work (in conjunction with the Ministry of Labour and Social Protection of the Russian Federation), etc. [19].
Ministry of Transport of the Russian Federation (Mintrans of Russia) <a href="http://www.mintrans.ru">www.mintrans.ru</a>	Regulation in the sphere of road infrastructure; organization of safety navigational hydraulic structures; ensuring security during transportation of dangerous goods, etc. [20].
Ministry of Energy of the Russian Federation (Minenergo of Russia) <a href="http://www.minenergo.gov.ru">www.minenergo.gov.ru</a>	Regulation in the oil and fuel sector, including issues related to the electric power industry, oil production, oil processing, gas, fuel, peat and shale industries, major oil and gas pipelines, oil and gas products, renewable energy sources, development of hydrocarbon fields on the basis of production-sharing agreements, and the petrochemical industry; providing state services and managing state property in the production and use of oil and fuel resources, etc. [21].
Ministry of Labour and Social Protection of the Russian Federation (Mintrud of Russia) <a href="http://www.rosmintrud.ru">www.rosmintrud.ru</a>	Regulation in the sphere of labour and social protection of citizens affected by emergencies; functions of control and supervision over the state examination of working conditions; compensation of harm caused to the health of citizens affected by radiation accidents and disasters; organization of works in the field of protection of the population and territories from emergency situations, etc. [22].
Ministry of construction, housing and utilities of the Russian Federation (Minstroy of Russia) <a href="http://www.minstroyrf.ru">www.minstroyrf.ru</a>	Regulation in the field of urban development and industry of building materials (articles) and building construction; functions of productibility confirmation for use in the construction of new products and technologies the requirements to which are not regulated by regulatory documents in whole or in part and on which the safety and reliability of buildings and structures depend, etc. [23].
Ministry of the Russian Federation for Civil Defence, Emergencies and Elimination of Consequences of Natural Disasters (EMERCOM of Russia) <a href="http://www.mchs.ru">www.mchs.ru</a>	Functions of management, coordination, control and response in the matters of the civil defence, protection of the population against emergency situations, provision of fire protection and safety of people on water bodies; ensuring fire safety and prompt notification of citizens in emergency situations; organization of radiation, chemical, biological and medical protection of the population, etc. [24].
Federal Environmental, Industrial and Nuclear Supervision Service (Rostekhnadzor) <a href="http://www.gosnadzor.ru">www.gosnadzor.ru</a>	Regulation in the field of industrial safety, safety in atomic energy uses, safety of production, storage and application of industrial explosives; functions of registration of chemical-hazardous and explosive production facilities, as well as maintaining the state register of such industrial facilities; establishment of standards of maximum allowable emissions of radioactive substance into atmospheric air and standards of allowable discharges of radioactive substance into water bodies, etc. [25].
Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing	Functions of ensuring of sanitary and epidemiological wellbeing of population by means of licensing of activities posing potential hazard to a human being; social-hygienic

## The Russian Federation

Federal executive authority	Sphere of responsibility
(Rosпотребнадзор) <a href="http://www.rosпотребнадзор.ru">www.rosпотребнадзор.ru</a>	monitoring ; state registration of potentially dangerous for a human being chemical and biological substances, separate product kinds, radioactive substances, production and consumption waste, and also importable for the first time to the territory of the Russian Federation separate product kinds; sanitary and epidemiological expertise of pesticides and agrochemicals; state sanitary and epidemiological normalization, etc. [13].
Federal Service for Accreditation (RusAccreditation) <a href="http://www.fsa.gov.ru">www.fsa.gov.ru</a>	Functions of accreditation of legal entities and individual entrepreneurs in the national accreditation system; organization of work on registration of declarations of compliance concerning production included in the Uniform List of Production subject to confirmation of compliance within the Customs union with issue of uniform documents; formation and maintaining of the national part of the Unified Register of Issued Certificates of Conformity and Registered Declarations Of Compliance issued in a uniform form; carrying out of recognition and assessment of compliance of test laboratories (centers) to the principles of appropriate laboratory practice, to the corresponding principles of appropriate laboratory practice of the Organization for Economic Cooperation and Development; formation and maintaining of the national part of the Unified Register of Certification Bodies And Testing Laboratories (Centers) of the Customs union, etc. [26].
Federal Customs Service (FCS of Russia) <a href="http://www.customs.ru">www.customs.ru</a>	Functions of the transport control in the stations of passing over the state border of the Russian Federation and sanitary-quarantine, quarantine phyto-sanitary and veterinary control, document check in specially equipped and provided for these purposes border checkpoints on the state border of the Russian Federation, etc. [27].

Federal executive authorities may set up coordinating, advisory and expert bodies (councils, commissions, groups, colleges), including interministerial ones, in order to exercise their powers in the established sphere of responsibility, as well as to solve specific tasks. Within the framework of such bodies the discussions are held and proposals are being developed to improve of the Russian chemicals management system, as well as a official position is formed on certain issues that need to be coordinated and presented at the international level.

One of the leading participants of the regulatory system is industry. Industry representatives through association in sectoral unions can promote a consolidated position on various issues on behalf of the industry sector as a whole. The largest association of the chemical industry in the Russian Federation is the Russian Chemists Union (RCU). The RCU unites more than 600 enterprises of chemical sector, scientific research institute, the unions and associations of a chemical orientation, vertically - integrated structures of Russia. The main activity of the Union is protection and representation the interests of domestic commodity producers, participation in the development and adoption by state authorities of various kinds of decisions: legislative, regulatory and other acts that contribute to improvement of economic conditions and increase of competitiveness in the international and national markets, the creation of reliable conditions of workers' social security. The RCU actively cooperates with the International Council of Chemical Associations (ICCA), the European Chemical

Industry Council (CEFIC), the Finnish Chemical Industry Confederation, the American Chemistry Council (ACC) and other national industry associations. The format of interaction allows representatives of Russian companies to participate in international events, exchange information on planned changes in the legislative framework, including standards and experience of the non-regulatory mechanisms applying [28].

An important role in the functioning of the chemicals management system is played by research institutes and centers. The activities of such organizations include a comprehensive toxicological and hygienic assessment of chemicals; development of maximum allowable concentrations and temporary standards for the content of pollutants in various environmental media; development of recommendations for improving manufacturing technologies and preventing negative consequences for human health, etc.

For example, the Institute of Hygiene, Toxicology of Pesticides and Chemical Safety Federal Budget Institution of Science "Federal Scientific Centre of Hygiene named after F.F. Erisman" of Rospotrebnadzor among other activities is developing and improving the methodology for assessing the hazardous pesticides and products of chemicalization for the population, taking into account the combined effects, as well as determining the mutagenic activity of environmental factors in order to identify potentially hazardous substances [29].

A key organization providing scientific management of researches in the Russian Federation, as well as directly carrying out scientific researches, is the Russian Academy of Sciences (RAS). The main aim of the RAS activities is to obtain new knowledge regarding the laws of the development of nature, society, and human beings and contribute to the technological, economic, social and spiritual development of Russia. The RAS unites in its structure more than 650 organizations, including institutes, research centers, separate laboratories and other scientific institutions [30].

Separately, there can be singled out the organizations whose research interests include studying regulatory practices of various countries regarding chemical safety, as well as, international initiatives and current trends in this field. The result of such studies is the formation of analytical reviews and the development of proposals for improving the chemical management system in the Russian Federation, taking into account international experience and national context. One of the centers of competence in this area is the Association "Non-Commercial Partnership Coordination and Information Center of the CIS Member States on the approximation of regulatory practices" (Association "CIS Center"). Members of CIS Center are the following organizations:

- *Federal State Unitary Enterprise "All-Russian Research Institute for Standardization of Materials and Technologies";*
- *Scientific-Production Republican Unitary Enterprise "Belarusian State Institute for Standardization and Certification";*
- *non-commercial organization "Russian Chemists Union";*
- *Association of analytical centers "Analytics".*

Furthermore, the Association "CIS Center" has partner agreements with a number of industry-specific national and international organizations.

The purpose of the foundation and activities of the Association "CIS Center" is the development, under the instructions of the Government and federal executive authorities of the Russian Federation, the coordinated and substantiated approaches, methods, programs, projects on the approximation of regulatory practices in the CIS countries, including on the circulation of chemicals, raw materials and materials; performing of the technical regulation, standardization, metrology and conformity assessment [31]. These developments are provided by the Association in accordance with the Work plan for the interaction of the Russian Federation with the OECD [32,33] and the Comprehensive plan for the interaction of the Russian Federation with APEC [34], approved by the Chairman of the Government of the Russian Federation. One of the activity areas of the Association is the organization of annual conferences on topical issues of chemicals management in the CIS

countries. The participants of the conference are representatives of state structures, industrial enterprises and professional associations, as well as foreign experts. During the conference's sessions the participants share experience of the regulatory mechanisms use in their practice, discuss aspects of the development and harmonization of legislation in the CIS countries, the advantages of using non-regulation mechanisms and other issues.

### **3 - 4 .      I n f l u e n c e s :      N a t i o n a l      p r i o r i t i e s      a n d      I n t e r n a t i o n a l      a c t i v i t i e s**

National priorities of the Russian Federation in the field of chemicals regulation for the near future are established in the following strategic planning documents which refer to a broad range of questions on chemical management [35,36,37,38,39]:

- *Principles of State Policy in the Sphere of Ensuring Chemical and Biological Security of the Russian Federation for the period up to 2025 and beyond;*
- *2020 Strategy: in order to improve the competitiveness of production and non-resource exports;*
- *Strategy for the development of the chemical and petrochemical sector for the period up to 2030;*
- *Concept of development of the state regulation system of the handling of chemical substances and chemical products;*
- *Thematic priorities of the Government of the Russian Federation for the period up to 2018;*
- *Concepts of long-term social and economic development of the Russian Federation for the period up to 2020.*

In particular, in the field of chemical safety, the following four priority areas of state policy are specified:

1. *identification, analysis, forecasting, implementation of common criteria for assessment and prioritization of risks associated with the adverse effect of chemical factors;*
2. *improvement of legal regulation and state administration;*
3. *development of resource support for functional elements of the national chemical safety framework of the Russian Federation;*
4. *implementation of a complex of measures designed to neutralize chemical threats, prevent and minimize the risks of adverse effects of chemical factors, improve the security of the population and the environment, and evaluate the effectiveness of these activities.*

The Russian Federation is a member of the Eurasian Economic Union (EAEU), which also includes the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan and the Kyrgyz Republic. Implementing the Agreement on common principles and rules of technical regulation in the countries of the Eurasian Economic Commission, Russia complies with the requirements of the technical regulations of the Customs Union. These technical regulations establish the requirements mandatory for use and execution in the customs territory of the Customs Union for the production, as well as for related processes of its manufacture, installation, maintenance, operation, storage, transportation, sale and disposal. By way of establishing a restriction or prohibition on the use of some chemicals the technical regulations form the trend of development of the chemical and related industries. Thus, through the Decision of the Eurasian Economic Commission of March 3, 2017 the technical regulation of the EAEU "On the safety of chemical products" was adopted. As far as the legislation of EAEU has priority over similar national legislation of member-state of EAEU, with the entry into force the technical regulation of EAEU "On the safety of chemical products", it will take precedence over national Russian technical regulation "On the safety of chemical products" [4].

International activity of the Russian Federation includes participation in the work of relevant international organizations and forums, as well as compliance with international obligations.

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Russia has joined the numerous international agreements whose objective is to protect human health and the environment against the adverse effects of different groups of hazardous chemicals, in particular the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and etc. A full list of the Conventions signed and/or ratified by the Russian Federation is presented in Table 3.10.2.

**Table 3.10.2. - International conventions in the field of the chemicals management, signed and/or ratified by the Russian Federation**

<b>Name of the Convention</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA) Accession (a)</b>	<b>Signed</b>	<b>Remark</b>
The Stockholm Convention on Persistent Organic Pollutants	yes	17.08.2011	22.05.2002	Entry into force: 15.11.2011 [6]
The Montreal Protocol on Substances That Deplete the Ozone Layer to the Vienna Convention for the Protection of the Ozone Layer	yes	10.11.1988	16.09.1987	Entry into force: 01.01.1989 [40]
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	25.11.1994	23.03.1990	Entry into force: 01.05.1995 [41]
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	no	28.04.2011 (a)	-	Entry into force: 27.07.2011 [42]
Kyoto Protocol to the United Nations Framework Convention on Climate Change	yes	18.11.2004	11.03.1999	Entry into force: 16.02.2005 [43]
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	05.11.97	13.01.93	Entry into force: 05.12.97 [44]
The Minamata Convention on Mercury	no	-	24.09.2014	-
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	09.10.1990	yes	Entry into force: 17.04.1991 [45]
United Nations Convention on Psychotropic Substances, 1971	yes	23.10.1978	03.12.1971	Entry into force: 01.02.1979 [46]
Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972 (London)	yes	30.12.1975	yes	Entry into force: 29.01.1976 [47]

Convention), supplemented by the 1996 Protocol				
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Active participation in the International structures such as, for example, OECD Chemicals Committee, Chemical Dialogue APEC, UN Subcommittee of experts on GHS and SAICM meeting at high and expert levels, allows ensure the contribution of the Russian side in the development of international initiatives in the field of chemical safety, and is seen as a valuable mechanism for sharing experiences on best regulatory practices and the harmonization of legislation for reducing the trade barrier.

## 5. Parameters of regulation

Regulatory indicators include the criteria and key figures by which the regulator can evaluate the current level of development of the chemicals management system, the degree of compliance of the achieved results with the planned ones, and also predict the future state of the system based on the identified trends.

Target indicators of the solution effectiveness of the main state policy objectives are set in the main areas of activity of the Government of the Russian Federation, the concepts of long-term socio-economic development of the Russian Federation for the relevant periods, as well as, in federal and regional programs in the field of chemical safety [35]. These indicators usually are quantitative with a clear timeframe for their achievement and serve to control and evaluate the effectiveness of the programs and concepts implementation through the provision of reporting on a regular basis (usually annually). In case of deviations between the actual indicators and the target ones, an analysis of the causes of the identified non-compliance is conducted and a list of corrective actions is formed.

An example of the target indicators of the Strategy for the development of the chemical and petrochemical sector for the period up to 2030 is the increase in the share of the chemical sector in the structure of the Russian's GDP up to 1.75% in 2020 compared to GDP of 1.18% in 2014, as well as an increase in the consumption of chemical sector's products per capita (up to 283 kg / person in 2020 compared to 223.6 kg / person in 2014) [35].

## 6. Key procedures for control of regulated objects

Legal and normative acts of the Russian Federation and technical regulations of the EAEU establish specific administrative procedures providing for the management of chemical substances and products in the territory of Russia. Such procedures include, for example, prohibition or restriction on the use of certain chemicals, certification and state registration of certain categories of chemicals, socio-hygienic monitoring, implementation of the best available techniques, etc.

### 6.1. Prohibition or restriction on the use of certain chemicals

Lists of narcotic drugs, psychotropic substances and their precursors, whose handling in the Russian Federation is prohibited or restricted, and for which control measures are in effect according to the national legislation and international treaties, are approved by RF Government Decree No. 681 of June 30, 1998. List of precursors (list IV) whose handling in the Russian Federation is restricted, and for which the specific or common control measures are established, was expanded by RF Government Decree of June 3, 2010 No. 398.

The list of ozone depleting chemicals, the handling of which is subject to state regulation, is approved by the RF Government Decree "On measures of state regulation of consumption and handling of substances that deplete the ozone layer" of March 24, 2014 No. 228. According to this document the handling of ozone depleting chemicals is allowed only in reusable containers, except for

the handling of ozone depleting chemicals in packagings less than 3 liters for laboratory and analytical uses defined by international treaties of the Russian Federation.

The list of substances prohibited for use in perfumes and cosmetics includes 1328 items and is contained in Annex 1 to the technical regulations of the Customs Union (TC) "On the safety of perfume and cosmetic products" [48]. Annex 2 of the document includes a list of substances permitted for use in specific applications of perfumery and cosmetic products, taking into account some limitations.

In accordance with the technical regulations of the Customs Union "On requirements for motor and aviation gasoline, diesel and marine fuels, jet fuel and mazout" [49] in the Russian Federation, metal-containing additives (containing manganese, lead and iron) are not allowed to be used in motor gasoline and diesel fuel.

The ban on the use of lead, mercury, cadmium and chromium in electronic engineering will be in effect in the Russian Federation from the moment the technical regulation of the EAEU "On limiting the use of hazardous substances in electrical and radioelectronic products" will take into force [50]. According to this regulation, "the product of electronic engineering and radio electronics shall be designed and manufactured in such a way that it does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated biphenyl ethers". While in the homogeneous materials used in the manufacture of equipment, the concentration of these substances "shall not exceed 0.1% (w/w), and cadmium - 0.01% (w/w)". The technical regulation will come into force on March 1, 2018; however, a transitional period is envisaged for easy and comfortable adaptation of the business to new legislative framework. Thus, the manufacture and sales of electrical and radio electronics products are allowed without assessing compliance with new requirements until March 1, 2020.

### *6.2. New chemicals notification*

The procedure of pre-market notification for new substances is stipulated in the technical regulation "On the safety of chemical products". This procedure applies to new chemicals as they defined according to the technical regulation as follows: "substances, information about which is absent in the Register of chemical substances and mixtures". For notification procedure, the applicant shall submit to the relevant authority information on the substance, including a chemical safety report. The provisions concerning notification process and information are expected to be detailed within the second-tier document «On the notification of the new chemical substances» the development and approval of which should be performed before the technical regulation comes into force in 2021.

### *6.3. Compliance confirmation in the form of certification and declaration*

According to the Federal Law of December 27, 2002, No. 184-FZ "On Technical Regulation", the compliance confirmation of products to be circulated in the territory of the Russian Federation with the requirements of technical regulations, provisions of standards, sets of rules or terms of contracts may of a voluntary or mandatory nature.

In particular, by the law, voluntary confirmation of compliance shall be carried out in the form of voluntary certification at the applicant's initiative on the terms of a contract between the applicant and the certification body. The objects of voluntary certification can be represented by products, processes of manufacture, operation, storage, transportation, sale and reclamation, works and services and also other objects, with requirements for them established by standards, voluntary certification systems and contracts. Voluntary confirmation of compliance can be carried out to establish compliance with standardization documents, voluntary certification systems, terms of contracts in order to building of consumer trust. According to Rosstandart's data as of January 1, 2017, 1560 voluntary certification systems were registered, including 213 systems in 2016.

Mandatory confirmation of compliance is carried out in the following forms:

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- *adoption of a declaration of compliance (compliance declaration);*
- *mandatory certification.*

Mandatory confirmation of compliance shall be carried out only in cases stipulated by the relevant technical regulation and exclusively for compliance with the requirements of such technical regulation.

A single list of products subject to mandatory assessment (attestation) of compliance within the Customs Union with the issuance of common documents (compliance certificate and compliance declaration) according to uniform forms was approved by the Decision of the Commission of the Customs Union [51]. Products not included in the single list can be subject to mandatory assessment (attestation) under the national legislation of the states - members of the Customs Union.

Thereby the Government of the Russian Federation has approved and annually specifies a single list of products subject to mandatory certification, as well as a single list of products, which confirmation of compliance is carried out in the form of adoption of a declaration of compliance [52].

The compliance declaration and the compliance certificate are regarded as equally valid, regardless of the systems of obligatory confirmation of compliance, and they shall operate throughout the territory of the Russian Federation [53].

### *6.4. State registration*

The list of goods subject to the state registration procedure is established in Section II of Annex 1 to the Decision of the Commission of the Customs Union of May 28, 2010 No. 299 "On the application of sanitary measures in the Eurasian Economic Union". This list includes, among others, the following product categories, which are subject to state registration if they manufactured for the first time on the Customs Union customs territory, as well as imported for the first time to the Customs Union customs territory:

- *potentially hazardous chemical and biological substances, and preparations manufactured on their basis that are potentially dangerous to human (other than pharmaceuticals); individual substances (compounds) of natural or human-made origin that can have adverse effects on human health and the environment in the context of production, use, transportation, processing and in household use;*
- *sanitizers, insecticides and deratization agents (for use in everyday life, in medical and preventive treatment facility and at other sites (except for those used in veterinary medicine));*
- *cosmetic products; oral hygiene means and products;*
- *household chemical products.*

Raw material, active ingredients, intended by the manufacturer (producer) only for the production of perfumery and cosmetic products, household chemical products, plant-protecting, fumigation, pest control and extermination products, as well as pharmaceutical products, are not subject to state registration.

More details on the list of goods under supervision (control) and relevant items of FEACN CU can be found on the official website of the Eurasian Economic Commission [54].

The procedure of state registration of potentially hazardous chemicals is carried out in two stages. At the first stage, the sanitary and epidemiological expertise of potentially hazardous chemicals is carried out by the Federal Budget Healthcare Institution "Russian Register of Potentially Hazardous Chemical and Biological Substances" of Rospotrebnadzor. The second stage is the procedure of state registration for the chemical product introduced or imported into the territory of the Russian Federation for the first time. [55,56].

For the second stage of chemicals state registration, the manufacturer / supplier shall submit to Rospotrebnadzor an application and provide a number of required documents: a copy of the technical document, according to which the products are produced; a copy of the label; research reports; expert

opinions (including those received at the first stage of registration), etc. [57]. On the basis of the expert opinion and the Information card for potentially hazardous chemical and biological substances, Rospotrebnadzor issues a Certificate of state registration according to the uniform format of the Customs Union and includes it in a Single Register of certificates. The certificate is provided for the whole period of the manufacture or delivery of chemical products on the Customs Union territory and it confirms that the product was entered in the Register and is compliant with hygienic and sanitary standards. For products that are not subject to mandatory state registration, it is possible to voluntarily formalize an expert opinion of Rospotrebnadzor in order to inform consumers about its safety.

A separate procedure of state registration is provided for pesticides and agrochemicals. This service is provided by the Ministry of Agriculture of the Russian Federation in accordance with the approved procedure [58, 59] which includes the following stages:

- a) *organization of registration tests of a pesticide or agrochemical;*
- b) *organization and carrying out the expert evaluation of regulations for the use of a pesticide or agrochemical;*
- c) *organization and carrying out the expert evaluation of the results of registration tests of a pesticide or agrochemical;*
- d) *state registration of a pesticide or agrochemical;*
- e) *issuance of a certificate of state registration of a pesticide or agrochemical to the applicant;*
- f) *inclusion of a pesticide or agrochemical into the State catalog of pesticides and agrochemicals permitted for use on the territory of the Russian Federation.*

Pesticides and agrochemicals that are not included in the State catalog are not allowed for importation and circulation on the Russian market [60].

The list of organizations admitted to conducting registration tests, as well as institutions responsible for the expert evaluation, was approved by the Ministry of Agriculture of the Russian Federation and presented on the official website of the Ministry [61].

### *6.5 Socio-hygienic monitoring*

Socio-hygienic monitoring is a government's system for monitoring the public health and the environment, their assessment, analysis, and forecast in order to identify causal relationships between the public health status and the environmental factors. In accordance with the legislation, social and hygienic monitoring is the direction of the Federal Service in the field of consumer protection and welfare (Rospotrebnadzor) and an important tool for making science-based decisions in the public health field, sanitary and epidemiological well-being, with no harmful effects environmental factors per person and provided favorable conditions for his life.

Monitoring provides:

- a) *the establishment of factors that have a harmful effect on humans, and their assessment;*
- b) *forecasting the public health status and the environment;*
- c) *determination of immediate and long-term actions for prevention and elimination of harmful factors of the environment on the public health;*
- d) *development of proposals for actions in the field of ensuring the sanitary and epidemiological well-being of the population;*
- e) *informing public authorities, local governments, organizations and the public about the results obtained during the monitoring.*

For the purpose of monitoring, data of observations carried out by federal executive bodies are used:

- a) *health status of the population - observations are carried out by the Federal Service for Supervision of Consumer Rights Protection and Human Welfare and the Federal Service for Supervision of Health Care and Social Development;*

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- b) *for human environmental factors, including:*
- *biological (viral, bacterial);*
  - *chemical, including sources of anthropogenic impact on the environment;*
  - *physical (noise, vibration, ultrasound, infrasound, thermal, ionizing, non-ionizing and other radiation);*
  - *social (structure and quality of food, food safety, water supply, living conditions, work and rest);*
  - *natural and climatic factors, including sources of anthropogenic impact on the environment.*

Based on the monitoring data, the Federal Service for Supervision of Consumer Rights Protection and Welfare forms the federal information database of socio-hygienic monitoring database on the health status of the population and the human environment, formed on the basis of permanent system observations, as well as normative legal acts and methodological documents on the analysis, prediction and determination of cause-effect relationships between the state of public health and the influence of factors of human environment. [67]

## 7. Non-regulatory mechanisms

The most common non-regulatory mechanism is the international program Responsible Care® which is a voluntary commitment by the global chemical industry to drive continuous improvement and achieve excellence in environmental, health and safety and security performance. In the Russian Federation this program was launched in 2007 with the support of the Russian Chemists Union (an official member of the ICCA since 2011) that manages and oversees its implementation till now. The program was realized at more than 30 major chemical industry enterprises, including PJSC Nizhnekamskneftekhim, OJSC Apatit, OJSC Russian Paints, OJSC Schekinazot, Reahim Group of Companies and others [28].

An example of combining the efforts of science and industry is a joint project called Green Chemistry for Life of a Russian phosphate-containing fertilizer producer PhosAgro, the United Nations Educational, Scientific and Cultural Organization (“UNESCO”) and the International Union of Pure and Applied Chemistry (“IUPAC”) [62]. This project is unique in that for the first time in UNESCO’s long history, and in the entire UN system, this kind of initiative is being implemented with extra-budgetary funds provided by Russian business. PhosAgro has allocated 1.4 million US dollars to finance this five-years project. The initiative is aimed at providing support for talented young scientists from around the world that are conducting research in the field of green chemistry. Their goal is to protect the environment and human health through the development of energy-efficient and environmentally friendly technologies.

## 8. Availability of data

The information on hazard properties of chemicals, as well as data on key procedures of state regulation as to specific categories of Russian chemical industry goods are presented in the following lists, registers, catalogues and/or data bases:

- 1) *SanPiN 1.2.2353-08 “Carcinogenic factors and basic requirements for prevention of carcinogenic hazard” and SanPiN 1.2.2834-11 Amendments and additions No. 1 to SanPiN 1.2.2353-08 contain the list of chemicals which recognized as carcinogens in the Russian Federation;*
- 2) *Annex 2 of SanPiN 2.2.0.555-95 “Hygienic requirements for the work conditions of women” includes the list of potentially hazardous chemicals with reproductive toxicity (adverse effects on gonads and/or embryos);*
- 3) *Single list of goods subject to sanitary-and-epidemiologic supervision (control) at the customs border and on the customs territory of the Customs Union includes several lists:*

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- list of goods subject to sanitary-and-epidemiologic supervision (control) is contained in part I;
  - list of goods subject to state registration is contained in part II;
  - list of goods which do not require submitting a state registration certificate, regardless of the FEACN CU code assigned in accordance with the List of goods subject to state registration is contained in part III;
- 4) register of state registration certificates is available on the official website of Eurasian economy commission [54] and as of March 31, 2017 it is contained 488187 records. Advanced search through registry may be performed by different types of requests including certificate number, date of document, name of chemicals, application scope of product, etc.;
  - 5) register of compliance certificate and compliance declaration, including the Russian national part of the register is available on the official website of the Federal Service for Accreditation (RusAccreditation) [63];
  - 6) state catalog of pesticides and agrochemicals allowed for use on the territory of the Russian Federation is available on the official website of the Ministry of Agriculture of the Russian Federation [61]. The catalog is valid until the next edition;
  - 7) automated distributed data retrieval system (ARIPS) "Hazardous Substances" maintained by FBUZ "Russian Register of Potentially Hazardous Chemical and Biological Substances" of Rospotrebnadzor contains information on more than 10 560 substances, however, the access to this system is provided on a fee paid basis. Using the ARIPS, it should be remembered that currently in the Russian Federation there is no list of chemicals classified according to the GHS criteria, therefore the classification results presented in ARIPS are not officially approved.

Separately the state information system of industry (GISP) should be noted. It was created in accordance with the Federal Law No. 488-FZ "On Industrial Policy in the Russian Federation" [64]. GISP is focused on the development of a system of industrial balances and designed for the following processes:

- automation of the collection and processing of information necessary for the implementation of industrial policy and the exercise of the powers of state authorities to stimulate activities in the sphere of industry;
- information sharing regarding provided support to the subjects of activity in the sphere of industry;
- improving the efficiency of information exchange on the state of the industry and the forecast of its development.

Concept of development of the state regulation system of the handling of chemical substances and chemical products [37] provides for creation of information and analytical subsystem (IAP) as integral part of the GISP in order to collect and process information on the chemicals handling in the territory of the Russian Federation throughout their life cycle. It is understood that the IAP can also serve as a basis for developing proposals to support the state decision-making in the field of import substitution and localization of modern industrial technologies.

The development of a register of substances and mixtures handling in Russia is stipulated by the technical regulation "On the Safety of Chemical Products" and should be performed before this regulation comes into force in July 2021. Various aspects of the formation of the register, including a list of data sources and confirmation of their reliability, issues of mutual data recognition and protection of confidential business information, will be specified through the second level document - the procedure for the formation and maintenance of the register of substances and mixtures.

An additional source of information, which can also be used for formation of a register of substances and mixtures, is the Register of Safety Data Sheets (SDS). The Register of SDS is maintained by the Association "Non-Commercial Partnership Coordination and Information Center of the CIS Member States on the approximation of regulatory practices" in accordance with the Order of

the Federal Agency for Technical Regulation of June 11, 2014 No. 963. As of April 1, 2017, the Register of SDS includes more than 45,800 documents developed under interstate standard GOST 30333-2007.

## 9. Laboratory infrastructure

Testing of chemicals for compliance with technical regulation requirements as well as other regulatory and legal acts shall be conducted in laboratories that have an appropriate scope of accreditation. The procedure of laboratories conformity assessment with the accreditation criteria is established by the Federal Law of December 28, 2013 No. 412 [65]. Accreditation in the national accreditation system is aimed to ensure the credibility of conformity assessment results and creating conditions for the mutual recognition of conformity assessment results by trading partner states of the Russian Federation.

The accreditation criteria and the list of documents confirming the compliance of the laboratory with the criteria for accreditation are established in the Executive Order of Ministry of Economic Development of the Russian Federation No. 326 dated May 30, 2014. In particular, one of the accreditation criteria is the availability of independent ensuring system and laboratory impartiality during of its activities; rules for the selection and using of research methods (tests) and measurements which are relevant to the laboratory field of activity, as well as rules for developing, assess the suitability and using of non-standard techniques by the laboratory.

The functions of the National Accreditation Authority are carried out by the Federal Service for Accreditation (RusAccreditation) under the Ministry of Economic Development of the Russian Federation. RusAccreditation within its mandate performs formation, maintenance and provision of data from the next information resources (which are presented in the .xls format on official website of the Federal Service) [63]:

- *the national part of the Unified Register related to Certification authorities and testing laboratories (centers) of Customs Union;*
- *register of accredited persons;*
- *register of accreditation experts;*
- *register of technical experts;*
- *register of expert organizations;*
- *register of testing laboratories (centers) consistent with principles of Good laboratory practice (GLP) of the Organization for Economic Co-operation and Development (OECD).*

The Russian Federation has an extensive testing facilities base numbering approximately 2500 accredited testing laboratories (centers), a third of which assesses products for compliance with sanitary and epidemiological requirements.

### 9.1. Good laboratory practice, GLP

The main document establishing the principles of GLP in Russia is GOST R 53434-2009 identical to the OECD Guidance document 'Principles of good laboratory practice. No 1: OECD Principles on Good Laboratory Practice'. This standard initiated the establishment of a regulatory framework for the application in the Russian Federation of the GLP principles in the field of monitoring non-clinical laboratory research of chemicals with the view of assessing their safety for the environment and human health.

The national program for the implementation of OECD GLP principles was approved by Decree of the Russian Government No. 2603-p dated December 28, 2012. This program establishes the OECD GLP principles in the activities of Russian testing laboratories (centers) in the non-clinical laboratory research of objects contained in the following product types: pesticides, cosmetic products,

medicines for medical use and medicines for veterinary use, food and feed supplements, as well as industrial chemicals.

Decree of the Russian Government No. 1172 dated December 17, 2013 adopts rules for recognition and conformity assessment of testing laboratories (centers) with the GLP principles in the territory of the Russian Federation. The authority to carry out recognition and conformity assessment of testing laboratories (centers) with the GLP principles, as well as maintenance of the registry of testing laboratories (centers), which received such recognition, are assigned to the RusAccreditation.

Currently, one of the key objectives of RusAccreditation is the achieving of international recognition through the membership in the largest international associations like International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). The benefits from membership in these organizations is the recognition of the accreditation results of Russian accreditation authority and testing laboratories by ILAC and IAF member countries; and in case of signing the relevant bilateral agreements it is recognition of Russian conformity certificate for products.

One of the conditions for joining ILAC is membership in the regional association and preparatory activities in this area were held in 2015. In particular, a road map on ensuring the international integration of national accreditation system was approved, including the accession of RusAccreditation to specialized regional and international organizations. The Government of the Russian Federation issued orders to ensure the participation of RusAccreditation in the activities of the IAF [66] and the Asia-Pacific Laboratory Accreditation Organization (APLAC) [67]. The external evaluation of Russian accreditation system by international experts of APLAC was held in 2016 and as a result, RusAccreditation was recognized as an ILAC associated member.

At the present time, there are 10 laboratories in the Russian Federation that carry out research in accordance with GLP principles and one of it has an official international recognition since 2013.

### *9.2 Implementation of OECD methodologies*

Technical Committee 339 "Safety of raw materials, materials, and substances", starting in 2013, approve inter-state standards, developed on the basis of OECD research methods and widely used in laboratory practice:

- *23 standards for the assessment of physicochemical parameters;*
- *53 standards establishing test methods for chemical products that are hazardous to the environment,*
- *31 standard establishing test methods for the effects of chemical products on the human body.*

## **10. Information sharing**

Ensuring access to information on the potential adverse effect of chemicals on human health and the environment and prevention of such effects or minimizing its impact is an essential condition for safe handling of chemicals as well as one of the priorities in many countries including the Russian Federation. Thus, accessibility of information and raising public awareness in the field of chemical safety is a fundamental principle of national chemical safety policy realization in Russia. The Global harmonized system of Classification and Labelling of Chemicals (GHS) implementation is an integral part of Russian chemical safety policy (section 11, paragraph (b)) [35].

### *10.1. Global harmonized system of Classification and Labelling of Chemicals (GHS)*

Harmonized hazard communication elements as provided by UN-GHS Recommendations are implemented into Russian legislation framework by the following interstate and national standards:

- *GOST 30333-2007 Chemical production safety passport. General requirements;*
- *GOST 31340-2013 Labelling of chemicals. General requirements;*
- *R 50.1.102-2014 Compilation and execution of safety data sheet of chemical products;*
- *R 50.1.101-2014 Guidance on the selection of precautionary statements for the labelling in accordance with GOST 31340-2013.*

The most informative document on chemical products is a Safety Data Sheet. It contains data on hazard properties, harmful effect on human health and the environment, as well as consequences of such exposures and measures to prevent and reduce risks at all stages of the life cycle.

In accordance with GOST 30333 the SDS is an integral part of technical documentation for chemicals (substance, mixture, material, industrial waste) and serves to provide a customer with reliable information on safe industrial application, storage, transportation and utilization of chemicals as well as their household use. In particular, the SDS is included in the documentation provided for standardization, certification of substances and materials, state environmental expertise, licensing. The SDS is also important as part of documentation required for the transport of chemical products through the territory of the Russian Federation and for export-import transactions by custom services.

The results of chemicals hazard classification should be represented in the second section of SDS. Classification is carried out in accordance with the following interstate standards implementing the provisions of the fourth revised edition of the GHS:

- *GOST 32419-2013 Classification of chemicals. General requirements;*
- *GOST 32423-2013 Mixtures classification of hazard for health;*
- *GOST 32424-2013 Classification of chemicals for environmental hazards. General requirements;*
- *GOST 32425-2013 Mixtures classification of hazard for environmental;*
- *GOST 32421-2013 Classification of chemicals which hazard is caused by physical and chemical properties. Test methods of explosives.*

All necessary data for the SDS development should be obtained from sources recognized as competent in matters relating to the relevant sections of the SDS (official hygienic normatives, reference books, safety standards, information cards, Safety Data Sheet from foreign material supplier) or from test results obtained in the accredited laboratories. One of the features of the SDS under GOST 30333 in comparison with SDS of other countries is mandatory indication of reference to sources of information, which were used for compilation of the document. This feature allows to check information in case of any doubt. The general list of sources used for SDS compilation is given in the 16th section of SDS named “Additional information” and may count more than twenty items.

The organization (person) manufacturing and delivering any chemicals for the market compiles SDS, has responsibility to its completeness and reliability and shall provide customer with SDS free of charge.

However, in most cases, chemicals consumers do not request SDS from manufacturers/suppliers. Therefore, labelling can be the only source of information on potential hazards of chemical and measures of its safe handling. In this regard, the presence of intuitive clear symbols that characterize chemicals hazard (e.g. “Flame” or “Corrosion”), signal word (“Danger” or “Warning”), as well as standard hazard and precautionary statements in simple and understandable forms is of particular importance.

Labelling and SDS according to GOST 30333 are important informational sources on chemicals and can be used in different processes, including:

- *to ensure safety at workplaces: briefings, hazard prevention trainings and performance assessment of staff;*

- *drafting a Emergency Response Assistance Plans (PLAS);*
- *accounting and control of chemicals at the enterprise;*
- *using as visual information and agitation on safety handling of chemicals;*
- *to provide information support for emergency response services for the elimination of emergencies with chemicals, etc.*

### *10.2. Response on emergency situations involving chemicals including poisoning*

Article 4 of the Federal Law of the Russian Federation "On protection of the population and the territories against emergency situations of natural and technogenic nature" [68] introduces the concept of a unified state system of the prevention and elimination of emergencies which operates during emergency situations including ones at chemical industrial facilities. The main objectives of the system in terms of information are:

- *collection, processing, interchange and share of information on protection of the population and the territories against emergency situations;*
- *management of emergency public notification.*

According to Decree of the Russian Government No. 794 dated December 30, 2003 "On a unified state system of emergency prevention and response" the information support within unified system is carried out using an automatic management information system (MIS). MIS is a combination of technical systems, communications facility and alerting, automating and information resources and provides an exchange, preparing, collection, storage, processing, analysis and share of information.

Universal number "112" is using to receive emergency communications, including those involving hazardous chemicals.

In case of emergency, the public notification is conducted by the regional center for monitoring and responding to emergencies of EMERCOM of Russia. Information resources used to respond to emergencies include internal databases that are generated using sources such as PLAS, as well as a SDS and labelling.

Measures to prevent and mitigate emergency situations and their consequences are contained in section 6 of SDS and include the following information:

- *necessary actions of general nature under emergency response;*
- *personal protective equipment for emergency response team;*
- *actions at leakage, spill, release, including response and prevention measures protecting environment;*
- *actions at fire [5].*

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48. Технический регламент Таможенного союза «О безопасности парфюмерно-косметической продукции» (ТР ТС 009/2011) (утв. Решением Комиссии Таможенного союза от 23.09.11 №799).
49. Технический регламент Таможенного союза «О требованиях к автомобильному и авиационному бензину, дизельному и судовому топливу, топливу для реактивных двигателей и мазуту» (ТР ТС 013/2011) (утв. Решением Комиссии Таможенного союза от 18.10.11 №826).
50. Технический регламент Евразийского экономического союза «Об ограничении применения опасных веществ в изделиях электротехники и радиоэлектроники» (ТР ЕАЭС 037/2016) (принят Решением Совета Евразийской экономической комиссии от 18.10.16 №113).
51. Решение Комиссии Таможенного союза от 07.04.2011 № 620 (ред. от 18.10.2016) «О Едином перечне продукции, подлежащей обязательному обязательной оценке (подтверждению) соответствия в рамках Таможенного союза с выдачей единых документов».
52. Постановление Правительства РФ от 01.12.2009 № 982 (ред. от 26.09.2016) «Об утверждении единого перечня продукции, подлежащей обязательной сертификации, и единого перечня продукции, подтверждение соответствия которой осуществляется в форме принятия декларации о соответствии».
53. Федеральный закон от 27.12.2002 г. №184-ФЗ «О техническом регулировании».
54. Официальный сайт Евразийской экономической комиссии. – URL: <https://portal.eaeunion.org/sites/odata/layouts/15/Portal.EEC.Registry.Ui/DirectoryForm.aspx?ViewId=1631d8b8-efd5-4a46-80d9-5e252e7986bb&ListId=0e3ead06-5475-466a-a340-6f69c01b5687&ItemId=231#>.
55. «Инструкция о порядке государственной регистрации потенциально опасных химических и биологических веществ» (утв. Минприроды РФ № 37-2-7/435, Госкомсанэпиднадзором РФ № 01-19/22-22 25.05.1993).
56. Постановление Правительства РФ от 20 июля 2013 № 609 «О ведении федерального регистра потенциально опасных химических и биологических веществ, изменении и признании утратившими силу некоторых актов Правительства Российской Федерации» (вместе с «Положением о ведении федерального регистра потенциально опасных химических и биологических веществ»).
57. Приказ Роспотребнадзора от 23 июля 2012 г. № 781 (ред. от 07.04.2016) «Об утверждении Административного регламента Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека по предоставлению государственной услуги по государственной регистрации впервые внедряемых в производство и ранее не использовавшихся химических, биологических веществ и изготавливаемых на их основе препаратов, потенциально опасных для человека (кроме лекарственных средств); отдельных видов продукции, представляющих потенциальную опасность для человека (кроме лекарственных средств); отдельных видов продукции, в том числе пищевых продуктов, впервые ввозимых на таможенную территорию Таможенного союза».
58. Приказ Минсельхоза России от 9 июля 2015 г. № 294 «Об утверждении Административного регламента Министерства сельского хозяйства Российской Федерации по предоставлению государственной услуги по государственной регистрации пестицидов и (или) агрохимикатов» (в редакции от 17 мая 2016 г. № 187).
59. Приказ Роспотребнадзора от 1 августа 2006 г. № 225 «О санитарно-эпидемиологической экспертизе пестицидов и агрохимикатов».

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60. *Федеральный закон от 19.07.1997 г. № 109-ФЗ «О безопасном обращении с пестицидами и агрохимикатами».*
61. *Официальный сайт Министерства сельского хозяйства Российской Федерации. – URL: <http://mcx.ru/>.*
62. *Официальный сайт ОАО «ФосАгро». Новости компании – URL: <https://www.phosagro.ru/press/company/item4343.php>.*
63. *Официальный сайт Федеральной службы по аккредитации (Росаккредитация) – URL: <http://fsa.gov.ru/index/staticview/id/294/>.*
64. *Федеральный закон от 31.12.2014 № 488-ФЗ (ред. от 29.12.2015) «О промышленной политике в Российской Федерации» (в ред. федеральных законов от 13.07.2015 г. № 216-ФЗ; от 03.07.2016 г. № 365-ФЗ).*
65. *Федеральный закон от 28.12.2013 № 412-ФЗ «Об аккредитации в национальной системе аккредитации».*
66. *Распоряжение Правительства РФ от 4 сентября 2015 г. № 1735-Р.*
67. *Распоряжение Правительства РФ от 2 декабря 2015 г. № 2468-Р.*
68. *Федеральный закон «О защите населения и территорий от чрезвычайных ситуаций природного и техногенного характера» от 21 декабря 1994 № 68-ФЗ*

## **T h e R e p u b l i c o f S i n g a p o r e**

Composed by Russian Federation  
Reviewed by Singapore

### **I n t r o d u c t i o n**

Chemical industry is a very important part of industries in Singapore. As one of the world's leading energy and chemical industry hubs, Singapore's contribution to the industry is vast, both in terms of output and research, and the Republic is constantly working to stay at the forefront of the industry's advancement.

Although Singapore lacks natural resources, many surrounding countries in the region are rich in oils and other resources, which provide starting materials to Singapore's chemical industry. Since Singapore is small, all development projects are very closely related to government policies. In 1993, the government established an overall development plan for the chemical industry. This plan sets an objective that the chemical industry must grow in proportion to the rest of the manufacturing economy and should maintain a minimum of 21% in comparison to the total manufacturing output of the nation. Since 1993, the chemical industry has been quite successful. In 2010, the chemicals and chemical products sector contributed \$38 billion of the manufacturing output, a significant rise from \$28 billion in 2009.

Singapore's chemical industry (excluding petroleum & petrochemicals) contributed nearly 1% of Singapore's GDP in 2011. It contributed 29% to the Singapore manufacturing sector in 2015, a 5% dip as compared with 2014 [1].

The chemicals industry processes raw materials into chemical products. In Singapore, the sector is a diverse one and serves major industries such as construction, packaging, chemicals, automotive, electronics, food manufacturing, and pharmaceuticals.

### **1 . R e g u l a t e d   g o o d s**

By reason of the facts that Singapore is located at the crossing of the major trade flows in APEC region as well as in the whole world and it has become a status of an internationally recognized hub, where thousands of different kinds of goods are handled and distributed on the one side, the Singapore's efforts to enhance the manufacturing output of the chemicals based on the model of sustainable development domestically on the other side testify thousands of chemicals on different stages of life cycle within various aspects of human activities are circulated in Singapore. The ones of particular concern to Singapore are - hazardous chemicals [2], Chemical Weapon Convention (CWC) scheduled chemicals and unscheduled discrete organic chemicals (DOCs) [3], toxic chemicals, their precursors, psychotropic substances, controlled drugs [4], petroleum and flammable materials, which are regulated under our domestic legislations.

Chemicals are used extensively in the industry. Many useful products such as paints, plastics, adhesives, detergents and pharmaceuticals are derived from chemicals. However, it is important to exercise caution in the usage of chemicals. Some chemicals are inherently dangerous that need to be stored in special containers to avoid contact with air. Others may appear harmless but can cause injury almost immediately upon contact. For many toxic chemicals, the health effects may take a long period of time to develop.

For example, the following chemical products are produced in Singapore and are subject to regulation: petroleum, petrochemicals, specialty chemicals, food and beverage, pharmaceuticals, and healthcare and etc. The manufacturing output amounts of these chemical products used in every day live in different aspects of human activities and the hazards or risks posed to both human health and the environment from the manufacturing, storage, transport, and use of these chemicals justify the need to implement the proper chemicals management regulation.

### **2 . P a r t i c i p a n t s   o f   t h e   r e g u l a t o r y   s y s t e m**

## The Republic of Singapore

In Singapore, there are several chemical regulatory agencies in Singapore (National Environment Agency (NEA), the Health Sciences Authority (HSA), the Singapore Police Force (SPF), the Singapore Civil Defence Force (SCDF), Singapore Customs and Ministry of Manpower (MOM)). A coordinated Whole-of-Government (WOG) system is adopted for the control of chemicals and their safe management. An inter-agency department (Major Hazard Department) comprising officers from MOM, SCDF, NEA coordinate governmental efforts to regulate major hazard installations comprising mainly the chemical and oil/petrochemical industries. Chemical and oil/petrochemical installations have hazardous chemicals that meet or exceed the prescribed quantities would be subjected to a safety case regime. There is also strong collaboration with chemical industry to develop standards and share good practice on the management of chemicals in Singapore e.g. National Chemical Management and with the Globally Harmonised System (GHS) task force.

The NEA licenses the import, storage, usage and disposal of prescribed hazardous substances that can pose environmental health problems. The SCDF controls the import, transport by road, storage and conveyance by pipelines of petroleum and flammable substances. The SPF regulates explosives and their precursors for security reasons. Singapore Customs regulates the production, import/export, processing, consumption, storage and the local transfer of certain CWC scheduled chemicals and unscheduled DOCs.

Safeguarding persons against hazardous chemicals at workplace falls under the purview of the MOM. Under the Workplace Safety and Health (General Provisions) Regulations, all hazardous substances used in a workplace are required to be placed under the control of a competent person who has adequate knowledge of the properties of the substances and its dangers.

The primary bodies involved in the chemicals regulation are the governmental bodies, public institutions, statutory boards, professional bodies and trade associations. The Government of Singapore (<http://www.gov.sg/>) promulgates Acts and Regulations concerning the proper use of chemicals. The promulgated chemicals management acts and regulations are implemented by the Ministries according to their scopes of jurisdiction and mandates. A list of web pages of the bodies involved in chemicals management regulation is outlined below:

1. *Ministry of Manpower (MOM):* <http://www.mom.gov.sg/Legislation/Pages/default.aspx>;
2. *National Environment Agency (NEA):* <http://app2.nea.gov.sg/Legislation.aspx>;
3. *Singapore Civil Defence Force (SCDF):* [http://www.scdf.gov.sg/scdf\\_internet/en/building-professionals/publications.html](http://www.scdf.gov.sg/scdf_internet/en/building-professionals/publications.html);
4. *Maritime and Port Authority of Singapore (MPA):* <https://www.mpa.gov.sg/web/portal/home/port-of-singapore/maritime-legislation-of-singapore>;
5. *Public Utilities Board (PUB):* <http://www.pub.gov.sg/general/Pages/PreventionofDamage.aspx>;
6. *Enterprise Singapore [5]:* <http://www.enterprisesg.gov.sg/quality-standards/standards>;
7. *Singapore Police Force (SPF):* <http://www.police.gov.sg/licence>;
8. *Ministry of Health (MOH):* <http://www.moh.gov.sg/mohcorp/legislations.aspx?id=214>;
9. *Civil Aviation Authority of Singapore (CAAS):* <https://www.caas.gov.sg/legislation-regulations/legislation>;
10. *Central Narcotics Bureau (CNB):* <http://www.cnb.gov.sg/drug-information/misuse-of-drugs-act> ;
11. *Singapore Customs (Customs):* <https://www.customs.gov.sg/about-us/acts-and-subsidary-legislation>;
12. *National Authority (Chemical Weapons Convention) (NACWC):* <https://www.customs.gov.sg/businesses/chemical-weapons-convention/introduction>;
13. *Ministry of Trade & Industry (MTI):* <http://app.mti.gov.sg/default.asp?id=565>;
14. *The key chemical Industry (the private sector) is the Singapore Chemical Industry Council Limited (SCIC):* <http://www.scic.sg/>.

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The SCIC consists of a Board of Directors and Committees on

- *Responsible Care®*;
- *Regulatory Affairs*;
- *Logistics & Distribution*;
- *Chemical Industry Manpower Advisory Committee (CHIMAC)*;
- *Process & Engineering Committee*;
- *Trade and Commerce*.

Many chemical companies in Singapore are members of the SCIC. The SCIC is represented on Government and is appointed as the Standards Development Organisation for the standards development and promotion work of the Chemical Standards Committee, including the Technical Committees and Working Groups.

15. *Singapore Business Federation (SBF): <http://www.sbf.org.sg/>.*

### 3 - 4 . I n f l u e n c e s : N a t i o n a l p r i o r i t i e s a n d I n t e r n a t i o n a l a c t i v i t i e s

The major acts of Singapore in the field of chemicals management were adopted within the strategic programs on chemicals safety developed by responsible Ministries according to their jurisdictions in order to protect human safety, health and environment and to implement the Singapore's commitments under the international conventions and protocols on reducing the negative impact of chemicals (the Basel Convention, the Hague Protocol, the Montreal Protocol, Rotterdam Convention (PIC) and the Chemical Weapons Convention. A few of them are outlined below in table 3.11.1.

**Table 3.11.1. – Major acts and regulations of Singapore in the field of chemicals management [6]**

Regulation, COP, Guideline, Standard	Authority/ Board/Body	Key Characteristics
Workplace Safety and Health Act 2006	MOM	The Act requires measures to be taken to ensure the workplace and any machinery, equipment, plant, article or substance kept in the workplace are safe and without risks to health to every person in the workplace. The manufacturer or supplier of hazardous substances stated in Fifth Schedule which are used at workplace will have to provide information on the safe use of the hazardous substances.
WSH(Risk Management) Regulations	MOM	The Regulations detail the steps required to manage the safety and health risks at workplace. Employers, principals and self-employed persons must conduct a risk assessment for all work (routine or non-routine) in the workplace, identify workplace safety and health hazards, take reasonably practicable measures to eliminate or reduce workplace safety and health risks, and establish safe work procedures if the risks cannot be eliminated.
WSH(Major Hazard Installations)	MOM	The Regulations require any workplace that engages in high-risk activities such as processing or manufacture of petroleum products, petrochemicals or petrochemical products to be registered as a Major Hazard Installation

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Regulation, COP, Guideline, Standard	Authority/ Board/Body	Key Characteristics
		(MHI) and be subjected to periodic renewal. The Regulations require MHIs to prepare and maintain Safety Cases, report process-related incidents and share pertinent information to better address domino effects.
WSH(General Provisions) Regulations	MOM	The Regulations protect workers from chemical hazard and it includes technical provisions relating to toxic airborne contaminants, permissible exposure levels (PEL) of toxic substances, hazardous substances, warning labels, safety data sheet, and safety and health management system.
WSH (Approved Codes of practice) Notification 2016	MOM	<p>In accordance with section 40B(3) of the Workplace Safety and Health Act, the gazetted Approved Codes of Practice by the Workplace Safety and Health Council related to chemicals.</p> <ol style="list-style-type: none"> <li>1. Code of Practice on WSH Risk Management</li> <li>2. SS 506: Occupational safety and health (OSH) management system Part 3: Requirements for the chemical industry 2013</li> <li>3. SS532: Code of Practice for the storage of flammable liquids Incorporating Corrigendum No. 1 2016</li> <li>4. SS 586: Specification for hazard communication for hazardous chemicals and dangerous goods- Part 1: Transport and storage of dangerous goods 2014</li> <li>5. SS 586: Specification for hazard communication for hazardous chemicals and dangerous goods - Part 2: Globally Harmonised system of classification and labelling of chemicals – Singapore’s adaptations</li> <li>6. SS 586: Specification for hazard communication for hazardous chemicals and dangerous goods - Part 3: Preparation of Safety Data Sheets (SDS)</li> </ol>
Guidelines	MOM, WSH Council	<p>Guidelines published by MOM and Workplace Safety and Health Council related to chemicals:</p> <ul style="list-style-type: none"> <li>• WSH Guidelines on Management of Hazardous Chemicals Programme</li> <li>• WSH Guidelines on Flammable Materials</li> <li>• WSH Guidelines on Laboratories Handling Chemicals</li> <li>• Safety Case Technical Guide</li> <li>• Safety Case Assessment Guide</li> </ul>
Environmental Protection And Management Act (Chapter 94A) 2002 Revised Edition.	NEA	<p>This is the main Act for pollution control. This Act consists of 14 parts and 3 Schedules.</p> <p>Part I: Interprets the terms used in the act.</p> <p>Part II: Administration</p> <p>Part III: Specifies what are scheduled premises and list out the conditions to the licence.</p> <p>Part IV: Specifies the Air Pollution Controls requirements.</p> <p>Part V: Specifies the Water Pollution Controls requirements.</p> <p>Part VI: Specifies the Land Pollution Controls</p>

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Regulation, COP, Guideline, Standard	Authority/ Board/Body	Key Characteristics
		<p>requirements.            Part VII: Specifies the Hazardous Substances Controls requirements.            Part VIII: Specifies the Noise Controls requirements.            Part IX: Specifies the conditions for Licences and Industrial Plant Works.            Part X: Environmental Pollution Control Measures.            Part XI: Enforcements.            Part XII: Compensation, Damages, Fees, Costs and Expenses.            Part XIII: Miscellaneous Provisions.            First Schedule: Defines Scheduled Premises.            Second Schedule: List of Hazardous Substances and exemptions.            Third Schedule: Subject Matters of Regulations.</p>
<p>Environmental Protection and Management (Hazardous Substances) Regulations 2008 Revised Edition  EPM(HS) Regulations</p>	<p>NEA</p>	<p>These Regulations establish requirements for the transport and consignment for transport of any hazardous substance in an amount exceeding the specified quantities. Requirements include emergency planning, employee training, agency approval, documentation, release notification, operating procedures and import standards.            Controls over drivers, routes, panels, labels and documentation.            List of hazardous substances are on the internet. Proper records must be kept.</p>
<p>Hazardous Waste (Control of Export, Import and Transit) Regulations Chapter 122A 2000 Revised Edition (Last amended on Jan 2000)</p>	<p>NEA</p>	<p>This Act sets forth the requirements for controlling the movement of hazardous and other wastes in, through and out of Singapore. Licenced operators required for disposal outside Singapore. Implements the Basel Convention in Singapore.</p>
<p>Air Navigation Act Act (Chapter 6) 2014 Revised Edition</p>	<p>CAAS</p>	<p>These regulations implement the Standards in Annex 18 to the Convention on International Civil Aviation on the safe transport of dangerous goods by air.</p>
<p>Chemical Weapons (Prohibition) Act (Chapter 37B) 2001 Revised Edition (Last amended in 2012)</p>	<p>Singapore Customs</p>	<p>An Act to give effect to the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction concluded at Paris on 13th January 1993.</p>
<p>Fire Safety Act (Chapter 109A) and Fire Safety (Petroleum</p>	<p>SCDF</p>	<p>These Act and Regulations contains the requirements for controlling the import, storage, transport by road, conveyance by pipelines of petroleum and flammable</p>

Regulation, COP, Guideline, Standard	Authority/ Board/Body	Key Characteristics
and Flammable Materials) Regulations		materials in Singapore.

## 5. Parameters of regulation

*Information from the open sources is not available.*

## 6. Key procedures for control of the regulated objects

Chemical industry in Singapore has grown to a world-class chemical hub with good connectivity to end markets and for investors. Chemicals are a vital part of our daily life; they provide society with a wide range of benefits, increase productivity and improve the control of disease. On the other hand, chemicals have the potential to cause considerable health, safety and environmental problems throughout their life cycle, from production through to disposal. To ensure that chemicals are managed safely to protect the environment and human health and safety, Chemicals are managed in Singapore by a variety of processes:

- - Regulation (Acts, Regulations, referenced standards or codes and administrative processes);
- - Coregulation (When regulations are required for a segment of industry);
- - Administrative and licensing controls (Where the government agencies are able to set requirements for industry that is not specifically imposed in the regulations);
- - Voluntary Agreements (An agreement negotiated or entered into forth by a government or other public institution that does not have a regulation on its basis).

As it was mentioned above in Singapore, the more hazardous chemicals are regulated or licensed by relevant authorities. For example, the NEA has licensing control over hazardous substances that are controlled under the Environmental Protection and Management Act (EPMA) and EPM (Hazardous Substances) Regulations, the Singapore Civil Defence Force (SCDF) regulates petroleum and flammable materials, the Singapore Police Force regulates the explosive precursors while Singapore Customs regulates CWC scheduled chemicals and unscheduled DOCs. The Ministry of Manpower (MOM) administers the WSH Act and its subsidiary legislation relating to the safety, health and welfare of the general workforce.

According to this the following legal acts are building up the Regulatory framework of Singapore in the field of chemicals management:

- WSH Act;
- WSH (General Provisions) Regulations;
- WSH(Major Hazard Installations) Regulations;
- Fire Safety Act;
- Environmental Protection & Management Act;
- Environmental Protection & Management (Hazardous Substances) Regulations.

### *Hazardous substances controlled by the NEA*

#### Requirements on Hazardous Substances

- A licence is required to manufacture, import, sell or export any hazardous substance controlled under the EPMA and EPM (HS) Regulations.

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- *A permit is required to purchase, store or use any hazardous substance controlled under the EPM (HS) Regulations.*
- *A licence is required to transport any hazardous substance in quantities exceeding those specified in the EPM (HS) Regulations before applying for transport approval.*
- *Containers, tankers and vehicles must be properly labelled and carry appropriate hazard warning panels.*

There is a list of controlled hazardous substances available on <http://www.nea.gov.sg/docs/default-source/anti-pollution-radiation-protection/chemical-pollution/hazardous-substances/hs--table-1>.

### Restriction of hazardous substances

The content of 6 Hazardous Substances (HS) in 6 types of Electrical and Electronic Equipment (EEE) is restricted in Singapore. See table 3.11.2.

**Table 3.11.2. - Restriction of Hazardous Substances (RoHS) in Electrical and Electronic Equipment (EEE)**

6 Restricted Hazardous Substances (HS)	Allowable Concentration Limits	Controlled EEE
Lead (Pb)	Maximum 1,000ppm (0.1% by weight)	Currently, the types of EEE identified for control are: mobile phones; portable computers; refrigerators; air conditioners; panel TVs and washing machines
Mercury (Hg)		
Hexavalent Chromium (Cr VI)		
Polybrominated Biphenyls (PBBs)		
Polybrominated Diphenyl Ethers (PBDEs)		
Cadmium (Cd)	Maximum 100ppm (0.01% by weight)	

These controls are implemented at the import stage. Controlled EEE which exceed the allowable concentration limits for the 6 HS, are not allowed to be imported for local use and distribution after 1 June 2017. However, existing stocks of the controlled EEE imported prior to 1 June 2017, will be allowed for sale until these stocks are depleted.

### Control of Asbestos in Singapore

Since late 1980s, the use of asbestos materials in buildings and the import of raw asbestos have been prohibited by Singapore.

However, old buildings may have asbestos-containing materials such as corrugated roofs, ceiling boards and partition walls. Asbestos in the form of crocidolite, actinolite, anthophyllite, amosite, tremolite and chrysotile, as well as products containing these forms of asbestos are controlled as hazardous substances (HS) under NEA's EPMA. The import, export and/or sale of asbestos or asbestos products are controlled and they are not allowed to be imported into Singapore for local use.

Asbestos is controlled under the Rotterdam Convention and export of asbestos requires Prior Informed Consent (PIC) from the importing country.

Under the Workplace Safety and Health (Asbestos) Regulations which are administered by the MOM, asbestos-removal work can only be carried out by Approved Asbestos-Removal Contractor (AARC). AARC, who undertakes asbestos-removal work must notify the Commissioner for Workplace Safety and Health at least 7 days prior to the commencement of such work. Employers including contractors must conduct risk assessments and take measures to safeguard the health and safety of their workers as required under the Workplace Safety and Health (Risk Management) Regulations. The disposal of asbestos waste shall only be carried out by NEA approved asbestos disposal contractors.

*Use of Hazardous chemicals in Workplaces controlled by the Ministry of Manpower (MOM)*

The list of hazardous chemicals covered under the WSH Act are stated in the 5th Schedule of the Act. Under the WSH (General Provisions) Regulations, these substances should be kept, stored, used, handled or disposed properly so that it will not pose a risk to the health and safety of any person at work. The law also requires hazard communication through the use of warning signs, container labelling and safety data sheets [7].

Practicable measures are mandatory to control toxic airborne contaminants and there are specific permissible exposure limits (PEL) for over 600 toxic substances listed in the First Schedule of the WSH(General Provisions) Regulations. Regular workplace monitoring is required to ensure that workers are not exposed to toxic substances above the PEL. Pre-employment and periodic medical examinations are necessary if workers are exposed to 17 prescribed toxic substances under the Workplace Safety and Health (Medical Examinations) Regulations.

*Fire Safety Act –under Singapore Civil Defence Force (SCDF) [8]  
Fire Safety (Petroleum & Flammable Materials) Regulations*

- *A licence is required to import, transport by road, store, and convey through pipelines in public areas petroleum and flammable materials above the exemption quantity.*
- *Petroleum (flash point below 60oC), diesel and 366 flammable materials & their mixtures are subjected to licensing control.*
- *Vehicle transporting and premises storing regulated petroleum and flammable materials must be labelled in accordance with SS 586 for hazard communication*
- *SS 586 requires individual container (e.g. drum, package) for transportation and storage of hazardous chemicals be labeled in accordance with GHS; vehicle transporting and premises storing hazardous chemicals be provided with Emergency Information Panel.*

**7. Non-regulatory mechanisms**

Self-regulation exists when there is a strong organisation or a professional organisation with powers to administer the activities of the organisation and to discipline members of the organisation. The organisation may be given powers by the Government to administer aspects of the organisation. Another form of self-regulation is where the members of an organisation voluntarily agree to comply with the organisation's standards. Failure to perform to the association's standards in either case will result in disciplinary action.

*Voluntary initiatives*

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Some Governments are increasingly seeking voluntary agreements to accomplish public policy objectives or to regulate industry behavior. These voluntary agreements take many different forms. Whilst they have potential benefits, they also have potential adverse consequences. These proposals are often accompanied by an implicit or explicit statement from government that unless compliance is achieved "voluntarily" then the objective will be mandated by enacting a new law or regulation. Governments sometimes seek these agreements in order to compress a lengthy regulatory process or to address issues where legislation is not deemed politically viable. In other cases, companies or industry associations have proposed voluntary agreements to try to address issues in a negotiated fashion.

Voluntary initiatives are adopted by industry either on its own initiative or driven by customers. The initiatives usually adopt standards that are national or international. These standards do not require regulatory compliance although conformance to criteria in the standards may be required for continuing certification. Voluntary initiatives are implemented when an organisation believes that adopting a standard or a code of practice that will provide them with a level of performance above the minimum level of performance that will provide them with a competitive advantage.

### *Responsible Care*

Responsible Care is the chemical industry's global voluntary initiative under which companies, through their national associations, work together to continuously improve their health, safety and environmental performance, and to communicate with stakeholders about their products and processes.

In some countries industry association has requirements for company to be a signatory to RC as a condition of membership. In these countries RC is a self-regulating system. This is not the case in Singapore. RC is a voluntary initiative.

The SCIC is the industry association recognized by the Singapore Government Agencies and International Chemical Industry National Organisations as the single voice representing the Chemical Industry in Singapore. As a member of the International Council of Chemical Associations (ICCA), SCIC adopted Responsible Care in 1990, and launched the Responsible Care Awards in 2001. The Awards aim to recognise the efforts of companies who have committed to practice and implement at least 1 out of the 6 Responsible Care Codes of Management Practices. These Codes of Management Practices are:

- *Community Awareness & Emergency Response;*
- *Distribution;*
- *Employee Health & Safety;*
- *Pollution Prevention;*
- *Process Safety;*
- *Product Stewardship.*

### *The Singapore Green Labelling Scheme (SGLS)*

The Singapore Green Labelling Scheme (SGLS) was launched in May 1992 by the Ministry of the Environment to endorse industrial and consumer products that are more environmentally friendly. The SGLS is now administered by the Singapore Environmental Council (SEC). The scheme applies to most products, except food, drinks and pharmaceuticals. It does not apply to services and processes.

See the list of voluntary initiatives connected with chemicals management in the table 3.11.3.

**Table 3.11.3. - The list of voluntary initiatives connected with chemicals management**

<b>Regulation, COP, Guideline, Standard</b>	<b>Authority/ Board/Body</b>	<b>Key Characteristics</b>
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Regulation, COP, Guideline, Standard	Authority/ Board/Body	Key Characteristics
Responsible Care	SCIC	Responsible Care is the chemical industry's global voluntary initiative under which companies, through their national associations, work together to continuously improve their health, safety and environmental performance, and to communicate with stakeholders about their products and processes.
The Singapore Green Labelling Scheme (SGLS)	SEC	The scheme applies to most products, except food, drinks and pharmaceuticals. It does not apply to services and processes.
ICCA-HPV program ICCA-LRI program	SCIC	ICCA-HPV program [9] - a global initiative on High Production Volume (HPV) chemicals ICCA-LRI program[10] Long-Range Research Initiative focused on improving our understanding of potential health and environmental risks and catalyzing advanced approaches for the scientific assessment of the safety of chemicals. (both on the basis of OHSAS 18000, ISO 14000)

## 8. Availability of data

Some orders, codes of practice and administrative processes are available on Ministry and Statutory Boards websites [11].

There are tools used in Singapore that Government organisations interact with to enable them to manage chemicals, such as the TradeNet, [http://www.tradenet.gov.sg/trdnet/index\\_home.jsp](http://www.tradenet.gov.sg/trdnet/index_home.jsp) administered by Customs. This is an electronic database of goods moving across Singapore's borders.

To determine if your product is controlled in Singapore and by what Competent Agency you may use the following search engine of the Singapore customs: <https://www.tradexchange.gov.sg/tradexchange/portlets/search/searchHSCA/searchInitHSCA.do>

The lists of hazardous chemicals for which the permit or licence must be obtained is outlined below. See table 3.11.4.

**Table 3.11.4. - Permit and Licensing**

Permit/ license	Agency	Form (s)
Hazardous Substance (HS) Permit	<a href="#">NEA</a>	- <a href="#">List of controlled hazardous substances</a> - <a href="#">List of hazardous substances</a>
Explosive precursor (EP) license	<a href="#">SPF</a>	- <a href="#">List of Explosive Precursors</a>
Chemical Weapon Convention (CWC) license	<a href="#">Singapore Customs</a>	- <a href="#">Controlled chemicals under CWC</a> - <a href="#">Licensing Requirements</a>

		<a href="#">- Application for licence</a>
Petroleum and Flammable (P&FM) license	<a href="#">SCDF</a>	Petroleum (flash point below 60°C), diesel, flammable materials and their mixtures List of flammable materials under Fourth Schedule of Fire Safety (Petroleum & Flammable Materials) Regulations
Ionising Radiation (IR) licence	<a href="#">NEA</a>	<ul style="list-style-type: none"> <li>- <a href="#">L1 - Application for a licence to manufacture, possess for sale or deal in irradiating apparatus</a></li> <li>- <a href="#">L2 - Application for a licence to manufacture, possess for sale or deal in radioactive materials</a></li> <li>- <a href="#">L3 - Application for a licence to keep or possess an irradiating apparatus for use other than sale</a></li> <li>- <a href="#">L4 - Application for a licence to keep or possess radioactive materials for use other than sale</a></li> <li>- <a href="#">L5 - Application for a licence to use irradiating apparatus (other than sale)</a></li> <li>- <a href="#">L6 - Application for a licence to use, handle and transport radioactive materials (other than sale)</a></li> <li>- <a href="#">L7 - Application for a licence to import or export a consignment of irradiating apparatus</a></li> <li>- <a href="#">L8 - Application for a licence to import or export a consignment of radioactive materials</a></li> <li>- <a href="#">R1 - Registration as a radiation worker</a></li> </ul>

## 9. Laboratory infrastructure

### *Good Laboratory Practice (GLP) Program*

Singapore is the first Asian non-OECD member state to be accepted into the Organisation for Economic Co-operation and Development (OECD) Mutual Acceptance of Data framework. With this OECD-MAD status, data generated by local testing facilities that comply with the OECD Principles of Good Laboratory Practice (GLP) will be simultaneously accepted by over 30 OECD and non-OECD member states.

Enterprise Singapore ([www.enterprisesg.gov.sg](http://www.enterprisesg.gov.sg)) is the local GLP Monitoring Authority. It administers a series of GLP Compliance Programs and conducts periodical surveillance inspections to verify compliance status of certified facilities. A list of GLP certified facilities in Singapore might be found on Enterprise Singapore's website.

### *Singapore Accreditation Council*

The Singapore Accreditation Council (SAC) [12], managed by Enterprise Singapore, is Singapore's national accreditation body. It offers schemes to accredit various inspection and management system certification bodies as well as laboratories conducting tests, calibrations and measurements. Bodies offering certification services may also be accredited by SAC so as to gain

recognition for their competency in internationally recognized standards. SAC is also a signatory of a number of multi-lateral Mutual Recognition Arrangement (MRAs) which promotes cross-border recognition of accredited bodies. A list of the various signed MRAs may be found on the SAC's website. See picture 3.11.1.

**Picture 3.11.1. – SAC Certificates which are recognized abroad**



## 10. Information sharing

### 10.1 The implementation of GHS in Singapore

Singapore has adopted the GHS in workplace since 2008. Under the Work Safety and Health (General Provisions) Regulations 2011 administered by MOM, the seller or agent of the seller of hazardous substances must provide Safety Data Sheet (SDS) in accordance with Singapore Standard relating to Safety Data Sheet ie. SS586 Part 3, and any occupier of a workplace must label the containers of hazardous substances in accordance with Singapore Standard relating to classification and labelling of chemicals, ie. SS 586 Part 2.

GHS Laws & Regulations in Singapore (See table 3.11.5.)

- *Workplace Safety and Health (General Provisions) Regulations Part IV Special Provisions relating to Health, Safety and Welfare;*
- *SS 586:2014 Specification for hazard communication for hazardous chemicals and dangerous goods, which consists of the following three parts:*
- *Part 1 : Transport and storage of dangerous goods,*
- *Part 2 : GHS of classification and labelling of chemicals - Singapore's adaptations, and*
- *Part 3 : Preparation of SDS.*

**Table 3.11.5. – The list of GHS Laws, Regulations and related Standards in Singapore**

<b>Regulation, COP, Guideline, Standard</b>	<b>Authority/ Board/Body</b>	<b>Key Characteristics</b>
SS 532 : 2016 Code of practice for the storage of flammable liquids	Enterprise Singapore	<p>Sets out requirements and recommendations for the safe storage and handling of flammable liquids, as classified in the chapter on the flammable liquids in the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS) listed in the Chapter of Flammable Liquids. Cover flammable liquids of Category 1, 2, 3 and 4 as classified in GHS. Also covers liquids of flash point up to 150<sup>0</sup>C.</p> <p>The standard does not apply to the following:</p> <ul style="list-style-type: none"> <li>a) Shipboard installations;</li> <li>b) Any storage that is mobile (fuel tanks and tankers, ISO tanks and tankers), except as defined for transit storage purpose;</li> <li>c) Any plant or equipment in which liquid is processed, together with any vessels which form an integral part of the processing plant or equipment;</li> <li>d) Bitumen and its mixtures prepared for road making;</li> <li>e) Flammable liquids stored in a tank exceeding 175 millibar above atmospheric pressure;</li> <li>f) Liquefied gases that are maintained in the liquid phase for storage by means of pressure or refrigeration;</li> <li>g) Laboratories; and</li> <li>h) Petrol service stations</li> </ul>
SS 586 - 2 : 2014 Specification for hazard communication for hazardous chemicals and dangerous goods – Part 2 : Globally harmonised system of classification and labelling of chemicals - Singapore's adaptations	Enterprise Singapore	<p>Provides guidance on the implementation of the United Nation Globally Harmonised System (GHS) of Classification and Labelling of Chemicals in Singapore. It provides standard hazard communication elements including labels and safety data sheets.</p> <p>The GHS helps to ensure that information on physical, health and environmental hazards from chemical is made available, in order to enhance the protection of human health and the environment during the handling, transport and use of these chemicals. The GHS provides for the global harmonisation of rules and regulations on the classification and labelling of chemicals as well as hazard communication about chemicals.</p>
Guidelines On Quantitative Risk Assessments (QRA) (Last amended on Apr 2010)	NEA	<p>These Guidelines assist facilities in conducting an evaluation to identify causes of possible accidents to determine the likelihood of the occurrence and potential consequences of accidents involving the storage, transport or use of hazardous substances. Typical QRA</p>

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		assessment outlined. Consultants with expertise in conducting QRAs listed
SS 586 - 3 : 2008 (2014) Specification for hazard communication for hazardous chemicals and dangerous goods - Preparation of safety data sheets (SDS)	Enterprise Singapore	Gives recommendations for the preparation, review, issue and use of SDS. Covers the responsibility of the suppliers and manufacturers of chemical substances, as well as that of the users (employers and employees) to make use of the information in the SDS to prevent unnecessary exposure of person or an animal. It does not cover pharmaceutical substances and preparations during its intended use, but the industrial production of the substances are covered.
SS 586 - 1 : 2014 Specification for hazard communication for hazardous chemicals and dangerous goods – Part 1 : Transport and storage of dangerous goods	Enterprise Singapore	Adopts the United Nations Recommendations on the Transport of Dangerous Goods, which provides an international system for the classification of dangerous goods by the types of hazards that they present. Also provides standard hazard communication labels. Applies to the transportation and storage of dangerous goods by road in Singapore.
SS 508 - 1 : 2013 Graphical symbols - Safety colours and safety signs - Design principles for safety signs and safety markings	Enterprise Singapore	Applies to workplaces and all locations and all sectors where safety-related questions may be posed. Does not apply to the signalling used for guiding rail, road, river, maritime and air traffic. Establishes the safety identification colours and design principles for safety signs to be used in workplaces and in public areas for the purpose of accident prevention, fire protection, health hazard information and emergency evacuation. Also establishes the basic principles to be applied when developing standards containing safety signs.
SS 508 - 2 : 2013 Specification for graphical symbols - Safety colours and safety signs - Design principles for product safety labels	Enterprise Singapore	Establishes additional principles to SS 508-1 - "Design principles for safety signs in workplaces and public areas" for the design of safety labels for products, i.e. any items manufactured and offered for sale in the normal course of commerce, including but not limited to consumer products and industrial equipment. The purpose of product safety label is to alert persons to a specific hazard and to identify how the hazard can be avoided.
SS 508 - 3 : 2013 Graphical symbols - Safety colours and safety signs - Design principles for graphical symbols for use in safety signs	Enterprise Singapore	Provides the principles, criteria and guidance for the design of graphical symbols for use in safety signs as defined in SS 508-1, and for the safety sign element of product safety labels as defined in SS 508-2.
SS 508 - 4 : 2013 Graphical symbols -	Enterprise Singapore	Gives principles, criteria and guidance for the design of graphical symbols

Safety colours and safety signs - Colorimetric and photometric properties of safety sign materials		for use in safety signs as defined in SS 508-1 and the safety sign element of product safety labels as defined in SS 508-2.
SS 508 - 5 : 2013 Graphical symbols – Safety colours and safety signs – Registered safety signs	Enterprise Singapore	Covers the safety signs for the purposes of accident prevention, fire protection, health hazard information and emergency evacuation. The shape and colour of each safety sign are according to SS 508-1 and the design of the graphical symbols is according to SS 508-3.

### Safety Data Sheet

Safety data sheets (SDS) are the main communication tool between the chemical suppliers and the end users. The SDS of all hazardous chemicals listed in the register should be obtained from the respective suppliers and compiled. The SDS should contain the following key information:

- *identity of the substance;*
- *safety and health information pertaining to the substance;*
- *composition of and ingredients used in the substance;*
- *first aid measures;*
- *fire-fighting measures;*
- *accidental release measures;*
- *precautions to be taken for safe handling;*
- *exposure controls and personal protection needed;*
- *physical and chemical properties;*
- *Request for chemical*
- *Material control*
- *Check SDS on information of chemicals*
- *Select chemical based on criteria/GHS hazard category*
- *Consider (a) Restriction (b) Ban (c) No restriction*
- *stability and reactivity of the substance;*
- *toxicological information;*
- *ecological information;*
- *disposal considerations;*
- *transport information; and*
- *regulatory information.*

Management should study the information in the SDS and take necessary measures to ensure the safe use of the hazardous chemicals. The SDS should be available to persons who are exposed or liable to exposure of hazardous chemicals. Copies of SDS should also be located near the work station and kept in the office.

Each hazardous chemical used should have SDS containing the information described in table 3.11.6.

Chemical manufacturers or suppliers should prepare or provide SDS for all hazardous chemicals they produce or supply. They should ensure that the information contained in the SDS is adequate, accurate, up-to-date and made available to consumers along the supply chain.

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Chemical suppliers should provide workplace occupiers and employers with SDS at the first time when the hazardous chemical is supplied to the factories and on request.

Workplace occupiers and employers should obtain an SDS for each hazardous chemical used. They should assess all relevant information provided on the SDS and take necessary measures to ensure safe use of chemicals in the workplace.

Workplace occupiers and employers should not purchase any proprietary chemicals which are sold under a commercial name without a SDS.

Workplace occupiers and employers should not accept incomplete SDS, but instead, they should request for full information from the suppliers. If necessary, they should approach other suppliers who are able to provide the chemicals with complete SDS information.

Workplace occupiers and employers should maintain a collection of the SDS of all hazardous chemicals used in the factories. They should not withhold any information or alter the SDS, unless an SDS is labelled in a foreign language which needs to be translated to English or other languages understood by the workers.

Workplace occupiers and employers should ensure that SDS is easily accessible to persons who are exposed or likely to be exposed to hazardous chemicals.

Persons who handle any hazardous chemicals, or may be exposed to or affected by these chemicals should be informed of the hazards and procedures for safe handling, usage, storage, transport and disposal.

**Table 3.11.6. - A summary of safety data sheets key information**

<b>Minimum information for an SDS</b>	
<b>1. Identification</b>	<ul style="list-style-type: none"> <li>- Product identifier;</li> <li>- Other means of identification;</li> <li>- Recommended use of the chemical and restrictions on use;</li> <li>- Supplier's details (including name, address, phone number etc);</li> <li>- Emergency phone number</li> </ul>
<b>2. Hazards identification</b>	<ul style="list-style-type: none"> <li>- GHS classification of the substance/ mixture and any national or regional information;</li> <li>- GHS label elements, including precautionary statements (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol e.g., flame, skull and crossbones);</li> <li>- Other hazards which do not result in classification (e.g., dust explosion hazard) or are not covered by the GHS</li> </ul>
<b>3. Composition/ information on ingredients</b>	<p>Substance</p> <ul style="list-style-type: none"> <li>- - Chemical identity;</li> <li>- - Common name, synonyms, etc;</li> <li>- - CAS number, EC number, etc;</li> <li>- - Impurities and stabilising additives which are themselves classified and which contribute to the classification of the substance</li> </ul> <p>Business Information in SS 586 Part 3 Mixture</p> <ul style="list-style-type: none"> <li>- - Chemical identity</li> <li>- - Concentration or concentration ranges of all</li> </ul>

	<p>ingredients which are hazardous within the meaning of the GHS and are present above their cut-off values</p> <p>NOTE - For information on ingredients, please refer to the rules on Confidential</p>
<b>4. First aid measures</b>	<ul style="list-style-type: none"> <li>- Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion;</li> <li>- Most important symptoms/ effects, acute and delayed;</li> <li>- Indication of immediate medical attention and special treatment needed, if necessary</li> </ul>
<b>5. Fire-fighting measures</b>	<ul style="list-style-type: none"> <li>- Suitable (and unsuitable) extinguishing media;</li> <li>- Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products);</li> <li>- Special protective actions for fire fighters</li> </ul>
<b>6. Accidental release measures</b>	<ul style="list-style-type: none"> <li>- Personal precautions, protective equipment and emergency procedures;</li> <li>- Environmental precautions;</li> <li>- Methods and materials for containment and cleaning up</li> </ul>
<b>7. Handling and storage</b>	<ul style="list-style-type: none"> <li>- Precautions for safe handling;</li> <li>- Conditions for safe storage, including any incompatibilities</li> </ul>
<b>8. Exposure controls/ personal protection</b>	<ul style="list-style-type: none"> <li>- Control parameters e.g., occupational exposure limit values or biological limit values;</li> <li>- Appropriate engineering controls;</li> <li>- Individual protection measures, such as personal protective equipment</li> </ul>
<b>9. Physical and chemical properties</b>	<ul style="list-style-type: none"> <li>- Appearance (physical state, colour, etc);</li> <li>- Odour;</li> <li>- Odour threshold;</li> <li>- pH;</li> <li>- Melting point/ freezing point;</li> <li>- Initial boiling point and boiling range;</li> <li>- Flash point;</li> <li>- Evaporation rate;</li> <li>- Flammability (solid, gas);</li> <li>- Upper/ lower flammability or explosive limits;</li> <li>- Vapour pressure;</li> <li>- Vapour density;</li> <li>- Relative density;</li> <li>- Solubility;</li> <li>- Partition coefficient: n-octanol/ water;</li> <li>- Auto-ignition temperature;</li> <li>- Decomposition temperature;</li> <li>- Viscosity</li> </ul>
<b>10. Stability and reactivity</b>	<ul style="list-style-type: none"> <li>- Chemical stability;</li> <li>- Possibility of hazardous reactions;</li> <li>- Conditions to avoid (e.g., static discharge, shock or vibration);</li> <li>- Incompatible materials;</li> <li>- Hazardous decomposition products</li> </ul>
<b>11. Toxicological</b>	<p>Concise but complete and comprehensible description of the</p>

<b>information</b>	various toxicological (health) effects and the available data used to identify those effects, include: <ul style="list-style-type: none"> <li>- Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);</li> <li>- Symptoms related to the physical, chemical and toxicological characteristics;</li> <li>- Delayed and immediate effects and also chronic effects from short- and long-term exposure;</li> <li>- Numerical measures of toxicity (such as acute toxicity estimates)</li> </ul>
<b>12. Ecological information</b>	<ul style="list-style-type: none"> <li>- Toxicity (aquatic and terrestrial, where available);</li> <li>- Persistence and degradability;</li> <li>- Bioaccumulative potential;</li> <li>- Mobility in soil;</li> <li>- Other adverse effects</li> </ul>
<b>13. Disposal considerations</b>	Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging
<b>14. Transport information</b>	<ul style="list-style-type: none"> <li>- UN number;</li> <li>- UN proper shipping name;</li> <li>- Transport hazard class(es);</li> <li>- Packing group, if applicable;</li> <li>- Marine pollutant (Yes/ No);</li> <li>- Transport in bulk (according to Annex II of Marpol 73/78 and IBC code);</li> <li>- Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises</li> </ul>
<b>15. Regulatory information</b>	Safety, health and environmental regulations specific for the product in question
<b>16. Other information including information on preparation and revision of the SDS</b>	—

For more information on SDS, please refer to Singapore Standard SS 586 - 3 : 2008 (2014) Specification for Hazard Communication for Hazardous Chemicals and Dangerous Goods Preparation of Safety Data Sheets (SDS).

### Transportation of Dangerous Goods (TDG)

An accident during the transport of hazardous chemicals can have catastrophic consequences such as fire, explosion and toxic release to the environment and public spaces. Whenever hazardous chemicals are transported within or outside a company, precautionary measures should be taken to ensure that the potential risks are communicated to persons who will come into contact with the chemicals during transportation. This can be accomplished through marking and labelling of packages or containers to indicate the hazards of the consignment. The relevant information can be included in the transport documents, and by placing or sticking placards on the transport units i.e., vehicles and containers. These labels should conform to the Singapore Standard SS 586 – 1 : 2014 Specification for Hazard Communication for Hazardous Chemicals and Dangerous Goods - Part 1: Transport and Storage of Dangerous Goods.

In addition, the vehicles should be equipped with appropriate fire-fighting appliances and drivers should be trained in the safe transport of Dangerous Goods as well as be proficient in knowing how to manage emergency situations in a sound manner.

Loading, unloading and transfer operations are prone to accidents, and should be managed properly. Control measures should be implemented to reduce the risks. Safe work procedures should also be established and carried out in order to avoid unnecessary risks [13].

*Classes of Dangerous Goods*

Dangerous Goods can be explosive, flammable, toxic, radioactive, corrosive or harmful to humans, animals or the environment. Dangerous Goods are classified by the United Nations Model Regulations on the Transport of Dangerous Goods (UNRTDG) into 9 classes below.

**Table 3.11.7. - List of Classes of Dangerous Goods**

<b>Class</b>	<b>Dangerous Goods</b>
<b>1</b>	<b>Explosives</b>
<b>2</b>	<b>Gases</b> • Flammable gases • Non-flammable, non-toxic gases • Toxic gases
<b>3</b>	<b>Flammable Liquids</b>
<b>4</b>	<b>Flammable Solids</b> • Flammable solids • Substances liable to spontaneous combustion • Substances which in contact with water, emit flammable gases
<b>5</b>	<b>Oxidising Substances; Organic Peroxides</b> • Oxidising substances • Organic peroxides
<b>6</b>	<b>Toxic (Poisonous) Substances</b> • Toxic substances • Infectious substances
<b>7</b>	<b>Radioactive Materials</b>
<b>8</b>	<b>Corrosive Substances</b>
<b>9</b>	<b>Miscellaneous Dangerous Substances</b>

For packing purposes, Dangerous Goods are divided into three groups based on the degree or severity of the danger they present:

- - *Packing Group I – Higher danger;*
- - *Packing Group II – Medium danger;*
- - *Packing Group III – Lower danger.*

*Dangerous Situations*

An accident occurring during transport of Dangerous Goods can cause extensive damage and have serious consequences. A risk of an accident is present when:

- - *load shifts during transport;*
- *package or container of Dangerous Goods runs loose because it is not properly secured;*
- *vehicles carrying Dangerous Goods are left to stand unattended; and*
- *spillage is not promptly or properly cleaned.*

There is always a risk of spillage during transportation and handling of Dangerous Goods.

Spillage can happen in the following situations:

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- *when there is a vehicle or road accident;*
- *goods are not packed properly;*
- *defective valves that cannot be tightened completely;*
- *handling of goods e.g., during unloading, unloading and transfer operations without referring to the contents; and*
- *when the load or vehicle is burning.*

Common hazards in the handling of Dangerous Goods include:

- *burns from chemical fire;*
- *explosion due to flammable chemicals or explosives;*
- *exposure to toxic chemicals; and*
- *damage to the environment.*

Mixing of incompatible chemicals can produce heat to cause fire or explosion and can release dangerous gases.

### *Documentation for Transport*

A transport document should be prepared for the transportation of Dangerous Goods. The document should contain:

- *appropriate shipping name;*
- *class and assigned category as appropriate;*
- *UN number and the assigned packing group as appropriate;*
- *total quantity of Dangerous Goods (by mass, volume as appropriate); and*
- *name and address of the consignor and the consignee.*

If dangerous waste is transported for disposal, the proper shipping name should be preceded by the word “WASTE”.

In addition, a declaration or certificate indicating that the consignment is accepted for transportation, and the goods are packed, marked and labelled properly.

### *Vehicle Requirements*

Each vehicle carrying Dangerous Goods should be equipped with:

- *placards according to the transported goods;*
- *fire-fighting appliances suitable for the type of load;*
- *tool kit for emergency repairs of vehicle;*
- *at least one scotch (mechanical brake);*
- *two independent amber lights;*
- *protective equipment (PPE, absorbing material for spills, etc);*
- *vehicle transporting petroleum and flammable materials in excess of 3 metric tonnes have to be installed with orange color plate, tracking system, horns and blinkers, and immobiliser.*

### *Responsibilities*

The responsibilities of the consignor are to see that:

- *goods are correctly classified;*
- *limitations on transport of certain goods are observed;*
- *goods are properly marked and packed; and*
- *appropriate documents are attached to the goods.*

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The responsibilities of the transporter are to:

- *equip the vehicle with the necessary equipment;*
- *see that the drivers and workers are trained; and*
- *plan the transport:*
  - *routes to avoid dense population areas;*
  - *observe time restrictions on transportation; and*
  - *arrange supervision during parking.*

*The Driver is responsible for:*

- *having the proper licenses and training;*
- *having the Hazardous Material Transport Driver's Permit for transporting petroleum and flammable materials*
- *having the necessary transport/shipping document;*
- *checking the vehicle, tank, valves/ hoses, earthing strap touching the ground, and fire fighting equipment;*
- *accepting only marked/ labelled and undamaged packages and containers;*
- *adhering to speed limit, approved routes, hours of transport and allowable quantity to be transported; and*
- *following instructions given e.g., use of personal protective equipment as necessary.*

*Common Rules for Transportation*

- *Do not leave vehicle carrying Dangerous Goods unattended.*
- *Do not take passengers.*
- *Do not smoke inside the vehicle or during loading operation.*
- *Do not keep engines running when they are not needed for loading.*
- *Do not use open flames in areas where there are Dangerous Goods.*
- *Read the transport documents before loading – master the loading and know what to do in case of spill.*
- *Make sure the labels are placed on the vehicle and the Dangerous Goods.*
- *Separate Dangerous Goods from other goods that are transported in the same vehicle.*
- *Make sure the load cannot move during transport.*
- *Ensure that the necessary equipment for unloading and transport safety e.g., grounding cables and personal protective equipment are available.*
- *Do not accept damaged goods or leaking packages or containers for transport.*
- *Do not open packages or containers of Dangerous Goods.*

For more details on transport of Dangerous Goods, please refer to Singapore Standard SS 586:2008 Specification for Hazard Communication for Hazardous Chemicals and Dangerous Goods. Part 1: Transport and Storage of Dangerous Goods.

For more details on transport of petroleum and flammable materials, refer to SCDF website at [www.scdf.gov.sg](http://www.scdf.gov.sg).

### GHS Labelling

The objective of labelling is to enable users of chemicals to know the chemicals that they are handling, hazards involved and precautionary measures to take.

- *Suppliers of chemicals should ensure that all containers of toxic and hazardous chemicals that they supply are properly labelled.*

- *The label should indicate the chemical name, ingredients where appropriate, symbols (hazard pictograms), signal words (danger or warning), hazard statements (hazard or risk phrases), precautionary statements (precaution or safety phrases), and supplier identification. Please refer to the GHS Booklet developed by the National Chemical Management and GHS Taskforce found at this link ([www.wshc.sg/ghs](http://www.wshc.sg/ghs))*

### *10.2 Response on emergency situations involving chemicals, including poisoning*

A succession of environmental disasters has made the world aware of the dangers of poisonous and aggressive chemicals. When an incident occurs, rescue, containment and clean up operations must be quickly initiated. It is vital that those personnel who come into contact with dangerous and sometimes unidentifiable vapors and chemicals are competent to deal with the situation and are equipped with the proper tools.

Emergency planning is needed to respond to chemical accidents such as fires, explosions, spills, leaks or release of hazardous chemicals as well as release from pipelines and transport vehicles. Emergency procedures should be established so that the source of release can be promptly rectified, and the area of contamination can be contained and decontaminated properly. The procedures should also indicate how contaminated materials should be safely disposed of. Emergency drills should be conducted at suitable intervals to ensure that all employees are trained to take necessary actions during an emergency.

The national authorities responsible for regulating and controlling of the hazardous chemicals in Singapore (such as the National Environment Agency, the Singapore Civil Defence Force, Maritime and Port Authority of Singapore, Ministry of Manpower, etc) could be involved during the emergency situations involving hazardous chemicals under their jurisdictions.

For example, the Maritime and Port Authority of Singapore (MPA) is the national authority responsible for regulating and controlling oil spill response operations within Singapore territorial waters. A senior officer from the MPA will assume the role of On-Scene Commander. Under the regulations promulgated under the Prevention of Pollution of the Sea Act, the MPA can call upon equipment, materials and manpower held by the various oil companies and other private enterprises operating in Singapore. If the oil spill impacts the shore, NEA will activate the necessary departments for the cleanup and monitoring actions [14].

Singapore's Chemical Contingency Plan (Marine) is a supplement to the Marine Emergency Action Procedure and deals with incidents involving bulk chemicals carried by ship at sea and at terminals. The relevant MPA officers are trained in Hazardous and Noxious Substance (HNS) response and have access to CHEMWATCH, a Safety Data Sheets (SDS) database. All chemical tankers arriving in Singapore are required to provide an advance notification to the MPA containing details of the chemical cargo they are carrying.

Among the requirements of the Competent authorities the companies that are dealing with hazardous chemicals must obtain the license on business activity (it must be transportation or storage of hazardous chemicals or dangerous goods containing hazardous chemicals, manufacturing of goods using hazardous chemicals), the employees must be trained and have a license on this kind of occupation, Emergency response plan must be developed and approved by a competent authority. To get such an approval the company must prepare a range of documents (SDS, etc) and Emergency response plan, where the possible emergency situations are described and the mitigation plan is described. Companies can obtain help in this regard from the competent institution and centers, which are specialized on Emergency situations liquidation.

Large scale chemical emergencies are under the purview of the Homefront Crisis Management System (HCMS). The HCMS provides strategic and political guidance on handling a crisis and

manages all crisis situations that occur in Singapore. Chemical industries have their own CERT for initial management of a chemical incident. CERTs are subjected to regular audit by the SCDF. Various community involvement programmes are also available to provide members of public with information on how to respond during an emergency (e.g. In-place protection procedures). There is close coordination among the agencies during any response/incidents.

In Singapore there is an Incident Management Center. The center, otherwise known as the Asia Chemical Transportation Emergency Center (ASCTEC) [15]. It offers:

- *Level 1: Communication services entailing the storage, maintenance and dissemination of material safety data sheet (MSDS) information, encompassing more than 1.2 million pure and mixed substances, and associated emergency response protocols and support information, on a 24 / 7 basis in more than 23 official languages;*
- *Level 2: Technical Consultants providing full time competent personnel strategically located throughout the Asia Pacific and Middle East for immediate mobilization and on – scene technical consultation and;*
- *Level 3: Emergency Response services entailing the provision of competent response personnel and equipment for the containment, control, clean-up and disposal of waste involving dangerous goods incidents. These services encompass a 24 hour global communications network; chemical database and response protocols; chemical and environmental engineers, chartered chemists and laboratories; and Hazardous Material Control Teams whose extensive field experience provides a wealth of knowledge involving hazardous material incidents within the chemical, marine, petroleum, petrochemical and transportation industries.*

Incident Management Center maintains integrated response packages containing detection, sampling and onsite analysis systems; personnel protective equipment; vapor control and re-condensation products; product containment; control systems; decontamination materials; product packaging, labeling, and shipment; and waste treatment management services.

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## **C h i n e s e   T a i p e i**

Composed by Russian Federation  
Reviewed by Chinese Taipei

## **I n t r o d u c t i o n**

The chemical industry is the most important and largest industry in Chinese Taipei, particularly petrochemicals manufacturing with more than 2,500 chemical products manufactured by 2,300 chemical producers. The sector includes research, design, construction, operation, manufacturing, distribution and recycling and disposal. All areas of chemical manufacturing are covered, from raw materials and petrochemical intermediates, plastics and synthetic rubber and downstream products, petroleum and coal-based products, and fibers. The industry also supports associated engineering activities and equipment supplies.

Plastics and organic chemicals export volume in 2015 totaled about 18,5 and 8,6 billion USD respectively, other chemicals – around 3,6 billion USD. Synthetic fibers production is the third by volume worldwide with average volume 2,5-2.9 Mt/y.

Now chemical industry in Chinese Taipei is also focused at the high-technology products, including plastics, coatings, pharmaceuticals and nanomaterials.

## **1 . R e g u l a t e d o b j e c t s**

According to the main chemical regulation in Chinese Taipei, Toxic Chemical Substance Control Act (TCSCA) of Chinese Taipei, the objects of regulation are chemical substances: new chemical substances (new substance shall be registered 90 days prior to production or import) and designated existing substances.

A new substance is defined as a substance that is not listed in Chinese Taipei's existing substance inventory, Taiwan Chemical Substance Inventory, TCSI.

Several exemptions apply:

- *Naturally occurring substances*
- *Chemical substances accompanied in the machines and equipment for test-run purpose*
- *Inseparable intermediates from the chemical reaction in the reaction vessel or in the production process*
- *Chemical substances for national defense purpose(5) Chemical substances under customs supervision*
- *Wastes*
- *Incidental reaction products or impurities without intended commercial purpose*
- *Mixture (not applicable to chemical substances in the mixture containing new chemical substance)*
- *Articles (not applicable if the substances contained in the article will be intentionally released during normal use)*
- *Polymer applicable to the 2 % Rule & monomers listed in TCSI*
- *In addition, new chemicals are also subject to notification*

## **2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m**

At the moment, Environmental Protection Administration of Chinese Taipei, EPA, is a regulatory body in charge of the registration of new and existing chemicals in accordance with TCSCA of Chinese Taipei.

## **3 - 4 . I n f l u e n c e s : E c o n o m y p r i o r i t i e s a n d I n t e r n a t i o n a l a c t i v i t i e s**

## Chinese Taipei

Chinese Taipei is following the world trends in chemical management for the goals of the sound management of chemicals throughout their life cycle by 2020 setting by UN Strategic Approach to International Chemicals Management (SAICM). To achieve the goals, Chinese Taipei has been carrying out the reforms on chemical management regulations: OSHA, TCSCA, and several other regulations have been amended or developed to foster the safe use of chemicals to protect human and environmental health.

### *Vienna Convention and Montreal Protocol*

Taiwan is not a Party to the Montreal Protocol, but it has striven to control and phase out ODS proactively since the date the agreement ratified. Despite all the difficulties, Chinese Taipei committed to comply with control measures set to the industrialized nations (non-Article 5 countries) to this multilateral environmental agreement voluntarily. It has phased out consumption of various regulated Ozone Depleting Substances (ODS) since 1994, including halon, chlorofluorocarbons (CFCs) and methyl bromide, as well as reduced level of consumption of Hydrochlorofluorocarbons (HCFCs) according the agenda stipulated in the protocol.

### *Stockholm Convention*

To promote the “Chinese Taipei Implementation Plan for Persistent Organic Pollutants (POP)” through “Toxic Chemical Substances Control Act”, “Environmental Agents Control Act”, “Pesticides Control Act”, nine items of organic chlorine pesticides including DDT, and dioxin, furan, PCB, making a total of 12 items of the convention controlled chemical substances are prohibited to be used. At the same time, Chinese Taipei is dedicated to source control and contamination incidents emergency response for POP, the control of environmental POP distribution to promote the pollution source and production control strategy in order to establish a non-toxic living environment and lower Chinese Taipei’s environmental pollution risk. The dioxin emission level has dropped 78% in 2008 since the control started in 1997.

### *Chinese Taipei’s actions and achievements toward the Basel Convention*

#### *Response measures to the Basel Convention*

In order to properly manage the import and export of domestic wastes, as well as to fully comply with the Basel Convention, the Executive Yuan ratified the “Waste Import and Export Management and Basel Convention Implementation Plan” in 2000. The main measures implemented through this plan are outlined in the chart below. Through continual effort, Chinese Taipei has made significant achievements in controlling waste export and import.

#### *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*

Chinese Taipei does not possess nuclear weapons, although it historically possessed a nuclear weapons program. Chinese Taipei is not believed to have biological or chemical weapons programs, but it has been accused of possessing such programs in the past. Because of its unique status, Chinese Taipei is not a member of the United Nations, and cannot participate in nonproliferation regimes as an internationally-recognized state would. Chinese Taipei asserts that it maintains policies in accordance with widely followed export control regimes, despite not being able to participate in them in an official capacity. The Chinese Taipei denies having any weapons of mass destruction. There is no evidence of Chinese Taipei possessing any chemical or nuclear weapons though it has pursued nuclear weapons in the past.

### *Minamata Convention*

Chinese Taipei will implement any international environmental treaty in step with other economies and will continue to share its knowledge and experience with the international community. Chinese Taipei’s mercury controls are already concordant with those of developed nations.

## 5. Parameters of regulation

*Information from the open sources is not available.*

## 6. Key procedures for control of regulated objects

### *New and Existing Chemical Substance Registration*

The main chemical regulation in Chinese Taipei is Toxic Chemical Substance Control Act (TCSCA). It was first adopted in 1986, its latest revision is dated 11 Dec 2013 and fully came into force on 11 Dec 2014.

The Act will adopt a European REACH-style registration scheme which requires manufacturers and importers to register their new and existing chemical substances prior to entering Chinese Taipei's market in the EPA.

TCSCA requires companies who handle specific controlled toxic chemical substances to apply for permits, registration or approval and comply with relevant management measures. In this context "handling" includes manufacture, import, export, sale, transport, use, storage or discarding of chemical substances.

Different types of the registration are foreseen for the new and existing chemical substances.

A detailed implementation scheme, which involves data requirements, tonnage thresholds, exposure and risk assessments, etc., are fleshed out in the Regulation on Registration of New and Existing Chemical Substances. Followings are other important supporting documents.

- *Toxic Chemical Substances Control Act Enforcement Rules .*
- *Approval Regulation for Class 4 Toxic Chemical Substances.*
- *Regulation on Commission on New Chemical Substances and Existing Chemical Substances Registration Dossier Review.*
- *Toxic Chemical Substances Labeling and Safety Data Sheets Regulations.*
- *Standard on Toxic Chemical Substances Handling Application Fee and Chemical Registration Fee.*

Registrants are chemical substances domestic producers and importers, foreign companies cannot submit a registration in Chinese Taipei but can appoint a third-party representative in order to comply with the TCSCA requirements.

The new chemical substance should be registered 90 days before manufacture or importation. Based on the tonnage band and usage information, three registration types are adopted for the new chemicals, including standard registration, simplified registration, and low-volume registration.

Data requirements of new chemical substance registration under revised TCSCA differ for these three registration types.

**Table 3.12.1. - Data requirements of new chemical substance registration under revised TCSCA**

<b>Registration type</b>	<b>Required Information</b>	<b>Review period and validity</b>
Low-volume registration	Basic registrant and substance identification data Production and use information	7 wd as a review period with validity of 2 years (5 years for polymer of low concern registrations)
Simplified registration	Information required for the low-	14 wd as a review period with

## Chinese Taipei

Registration type	Required Information	Review period and validity
	volume registration plus Exposure information Hazard C&L info Information on the safe use Physicochemical substance properties	validity of 2 y
Standard registration	Simplified registration information plus Information on toxicological and ecotoxicological properties Hazard and exposure assessments	45 wd as a review period with validity of 5 y

For the standard registration, toxicology and ecotoxicology data requirements increase with the volume of a substance to be registered. There are 4 levels (Level I 1-10t, Level II 10-100t/y, Level III 100-1000t/y, and Level IV 1000t/y+). On-site isolated intermediates and substances for R&D or PPORD purpose benefit from reduced data requirements (level I data). Data requirements for CMR substances are more stringent than regular substances.

New chemicals that were registered through the standard registration process are added to the TCSI after 5 years from their registration.

For the registration of the existing substances there are foreseen three registration types:

- *phase 1 registration (analogues to EU REACH pre-registration), for all chemical substances in the scope of TCSCA that are produced or imported in quantities more or equal to 0,1 t/y. Deadline for the phase 1 registration, 31 March 2016, has already passed;*
- *post phase 1 registration is applicable to existing chemical substances produced or imported for the first time starting from the 31 March 2016 in quantities more or equal to 0,1 t/y.*
- *standard registration is required for the designated chemical substances that are produced or imported in quantities more or equal to 1 t/y. The standard registration for existing chemical substance will be carried out in 2019. (106 chemical substances has been announced by EPA designated for the first batch of existing chemical substance standard registration).*

For new chemical substances, individual submission is suggested. The potential registrants can decide whether to make joint submission or not. For existing chemical substances, joint submission will NOT be mandatory. Joint registrants or early and late registrants of the same substance can utilize data already submitted by other registrants to avoid duplication of testing data. Cost sharing agreements are negotiated by the registrants, and the EPA will intervene to coordinate only by request. Individual submission could be applicable where confidentiality and cost issues arise..

In addition to TCSCA, new chemicals are regulated under the Occupational Safety and Health Act (OSHA) of Chinese Taipei. OSHA of Chinese Taipei was issued on the 3 July 2013 and entered into force since 3 July 2014, it is an amended version of the previous Labour Safety and Health Act. According to OSHA of Chinese Taipei provisions, producers or importers shall not manufacture or import new substances prior to submitting hazard information and obtaining registration approval from Chinese Taipei .

**Table 3.12.3. – Differences between the registration system under OSHA and TCSCA**

Parameters	OSHA	TCSCA
Scope of registration	New chemical substances	Both new and existing substances
Type of registration	Standard registration, simplified registration and low volume	Same as OSHA with one additional type: Phase I

## Chinese Taipei

	registration	registration of existing substances
Standard Registration - Hazard Data	Same as TCSCA's requirement except no need of ecotoxicology data;	Extra requirement on ecotoxicology data and PBT/vPvB assessment;
Chemical Risk Assessment	Required for $\geq 1$ t/y CMR substances and $\geq 10$ t/y regular new substances;	Required for $\geq 1$ t/y CMR substances and $\geq 1000$ t/y regular substances.
Transitional Measures	New substances manufactured or imported into Taiwan prior to 11 Dec 2014 need to go through small quantity registration process; certificate valid for 1 year only.	Substances M/I prior to 11 Dec 2014 are eligible for inclusion in existing substance inventory without notification.
Registration Platform	OSHA CSNN;	TSCA Chem Reg

The OSHA protects CBI of registered new chemical substance identification automatically, except for safety relevant information. The TCSCA also allows registrants to apply for CBI protection if the prerequisites are met. In addition, the TCSCA will not release any CBI information of substances in phase 1 existing registration. The registrants will be secured by the CBI protection.

### *Management of controlled toxic chemicals under TCSCA*

In accordance with TCSCA EPA sets procedures of control for handling of toxic chemicals after assigning them one of 4 classes. As of 2016 there were around 310 substances regulated under this procedure. EPA also announces if the handling of a controlled substance is restricted or prohibited.

**Table 3.12.2 – Classes of controlled toxic chemicals under revised TCSCA**

Class	Definition
Class 1	Persistent substances that do not decompose in the environment or pose harm for human health due to their bioaccumulative properties, bioconcentration or biotransformation
Class 2	Carcinogenic, mutagenic, teratogenic substances or substances causing other chronic diseases
Class 3	Chemical substances that pose danger to human health or other living organisms immediately after exposure
Class 4	Chemical substances for which there is a concern of polluting environment or human health harm

If a substance has been announced as Class 1, 2, 3, or 4 toxic chemical substance, enterprises who handle it will need to apply for permits, registration or approval and comply with relevant management measures.

### *Occupational Safety and Health Act (OSHA) of Chinese Taipei*

In addition to the new chemical substances registration, three measurements were adopted to protect workers' safety and health in workplace under the OSHA of Chinese Taipei:

- *Chemical control banding (CCB) - Article 11 of the OSHA of Chinese Taipei*  
With regard to hazardous chemicals with GHS health hazards, the employers shall assess risk degree of the chemicals based on their hazards to health, distribution, quantity of use and other conditions, and adopt management measures according to risk ranking.
- *Priority Management Chemicals - Article 14 of the OSHA of Chinese Taipei*

## Chinese Taipei

For the priority management chemicals designated by the Chinese Taipei, manufacturers, importers, suppliers or the employers shall report relevant handling information, to the central competent authority and update annually on regular basis. Presently 601 designated chemicals were announced under this regime. The second batch of the priority management chemicals will be made public for comment before the end of second quarter of 2018.

- *Controlled Chemicals - Article 14 of the OSHA of Chinese Taipei*

The controlled chemicals designated by the Chinese Taipei, shall not be manufactured, imported, supplied, or provided for workers to handle or use by manufacturers, importers, suppliers, or the employers. Such chemicals with permission from the central competent authority are not subject to this restriction. Presently 18 Controlled Chemicals (Specific chemicals Category 1 and 2) are announced under this regime.

On 13 April 2015, Chinese Taipei has published the first list of 580 priority management chemical substances for public consultations. The list was entered into force on 31 May 2015. Among the published 580 substances, 123 substances are CMR category 1 substances and 457 substances have physical or health hazards. Another 594 substances for second batch of the priority management has been released in 2018,

## 7. Non-regulatory mechanisms

The Taiwan Chemical Industry Association (TCIA) (Chinese Taipei) was set up in 2003. TCIA is a non-profit organization and up to date unites 112 various companies and associations. It seeks to increase co-operation with other national and foreign industry associations on chemicals management (e.g. REACH, GHS, Rotterdam Convention and information exchange) as well as regulators. It also promotes Responsible Care programme.

Responsible Care is also implemented by the Taiwan Responsible Care Association (TRCA) (Chinese Taipei) that was established in 1998. It made a formal application for ICCA Observer Status in 2005. TRCA has 72 member companies and leads the implementation of world class health, safety and environmental management systems throughout the chemical industry in Chinese Taipei.

In 2005 both associations have obtained an observer status within ICCA (“TCIA& TRCA”) and declare that active participation in the ICCA activities provides for the development of the chemical industry in line with main worldwide trends.

## 8. Availability of data

Chinese Taipei's existing chemical inventory is the newest among global inventories.

In 2009, Chinese Taipei started up integrated collaborations to establish the framework of source management on chemicals. Since then, the MOL has incorporated relevant information nominated by industries and stakeholders to establish the very first inventory, TCSI, which was announced on December 31st, 2014.

On August, 2015, the second edition of TCSI has been officially released. The Inventory is the only chemical substance inventory of Chinese Taipei. The Inventory lists over 100,000 chemical substances TCSI, including three batches of existing chemical nomination before 2014 and another 7,500 substances received while implementing the latest existing chemical nomination from January to March in 2015. This TCSI has become the cornerstone of further chemical management modernization in Chinese Taipei for the competent agencies to carry out new schemes of chemical management. Moreover, it distinguished the existing chemical substances from new chemical substances within the registration scheme under both TCSCA and OSHA of Chinese Taipei.

The last update of the TCSI was made in March 2016. Chemicals on the list can be searched via [http://csnn.osha.gov.tw/content/home/Substance\\_Query\\_Q.aspx](http://csnn.osha.gov.tw/content/home/Substance_Query_Q.aspx) by the identification number, serial number or chemical name.

On 5 Oct 2015, Chinese Taipei EPA issued the offline chemical registration tool, CHEMical Information System and Tool - CHEMIST 3.0, which improves upon the previous version and fixes some key problems. The function for offline preparation of phase 1 existing chemical registration dossier has been newly incorporated into new version of CHEMIST. In addition, the current online dossier submission platform was improved to accept phase 1 existing chemical registration dossier in XML format exported directly through CHEMIST.

### **9 . L a b o r a t o r y i n f r a s t r u c t u r e**

Taiwan Accreditation Foundation (TAF) is the Good Laboratory Practice (GLP) Compliance Monitoring Authority (CMA) in Chinese Taipei, officially designated by the Chinese Taipei Environmental Protection Administration (EPA), the Chinese Taipei Council of Agriculture (COA) and the Industrial Development Bureau (IDB) of Chinese Taipei, Ministry of Economic Affairs (MOEA) of Chinese Taipei. Since 2004, under supervision of the Bureau of Standards, Metrology, and Inspection (BSMI) of Chinese Taipei, MOEA, TAF began to establish a GLP compliance monitoring program.

Chinese Taipei's "GLP Compliance Monitoring Program", launched in 2006, is operated by TAF in accordance with the OECD (Organization for Economic Cooperation and Development) GLP Guidance Documents for Compliance Monitoring Authorities, i.e. "No 2: Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice", "No 3: Revised Guidance for the Conduct of Laboratory Inspections and Study Audit" and "No 9: Guidance for the Preparation of GLP Inspection Reports", as well as the Advisory Documents of the Working Group on GLP, i.e. "No 12: Requesting and Carrying Out Inspections and Study Audits in Another Country". TAF performs inspections and study audits to GLP test facilities. They will be registered in the GLP compliance registration list once they are deemed to be compliant with OECD Principles. TAF also cooperates with the receiving authorities of GLP studies. A test facility that has been registered by TAF after inspection is guaranteed to be compliant with the OECD Principles on GLP, and shall be monitored by TAF on regular basis.

TAF has been participating in the annual meeting of the OECD Working Group on GLP as an ad hoc observer since 2006. Three TAF staff had participated in the OECD GLP Inspector Training Course.

On 3 February 2010, a "Letter of Confirmation" was signed by the Taipei Economic and Cultural Representative Office in the U.S. (TECRO) and the American Institute in Taiwan (AIT). It is a confirmation that Chinese Taipei has a GLP program for pesticides and industrial chemicals that US EPA recognizes as compatible to the US EPA's. In light of this, any test facility in Chinese Taipei that has been inspected by the TAF and is in compliance with OECD Principles of GLP is accepted by the US EPA if they generate pesticides and industrial chemical data for US EPA submission.

The main task of the GLP compliance monitoring authority is to inspect, recognize and monitor that the test facility complies with the Principles of Good Laboratory Practice (GLP) of the Organization for Economic Cooperation and Development (OECD) as well as to maintain the registration of the compliance test facility under the program.

TAF represents as the GLP compliance monitoring authority in Chinese Taipei under the program "OECD Good Laboratory Practice (GLP) National Compliance Monitoring System".

### **1 0 . I n f o r m a t i o n s h a r i n g**

### 10.1. GHS implementation

GHS in Chinese Taipei is implemented by the TSCA and OSHA as well as by the following documents:

- *Chinese Taipei Standards CNS 15030 Classification and Labeling of Chemicals aligned its classification and labelling requirements with the GHS fourth revised edition on January, 2015;*
- *Regulations for the Labeling and Hazard Communication of Hazardous Chemicals (effective on December 31, 2008) Directive of the Executive Yuan Council of Labor Affairs, October 19, 2007 (CLA No. 0960145703) [Amended on June 27, 2014] ("MOL Regulation");*
- *Management Measures on Toxic Substances Labeling and Material Safety Data Sheet, December 17, 2007 (EPA No. 0960095329) (Effective Date: December 31, 2008) ("EPA Regulation").*

CNS 15030 is the main Chinese Taipei standard for chemical classification and labelling. All other GHS-related regulations have referred to this standard. The standard was issued by the Bureau of Standards, Metrology and Inspection (BSMI) of the Ministry of Economic Affairs of Chinese Taipei. The latest version is issued in January 2015 and is based UN GHS Rev. 4.

The revised Regulation of Labeling and Hazard Communication of Dangerous and Harmful Substances requires manufacturers, importers or suppliers to provide labelling and SDSs for all hazardous chemicals with physical and health hazards from 1 Jan 2016.

According to Article 5-6 in MOL regulation, if the hazardous substances inside the containers are in mixtures, the hazardous ingredients on the label should indicate that the hazard of the mixture is in accordance with Chinese Taipei Standards 150307 for Chemical Goods Classification and Labeling along with all of the ingredients that are physically hazardous or that are hazardous to health.

- *Small package: If the volume of the first container is 100 ml or less, then the container need only be labeled with the name, hazard or hazard pictogram and signal word;*
- *Language on labels: Traditional Chinese should be used as the standard. A foreign language may be used if necessary. Both Chinese and English chemical names are required.*

Appendix 5 of MOL regulation gives a template for Material Safety Data Sheet (renamed as "safety data sheet" after amendment in 2014).

- *The 16-sections SDS is in accordance with UN GHS;*
- *The emergency telephone number for SDS should be a phone number that is available at any time and available for consultation in the event of an accident.*

Companies who do not wish to disclose the name or concentration of hazardous chemicals or suppliers' names in SDSs for the necessity of trade secret protection shall provide a written document to authority and obtain an approval. However, chemicals with the following hazard classifications are not allowed to be withheld from public disclosure:

- *Acute toxicity cate. 1, 2 & 3;*
- *Skin corrosion and irritation cate. 1;*
- *Serious eye damage/irritation cate. 1;*
- *Respiratory or skin sensitisation;*
- *Carcinogenic, Mutagenic or Reproductive Toxicant;*
- *STOT single exposure or repeated exposure - cate. 1*

On the 6th of January 2016 MOL of Chinese Taipei published recommended GHS classifications for 6000 chemical substances. Most of the classifications correspond to those provided in the Annex VI of the EU CLP Regulation.

### SDS and Label under TCSCA

## Chinese Taipei

Under revised TCSCA, the handler shall, pursuant to regulations, mark matters related to toxicity and pollution control on Class 1 to Class 4 toxic chemical substance containers, packaging, handling sites, and facilities, and shall keep safety data sheets for the corresponding toxic chemical substances. GHS SDSs and labels are compulsory for Class 1 to Class 4 toxic chemical substances and mixtures containing them.

### *10.2. Response on emergency situations involving chemicals, including poisoning*

In accordance with Articles 24 and 24-1 of TCSCA companies that are handling chemicals as well as local competent authorities are responsible for actions in emergency situations.

In case of emergency companies that are handling chemicals should take immediate actions on response, inform local competent authorities within 1 hour of the accident. In case of a transport accident a company handling chemicals involved should send trained personnel to an accident site within 2 hours in order to provide for proper accident management. Taiwan EPA is also operating an emergency response call center and providing three incident response teams in handling of chemical accidents.

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**T h e K i n g d o m o f T h a i l a n d**

Composed by Russian Federation  
NOT Reviewed by Thailand

### **I n t r o d u c t i o n**

The chemical industry is regarded as one of the most important business branches of the Thailand's economy and plays an essential supporting role to many other sectors such as food processing, plastics, detergents, textiles, furniture, pharmaceuticals and water purification.

The country produces adhesives, dyestuffs, fertilizers, film products, acids, paints, UV coatings, petrochemicals and plastic resins. The basic chemicals sector comprises mainly of the chloralkali market with annual production over 850,000 metric tons, chlorine production over 750,000 metric tons and sulfuric acid about 650,000 metric tons. All sectors are highly competitive and growing export to neighboring countries.

The Thailand's government plays a vital role in the development of the chemical industry. During the period until 2018, several programs of Thailand's government for the petrochemical industry should bring public investments of around €10 billion for the expansion of this sector. Moreover, the Thailand Board of Investment continues to offer non-tax and zone-based tax incentives to foreign chemical enterprises that wish to locate operations in the country. These include land ownership rights, corporate tax holidays and reduced machinery import duties.

### **1 . R e g u l a t e d o b j e c t s**

The object of the regulation in Thailand are "hazardous substances" contained in the Hazardous Substances List that is required by the main regulation on chemicals safety in Thailand - the Hazardous Substances Act, B.E. 2535 (1992), its latest amendment – the 2nd revised version (No. 3, 2008) B.E. 2551 (hereinafter referred as «the Act»).

The Act promulgates the List of hazardous substances for special conditions of use in agriculture, public health, personal consumables and household products and classifies them into four types according to the needs for control. The List of hazardous substances was firstly published in 1995 as Notification by the Ministry of Industry, B.E. 2538; the latest consolidated version was published in 2013 (Notification of the Ministry of Industry, B.E. 2556) and amended by Notification B.E. 2558 in February 2015.

As specified in section 4 of the Act «hazardous substance» means the following:

1. *an explosive;*
2. *an inflammable substance;*
3. *an oxidizing agent and a peroxide substance;*
4. *a toxic substance;*
5. *an infectious substance;*
6. *a radioactive substance;*
7. *a mutagen;*
8. *a corrosive substance;*
9. *an irritating substance;*
10. *other substance, whether chemical or else, which may be harmful to person, animal, plant, property or environment.*

It should be noted that hazardous substances include both substances and mixtures.

In accordance with section 18 of the Act for the purpose of control, hazardous substance shall be classified into the following categories:

- *1st Category – hazardous substance which production, import, export or possession shall be in accordance with the determined rules and procedure;*
- *2nd Category – hazardous substances which production, import, export or possession shall be notified in advance to the competent authority and shall be in accordance with the determined rules and procedure;*

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- *3rd Category – hazardous substances which production, import, export or possession shall be licensed;*
- *4th Category – hazardous substances which production, import, export or possession is prohibited.*

Hazardous substances of 2nd and 3rd Categories are also subject to registration.

The actual List of hazardous substances contains about 1 600 substances which are divided into 6 parts (Annexes) being subject to control by various authorities.

## **2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m**

The Hazardous Substances Act B.E. 2535 was issued under responsibility of the Ministry of Industry (Department of Industrial Works, DIW).

Also, according to section 5 of the Act the following state bodies could be directly involved in control of hazardous substances:

- *the Ministry of Agriculture and Cooperatives (Department of Agriculture, DOA, Department of Fisheries, DOF, Department of Livestock Development, DLD);*
- *the Ministry of Public Health (Food and Drug Administration, FDA);*
- *the Ministry of Energy (Department of Energy Business, DOEB);*
- *the Ministry of National Resources and Environment;*
- *the Ministry of Transport;*
- *the Ministry of Interior;*
- *the Ministry of Science and Technology;*
- *the Ministry of Defense.*

In relation to the List of hazardous substances:

- *Department of Agriculture is responsible for control of substances included into Annex 1 (pesticide active ingredients, products containing active ingredients and banned pesticides);*
- *Department of Fisheries – Annex 2 (chemicals used in biocides for the purpose of controlling, preventing, and destroying microorganisms, parasites, plants or other animals in fisheries and aquatic animal farming);*
- *Department of Livestock Development – Annex 3 (veterinary drugs and chemicals used in disinfection and cleaning products for animal feed manufacturing, animal farm, slaughter house and animal processing product manufacturing);*
- *Food and Drug Administration – Annex 4 (chemicals used in household or public health activity (killing or preventing insects, rodents, etc.));*
- *Department of Industrial Works – Annex 5 (chemical substances with clear identifiers, chemical wastes, used electrical and electronic appliance, chemical weapons and all other chemicals meeting the definition of hazardous substance (sub-list 5.6));*
- *Department of Energy – Annex 6 (natural gas and liquefied petroleum gas).*

## **3 - 4 . I n f l u e n c e s : n a t i o n a l p r i o r i t i e s a n d i n t e r n a t i o n a l a c t i v i t i e s**

Thailand's Department of Industrial Works (DIW) has announced the plans on development of the National Inventory of Existing Substances and introduction of REACH-like regulation for new substances. The National Inventory will be compiled on basis of:

- *the chemicals listed in the consultation database of the Department of Industrial Works;*
- *the national single window list obtained by the Customs Department of Thailand;*

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- *the latest hazardous substance notification list obtained by the Hazardous Substances Control Bureau (HSCB) of the DIW;*
  - *the sub-list 5.6 of the List of hazardous substances (see more info in section 6).*
- Chemicals included into the National Inventory would be defined as «existing». Any substance not notified by a provisional date of December 31, 2016 will not be listed on the National Inventory and will be treated as a «new» substance subject to special regulation.

### *International conventions*

**Table 3.13.1. – Conventions on chemicals regulation ratified by Thailand**

<b>Name of the Convention</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark / source link</b>
The Stockholm Convention on Persistent Organic Pollutants	yes	2005	2002	The National Plan for Implementation of the Stockholm Convention on the Persistent Organic Pollutants (POPs) was approved in 2007, the Ministry of Natural Resources and Environment is responsible for its fulfilment
The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	1989	1988	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	1997	1990	The Factory Act B.E. 2535 and The Hazardous Substance Act B.E. 2535 regulate responsibilities under Convention, the Department of Industrial Works (DIW) is in charge
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous		2002 (a)		The Department of Agriculture and the Department of Industrial Works are responsible for implementation of the

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Name of the Convention	Status of ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed	Remark / source link
Chemicals and Pesticides in International Trade				Convention
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	2002	1993	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Minamata Convention on Mercury	no			<a href="http://www.mercuryconvention.org/Countries">http://www.mercuryconvention.org/Countries</a>
Vienna Convention for the Protection of the Ozone Layer		1989 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol	no		1975	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention on Psychotropic Substances, 1971		1975 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988		2002 (a)		<a href="https://treaties.un.org/">https://treaties.un.org/</a>

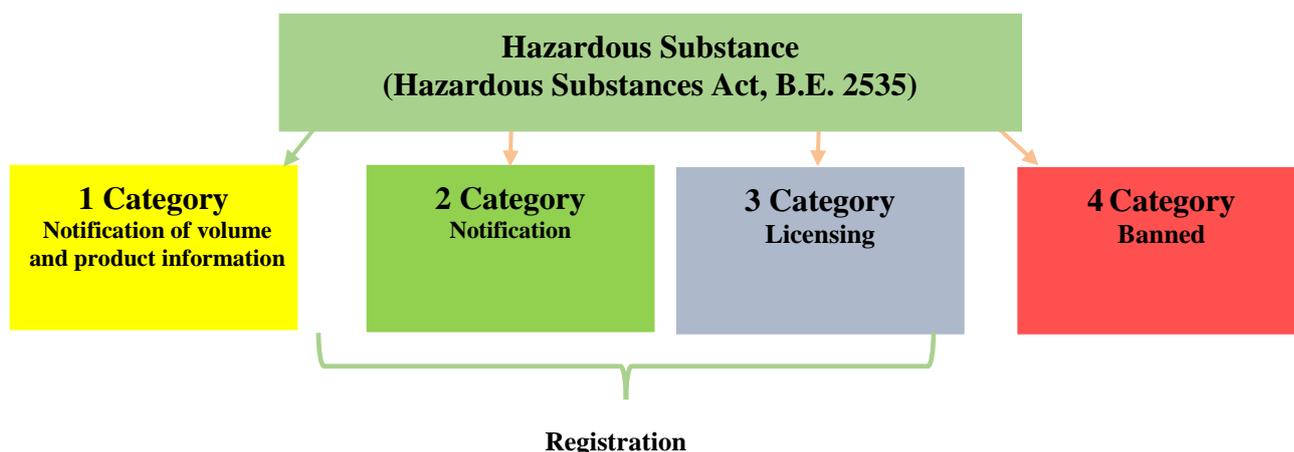
**5. Parameters of regulation**

Information from the open sources is not available.

## 6. Key procedures for control of regulated objects

Classification of hazardous substances under the Hazardous Substances Act, B.E. 2535 is shown on scheme 3.13.1.

### Scheme 3.13.1. – Classification of hazardous substances under the Hazardous Substances Act



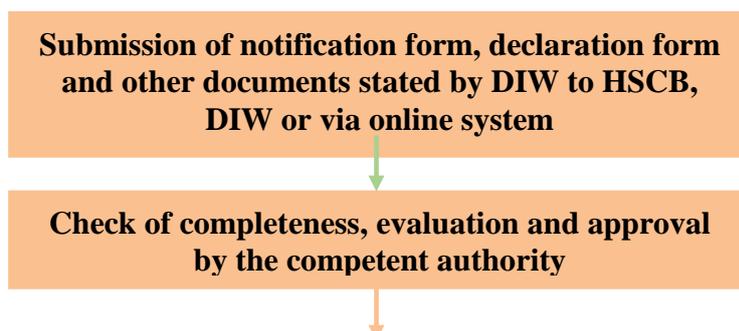
The process of notification for substances of Category 1 includes submission of notification form, declaration form and other documents stated by DIW to HSCB, DIW or via online system, check of completeness of documents by the authorities and endorsement of notification form following by assignment of notification number. Any producer, importer, exporter or possessor of hazardous substance of Category 1 should apply the following information: company details (name, address, TAX ID, etc.), chemical or trade name of hazardous substance, number according to the List of hazardous substances (Category 1), quantity, 100% composition (for mixtures/products).

All forms of applications in relation to registration, notification, licensing and requirements to enclosed documents are stated by Notifications of Ministry of Industry and Regulations of Department of Industrial Works. Documents required for registration, notification and licensing could include SDSs, GHS classifications, pictures of containers and packages, and analysis reports.

All producers, importers, carriers and persons in possession of listed hazardous substances of Categories 2 and 3 must register at the Hazardous Substances Control Bureau of DIW.

Process of registration is presented on scheme 3.13.2.

### Scheme 3.13.2. – Registration outline

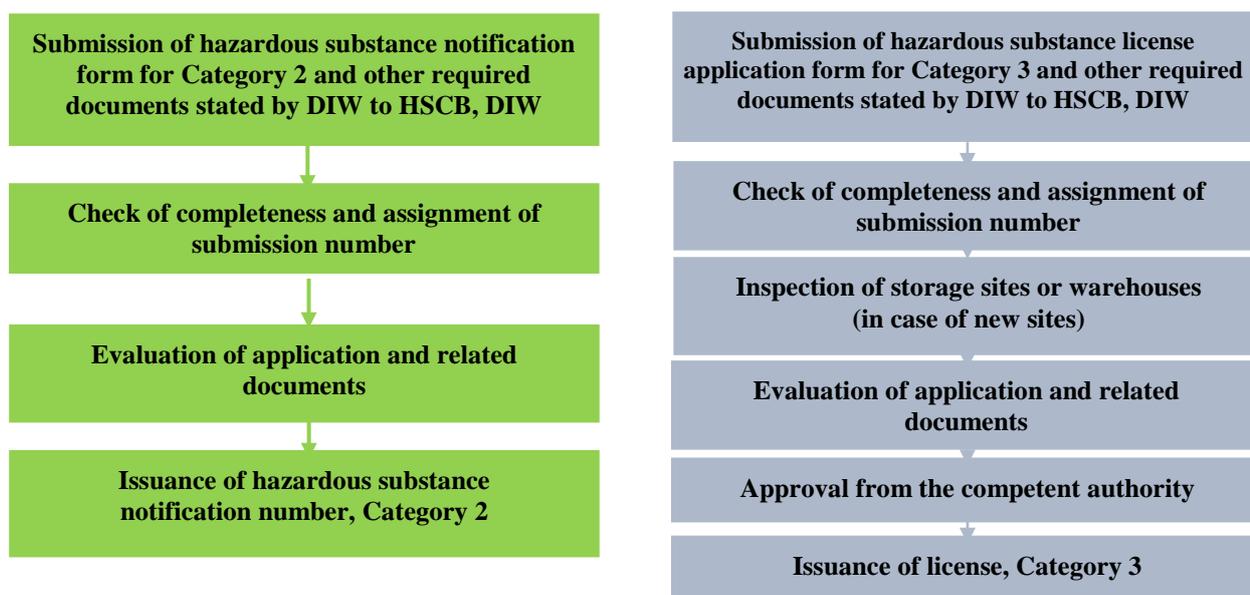


**Issuance of registration certificate**

Only after registration producers, importers, carriers and persons in possession can apply for notification or licensing.

Process of notification (for substances of Category 2) and licensing (for substances of Category 3) are shown on scheme 3.13.3.

**Scheme 3.13.3. – Notification and licensing outlines**



It should be noted that in case of new substances or products (not included in the List of hazardous substances) or any unclarities, there is a need of online consultation and close discussion with the Hazardous Substances Control Bureau, DIW or other responsible authority.

Moreover, hazardous substances falling within the following groups are exempted from registration and notification:

- *hazardous substances regulated by other laws (Arms Control Act, Drug Act, Food Act, Fertilizer Act, Export and Import of Goods Act);*
- *hazardous substances of Category 4 used for R&D purposes and lab testing;*
- *hazardous substances being notified under sub-list 5.6.*

Annex 5.6 was added to the List of hazardous substances by the latest amendment (Notification B.E. 2558). So since February 20, 2015, manufacturers and importers of hazardous substances listed in annex 5.6 exceeding 1 ton per year are required to notify their hazardous substances to the Department of Industrial Works via online system. Such notification shall be submitted only once within 60 days from the date of manufacture or importation. Information required for notification includes planned usage, physical and chemical properties, toxicological information, ecological information, GHS classification and disposal recommendations. This new process is regarded as the first step in a more comprehensive approach to chemicals management in Thailand.

**7. Non-regulatory mechanisms**

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In 1967, The Federation of Thai Industries (FTI) was established in order to promote the interests of local manufactures. Today, it comprises 40 industrial clubs, including Chemical Industry Club (CIC), Petrochemical Industry Club, Pharmaceuticals Industry Club, Plastic Industry Club and others.

FTI's Chemical Industry Club (CIC) was formed in 1984 and has nearly 150 members making it the second biggest sector group in FTI. It includes five subgroups: Agro-Chemicals, Basic Chemicals, Paints & Dyestuffs, Soaps & Detergents, and Other Chemicals. The CIC is a non-profit organization operating as a center for exchange and distribution of information, knowledge, regulations, etc. for members, and interacts with concerned governmental agencies on behalf of members. The CIC participates in meetings with all levels of government and other organizations for policy formulation and regulation implementation.

The CIC is closely involved in chemicals management and chemical safety programs as well as promotion of the ICCA's Responsible Care program through the Responsible Care Management Committee of Thailand (RCMCT). RCMCT has been a member of Responsible Care Leadership Group since 1996.

Thailand chemical associations are not members of ICCA.

### 8. Availability of data

As mentioned in section 3 – 4 there is no national chemical database in Thailand, but the DIW is working on development of the National Inventory of Existing Substances.

At the moment a preliminary inventory of existing chemical substances is available for search by CAS no. or trade name via the following link <http://haz3.diw.go.th/invhaz/jsp/mainsys.jsp>

The inventory combined the hazardous substance list, the latest hazardous chemical notification list, the chemicals listed in the DIW consultation database and possibly the National Single Window List from the Customs, companies hazardous substance notifications submissions made in 2016. Those substances will be added to the inventory in 2017.

The existing chemical nomination was announced to be closed by December 31, 2016. After the closure of nomination, chemicals not listed on the existing chemical inventory will be considered to be new, and a notification will be required.

### 9. Laboratory infrastructure

At the present time the Bureau of Laboratory Quality Standards being a subsidiary of the Ministry of Public Health executes GLP Compliance Monitoring Programme.

The Programme is voluntary and aims at monitoring of test facilities of laboratories conducting non-clinical safety testing of public health products of the following categories:

- *pharmaceutical products (include bioequivalence studies);*
- *cosmetic products;*
- *veterinary drugs;*
- *food additives;*
- *household chemical products.*

### 10. Information sharing

*10.1. Implementation of GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

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Thailand has already implemented GHS through the Hazardous Substance Act B.E. 2535 and Notification on the Hazard Classification and Communication System of Hazardous Substances B.E. 2555 (2012). The Notification is based on 3rd revised edition (2009) of UN GHS.

According to Article 1 of the Notification GHS SDSs and labels are required for hazardous substances from March 13, 2013 and for mixtures from March 13, 2017.

Manufacturer or importer of hazardous substances shall comply with the requirements related to labels and SDSs annexed to the Notification as follows:

- *Labelling: The basic elements on labels required in Thailand are to be consistent with the 3rd revised edition of the UN GHS. Label shall have an appropriate size for container or package and shall be clearly displayed. For the label, no language requirement provision is stated explicitly; however, it is a common industry practice to provide them in Thai.*
- *Safety Data Sheet (SDS): SDS shall consist of 16 standard sections in accordance with Annex 4 of the 3rd revised UN GHS. For the SDS, no language requirement provision is stated explicitly; however, it is a common industry practice to provide them in Thai. Regulations on confidential business information (CBI) (such as information on ingredients or the names of chemicals and their concentrations in mixtures) will not be harmonized under the GHS. Now, full disclosure of the chemical composition is strictly required for notification. The competent authorities shall establish appropriate mechanisms for CBI protection.*

Currently, hazardous substances under the responsibility of DIW and Food and Drug Administration (FDA) are classified to conform to the GHS classification. The remaining authorities are working to classify their substances to align with the 3rd revised edition of the UN GHS.

### *10.2. Response on emergency situations involving chemicals, including poisoning*

Accidents and emergency situations are regulated by the following acts:

- *Hazardous Substance Act B.E. 2535;*
- *Public Health Act B.E. 2535 specifying the responsibility on taking actions on remediation or prevention of damage involving chemicals by the Ministry of Public Health;*
- *Factory Act B.E. 2535 stipulating the actions by Ministry of Industry in case of industrial accidents;*
- *Notification on the Land Transportation of Hazardous Substance B.E. 2546 stating the duties of Department of Industrial Works in relation of transportation of dangerous goods.*

Besides, since 1992 under the Ministry of Natural Resources and Environment the Pollution Control Department has been working. Its duties lay in coordinating and implementing measures to rehabilitate and remedy damages caused by pollution in the contaminated area and developing appropriate systems, methodologies and technologies for the application in the management of solid waste, hazardous substances, etc.

## **B I B L I O G R A P H Y & R E F E R E N C E S**

1. *International Council of Chemical Associations. <http://www.icca-chem.org/>*
2. *Thailand Board of Investment. <http://www.boi.go.th/>*
3. *Thailand Chemical Industry Overview. Thailand's Chemical Industry on Growth Curve. <http://www.process-worldwide.com/>*
4. *Ms. Montira Sriyai, Dr. Gunnar Kahl. Thailand – Overview on Chemical Control Legislation and Aspects of GHS. ChemCon Asia 2015.*
5. *Chemical Safety and Regulatory Professionals. [www.chemsafetypro.com](http://www.chemsafetypro.com)*
6. *Chemical Watch. Notification requirements enter into force. <https://chemicalwatch.com/>*

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7. *The Japan External Trade Organization (text of Hazardous substance Act, B.E. 2535 (1992) and related acts).* <https://www.jetro.go.jp/>
8. *Thailand Acts.* <http://thailaws.com/>
9. *The United Nations Treaty Collection.* <https://treaties.un.org/>
10. *The Minamata Convention on Mercury.* <http://www.mercuryconvention.org/>
11. *The Federation of Thai Industries.* <http://www.fti.or.th/>
12. *Responsible Care Management Committee of Thailand (RCMCT).*  
<http://www.responsiblecare.or.th/>
13. *The Bureau of Laboratory Quality Standards.* <http://blqs.dmsc.moph.go.th/>
14. *Chemical Inspection and Regulation Service.* [www.cirs-reach.com](http://www.cirs-reach.com)
15. *Pollution Control Department.* <http://www.pcd.go.th/>

**The United States of America**

Composed by Russian Federation  
Reviewed by US

## Introduction

The chemical industry is one of the United States' largest manufacturing industries, serving both a sizable domestic market and an expanding global market. It is also one of the top exporting sectors of U.S. manufacturing. The U.S. chemical industry is the world's largest national chemical industry, accounting for more than 21% of the \$3.1 trillion in world chemical sales.

U.S. chemical products can be divided into four general categories:

**Basic and intermediate chemicals:** The major products of this segment include polymers, bulk petrochemicals and intermediates, fertilizers, inorganic chemicals and other industrial chemicals. Employing almost a third of workers in the industry, this segment is the largest of the four, providing plastics for packaging, home construction, appliances, polyvinyl chloride (PVC), piping, toys and games.

**Specialty chemicals:** These chemicals are typically high value-added products with many differentiations. The major products of this segment include paints and coatings, adhesive sealants, catalysts, dyes and pigments, industrial gases, resins and plastic additives.

**Life science chemicals:** These are differentiated biological and chemical substances used to induce specific outcomes in humans, animals, plants and other life forms. The major products of this segment include agrochemicals, pharmaceuticals and biotechnology products.

**Science and technology chemicals:** These products include advanced materials that transform current technologies. They enhance the characteristics of traditional specialty chemical products.

## 1. Definition of Chemical Substances under the Toxic Substances Control Act

All chemical substances (manufactured, imported, processed, distributed in commerce, used, or disposed) meaning any organic or inorganic substances of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical, are regulated under the Toxic Substance Control Act (TSCA section 3, subparagraphs A and B). Mixtures of chemicals substances are regulated under TSCA as well. Chemical substances regulated under other U.S. statutes include: pesticides; foods and food additives; drugs; cosmetics; tobacco and tobacco products; nuclear materials; and munitions.

Additional laws such as the Clean Air Act (CAA), Clean Water Act (CWA), Hazardous Materials Transportation Act (HMTA), Consumer Product Safety Act (CPSA), etc. also address chemical substances.

TSCA classifies chemical substances as either existing chemicals or new chemicals. In accordance with section 3 of TSCA, "new chemical substance" means any chemical substance which is not included in TSCA Inventory of Chemical Substances. Existing chemicals are chemicals that were already in commerce when TSCA was enacted in 1976 or chemicals that have undergone pre-manufacture notice review by the U.S. Environmental Protection Agency (EPA) and listed by EPA on the TSCA Inventory of Chemical Substances upon notification of commencement of commercial manufacture, including import.

TSCA is the primary chemicals management law in the United States. On 22 June 2016, the President of the United States signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) which amended TSCA. For more information on TSCA, including the Lautenberg Act amendments, see: <https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act>.

## 2. Participants in the regulatory system

TSCA is administrated primarily by EPA and authorizes EPA to assess chemicals before they enter commerce (new chemicals) and review those already in commerce (existing chemicals) and to take a number of control actions with regard to these chemicals, in particular to prohibit or limit their manufacture, processing, use, distribution in commerce, or disposal.

At the state level, different state departments, for example, Department of Ecology, Department of Toxic Substances, Department of Environmental Protection, may also participate in the regulation of chemicals.

## 3 - 4. Influences: National priorities and International activities

Over the last 20 years, TSCA reform has been under consideration and the Lautenberg Act made changes to TSCA, including:

- *Mandatory requirement for EPA to evaluate existing chemicals with clear and enforceable deadlines;*
- *Risk-based chemical assessments;*
- *Increased public transparency for chemical information; and*
- *Consistent source of funding for EPA to carry out the responsibilities under the new law.*

The Act received broad stakeholder support and reflected compromises acceptable to business and public interest groups.

### *International Conventions*

**Table 3.14.1. – Conventions on chemicals regulation ratified by the USA**

<b>Name of the Convention</b>	<b>Status of ratifications (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Signed</b>	<b>Remark / source link</b>
The Stockholm Convention on Persistent Organic Pollutants	no		2001	<a href="https://treaties.un.org/">https://treaties.un.org/</a> The manufacture, processing, and distribution in commerce of PCBs are banned under TSCA.
The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	1988, ratification	1987	In April 2015, the United States, Mexico and Canada jointly submitted an amendment proposal to the Montreal Protocol that includes provisions to phase down the production and consumption, and eliminate byproduct emissions of hydrofluorocarbons

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				(HFCs).
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	no		1990	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	no		1998	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	1997	1993	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
The Minamata Convention on Mercury	yes	2013 (A)	2013	<a href="http://www.mercuryconvention.org/Countries">http://www.mercuryconvention.org/Countries</a>
Vienna Convention for the Protection of the Ozone Layer	yes	1986	1985	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol	yes	1972	1972	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention on Psychotropic Substances, 1971	yes	1980	1971	<a href="https://treaties.un.org/">https://treaties.un.org/</a>
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	1990	1988	<a href="https://treaties.un.org/">https://treaties.un.org/</a>

### 5. Parameters of regulation

*Information from the open sources is not available.*

## 6. Key procedures for control of regulated objects

### *New chemical substances*

Mandated by section 5 of TSCA, EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. The program functions as a "gatekeeper" that can identify conditions, up to and including a ban on production, to be placed on the use of a new chemical before it is entered into commerce. For purposes of regulation under TSCA, if a chemical is on the TSCA Inventory, the substance is considered an "existing" chemical substance in U.S. commerce. Any chemical that is not on the Inventory is considered a "new chemical substance." Section 5 of TSCA requires anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose to provide EPA with notice before initiating the activity. This notice is known as a premanufacture notice (PMN).

EPA's PMN Program to review new chemicals under TSCA has evolved into an efficient mechanism for identifying those new chemicals which are of greatest concern early on in the program's 90-day review process. A detailed analysis is focused on these cases with the ultimate goal of identifying and controlling unreasonable risks. EPA uses an integrated approach that draws on knowledge and experience across disciplinary and organizational lines to identify and evaluate concerns regarding health and environmental effects, exposure and release and economic impacts. EPA groups PMN chemicals with shared chemical and toxicological properties into categories in order to streamline the process for Agency review of new chemical substances. EPA has developed assessment methods, databases, and predictive tools to help evaluate what happens to chemicals when they are used and released to the environment and how workers, citizens, and the environment might be exposed to and affected by them. These tools may be helpful when laboratory studies or monitoring data are not available or need to be supplemented.

After EPA reviews a PMN, a Microbial Commercial Activity Notice (MCAN) or Significant New Use Notice (SNUN) and makes a determination under section 5 of TSCA, EPA may take certain actions. In cases where EPA determines that a new chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use, EPA will notify the submitter of its decision under TSCA section 5(a)(3)(C) and publish its findings in a statement in the Federal Register pursuant to TSCA section 5(g).

EPA can issue Significant New Use Rules (SNURs) for new chemicals following the Agency's review or during the review period. A SNUR requires that any manufacturer or processor – including the PMN submitter – who intends to undertake the activities subject to the SNUR must submit to EPA a significant new use notice (SNUN). Because there is detailed communication between EPA and PMN/MCAN/SNUN submitters during the review period leading to the Agency's final regulatory decision, EPA typically receives no adverse comments. Therefore, EPA generally issues these SNURs as "direct final" rules. EPA must either conclude, following review of a SNUN, that the activities are not likely to present an unreasonable risk, or take appropriate action under section 5(e) or 5(f) to protect against any unreasonable risk.

Another outcome of EPA's review of a PMN or MCAN for a new chemical substance or review of a SNUN for a significant new use is the issuance of an order under section 5(e) of TSCA. Most TSCA section 5(e) Orders issued by EPA are Consent Orders that are negotiated with the submitter of the notification. A section 5(e) order typically contains some or all of the following requirements as conditions:

- *Testing for toxicity or environmental fate once a certain production volume or time period is reached*

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- *Use of worker personal protective equipment*
- *New Chemical Exposure Limits (NCELS) for worker protection*
- *Hazard communication language*
- *Distribution and use restrictions*
- *Restrictions on releases to water, air and/or land, and*
- *Recordkeeping.*

If EPA determines that a new chemical or significant new use presents unreasonable risk of injury to health or the environment without consideration of cost or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation under the conditions of use, EPA may (1) limit the amount manufactured/processed/distributed in commerce or impose other restrictions on the substance via an immediately effective proposed rule under section 6 of TSCA, or (2) issue an order to prohibit or limit the manufacture, processing or distribution in commerce to take effect on the expiration of the applicable review period.

### *Existing chemical substances*

TSCA, as amended by the Lautenberg Act, requires EPA to evaluate the safety of existing chemicals via a three-stage process. The three stages of EPA's process for ensuring the safety of existing chemicals are prioritization, risk evaluation, and risk management. Prioritization is a risk-based screening process for designating chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluation is not warranted at the time. TSCA requires EPA to give certain preferences to prioritizing chemicals on the 2014 TSCA Work Plan, to consider certain criteria such as hazard/exposure, persistence and bioaccumulation, but otherwise does not significantly limit EPA's discretion to choose which chemicals enter the prioritization process. TSCA further prohibits EPA from considering non-risk factors (e.g., costs/benefits) during prioritization. Once initiated, the process provides stakeholders with ample notice of any EPA risk evaluation activity, as well as two opportunities for the public to submit relevant information to the Agency. The process has been designed to ensure that the Agency's limited resources are focused on chemicals with the greatest potential for risk.

If EPA designates a chemical as a High-Priority Substance, the chemical moves immediately to the risk evaluation phase. At the conclusion of the risk evaluation phase, EPA must use the risk evaluation as a basis to determine whether or not the chemical presents an unreasonable risk to health or the environment under the chemical's conditions of use. TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation. This includes risks to subpopulations who may be at greater risks than the general population, such as children and workers. The risk evaluation process has the following components:

- *a scope document that provides the public with information on the focus of the risk evaluation;*
- *hazard and exposure assessments and a risk characterization to inform the risk determination;*
- *a risk determination stating whether or not a chemical substance presents an unreasonable risk to health or the environment under its conditions of use.*

In addition to EPA's prioritization process, TSCA allows manufacturers to request that EPA conduct a risk evaluation on a particular chemical. When this happens, manufacturers are required to provide EPA with the information necessary to conduct a risk evaluation on those conditions of use that are of interest to them. Like the prioritization process, the risk evaluation process affords opportunities for public comment and submission of relevant information.

The third step in EPA's existing chemicals process is risk management. If at the end of the risk evaluation process, EPA determines that a chemical presents an unreasonable risk to health or the environment, the chemical must immediately move to risk management action under TSCA. EPA is required to implement, via regulation, regulatory restrictions on the manufacture, processing,

distribution, use or disposal of the chemical to eliminate the unreasonable risk. EPA is given a range of risk management options under TSCA, including labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, and a ban of the chemical or of certain uses. Like the prioritization and risk evaluation processes, there is an opportunity for public comment on any proposed risk management actions.

## **7 . N o n - r e g u l a t o r y m e c h a n i s m s**

EPA has established voluntary initiatives such as the Sustainable Futures Program, the Presidential Green Chemistry Challenge Awards, and the Safer Choice Program to encourage the development of safer chemicals, products, and practices.

The Sustainable Futures program provides chemical developers the same risk-screening models that EPA uses to evaluate new chemicals before they enter the market. The goal of Sustainable Futures is to provide these computer-based models and training in their use to help companies develop safer chemicals quickly and cost-effectively. Companies that take the training and graduate from Sustainable Futures become eligible for an expedited EPA pre-manufacture review.

The Presidential Green Chemistry Challenge Awards promote the environmental and economic benefits of developing and using novel green chemistry. These prestigious annual awards recognize chemical technologies that incorporate the principles of green chemistry into chemical design, manufacture, and use. EPA sponsors the Presidential Green Chemistry Challenge Awards in partnership with the American Chemical Society Green Chemistry Institute® and other members of the chemical community including industry, trade associations, academic institutions, and other government agencies. Throughout the 22 years of the awards program, EPA has presented awards to 114 winners. Since the program's inception, in 1996, EPA has received over 1,600 nominations. By recognizing groundbreaking scientific solutions to real-world environmental problems, this program has significantly reduced the hazards associated with designing, manufacturing, and using chemicals.

Safer Choice is EPA's label for safer chemical-based products. Companies apply for the label by submitting their products to Safer Choice for review. EPA evaluates every ingredient against a stringent set of health and environmental criteria. These criteria address potential health and environmental concerns, including, for example, if an ingredient is associated with causing cancer or reproductive harm, and if it accumulates in human tissue or in the environment. A product is only allowed to carry the Safer Choice label if each ingredient is among the safest in its ingredient class. As a condition of labeling, all ingredients must be disclosed either on the product or the manufacturer's website. Additionally, the product as a whole has to meet safety criteria and qualify as high-performing and be packaged in an environmentally friendly manner.

## **8 . A v a i l a b i l i t y o f d a t a**

Section 8(b) of TSCA requires EPA to compile, keep current and publish a list of each chemical substance that is manufactured or processed, including imports, in the United States for uses under TSCA. The initial reporting period by manufacturers, processors and importers was January to May of 1978 for chemical substances that had been in commerce since January of 1975. The Inventory was initially published in 1979, and a second version, containing about 62,000 chemical substances, was published in 1982. The TSCA Inventory has continued to grow since then, and now lists about 85,000 chemicals.

The Chemical Data Reporting (CDR) rule under TSCA requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce in large quantities. Under the CDR rule, EPA collects basic exposure-related information on the types, quantities, and uses of chemical substances produced domestically and imported into the United States. It constitutes the most comprehensive source of basic screening-level, exposure-related information on

chemicals available to EPA, and is used by the Agency to protect the public from potential chemical risks.

The information is collected every four years from manufacturers (including importers) of certain chemicals in commerce generally when production volumes for the chemical are 25,000 pounds or greater for a specific reporting year. Collecting the information every four years assures that EPA and (for non-confidential data) the public have access to up-to-date information on chemicals that are produced in large quantities. The CDR rule is required by section 8(a) of the Toxic Substances Control Act (TSCA), and was formerly known as the Inventory Update Rule (IUR).

To improve chemical safety and provide more streamlined access to information on chemicals, EPA has built and is populating a new database named ChemView, which greatly improves access to health and safety data on chemicals regulated under TSCA. EPA is populating the ChemView database in phases, and it currently contains information on 12,000 chemicals. ChemView provides key information in a layered summary format and provides links to underlying studies or other source documents.

### **9 . L a b o r a t o r y   i n f r a s t r u c t u r e**

In the United States, EPA and the U.S. Food and Drug Administration (FDA) both implement good laboratory practice regulations that include key elements of the OECD Principles of Good Laboratory Practice (GLP). EPA's Good Laboratory Practice Standards (GLPS) compliance monitoring program ensures the quality and integrity of test data submitted to EPA in support of a pesticide product registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), section 5 of TSCA, and pursuant to testing consent agreements and test rules issued under section 4 of TSCA. The FDA GLP compliance monitoring program assures the quality and integrity of the safety data to support or are intended to support applications for research or marketing permits for products regulated by the FDA, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products.

### **1 0 . I n f o r m a t i o n   s h a r i n g**

#### *10.1. Implementation of GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

The United States has implemented GHS in the workplace through revised Hazard Communication Standard (HCS) issued by the Occupational Safety and Health Administration (OSHA) in 2012. HCS is based on the 3rd revised version of GHS. OSHA's HCS requires that chemical manufacturers and importers classify the hazards of the chemical substances and mixtures that they produce or import, and prepare appropriate labels and SDSs to convey the hazards. The revised HCS standard became effective June 1st, 2015.

OSHA's HCS specifies what information must be included on the label, including a mandatory red pictogram border. However, OSHA does provide practical accommodations in the standard and through letters of interpretation for small containers where it is infeasible to include all required information on the label.

SDSs should contain 16 standard sections, sections 12 – 15 are not mandatory as they include information that is not within OSHA's jurisdiction, but the headings of these sections still must be included on the SDS. American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), OSHA permissible exposure limits (PELs), and any other exposure limit as well as International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) classifications shall be included into SDSs.

It should be noted that the Department of Transportation (DOT) has adopted GHS in the transport sector for chemicals with physical hazards and the most severe categories of acute toxicity; the Consumer Product Safety Commission (CPSC) has not adopted GHS in the consumer sector yet; EPA has not adopted GHS for pesticides yet.

### *10.2. Response on emergency situations involving chemicals, including poisoning*

Chemical emergency response in the United States is regulated by the following acts:

- *the Federal Water Pollution Control Act Amendments of 1972 and the Oil Pollution Act of 1990 regulate the response to releases of hazardous substances, as well as oil, to any navigable waters of the USA. The Oil Pollution Act broadens the response and enforcement authorities of the federal government;*
- *the Resource Conservation and Recovery Act (RCRA) gives EPA the authority to control hazardous waste from “cradle to grave”, including its generation, transportation, treatment, storage, and disposal;*
- *the Comprehensive Emergency Response, Compensation, and Liability Act (CERCLA) requires reporting of hazardous substances releases to any environmental media at or above a reportable quantity requiring emergency response actions;*
- *the Emergency Planning and Community Right-to-Know Act (EPCRA) establishes a chemical emergency response planning infrastructure at the state and local levels and provision of chemical risk, preparedness, and response information to the public and emergency responders.*

EPA is responsible for overall emergency prevention, preparedness, and response involving chemicals. EPA responds to oil spills, chemical, biological, and radiological releases and large-scale national emergencies, including homeland security incidents. In carrying out these responsibilities, EPA coordinates with other federal agencies, states, tribes, and local governments. This coordination is done through On-Scene Coordinators and EPA's Special Teams.

### *10.3 Pollutant Release and Transfer Register*

The Environmental Protection Agency's Toxics Release Inventory (TRI) Program was established in 1986 as the first Pollutant Release and Transfer Register (PRTR) in the world. TRI tracks the management of certain toxic chemicals that may pose a threat to human health and the environment. U.S. facilities in different industry sectors must report annually how much of each chemical is released to the environment and/or managed through recycling, energy recovery and treatment. (A "release" of a chemical means that it is emitted to the air or water, or placed in some type of land disposal.)

Since the creation of the TRI Program, the information collected and presented has provided a way for citizens to better understand possible sources of pollution in their communities. This better understanding can be the basis for actions, such as communications with facilities releasing chemicals to the environment and with regulatory authorities that have oversight responsibilities. This concept of citizen empowerment is summed up by the slogan, "A Right to Know, A Basis to Act."

It is important to note that TRI information is most useful when presented in context. Information that is often helpful to citizens in addition to TRI quantity information includes the health effects of the chemical in question, how the chemical is managed, and whether a relevant human exposure is likely. Additionally, many parties including industry are often interested in whether releases of a chemical can be minimized, reduced, or eliminated at its source. The TRI Program is committed to presenting as much of this information as possible to help inform the public.

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9. *The United Nations Treaty Collection.* <https://treaties.un.org/>
10. *The Minamata Convention on Mercury.*
11. *U.S. Food and Drug Administration.* <http://www.fda.gov/>
12. *U.S. Department of State.* <http://www.state.gov/>

## **T h e A r g e n t i n e R e p u b l i c**

Composed by Russian Federation  
NOT Reviewed by Argentine

## The Argentine Republic

Chemical industry is one of the most dynamic sectors in Argentina's economy. It accounts for 4,9 % of GDP and employs more than 52, 000 people. In 2001, chemical industry production was valued at US\$ 16,7 billion, and generated US\$2,2 billion in exports. Mercosur and other countries in Latin America are the main markets for Argentina, although exports to USA, Europe and Asia are also important. A significant number of SMEs are now exporting fine chemicals and specialties to more than 40 countries around the world.

### 1. Regulated objects

The following chemicals are regulated in Argentina: basic chemicals, agrochemicals and fertilizers, consumer products, drugs, foodstuff, medicinal products, diagnostic reagents, cosmetics, dietary supplements and household cleaning products.

There are also several chemicals of concern on international level that are being regulated as well. They are, for example, PCBs, mercury (Argentina's Chemical Weapons Law 26.247), Minamata Convention and asbestos (Resolution 823/01) (See Appendix. Legal instruments, where legislative instruments are described in more detail).

### 2. Participants of the regulatory system

Several governmental bodies are involved in the regulatory processes, as well as non-governmental organizations:

- *ANMAT (National Administration for Drugs, Food and Medical Technology) under the authority of the Ministry of Health;*
- *The Ministry of Health and Social Action (MSAS)*
- *The Ministry of Environment*
- *The Federal Ministry of Justice, Security, and Human Rights*
- *The Secretariat for the prevention of drug addiction and campaign against drug trafficking (SEDRONAR);*
- *The Directorate of Fair Trade (Direccion de Lealtad Commercial) under the Secretariat of Industry within the Ministry of the Economy;*
- *OAA (Argentinean accreditation body) the Argentine Accreditation Organization*

### 3 - 4. Influences: National priorities and International activities

National strategic documents, legislation on chemical regulations

MERCOSUR, UNASUR, CAN Regulations and Resolutions

*International Conventions*

Argentina ratified several significant conventions on regulation of chemicals (see Table 3.15.1.).

**Table 3.15.1. – Conventions on chemicals regulation ratified by Argentina**

Conventions	Status of Ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed
Stockholm Convention on Persistent Organic Pollutants	yes	25/01/2005	yes
Montreal Protocol on Substances That	yes	18/01/1990	yes

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Conventions	Status of Ratifications (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Signed
Deplete the Ozone Layer			
Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	27/06/1991	yes
Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	yes	11/06/2004	yes
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	02/10/1995	yes
Minamata Convention on Mercury	no		Yes 10/10/2013
GATT/WTO соглашения	yes	11/10/1967	yes
Vienna Convention for the Protection of the Ozone Layer	yes	18/01/1990	yes
Inter-American Convention against Illicit Manufacturing of and Trafficking in Firearms, Ammunition, Explosives and Other Related Materials (CIFTA), 1997	yes	08/13/2001	yes
United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol	yes	10/10/1963	yes
United Nations Convention on Psychotropic Substances, 1971	yes	16/02/1978	yes
United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	yes	28/06/1993	yes

### 5. Parameters of regulation

*Information from the open sources is not available.*

### 6. Key procedures for control of regulated objects

In Argentina there isn't any reporting requirements for new substances.

#### *Registration of domestic use chemical products*

The Ministry of Health (Resolution 709/98 (published September 10, 1998)) authorizes ANMAT (National Administration for Drugs, Food and Medical Technology) to administer the registration of chemical products for domestic use (household cleaning products including substances or preparations intended for cleaning, washing, odorizing, deodorizing, sanitizing, disinfecting or disinfestation, for use in the home, and / or public and / or private collective environments) that are produced, re-packaged, or imported into Argentina. ANMAT published guidelines for registration

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process of such products (Provision 7292/98) and to create the National Register for Domestic-Use Products, that had been also foreseen by the Resolution. Products subject to registration are divided into two categories (Risk I and Risk II) with different requirements for the registration process.

Each registration certificate is valid for 5-years. After that, producers or importers have to register again, but this process can be automatic in some cases. Failure to re-register results in cancellation of product registration without prior notice (Article 5 of Resolution 709/98).

Article 9 of the same Resolution prohibits the use in domestic-use products of substances, which have been classified as Group I Carcinogenic Agents for Humans by IARC/WHO.

If registered products were modified, ANMAT has to be informed.

Any violations of the Resolution are punishable under Decrees 141/53 and 341/192 (Article 8 of Resolution 709/98).

The registration of products may only be requested by companies previously authorized by the national health authority.

Registration process of producers, re-packagers, importers, exporters of sanitary products of Domestic Use is also foreseen by Resolution 709/98.

Annex V of Provision 7292/98 is a form that can be used for registration, it also contains specific instructions as to where and how to register. There is a fee required for the registration.

There is a search available at the ANMAT website to look for the registered household products (registered since March 2009).

### *Mandatory Registration of Chemical Precursors*

Law No. 23.737 on National Register of Chemical Precursors requires registration of chemicals and chemical products, which can serve as the basis for or be used in the manufacture of narcotic drugs, in the National Registry.

Annex I, Lists 1-3 Decree 1161 of December 6, 2000 (modifying Decree 1095/96) updates the list of precursors and chemical substances that can be used to manufacture illicit narcotics and psychotropic substances.

According to the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances obligations and Argentine Law 26,045 the Secretariat of Programming for the Prevention of Drug Addiction and the War Against Drug Traffic (SEDRONAR) maintains the creation and updating of the National Registry of Precursors, as well as issues the certificates for organizations operating with controlled chemicals and filing all the documentation specified in the forms to be filled.

### *Required Registration of Ozone Depleting Substances*

Decree 1609/2004 of November 17 regulates the import and export of ozone depleting substances, establishes a licensing system for that purpose as well as a National Registry for importers and exporters of ozone depleting substances per Article 1 of Law 24.040 of November 27, 1991.

### *Restricted, Prohibited or Banned Chemicals*

The following substances are strictly regulated according to the 2009 update by the National Program of Chemical Risk: aldicarb, aminotriazol, mercury bichloride, potassium bromate, methyl bromide, lindane and carbofuran.

- *Resolution 125/98 of January 22, 1998, Convention on The Prohibition of the Development, Production, Storage and Use Of Chemical Weapons and on their Destruction and in compliance with Argentina's ratification of CWC under Law 24.534 of August 9, 1995 restrict the export of: thiodiglycol, phosphorus oxychloride, phosphorus trichloride, hydrochloride dimethylamine, and sodium fluoride.*

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- *Through Resolution 823/01, signed on July 26, 2001, published July 31, 2001 in the Official Bulletin Argentina banned asbestos.*

According to Argentina's Chemical Weapons Law 26.247, that implements the Convention on the Prohibition of the Development, Production, Storage and Use of Chemical Weapons and on their Destruction (CWC) a list of chemicals is found therein, prohibiting substances that include chlordane, DDT, aldrin, arsenic, barium salts, PCBs, chlordane, dieldrin, hexacholocyclobenzene and white phosphorus.

### *Legal instruments*

Further there is an additional list of legislation acts

- *Decision No. 1929-1905 - Approves the "Guide for the Verification of Good Manufacturing Practices and Control for Household Hygiene Products Industries." - BO 14/04/05.*
- *Regulation No. 2335/02 (as amended by the Disp. 7841/04) - Approves the document "MERCOSUR Technical Regulation and Good Manufacturing Practices to Control Household Hygiene Products Industries" (GMC Resolution No. 23/01), and repealing Resolution GMC 30/97.- BO 21/06/02.*
- *Regulation No. 7596/00 - Amends Resolution No. 708/98 and No. ANMAT 7293/98. Timely forced companies registrants Sanitizing Products processors that were indirect (third party), to process their own National Register of Establishment, RNE, before the INAL-ANMAT. - BO 18/12/00.*
- *Resolution No. 708/98 - Registration of Establishments processors and importers of Sanitizing. - BO 10/09/98.*
- *Regulation No. 7293/98 - Register of household products. - BO 29/12/98.*

### *Sanitizing Product Registration - Prohibitions*

- *Regulation No. 3144/09 - Prohibits the consumer counter rodenticides and rodenticide pellets and grains. Only be permitted for OTC products in the form of solid paraffin or resin blocks. Should be dispensed to nose bag accompanied inaccessible to children and pets. Companies' registrants must submit laboratory tests to determine lethal dose fifty in rats performed in an official laboratory for proof of efficacy. Establishes the maximum concentrations of BO 07/02/09 Active Principles*

### *Sanitizing Product Registration*

- *Regulation No. 2013/10 - CLEANERS be incorporated, into national law, the Mercosur GMC Resolution No. 47/07 "MERCOSUR Technical Regulation Cleaning and Allied Products (GMC repeal of Resolution No. 10/04)." - BO 29/04/2010*
- *Regulation No. 2316/06 - Be incorporated into national law Mercosur GMC Resolution No. 24/05 MERCOSUR Technical Regulations "determining biodegradability of anionic" (complementation of the RES. GMC No. 25/96) "which is annexed and made part of the This arrangement BO 15/05/06*
- *Regulation No. 3314/05 - Registration Flowchart household products Risk II. - BO 17/06/05*
- *Regulation No. 4668/02 (as amended by the Disp. 6731/03) - Flowchart for the processing of applications for registration of products I. Risk - BO 09/10/02*
- *Provision No. 4377/01 (as amended by the Disp. 3361/02 and 2542/03) - Form for the export of food products for human consumption, raw materials for use in the food industry and household products. - BO 24/08/01*
- *Regulation No. 7292/98 (as amended by the Disp. 6254/09) - Requirements household products. - BO 29/12/98*
- *Resolution No. 709/98 - Sanitizing Product Registration. - BO 10/09/98*

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### Sanitizing Product Registration – Disinfectants

- *Regulation No. 3316/05 - Provision 3316/05 crop Prohibition of employment enterobacteria in formulating pesticide products domisanitary. - BO 17/06/05*
- *Regulation No. 3143/97 - Approval model labels for products with anticoagulants, setting deadlines for companies. - BO 31/07/97*

### Outsourcing Household Hygiene Products

- *Regulation No. 7725/06 - Be incorporated into national law Mercosur GMC Resolution No. 24/06 CONTRACTING SERVICES OUTSOURCING OF PRODUCTS MADE domisanitary MERCOSUR. BO 26/02/07.*

## 7. Non-regulatory mechanisms

As Argentina is a regular ICCA member, in the country some projects are carried out under different initiatives: Responsible Care, Global Product Strategy (GPS) and Product Stewardship.

For example, with regard to Responsible Care initiative CIQyP (La Cámara de la Industria Química y Petroquímica) is working towards harmonization of the Codes of Practice with the management systems used by industry and downstream to enable recognition of its Responsible Care Program by the local authorities and the Argentine Accreditation Organization (AAO).

Active Partners program including chemicals transporters, waste treatment and coatings companies – initial focus on chemicals manufacturers expanded in 1998 to cover transport of dangerous goods and the Responsible Care Program has 118 members: 53 chemical manufacturers, 48 transport companies, and 17 waste treatment companies that joined under a 2006 agreement with hazardous waste disposal association CAITPA.

Participating companies are periodically assessed through self- assessments, performance indicators and audits. Members use self-assessments as an implementation guide and tool to develop an improvement program – since 2005 audits have been conducted by external certification body IRAM, a member of ISO – verification checklist is in two sections: one for legal and documentary requirements and the other covering on-site facilities verification. Audits are adapted to company according to chemical manufacture, transporter or waste treatment, and evaluates improvement programs.

CIQyP plans to develop an online information management tool for companies. It also has discussions with RC companies underway to publicly report on worker health and safety.

## 8. Availability of data

In Argentina there are several inventories of dangerous prohibited or restricted substances (see the Table 3.15.2. below).

**Table 3.15.2. – Chemical inventories in Argentina**

<b>Name of inventory</b>	<b>Short description</b>
1. Agricultural Products and Byproducts - Prohibited Pesticides	This list includes pesticides that are regulated by the Argentinean Government and can not be used as pesticides for agricultural purposes.
2. Agricultural Products and Byproducts - Restricted Pesticides	This list includes pesticides that are regulated by the Argentinean Government and can be used only under the conditions described by the

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Name of inventory	Short description
	regulation.
3. Chemical Precursors and Regulated Essential Chemicals- List I	This list includes regulated chemical precursors and essentials chemicals under List I of the Argentinean Narcotics Decree.
4. Chemical Precursors and Regulated Essential Chemicals- List II	This list includes regulated chemical precursors and essentials chemicals under List II of the Argentinean Narcotics Decree.
5. Chemical Precursors and Regulated Essential Chemicals- List III	This list includes regulated chemical precursors and essentials chemicals under List III of the Argentinean Narcotics Decree.
6. Occupational Exposure Limits- Biological Exposure Indices (BELs)	This list contains a list of substances for which the government of Argentina has published a notice of intent to establish biological exposure indices (BEIs).
7. Occupational Exposure Limits- Carcinogens	This list contains the carcinogens as regulated by the Government of Argentina.
8. Occupational Exposure Limits-Ceilings (CMP-Cs)	This list contains the ceiling occupational exposure limits as regulated by the Government of Argentina.
9. Occupational Exposure Limits-Sensitizers	This list contains the substances regulated as sensitizers by the Government of Argentina.
10. Occupational Exposure Limits- Simple Asphyxiants	This list contains the substances regulated as simple asphyxiants by the Government of Argentina.
11. Occupational Exposure Limits- Skin Notations	This list contains the substances given the skin notation by the Government of Argentina.
12. Occupational Exposure Limits-STELs (CMP-CPTs)	This list contains the short term occupational exposure limits (STEL) as regulated by the government of Argentina.
13. Occupational Exposure Limits-TWAs (CMPs)	This list contains the time weighted average (TWA) occupational exposure limits as regulated by the Government of Argentina.
14. Substances Prohibited for Pesticide, Sanitation, or Household Use	This list identifies chemical compounds that can not be produced, import, commercialized, free acquisition and/or use of certain chemical substances or used as pesticide agents or for any other use involving sanitation reasons or household use, as regulated by the Argentinean Government.

## 9. Laboratory infrastructure

### *GLP*

The Argentine Accreditation Organization, AAO, is a private non-profit organization. It was established as part of a national system of standards, quality assurance and certification for performing the functions fixed in Regulation 1474/94. The AAO is recognized at the international level.

Argentina has joined the OECD system for the Mutual Acceptance of Data (MAD) in the Assessment of Chemicals. At the moment, the scope of Argentina's compliance monitoring programme is limited to non-clinical environment and health safety data developed in Argentina on

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pesticides, biocides and industrial chemicals, it is a full adherent country with respect to these types of chemicals. Argentina may add additional products to be covered by MAD in the future.

### **10. Response on emergency situations involving chemicals, including poisoning**

#### *10.1.GHS (Globally Harmonized System of Classification and Labelling of Chemicals)*

##### Law No. 22.802/83 (a General Law for Labeling)

As by Article 1 of Law No. 22.802/83 (supplemented by Resolution No. 252/00, published on November 7, 2000, and as amended by Law No. 26179, December 2006) of the Directorate of Fair Trade (Dirección de Lealtad Comercial) under the Secretariat of Industry within the Ministry of the Economy enacted: the label for domestically produced and imported products must include name of product, country of origin, quality, purity, blending description and net weight.

Article 2 states products manufactured domestically will be labeled with a statement “Industria Argentina”.

If the products have been manufactured with foreign raw materials, or any other elements that do not modify the nature of the product, it is still considered to be an Argentine product. Indication of the foreign origin of components in the final product is allowed; however, these indications must be less visible than the original labels.

Article 4 provides that all labeling of products must be in the Spanish language; but it is permitted for the label to contain other languages in addition to the information provided in Spanish.

Article 5 states that deceit or deliberate misrepresentation in relation to products is strictly prohibited.

Article 6 indicates that importers, manufacturers, and assemblers are responsible for failure mentioned in Article 5.

##### GHS at the workplace

Resolution 3359/2015 as of 29 September 2015 sets the timelines for the GHS Rev.5 implementation at the workplace. Corresponding Resolution N° 801/2015 (Resolución de la SUPERINTENDENCIA DE RIESGOS DEL TRABAJO (S.R.T.) N° 801) comes into effect on April 15, 2016 for substances and on January 1, 2017 for the mixtures.

##### Safety Data Sheets (SDS)

Chapter 17 (Articles 145-149) of Decree No. 351/79 of February 5, 1979 on Hygiene and Safety in the workplace requires that the workers must be informed about hazardous properties and safety measures to be taken during handling of substances and preparations at work.

As a rule the industry voluntarily follows international and national standards in the field (ANSI, ISO 1401) and provides SDSs when substances and preparations are marketed in Argentina.

SDSs should have 16 sections. Spanish is the preferred language for SDS.

IRAM 4140/2006 standard of October 2, 2006 (in line with GHS) is an identical adoption of ISO 11014 1:1994 Safety data sheet for chemical products.

##### Transport of dangerous goods

MERCOSUR countries (Argentina, Brazil, Paraguay, and Uruguay) are applying an agreement on the inland transport of dangerous goods (Acuerdo sobre Transporte de Mercancías Peligrosas en el MERCOSUR, 1994) which is based on the 7th revised edition of the UN Model Regulations and which is being updated on the basis of the 12th revised edition.

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### 10.2 Emergency response

Emergency Information Center for transportation of dangerous goods and wastes (CIPET) is established under the National Directorate of Civil Protection of Argentina Ministry of Interior. CIPET issues monthly bulletins presenting technical summary information on emergency response to different goods and hazardous wastes during transportation.

Article 35 of Decree 779/95 states that during the transportation of goods and wastes there must be in place the following documents: written instructions in emergency cases, emergency telephones of fire departments, law enforcement agencies, civil defense and environmental organizations. All transport vehicles have CIPET labelling with emergency toll-free number 0800-666-2282 available 24 hours. CIPET is directly connected to the central fire, police, gendarmerie, prefecture, hospitals, health centers across the country, civil defense, transport companies, shippers, crane rental companies and road machinery companies remediation, plus users of goods and hazardous wastes, what provides for quick response and timely eliminating of adverse effects. CIPET is in constant contact with twins information centers of MERCOSUR countries.

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## **T h e E u r o p e a n U n i o n**

Composed by Russian Federation  
NOT Reviewed by EU

### **I n t r o d u c t i o n**

The European Union (EU) is a politic-economic union of 28 European member-states. Legally, the EU was established in 1992 by the Maastricht Treaty.

The European Union is a common market of 28 countries, which is regulated by means of a standardized system of laws applying in all countries of the Union.

A full list of the member-states of the European Union as of 2017:

Austria, Belgium, Bulgaria, Great Britain, Hungary, Germany, Greece, Denmark, Ireland, Spain, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Finland, France, Croatia, Czech Republic, Sweden, Estonia.

As a subject of public international law, the Union is entitled to participate in the international relations and to conclude the international agreements.

EU countries for the benefit of their protection may optionally put in exceptions from REACH and CLP themselves in particular cases for certain substances in pure state or as part of a mixture or an article.

### **1 . R e g u l a t o r y o b j e c t s**

The scope of the regulation in the EU covers all substances, whether manufactured, imported, placed on the market, or used on their own or in mixtures: basic chemicals, agrochemicals and fertilizers, consumer products, drugs, foodstuff, medicinal products, diagnostic reagents, cosmetics, dietary supplements and household cleaning products.

In the EU, there is a comprehensive chemicals legislation, spearheaded by REACH Regulation and CLP, which aims to ensure a high level of protection of human health and the environment. Specific groups of chemicals, such as biocides, pesticides, pharmaceuticals or cosmetics, are covered by their own legislation. In addition, the European Commission is addressing the challenges posed by endocrine disruptors, chemicals that interfere with the hormone system causing adverse health effects.

The following are excluded from the scope of the REACH Regulation:

- *radioactive substances (covered by Directive 96/29/Euratom);*
- *substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to re-exportation or still in transit;*
- *substances used in the interest of defence;*
- *non-isolated intermediates;*
- *the transport of dangerous substances; and*
- *waste.*

The rules on registration, downstream users, evaluation and authorisation do not apply to substances used in medicinal products for human or veterinary use or in food or feedingstuffs (including additives) provided they fall within the scope of Community legislation on medicinal products or food. Registration is not needed for re-imported substances, recycled or recovered substances that have been already registered, low risk substances (Annex IV) and substances for which registration is not appropriate (Annex V).

### **2 . P a r t i c i p a n t s o f t h e r e g u l a t o r y s y s t e m**

At the moment by the agreements integrating all member -states on a common basis were formed the main principal and governing authorities of the EU, such as:

## The European Union

The **European Council** is the highest political body of the European Union, made of all the heads of state and government of Union's member states. The Council set out the main strategic directions of development of the EU.

The **European Parliament** has three major tasks: legislation, budgeting and monitoring of the European Commission. Since 1979 it is elected by the people. The main role of the European Parliament is the approval of the EU budget. Furthermore, almost any decision of the Council of the European Union requires either the approval of Parliament, or at least the request of its opinion. Parliament monitors the work of the Commission.

**Council of the European Union** along with the European Parliament is one of the two legislative bodies of the European Union.

**European Commission** is the executive body of the European Union. It is responsible for the implementation of the Union's decisions, monitoring of compliance with the law in the Member States. The Commission, if necessary, claims before the Court of the European Union against Member States for violation of membership obligations. The Commission plays a vital role in managing the day-to-day business of the EU, aimed at the upholding the basic treaties. It acts with legislative initiatives, and after the approval monitors their implementation. In case of violation of EU legislation, the Commission qualifies for invoke sanctions, including appeal to the European Court.

The Environment Directorate-General of the European Commission ('DG Environment') was set up in 1973 to protect, preserve and improve Europe's environment for present and future generations. It proposes policies and legislation that protect natural habitats, defend clean air and water, ensure proper waste disposal, improve knowledge of the toxicity of chemical substances, and help European businesses move towards a sustainable economy.

The DG also makes sure that Member States apply EU environmental law correctly. This means helping Member States comply with the legislation, and investigating complaints made by EU citizens and non-governmental organisations.

The Commission has the power to take legal action if it seems that EU environment law has been infringed.

DG Environment also represents the European Union in environmental matters at international meetings, including for instance the United Nations Convention on Biodiversity.

In international forums, the DG tries to agree international policies to stop the ongoing loss of biodiversity, reduce waste and air and water pollution, and strengthen the ecosystem services that make life on Earth possible.

The Environment DG is one of some 40 Directorates-General and services that make up the European Commission, which is the executive body of the European Union. The Commission is headed by the College of Commissioners, one from each of the 27 EU Member States.

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### *European Chemicals Agency (ECHA)*

The European Chemicals Agency:

- *manages all REACH, CLP, Biocides and PIC tasks by carrying out or co-coordinating the necessary activities;*
- *ensures a consistent implementation at Community level;*
- *provides Member States, European institutions and companies with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemical.*

The European Chemicals Agency is made up of different bodies. An Executive Director and a Management Board head it as effective corporate governance bodies.

The European Chemicals Agency comprises:

A Management Board, responsible for adopting the financial planning, work programme, and annual reporting of the Agency, inter alia.

The Management Board is composed of 36 members: one representative from each Member State appointed by the Council (28 members in all), three members representing the European Commission, two independent members appointed by the European Parliament and three representatives of interested parties appointed by the European Commission. The three interested parties are the European chemical industry, represented by the European Chemical Industry Council (CEFIC), environmental NGOs, represented by the Institute for European Environmental Policy (IEEP) and the European Trade Union Confederation. Although full members of the Management Board, the three interested parties' representatives do not have the right to vote.

The Management Board draws up the Agency's budget and oversees its implementation. It elects the Agency's Executive Director, the members of the Risk Assessment Committee and the Socio-Economic Analysis Committee, and the chairman, members and alternates of the Board of Appeal. The Management Board's remit also includes adopting the annual report, the Agency's annual and multiannual work programme, and the final annual budget. The Management Board is responsible for adopting the annual budget, work programme and report. It appoints the Executive Director of ECHA.

An Executive Director: the legal representative of the Agency, responsible for the day to day management and administration of the Agency, including responsibility over its finances.

A Member State Committee, to resolve differences of opinion on draft decisions proposed by the Agency or Member States and to make proposals for identification of substances of very high concern.

A Risk Assessment Committee, to prepare opinions on evaluation, on applications for authorisation, on proposals for restrictions and on classification and labelling.

A Committee for Socio-economic Analysis, to prepare opinions on applications for authorisation, on proposals for restrictions and on questions relating to the socio-economic impact of proposed legislative action.

A Forum on enforcement matters, to coordinate a network of Member State competent authorities responsible for enforcement.

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A Biocidal Products Committee, to prepare opinions on applications for approval and renewal of active substances, identification of active substances which are candidates for substitution, applications for inclusion in Annex I, applications for Union authorisation, scientific and technical matters concerning mutual recognition.

A Secretariat, under the leadership of the Executive Director, to support the Committees and Forum, and to undertake work on registration and evaluation processes as well as the preparation of guidance, maintenance of databases and provision of information.

A Board of Appeal, to decide on appeals against decisions taken by the Agency.

### Member states and competent authorities

ECHA works closely with the European Union Member States and the European Economic Area (EEA) countries Norway, Iceland and Liechtenstein. The Member State competent authorities cooperate with the Agency in its different processes.

The competent authorities designated under the different EU Regulations applicable to ECHA are ECHA's cooperation partners in the Member States. Many of them are ministries or agencies in the environmental sector. Some countries have also nominated organisations working with financial, health or labour issues to be responsible.

The competent authorities in the Member States (see Table 1 in Annex I) play a central role in ensuring the safe use of chemicals. They cooperate closely with ECHA and the European Commission. National authorities evaluate registered substances and are closely involved in adopting ECHA's evaluation decisions. Member States can propose restrictions for chemicals if their risks need to be addressed on EU level. They can also propose substances to be identified as potential substances of very high concern. Member States as well evaluate applications related to biocides.

ECHA and the Member State competent authorities have developed a common screening approach to systematically screen available information for substances in the REACH registration dossiers and other databases to identify substances for the following REACH and CLP processes:

- *Compliance check for dossier evaluation;*
- *Community rolling action plan (CoRAP) under substance evaluation;*
- *Potential further regulatory risk management measures under the REACH and CLP regulations i.e.:*
  - *Harmonised classification and labelling*
  - *Authorisation*
  - *Restriction*

The aim of this approach is to apply a common cross-process workflow to identify substances with certain hazard, exposure and risk profiles and process them using the most appropriate REACH or CLP process.

The enforcement of REACH and CLP Regulations is not made by ECHA. The national enforcement authorities (see Table 2 in Annex I) are responsible for making sure that companies comply with the chemicals legislation. The results of enforcement can be found on the website of the Forum for Exchange of Information on Enforcement.

### European Commission Directorates-General (DGs) and ECHA

While in contact with various Commission DGs, ECHA has close links with the DG for Internal Market, Industry, Entrepreneurship and SMEs (GROW) which is ECHA's official "partner DG", DG Environment (ENV) as well as DG Health and Food Safety (SANTE)

DG GROW is responsible for completing the internal market for goods and services and is implementing the industrial and sectorial policies to help turn the EU into a smart, sustainable and

## The European Union

inclusive economy. It also is the lead in administrative and budgetary matters, and support access to internationalisation.

DG ENV is together with DG GROW co-responsible for the implementation of the REACH and CLP Regulations. In addition, DG ENV is in charge of the PIC Regulation and leads EU activity regarding international chemicals policy (e.g. OECD, the Stockholm and Rotterdam Conventions, SAICM).

DG SANTE is responsible for the Biocides legislation and a number of scientific issue, such as criteria for endocrine disruptors.

ECHA also maintains close cooperation with the Commission's Joint Research Centre (JRC) with regard to issues including the risk assessment of nanomaterials; the Review Programme on the risk assessment of Biocides; and activities on the development and validation of alternatives to animal testing.

### The Council of the European Union and ECHA

As part of the EU's legislative branch, the Council of the European Union is responsible for decision on the content and final adoption of legislation governing and driving ECHA's work. This is done with the Parliament, through a process known as ordinary legislative procedure.

### The European Parliament and ECHA

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### The Commission of the European Union and ECHA

ECHA, as an EU agency, is governed by EU public law but operates independently from the EU Institutions (Council, Parliament, Commission etc.) and has its own legal personality. The Commission is, however, a crucial institutional stakeholder for ECHA and a partner in the implementation of its mandate.

As 'guardian of the Treaties', the Commission is responsible for the proper application of EU law, and hence also of ECHA's founding regulations, and executes a supervisory role for the use of public resources by the Agency, for example, by acting as the Agency's internal auditor. The Commission also holds three seats with voting rights on the Agency's Management Board and proposes three seats without voting rights for individuals from interested parties.

The Commission is responsible for updating and completing the EU Regulations defining ECHA's mandate (REACH/CLP/Biocides/PIC) and is charged with direct tasks connected to several of their processes, including taking decisions regarding the restriction of specific hazardous chemical substances; or identifying substances that should be subject to authorisation. It also decides upon the granting of authorisations under the REACH and Biocides Regulations.

Furthermore, the Commission can ask ECHA to prepare proposals for the restriction of chemical substances, or proposals for their identification as being of very high concern, and may also decide upon the identification of Substances of Very High Concern and on the evaluation of registration dossiers and substances, if no unanimous agreement can be reached by ECHA's Member State Committee.

In parallel to these tasks, the Commission also prepares implementing legislation necessary for the provisions to be put into effect, for example:

- *a regulation on fees, setting out the fees to be paid by industry for REACH and Biocides-related activities e.g. registration or authorisation applications;*
- *two regulations on the arrangements for the ECHA Board of Appeal; and*

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- *a regulation on test methods.*

More generally, the Commission is tasked with developing and negotiating proposals for EU policy on the management of risks and hazards from chemical substances, and may ask the Agency to provide scientific advice, including in support of the EU's international activities, in this regard.

In its implementation tasks, the Commission is assisted by Committees or other meetings composed of representatives from the Member States.

### Competent Authorities for REACH and CLP (E02385)

CARACAL is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP. CARACAL is composed of representatives of Member States competent authorities for REACH and CLP, representatives from competent authorities of EEA-EFTA countries as well as a number of observers from non-EU countries, international organisations and stakeholders.

### Other decentralised EU agencies

ECHA regularly cooperates with other decentralised EU agencies on issues of common interest, where this is of relevance to their respective mandates.

### Cooperation ECHA with accredited stakeholders

Any organisation if represent it's field of competence at EU level and have interested in closer cooperation with ECHA, is welcomed to apply to become an accredited stakeholder organisation (some criteria apply).

### Cooperation ECHA with accredited stakeholders

Cooperation with accredited stakeholders contributes to an efficient information flow both from the field to ECHA and vice versa. Accredited stakeholder organisations can support ECHA's work through various bodies and networks. 74 % of accredited stakeholders are associations representing industry (ECHA, 2017).

### Stakeholder consultation

The Commission engaged Member States and other stakeholders on the reviews, in most cases in a sub-group CARACAL, the Competent Authority Sub Group for the review of the Annexes of REACH (CASG (Annexes)).

### ECHA Stakeholders' Day

At the annual ECHA Stakeholders' Day participants have a chance to hear the latest news and updates from ECHA, European industry associations and NGOs, as well as to book one-to-one sessions with ECHA experts in the area of interest. At the ECHA Stakeholders' Day in April 2017 the main focus was made at the last REACH registration deadline in 2018.

### Awareness raising for key countries outside the EU

Non-EU authorities and industry, regularly request ECHA to host group visits and to deliver explanatory presentations on the EU regulations and ECHA's related work.

## **3 - 4 . Influences: National priorities and International activities**

Since 2006, when CEFIC in the ICCA's adoption of the non-binding SAICM agreement, Europe has been promoting action plans and policies that include, amongst others, the Integrated Product Policy (IPP) and Green Public Procurement (GPP).

Since 2007, the Registration, Evaluation and Authorization and Restriction of Chemicals Regulation (REACH) puts in place a comprehensive system and legislative framework for chemicals

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control in Europe. REACH requires firms, which manufacture and import chemicals to evaluate the risks resulting from the use of those chemicals and to take the necessary steps to manage any identified risk. Industry has the burden of proving that chemicals produced and placed on the market are safe.

The purpose of the regulation is to ensure a high level of protection of human health and the environment, and to strengthen the competitiveness of the chemicals sector and promote innovation.

The regulation of chemicals in Europe also occurs through the implementation of UN level agreements and conventions such as:

- *the Globally Harmonised System of Classification and Labelling (GHS) – in the form of the CLP Regulation,*
- *Sustainable Consumption and Production (SCP) programme known as the Marrakech Process.*

The Commission's Regulatory Fitness and Performance (REFIT) programme – a programme of legislation systematic evaluation in order to increase its effectiveness and efficiency. REFIT programme foresees checks of the chemicals regulations and REACH review.0

Also, following Conventions on chemicals regulation ratified by EU:

Convention	Note
<b>The Stockholm Convention on Persistent Organic Pollutants</b>	Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC
<b>The Montreal Protocol on Substances That Deplete the Ozone Layer</b>	This Protocol was adopted on 16 September 1987 at the Headquarters of the International Civil Aviation Organisation in Montreal. The Protocol came into force on 1 January 1989, when it was ratified by 29 countries and the EEC.
<b>The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal</b>	Critical uses are listed in the current Annex VI to Commission Regulation (EC) No. 1005/2009
<b>The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade</b>	EU Prior Informed Consent Regulation (PIC, Regulation (EU) 649/2012) places notification obligations on companies who wish to export certain hazardous chemicals to non-EU countries. Exporters have to notify the European Chemicals Agency (EHCA) of their intentions to export certain chemicals to a country outside the EU
<b>Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction</b>	COUNCIL COMMON POSITION 2007/469/CFSP of 28 June 2007 relating to the 2008 Review Conference of the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (CWC) All the Member States of the EU have ratified the Convention.
<b>The Minamata Convention on Mercury</b>	The EU signed the Minamata Convention on Mercury in October 2013 and thereby committed to ensure its ratification and implementation across the Union. The Commission adopted on 2 February 2016 a ratification package that will allow the EU to ratify the Convention once the legislative process is concluded. The foreseen Regulation on Mercury will repeal and replace Regulation (EC) 1102/2008.

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Convention	Note
<b>GATT/WTO</b>	<b>World Trade Organisation</b> - Contracting Parties: European Community, Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom <b>Authentic Texts</b> - English, French, Spanish
<b>Vienna Convention for the Protection of the Ozone Layer</b>	88/540/EEC: Council Decision of 14 October 1988 concerning the conclusion of the Vienna Convention for the protection of the ozone layer and the Montreal Protocol on substances that deplete the ozone layer
Inter-American Convention against Illicit Manufacturing of and Trafficking in Firearms, Ammunition, Explosives and Other Related Materials (CIFTA), 1997.	–
<b>United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol</b>	Council Decision 90/611/EEC of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.
<b>United Nations Convention on Psychotropic Substances, 1971</b>	Council Decision 90/611/EEC concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.
<b>United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988</b>	Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances. Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

### *National strategic documents, legislation on chemical regulations*

National governments and the EU have strict regulations on consumer and environmental protection, occupational health, chemical processes and transport of chemicals. As well as abiding by existing legislation, the chemical industry is committed to improving its management of chemicals and chemical processes through a combination of voluntary initiatives and specific action programmes, which are central to its commitment to Sustainable Development.

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This combination of key regulations, soft laws and voluntary initiatives governs our operations and is further developed hereunder.

### Regulations

The new EU chemicals legislation applies to all industry sectors dealing with chemicals and along the entire supply chain. It makes companies responsible for the safety of chemicals they place on the market.

### REACH

The REACH Regulation came into force on 1 June 2007 in the entire territory of the European Union. The goal of the new regulation is to ensure a high level of protection for human health and the environment and to make the European chemical industry more competitive.

After close to a decade's rancorous debate, REACH replaced over 40 old laws with a single streamlined regulation. The cornerstone of this reform is that it shifts the burden of proof from the Member States onto the industry. REACH says that manufacturers and importers must evaluate the risks of using chemicals, and must supply users with adequate safety information.

REACH regulates trade in and use of chemicals, but is buttressed by other EU laws purpose-designed to protect workers exposed to hazardous chemicals. Basically, these are the 1990 Carcinogens and Mutagens Directive, and the 1998 Chemicals Directive. Both of these have been carried over into national law in the 27 EU countries, and require employers to do a risk assessment and to take the requisite preventive and protective measures.

The Chemicals Directive sets indicative occupational exposure limit values (IOELVs) for hundreds of chemicals. These limits are not legally binding on States, which can continue to set them according to their national rules and practices. In practice, however, many States are bringing in binding national exposure limits based on IOELVs.

May 2018 is the final deadline under REACH for registering chemical substances manufactured or imported into the EU. Companies are also obliged by then to gather all available information about the properties of the substances and to update the safety data sheets.

More information on the REACH Regulation requirements can be found in the section 6 of this chapter.

### Connections with other EU legislation

Assessing hazardous chemicals under REACH is only one of the ways to control them. REACH provides a general approach to reducing dangerous chemicals in use across Europe. This is of course beneficial to the ambitions of other EU legislation:

- *Water Framework Directive. It was introduced in 2000. It establishes environmental quality standards for water across the EU. One aspect of this is to define the chemical pollutants of high concern. The Water Framework Directive can use the information provided through REACH in order to identify pollutants.*
- *European Pollutant Release and Transfer Register (E-PRTR). Water Framework Directive. Register was formed in 2006. It gathers environmental data sent from industrial facilities in the Member States. It covers nine economic sectors, one of which is the chemicals industry.*
- *Restriction of Hazardous Substances Directive (RoHS). It took effect on 1 July 2006. It restricts (with exceptions) the use of six hazardous materials in the manufacture of various types of electronic and electrical equipment.*
- *Waste Electrical and Electronic Equipment Directive (WEEE). Sets collection and recycling targets for electrical goods and is part of an initiative to reduce the large amounts of toxic electronic waste.*

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- *Plant protection products. EU legislation regulates the marketing and use of plant protection products and their residues in food.*
- *Legislation on specific chemicals (For example on fertilizers and detergents)*
- *Fluorinated greenhouse gases*

### CLP

CLP Regulation enforces GHS Recommendations at the EU territory. It ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals.

More information on the CLP Regulation can be found in the section 6 of this chapter.

### Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

The active substance / product-type combinations listed are all those for which an application for approval has been submitted under Directive 98/8/EC or Regulation (EU) No 528/2012, including "existing" active substances included in the Review Programme and "new" active substances.

### Prior Informed Consent Regulation

The Prior Informed Consent Regulation (PIC, Regulation (EU) 649/2012) administers the import and export of certain hazardous chemicals and places obligations on companies who wish to export these chemicals to non-EU countries. It implements, within the European Union, the Rotterdam Convention on prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

The section on chemicals subject to PIC includes all chemicals listed in the relevant annexes of the PIC Regulation. Chemicals listed in Part 1 of Annex I are subject to the export notification procedure; chemicals listed in Part 2 of Annex I, in addition to being subject to export notification procedure, qualify also for the PIC notification procedure. Chemicals listed in Part 3 of Annex I, are subject to the full PIC procedure under the Rotterdam Convention.

Annex V lists the chemicals and articles the use of which is prohibited in the European Union and which shall not be exported. Chemicals and articles listed in Part 1 of Annex V are subject to export ban and belong to the category of persistent organic pollutants; Part 2 of Annex V lists chemicals and articles subject to export ban other than persistent organic pollutants.

## 5. Parameters of regulation in EC

In the EU parameters of regulations are set by the legal acts, including such Regulations as REACH, CLP, BPR and PIC aimed at reducing risks that pose chemicals while circulation at the market.

SVHC Roadmap is one of the instruments used to reach this goal.

The ECHA has selected approximately 6 substances from the REACH registrations for further scrutiny by the Member State competent authorities (as of 21.12.2016). The competent authorities will carry out a manual examination of the dossiers to decide whether there is a need for regulatory action, such as compliance check, substance evaluation, harmonised classification and labelling, authorisation or restriction.

Member State competent authorities and ECHA conduct this exercise annually as part of the common screening approach. The aim of this collaborative effort is to identify substances that pose a

risk for human health or the environment and take them forward to the most appropriate REACH and CLP processes to ensure their safe use. The common screening approach is part of the SVHC Roadmap to 2020 implementation plan.

The SVHC Roadmap to 2020 anticipates the use of screening methods and risk management option analysis (RMOA) to identify the relevant substances of concern using information from the ECHA registration database, other REACH and CLP databases and additional relevant data. The SVHC Roadmap to 2020 lists certain groups of substances to be covered by the implementation plan:

- *Carcinogens, mutagens, reprotoxicants (Categories 1A/1B),*
- *Sensitisers,*
- *Persistent, bioaccumulative and toxic (PBTs) or very persistent, very bioaccumulative (vPvBs),*
- *Endocrine disruptors (EDs), and*
- *Petroleum/coal stream substances that are CMRs or PBTs.*

Each year, ECHA publishes a report on the progress of implementing the "SVHC Roadmap". The report(s), available in the links below, summarises the main achievements and activities carried out in the previous year and outline activities planned for the following year. The annual reports contain no substance specific information.

## 6. Key procedures for control of regulated objects

If not adequately controlled, chemicals with hazardous properties can cause substantial harm to the human organism and the environment. To tackle this situation, REACH requires that companies increase their knowledge about the chemicals they produce and pass that information on to their customers down the supply chain: to achieve the safe use of chemicals, many actors have a shared responsibility, that was made legally binding by the REACH and CLP Regulations.

### REACH.

REACH Regulation (EC 1907/2006) is the major chemical management framework in the EU. Its development and implementation has influenced a lot of other economies in terms of the chemical management regulatory changes. REACH aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances, assessment of their exposure and possible risks. This is achieved via the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

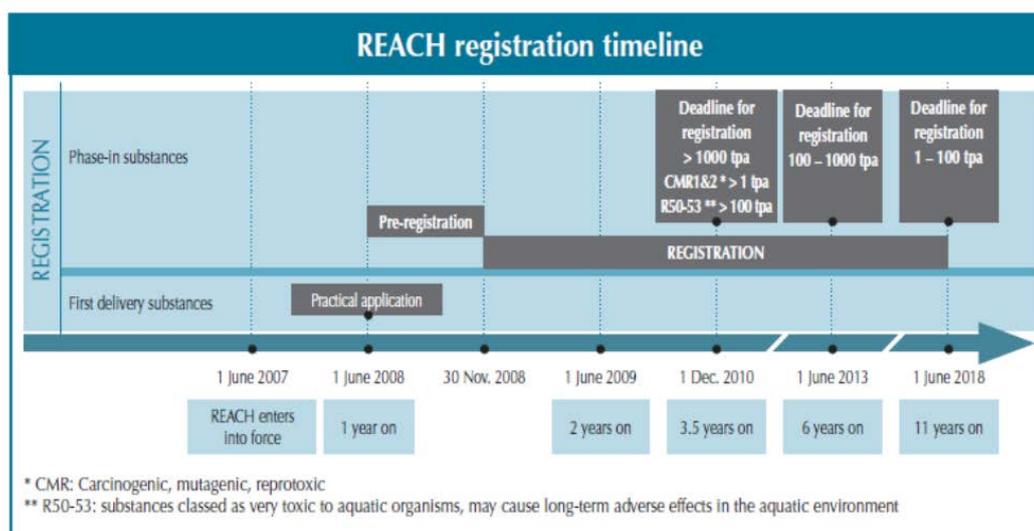
REACH regulation has introduced a "no data no market" approach. According to REACH, the responsibility lies on the industry to manage the risks from chemicals and to provide safety information on the substances down the supply chain. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database in ECHA. ECHA is the central point in the REACH system: it manages the databases necessary to operate the system, co-ordinates the in-depth evaluation of suspicious chemicals and is building up a public database in which consumers and professionals can find hazard information.

The Regulation also calls for the progressive substitution of the most dangerous chemicals (referred to as "substances of very high concern") when suitable alternatives have been identified.

One of the main reasons for developing and adopting the REACH Regulation was that a large number of substances have been manufactured and placed on the market in Europe for many years, sometimes in very high amounts, and yet there is insufficient information on the hazards that they pose to human health and the environment. A need was identified to fill these information gaps to ensure that industry is able to assess hazards and risks of the substances, and to identify and implement the risk management measures to protect humans and the environment.

Having entered into force in 2007, REACH provisions are being phased-in over 11 years. REACH registration timeline is reflected in the Figure 3.16.1.

**Figure 3.16.1. – REACH registration timeline**



### Registration

Registration is the key component of the REACH chemical management system. It is mandatory to register in a central database chemicals which are manufactured or imported in quantities of one tonne or more per annum. If a substance is not registered it cannot be produced or placed on the European market ("no data no market" approach).

Registration was made mandatory starting 1 June 2008, but transitional arrangements are envisaged till 1 June 2018 in some cases for certain substances which had to be pre-registered before.

Some groups of substances listed in the REACH Regulation are, however, exempt from the obligation to register, for instance:

- *polymers (however monomers which make up polymers must still be registered);*
- *some substances for which the estimated risk is negligible (water, glucose, etc.);*
- *naturally occurring and chemically unaltered substances;*
- *substances used in research and development, under certain conditions.*

Registration requires the industry (manufacturers and importers) to provide information on the properties and uses of chemicals and the precautionary measures to be taken when using them (technical dossier). The data required are proportional to the production volume of and the risks presented by the substance concerned (for example, extensive toxicity tests for substances manufactured or imported in quantities of more than 1000 tons per year). An application to register a substance which is imported or manufactured in a quantity of 10 tons or more per year must include a detailed description of the risks associated with that substance and the different possible exposure scenarios and risk management measures (chemical safety report).

There are lighter requirements for isolated intermediates, provided they are manufactured in strictly controlled conditions and for isolated intermediates which are transported and used under strict control in quantities of less than 1 000 tons per year. In these cases, only the classification, risk management measures and information already available on the properties are required. If more than 1 000 tons of the substance are being transported, further information is required.

Likewise, there are special arrangements for the registration of substances present in articles: given the millions of articles that are placed on the market in the EU and the potential risk some of them represent to human health and the environment, certain substances incorporated into articles must

be registered. Registration is compulsory when the substance in question is normally released when the article is used and is present in those articles in quantities totalling over one ton per producer or importer per year. For substances that are not normally released but which are particularly hazardous and are contained in a minimum concentration of 0.1% and placed on the market in quantities of over one tonne per producer or importer per year, simple notification is required, on the basis of which ECHA may request a registration.

ECHA is responsible for managing the database, receiving registration dossiers and developing technical guides aimed at helping manufacturers, importers and the competent authorities in implementing these provisions. During the first eleven years of application of the REACH system, around 30 000 substances already on the market should be registered. It is thought that about 80% of all registered substances will not need any further action.

At the current time there are preparations ongoing for successful registration under REACH 2018 deadline.

Apart from the general communication on REACH 2018 registration objectives and progress, ECHA has established a “one-stop-shop” for 2018 registrants on its website. The latter will provide a compilation of all the relevant documentation for the 2018 registration deadline in three layers of increasing complexity. Forthcoming improvements to ECHA’s scientific IT tools, processes and documents will be announced on the web pages.

### *Data sharing*

The Regulation lays down a number of rules on data sharing in order to reduce testing on vertebrate animals and to reduce costs to industry. Provision is made for relevant data to be shared between registrants in exchange for payment.

To the same end, the Regulation requires all registrants of the same substance to submit their applications for registration together (joint submission) except in cases where there are grounds for not doing so, to protect confidential information, in case of disagreement with other registrants, or where joint submission of an application for registration involves disproportionate costs.

### *Information communication in the supply chain*

Safety data has to be passed throughout the supply chain so that those using chemicals in their production process to manufacture other preparations or articles will be able to do so safely and responsibly, without endangering workers' or consumers' health and without putting the environment at risk. This requires information to be passed both up and down the supply chain, and between all actors in that supply chain via extended Safety Data Sheets. The data transmitted concern, inter alia, identification, composition and properties of the substances, the measures to be taken for use and transport without risk, the measures to be taken in case of fire or accidental release, and toxicological and ecological information. Sensitive information of a commercial nature does not have to be transmitted.

Downstream users must consider the safety of substances, based primarily on information from their suppliers, and to take appropriate risk management measures. These provisions also allow authorities to have an overview of the uses of a substance as it moves through the supply chain and, if necessary, to request further information and take appropriate measures.

### *Evaluation*

ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment.

Evaluation decisions are normally taken by ECHA, following a unanimous agreement in the ECHA Member State Committee (REACH, articles 51 and 52). If such an agreement cannot be

reached, the case is forwarded to the European Commission to prepare a draft decision, to be taken in accordance with the procedure referred to in Article 133(3) of REACH.

Evaluation makes it possible for the Agency to check that industry is fulfilling its obligations and avoiding tests on vertebrate animals when unnecessary. Two types of evaluation are provided for: dossier evaluation and substance evaluation.

Dossier evaluation is to be compulsory for any applications to carry out tests specified in Annexes IX and X to the Regulation (these are the most stringent tests, mostly involving the use of vertebrate animals). The aim is essentially to minimise the need for experiments of this kind. Dossier evaluation may also be carried out in order to check the conformity of a registration. The Agency is expected to carry out a thorough review of at least 5% of the dossiers filed.

If a substance is suspected of posing a risk to human health or the environment, the Agency will include this substance in a specific list and a designated Member State will carry out an evaluation in order to determine whether further information is required from the registrant.

The evaluation programme is developed by the Agency, in cooperation with the competent authorities.

Evaluation can lead to the following conclusions:

- *the substance must be subject to restriction or authorisation procedures;*
- *the classification and labelling of the substance must be harmonized at the EU level;*
- *information must be supplied to the other authorities so that they can adopt appropriate measures. For example, if, while the substance is being evaluated, information on risk management measures become available and could have an impact on the conditions of use of that substance, the information should be transmitted to the authorities responsible for this legislation.*

The MSC seeks unanimous agreement on Member State draft decisions on substance evaluation when amendments are proposed on them by other Member States or ECHA. The MSC takes into account the comments of the registrants on the proposed amendments to the draft decisions based on dossier and substance evaluations. Once agreed by the MSC, ECHA finalises the decision and provides it to the registrant.

The MSC provides opinions on:

A draft Community Rolling Action Plan (CoRAP) prepared by ECHA for substances to be evaluated by the Member States on the basis that the substances could pose a risk to human health or the environment.

Proposals from any Member State to add substances on CoRAP outside the annual updates.

On the basis of these MSC opinions, ECHA adopts the final CoRAP for substance evaluation.

The MSC also seeks agreement on cases where two or more Member States have expressed an interest in evaluating the same substance.

### *Authorisation*

Substances of extremely high concern may be subject to authorisation by the Commission with regard to particular uses. The objective is to ensure that the risks linked with these substances are validly controlled and that these substances are gradually replaced by other appropriate substances or technologies where this is economically and technically viable.

Substances of very high concern will be gradually identified in the 'Candidate list' and eventually might be included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used after a date to be set (the so-called "sunset date") unless the company is granted an authorisation.

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The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the authorisation procedure.

The Agency publishes and regularly updates a list of substances (list of candidate substances) identified as having characteristics of extremely high concern. These may include the following:

- *CMRs (carcinogens, mutagens and reproductive toxins);*
- *PBTs (persistent, bioaccumulative and toxic substances);*
- *vPvBs (very persistent and very bioaccumulative substances);*
- *some substances of concern which have irreversible serious effects on humans and the environment, such as endocrine disruptors.*

Companies may have immediate legal obligations following such inclusion which are linked to the listed substance on its own, in preparations and articles.

Further documentation or more detailed information on the identification process of substances of very high concern can be found on the web pages of ECHA's Member State Committee.

The inclusion of candidate substances on the list involves, under certain conditions, the requirement of information on the presence of this substance in the articles. After inclusion of this substance in Annex XIV to the Regulation any placing on the market and use of such chemical substances is subject to authorisation. This is granted if the risks arising from the substance in question can be validly controlled. If they cannot and if no alternative exists, the Commission is to assess the level of risk and the socio-economic advantages of using the substance and decide whether to authorise it or not. Some substances, such as PBTs and vPvBs can be authorised only if the socio-economic advantages override the risks and there are no alternatives.

The burden of proof is placed on the applicant. All authorisations must be reviewed after a certain period of time, determined on a case-by-case basis.

Downstream users may use a substance for an authorised use provided they obtain the substance from a company to which an authorisation has been granted and keep within the conditions of that authorisation. However, such downstream users must inform the Agency so that the authorities are fully aware of how certain substances of extremely high concern are being used.

At the moment Authorization list contains 31 unique substances (as of January 2016).

### Information on Candidate List substances in articles

The Information on Candidate List substances in articles contains the number of notifications, the article categories and the article types notified for use by consumers. It also contains the identified uses of the Candidate List substances where a registrant has linked the use to an Article Category in the use descriptor system.

The fact that an article contains an SVHC does not necessarily mean that consumers are exposed to it or that there is a risk for consumers.

Importers and producers of articles have to submit a notification to ECHA if a Candidate List substance is present in their articles above one tonne per year and in a concentration above 0.1% weight by weight. In some cases, in particular for articles produced in the EU, the use of the SVHC in articles will already have been covered in the registration dossier for the substance. In such cases, no separate notification by the article producer needs to be made to ECHA.

### Information on Candidate List substances in articles

This information provides examples of articles containing Substances of Very High Concern (SVHCs) that are included in the Candidate List, which are available for consumer use on the EU market. The data is based both on the notifications that companies have submitted to ECHA as well as on the information contained in the registration dossiers. Number of substances on the Candidate List substances in articles: 168 results (as of December 2016).

### *Restrictions*

REACH includes a restriction process for certain substances of very high concern if they pose an unacceptable risk to health or the environment. Such substances may be limited or even banned, if necessary. The restriction is designed to manage risks that are not addressed by the other REACH processes or by other Community legislation.

The restriction procedure provides a safety net, making it possible to manage the risks which are not adequately covered by other provisions of the REACH system. Proposed restrictions may relate to the conditions of manufacture, use(s) and/or placing on the market of a substance, or the possible prohibition of such activities, if necessary. They are suggested by Member States or by the Agency (at the Commission's request) in the form of a structured dossier and decided on by the Commission.

### REACH Annexes overview

#### Annex I

Annex I of REACH sets out the details of how to carry out a Chemical Safety Assessment and document it in a Chemical Safety Report (as a part of the registration dossier). The Annex has been supplemented by a technical guidance document on Information Requirements and Chemical Safety Assessment.

#### Annex II

Annex II describes what information should be included under each of the 16 headings of Safety Data Sheets (SDS).

Safety Data Sheets are an important element of hazard communication and provide a mechanism for transmitting appropriate safety information on classified substances and mixtures, and certain non-classified substances and mixtures, including information from the relevant Chemical Safety Report(s) down the supply chain to the immediate downstream user(s).

#### Annex IV

Annex IV sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACH as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties.

Substances included in Annex IV are exempted from registration (as well as downstream user requirements and evaluation) for all their possible uses irrespective of the tonnage in which they are manufactured or imported (currently or in the future). Originally, Annex IV essentially reproduced the list of substances exempt from the obligation to report information under the repealed Existing Substances Regulation (Regulation (EEC) No. 793/93).

The Commission agreed with the Member States and stakeholders a process for submission of proposals for amendments to Annex IV, criteria against which the proposals for amendment can be judged, documentation that should be provided and a timetable for completing this work. As part of the review, a study was commissioned to assess existing entries and proposals for amendments against those criteria.

As an outcome of the review, the Commission adopted the amendment of Annex IV (as well as Annex V) on 8 October 2008. Further details of the review process on these annexes are explained in a Commission Communication on Annexes I, IV and V and a related Staff Working Document as well as in the Final Report (Report, Appendix 1, Appendix 2, Appendix 3 from a contractor that was engaged by the Commission for the purposes of the review.

#### Annex V

Annex V of Regulation (EC) No. 1907/2006 (REACH) sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACH because registration is

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deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH.

Substances included in Annex V are exempted from registration (as well as downstream user requirements and evaluation) for all their possible uses irrespective of the tonnage at which they are manufactured or imported (currently or in the future). Annex V is mainly based on the reporting rules for the EINECS Inventory and reflects the experience in the operation of the Directive 67/548/EEC on classification, packing and labelling of dangerous substances, as collected in the Manual of Decisions (MoD) to this Directive. In addition, Annex V contains a number of changes made during the legislative procedure for the adoption of REACH.

The Commission undertook the review of Annex V, taking into account the comments received by Member States and stakeholders.

### Annex XI

Annex XI sets out the general rules for adaptation of the standard testing regime (waiving) specified in the information Annexes. Part 3 of Annex XI deals with substance-tailored exposure-driven testing for sections 8.6 and 8.7 of Annex VIII, Annex IX and Annex X, where, on the basis of the exposure scenario(s) developed in the Chemical Safety Report, testing may be waived.

### Annex XIII

Annex XIII sets out the criteria for the identification of PBT and vPvB substances; it does not apply to inorganic substances.

As mandated by Article 138(5), the Commission carried out a review of Annex XIII by 1 December 2008. Recital 76 requires the criteria in Annex XIII to be reviewed taking into account current and new experience in the identification of these substances and if appropriate to be amended with a view to ensuring a high level of protection of human health and the environment.

The experience reflected in the technical guidance document on Information Requirements and Chemical Safety Assessment, from the PBT working group under Regulation (EC) No 793/93 and Directive 67/548/EEC and from the Regulation 850/2004 on Persistent Organic Pollutants has been taken into account in the review of Annex XIII.

### Annex XVII

Annex XVII sets out the list of restrictions of the manufacture, placing on the market and use of certain dangerous chemical substances, mixtures and articles. The Annex contains the restrictions of the marketing and use of dangerous substances adopted since 1976 in the framework of Directive 76/769/EEC. In accordance with REACH Art. 141, Title VIII and Annex XVII came into force on 1 June 2009.

In consultation with all interested parties, the Commission carried out a revision of Annex XVII, to harmonise the terminology, to adapt the provisions to the definitions under REACH and to delete obsolete provisions.

The revised Annex XVII was adopted on 22 June 2009 and published on 26 June 2009.

### CLP

The REACH system is complemented by Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures. This Directive integrates the classification criteria and rules on labelling of the GHS with Community legislation and includes the REACH provisions governing the inventory of classifications and labelling.

The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals.

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Before placing chemicals on the market, the industry must establish the potential risks to human health and the environment of such substances and mixtures, classifying them in line with the identified hazards. The hazardous chemicals also have to be labelled according to a standardised system so that workers and consumers know about their effects before they handle them.

The harmonised classification and labelling for certain hazardous substances as set out in Tables 3.1 and 3.2 of Annex VI is also made available in the C&L Inventory.

CLP Regulation updating: Commission Regulation (EU) No 1297/2014 of 5 December 2014 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

The Regulation amends the CLP Regulation regarding additional provisions on outer and soluble packaging for liquid laundry detergents to ensure a better protection of the general public and especially young children and other vulnerable groups. The Regulation applies from 1 June 2015.

All hazardous chemicals (substances and mixtures) placed on the market must be classified, labelled and packaged according to the CLP Regulation (EC) No 1272/2008 by 1st June 2015.

The responsibility for labelling and packaging of hazardous substances and mixtures lies with:

- *manufacturers of substances,*
- *importers of substances or mixtures,*
- *formulators of mixtures, and*
- *distributors or Downstream Users, who do not reformulate or change the substances or mixtures but relabel/repackage them.*

### Exemptions from CLP

Waste and cosmetics, medicines, medical devices, veterinary products, foodstuffs or animal feed which are in their finished state, intended for the final user are not covered by the CLP Regulation.

Not all substances and mixtures classified and labelled according to the CLP Regulation require classification and labelling under the provisions of the transport of dangerous goods legislation, i.e. if they are not considered hazardous for transport.

Substance and mixtures which are not required to be classified and labelled under the provisions of the transport of dangerous goods need to still display CLP labels on the inner, intermediate and outer packaging.

This is an important new rule under the CLP Regulation as under the old rules, the outer packaging would previously have been left blank if transport rules did not apply, which meant that it was not apparent that a hazardous substance or mixture was being transported

Obligatory supplemental information includes hazard statements taken from the previous chemical legislation.

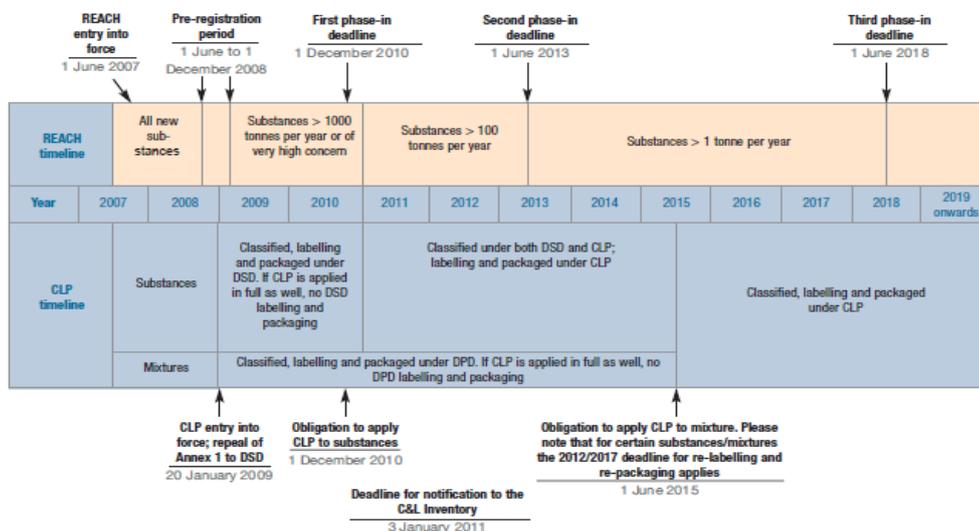
Non-obligatory supplemental labelling information, for example, instructions for use is not part of the legal labelling requirements under CLP. However, if provided it must not distract from nor contradict the obligatory label elements, hazard and precautionary statements. Statements such as 'non-toxic', 'non-polluting' may not be used on labels.

The hazard information on the label must be consistent with the classification in Section 2.1 and the label elements in Section 2.2 of the SDS provided for the same product.

The CLP Regulation is enforced by local authorities on all EU Member States (i.e. trading standards officers).

Implementation of the provisions of the CLP and REACH takes place almost simultaneously and connected time frames, as shown below, figure 3.16.2.:

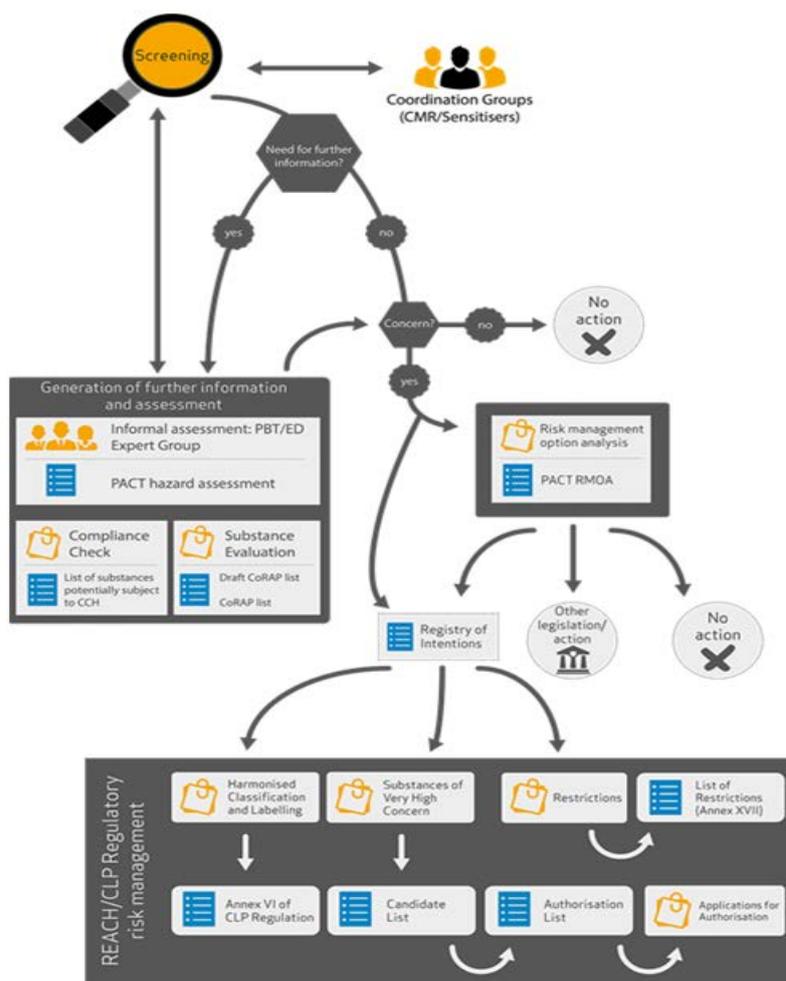
**Figure 3.16.2. – Implementation of the provisions of the CLP and REACH**



The figure 3.5.3. below displays the simplified version of how the activities and regulatory processes relate to each other. It also shows the various lists of substances that result from the work of the authorities and are published by ECHA on its website.

**Figure 3.5.3. – The simplified version of how the activities and regulatory processes relate to each other**

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\* information on regulatory processes and activities - yellow

\* substance lists - blue

## 7. Non-regulatory mechanisms

As EU is a regular ICCA member, in the country some projects are carried out protected by different initiatives: Responsible Care, Global Product Strategy (GPS) and Product Stewardship.

The global chemical industry's development and implementation of the Global Product Strategy and the Responsible Care® Global Charter is a measure of its commitment to product stewardship and an important part of its contribution to the SAICM.

### *Chemicals Health Monitor Project*

The Chemicals Health Monitor Project is a project of the Health and Environment Alliance in collaboration with other partner organisations across Europe. The project is aimed to contribute to the tools and structures necessary so that important health stakeholders can understand the REACH "labyrinth" and have their views about key decisions voiced. The project provides authoritative information (in a form accessible to the non-specialist public) to support measures to reduce harmful effects of hazardous chemicals on human health and the environment, and to choose safer alternatives.

### *Chemical Leasing Award*

Chemical Leasing is a service-oriented business model that shifts the focus from increasing sales volume of chemicals towards a value-added approach. The producer mainly sells the functions performed by the chemical.

### *CHEM Trust*

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CHEM Trust's mission is to prevent man-made chemicals from causing long term damage to wildlife or humans by ensuring that chemicals which cause such harm are substituted with safer alternatives. CHEM Trust aims to communicate widely the potential role chemicals play in generating adverse effects on wildlife and human health. It is working to raise awareness of the role chemical exposures may play in ill health, to improve chemicals legislation and to protect future generations of humans and wildlife.

### *SusCHEM (European Technology Platform Sustainable Chemistry)*

The European Technology Platform for Sustainable Chemistry seeks to boost chemistry, biotechnology and chemical engineering research, development and innovation in Europe. Chemistry is ubiquitous and is vital for the quality of modern life. More and better use of chemistry will enable European society to become more sustainable. This requires major chemical innovations and a successful and healthy EU chemical industry.

### *TEDX (The Endocrine Disruption Exchange, Inc.)*

TEDX is an organization that focuses primarily on the human health and environmental problems caused by low-dose and/or ambient exposure to chemicals that interfere with development and function, called endocrine disruptors.

## **8. Availability of data**

### *Information on chemicals in ECHA*

#### Information on Chemicals

This is unique source of information on the chemicals manufactured and imported in Europe. It covers their hazardous properties, classification and labelling, and information on how to use them safely. This information is a valuable resource for advancing the safe use of chemicals and for the replacement of the most hazardous ones by safer alternatives.

The Agency publishes on its website information on the chemicals that have been pre-registered and registered so far under REACH and their classification, labelling and packaging requirements.

ECHA's website also has information about biocidal substances and products.

#### REACH: Information on Chemicals

#### Registered substances information

The data comes from registration dossiers submitted to ECHA by the date indicated as last update. The Total Tonnage Band is compiled from all the dossiers with two exceptions; any tonnages claimed confidential and any quantity used as an intermediate to produce a different chemical. The Total Tonnage band published does not necessarily reflect the registered tonnage band(s).

All information about chemical properties of registered substances is directly accessible via eChemPortal. As up to April 2017 database contained 15469 unique substances and information from 58819 Dossiers.

As substances are registered under REACH, there is an obligation on registrants to provide information on the substances they manufacture or import. ECHA subsequently has the obligation to make certain of this information publicly available. On the website one can find a variety of information on registered substances: for example their hazardous properties, their classification and labelling and how to use the substances safely.

The data published is compiled from joint or individual submissions for a substance. Thus the search filters will be applied to compiled data from all of the registration dossiers submitted to ECHA. The data reflects the information contained in ECHA's databases as of the last updated date, and note

that not all data may be available for all substances. The total tonnage band for the compiled data is calculated from the non-confidential quantities of a chemical manufactured and / or imported by all registrants, excluding any quantity directly used as an intermediate to produce a different chemical. Therefore the total tonnage band published does not necessarily reflect registration tonnage band(s).

The amount of information provided can vary for different substances – information comes from companies' REACH registrations and the higher the production volume of the substance the more information companies need to provide.

The number of substances for which information is available in the database will increase over time as companies submit more registrations dossiers.

**Important Note on EC Numbers and List Numbers:**

Some substances returned via the search above did not previously have an EC Number assigned, or were contained in a dossier for which a registrant did not indicate the existing assigned EC Number. These substances may have been assigned a List Number by ECHA.

The EC numbers and List Numbers in the dissemination database and in the lists above come from the following sources (Table 3.16.1.).

**Table 3.16.1. – Correlation between EC numbers and source inventories**

EC Number	Source	Status
2xx-xxx-x	EINECS (European INventory of Existing Commercial chemical Substances) List	Official
3xx-xxx-x	EINECS (European INventory of Existing Commercial chemical Substances) List	Official
4xx-xxx-x	ELINCS (European LIst of Notified Chemical Substances) List	Official
5xx-xxx-x	NLP (No-Longer Polymers) List	Official
6xx-xxx-x	Automatically assigned to substances identified only with a CAS No.	Not Official
7xx-xxx-x	Assigned manually to validated substances from inquiries by ECHA	Not Official
8xx-xxx-x	Automatically assigned to substances identified only with a CAS No. (continuation of the 6xx-xxx-x series)	Not Official
9xx-xxx-x	Automatically assigned to substances without a CAS No. or other numerical identifier	Not Official

Note: List Numbers do not have any legal significance; rather they are purely technical identifiers for processing a submission via REACH-IT.

**Information from the Existing Substances Regulation (ESR)**

Before REACH entered into force, chemicals were regulated by a number of different regulations and directives, such as the Council Regulation (EEC) No 793/93. It introduced a comprehensive framework for the evaluation and control of "existing substances" (substances on the market before 1982).

The ESR stated that the Commission, in consultation with the Member States, would regularly draw up lists of priority substances which require immediate attention because of their potential effects to human health or the environment. Between 1994 and 2007 (the entry into force of REACH), four such priority lists were published, with a total of 141 substances.

The risk assessments were performed by the Member States for each of the 141 substances listed in the four priority lists.

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### Pre-registered substances

These pre-registration intentions were submitted to ECHA between 1 June and 1 December 2008. This list is used to find other potential registrants of your substance so that you can submit a registration dossier jointly, as required by REACH.

### EC Inventory

The EC inventory published below is a copy as received from the JRC in 2008 on the founding of ECHA. It is comprised of the following lists:

**EINECS** (European INventory of Existing Commercial chemical Substances) as published in O.J. C 146A, 15.6.1990. EINECS is an inventory of substances that were deemed to be on the European Community market between 1 January 1971 and 18 September 1981. EINECS was drawn up by the European Commission in the application of Article 13 of Directive 67/548/EEC, as amended by Directive 79/831/EEC, and in accordance with the detailed provisions of Commission Decision 81/437/EEC. Substances listed in EINECS are considered phase-in substances under the REACH Regulation.

**ELINCS** (European LIst of Notified Chemical Substances) in support of Directive 92/32/EEC, the 7th amendment to Directive 67/548/EEC. ELINCS lists those substances which were notified under Directive 67/548/EEC, the Dangerous Substances Directive Notification of New Substances (NONS) that became commercially available after 18 September 1981.

**NLP** (No-Longer Polymers). The definition of polymers was changed in April 1992 by Council Directive 92/32/EEC amending Directive 67/548/EEC, with the result that substances previously considered to be polymers were no longer excluded from regulation. Thus the No-longer Polymers (NLP) list was drawn up, consisting of such substances that were commercially available between 18 September 1981 and 31 October 1993.

### Dossier Evaluation decisions

This section on ECHA website contains the non-confidential versions of the decisions originating from compliance checks and examination of testing proposals (the two dossier evaluation processes). Decisions can be searched by evaluation process, decision number, the date on which the decision was issued. Additionally the search can be based, solely, on the substance name, EC or CAS number when these data are public.

By publishing the dossier evaluation decisions, ECHA increases the transparency of its process, and offers registrants and third parties an opportunity to follow and increase their insights in the evaluation processes of compliance check and testing proposal examinations.

Before publication of the decision, ECHA consults the addressees on the non-confidential version it intends to publish. ECHA notes that any personal data are removed and that the published documents represent decisions with blanked out sections that have been claimed confidential by the registrant and which were deemed to harm their commercial interest if disclosed. The decisions are only available in their original language.

### Testing Proposals Consultation Substance Evaluation - CoRAP

If a substance is on this list, it means that a member state has evaluated or will evaluate it over the coming years. The list is called the Community Rolling Action Plan (CoRAP).

For each substance, the table shows the evaluating MS, the (planned) year of evaluation and a short description of the concern which led to it being placed on the list.

Documents to do with substance evaluation are also available here. They include: decisions to request more information; Member States' conclusions and Member States' final evaluation reports for substances added to the list. Since 2013, documents justifying selection of the substances are also included.

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In 2017 CoRAP list for the years of 2017-2019 was published.

### PACT – RMOA and hazard assessment activities

The Public Activities Coordination Tool (PACT) lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB properties or endocrine disruptor properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.

The PACT is updated monthly to show the new substances being selected by authorities for RMOA or hazard assessment and to inform about the outcome of these preparatory steps and on the suggested follow-up.

Only substances undergoing PBT/vPvB or endocrine disruptor assessment in the REACH context are listed in the PACT. PBT/vPvB or endocrine disruptor assessments carried out under other legislations are not included in the PACT. If a substance is undergoing hazard assessment under the substance evaluation process and discussed in the PBT or endocrine disruptor expert groups, this is shown in the 'Follow up' column of the PACT table with the text 'Substance evaluation under development'.

PACT lists 371 substances (as of April 2017).

### Information on Candidate List substances in articles

This information provides examples of articles containing SVHCs that are included in the Candidate List, which are available for consumer use on the EU market. The data is based both on the notifications that companies have submitted to ECHA as well as on the information contained in the registration dossiers. As up to date of 31 March 2015, it contained 155 results.

This information is to be updated approximately every six months. It contains non-confidential information from notifications. Additional non-confidential data from the registration dossiers can be found in the registered substances database.

- *Candidate List of Substances of Very High Concern for Authorisation*
- *Substances requiring Authorisation*
- *Substances restricted under REACH*
- *Public Activities Coordination Tool (PACT)*

### CLP

### C&L Inventory

This database contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonised classifications. The database is refreshed regularly with new and updated notifications. However, updated notifications cannot be specifically flagged because the notifications that are classified in the same way are aggregated for display purposes.

Classifications derived from joint submissions to the REACH registration process are flagged accordingly.

C&L Inventory contains entries on 124 581 substances (as of December 2016).

### BPR

The summary table lists all active substance / product-type combinations for which an application for approval has been submitted under Directive 98/8/EC (BPD) or Regulation (EU) No 528/2012 (BPR), including "existing" active substances included in the Review Programme and "new" active substances, and those already "approved" and those where the application is on-going ("under review").

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The information in the tables is presented for information purposes only and may not be entirely accurate, for example due to time-lags. Usage of the information in the table remains under the sole responsibility of the user. ECHA does not accept any liability with regard to the use that may be made of the information contained in the table.

- *Biocidal Active Substances*
  - *Biocidal Products*
  - *List of active substance and suppliers*
- Information on Chemicals**

Database contains 789 active substance-product type combinations for which approval has been sought (as of April 2017).

### *PIC*

The section on chemicals subject to PIC includes all chemicals listed in the relevant annexes of the PIC Regulation. Chemicals listed in Part 1 of Annex I are subject to the export notification procedure; chemicals listed in Part 2 of Annex I, in addition to being subject to export notification procedure, qualify also for the PIC notification procedure. Chemicals listed in Part 3 of Annex I, are subject to the full PIC procedure under the Rotterdam Convention.

Annex V lists the chemicals and articles the use of which is prohibited in the European Union and which shall not be exported. Chemicals and articles listed in Part 1 of Annex V are subject to export ban and belong to the category of persistent organic pollutants; Part 2 of Annex V lists chemicals and articles subject to export ban other than persistent organic pollutants.

In addition, other chemicals have been identified that are also subject to the PIC Regulation, as they are members of chemical groups which are explicitly listed in Annex I or V. These chemicals, which are not themselves explicitly listed in a PIC Regulation Annex, are shown in italics.

It is possible to search for chemicals based on the Annex and part of the Annex they are listed under, EC and CAS number, chemical name and use category. It is also possible to refine the query by using multiple search filters.

### *SIN List*

The European Commission has stated that the SIN List is a major driver for innovation, and the United Nations Environment Programme has highlighted the SIN List as a useful tool for chemical hazard assessment and chemical and product prioritisation.

Another example of SIN List recognition was how , Janez Potocnik, the European Commissioner for Environment at the time, a few days after the launch of the SIN List 2.0 in 2011 stated that "the recently published second edition of the SIN list, which also includes substances with endocrine disrupting properties, should indicate to you the substances the European Commission will take into consideration for placement on the candidate list."

The following 32 substances have been identified as endocrine disrupting chemicals for the SIN List. This is currently the most well-founded list available of REACH relevant EDCs. These 32 EDCs require immediate action.

In the SIN List database [www.sinlist.chemsec.org](http://www.sinlist.chemsec.org) you can find much more information on each chemical including links to substitution case stories. 912 substances are listed on the list (as of April 2017).

*RISCTOX database* of hazardous substances that provides information on over 100,000 chemical agents. It provides clear, organized and concise information about health and environmental risks caused by chemicals contained in products generally used or handled by companies. This database has been developed by ISTAS - CC.OO. in cooperation with European trade union institute.

RISCTOX database include data on classification of the substance according to Regulation 1272/2008 (CLP):

- *Classification of the substance according to Regulation 1272/2008 (CLP)*
- *Specific health risks*
- *Specific environmental risks*
- *Environmental and health-related regulations*

### **9. Laboratory infrastructure**

#### *Good Laboratory Practice (GLP)*

The principles of GLP promote the quality and validity of data generated in the testing of chemicals and prevent fraudulent practices.

The EU has concluded Mutual Recognition Agreements for GLP with Israel, Japan, and Switzerland. The European Regulations and Directives also apply to Iceland, Liechtenstein, and Norway.

#### *Product oriented legal acts*

The principles of GLP are applied to the non-clinical safety testing of test items contained in a range of products. The application of GLP is required by a variety of different product-specific legislation.

#### **EU legislation/regulations on GLP: Directive 2004/10/EC (GLP)**

Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances is one of the two core EU GLP Directives together with Directive 2004/9/EC. It contains the principles of GLP in its Annex I.

Article 1(1) of the Directive requires that "Member States shall take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Directive 67/548/EEC, comply with the principles of good laboratory practice (GLP)". Directive 67/548/EEC is the Dangerous Substances Directive, which is repealed by the CLP Regulation (listed below) from 1 June 2015.

Article 1(2) specifies that this requirement "shall apply also where other Community provisions provide for the application of the principles of GLP in respect of tests on chemical products to evaluate their safety for man and/or the environment." These other provisions are listed in this document.

Article 13.4 of REACH Regulation (EC) No 1907/2006 requires that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency.

Annex XI of REACH (general rules for adaptation of the standard testing regime set out in annexes VII to X) provides for some exemptions for existing data in case that testing does not appear scientifically necessary, ECHA being a receiving authority.

Recital 30 of Regulation (EC) No 648/2004 states that tests specified for the biodegradability of surfactants should be carried out in laboratories meeting an internationally recognised standard, namely EN ISO/IEC17025 or the principles of good laboratory practice.

Article 5(2) on the granting of derogation states that applications for derogation shall include a technical file supplying all the information and results of tests necessary for evaluating the safety aspects related to the specific use of surfactants in detergents failing to comply with the biodegradability limits. The tests shall be carried out on the basis of an approach defined in a technical

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guidance document, which will specify those tests for which the principles of good laboratory practice should be applied.

Article 7 on the testing of surfactants requires that tests on detergents shall be conducted in compliance with EN ISO/IEC standard or the principles of good laboratory practice, except for those tests for which the principles of good laboratory practice have been made mandatory.

Article 8(2) on the duties of Member States requires that each Member State shall notify to the other Member States and to the Commission the list of approved laboratories that are competent and authorised to carry out the tests required by Regulation (EC) No 648/2004. Member States have to demonstrate the competence of the above laboratories according to the standard EN ISO/IEC 17025 or verify the compliance of these laboratories with the principles of good laboratory practice.

Annex I defines standards of accreditation, good laboratory practice and animal protection concerning the laboratories that are competent and authorised to provide the necessary service for checking compliance of detergents with the requirements of this Regulation and its Annexes.

Regulation (EC) No 1271/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures aligns previous EU legislation on classification, labelling and packaging of chemicals to the GHS (Globally Harmonized System of Classification and Labelling of Chemicals).

Article 8.4 requires that where the manufacturer, importer or downstream user carries out new ecotoxicological or toxicological tests and analyses, these shall be carried out in compliance with Article 13(4) of Regulation (EC) No 1907/2006 (REACH), which establishes that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (see above).

Article 8.5 requires that where new tests for physical hazards are carried out for the purposes of this Regulation, they shall be carried out, at the latest from 1 January 2014, in compliance with a relevant recognised quality system or by laboratories complying with a relevant recognised standard.

For these tests for physical hazards, ECHA Guidance on the Application of the CLP Criteria (November 2013) specifies that the requirement in Article 8.5 can be interpreted as follows:

1. *Compliance with the principles of good laboratory practice (GLP) (as formerly required by the DSD);*
2. *Application of EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories as amended as a relevant recognised standard;*
3. *Other internationally recognised standards of comparable scope.*

See links to National Web Sites on Good Laboratory Practice in table:

Country	Link
Austria	Federal Office for Safety in Health Care <a href="http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/">http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/</a> Federal Ministry for Agriculture, Forestry, Environment and Water Management <a href="http://www.lebensministerium.at/article/archive/30425/?SectionIDOverride=110">http://www.lebensministerium.at/article/archive/30425/?SectionIDOverride=110</a>
Belgium	Scientific Institute of Public Health <a href="http://www.GLP.be">http://www.GLP.be</a>
Czech Republic	Centre for Assessment of Laboratories (ASLAB) <a href="http://www.aslab.cz/spravna-laboratorni-praxe">http://www.aslab.cz/spravna-laboratorni-praxe</a> State Institute for Drug Control <a href="http://www.sukl.cz">http://www.sukl.cz</a>
Denmark	Danish Medicines Agency <a href="http://laegemiddelstyrelsen.dk/en/topics/authorisation-and-supervision/company-">http://laegemiddelstyrelsen.dk/en/topics/authorisation-and-supervision/company-</a>

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	<a href="#">authorisations/toxicological-and-pharmacological-trials/glp</a> The Danish Accreditation and Metrology Fund – DANAK <a href="http://webtool.danak.dk/Plone/">http://webtool.danak.dk/Plone/</a>
Finland	Finnish Medicines Agency <a href="http://www.fimea.fi/frontpage">www.fimea.fi/frontpage</a>
France	AFSSAPS <a href="http://www.afssaps.fr/content/search?SearchText=BPL">http://www.afssaps.fr/content/search?SearchText=BPL</a> anses <a href="http://www.anmv.anses.fr/">http://www.anmv.anses.fr/</a> Groupe interministériel des produits chimiques (GIPC) <a href="http://www.industrie.gouv.fr/enjeux/gipc.htm">http://www.industrie.gouv.fr/enjeux/gipc.htm</a>
Germany	German GLP Federal Bureau <a href="http://www.bfr.bund.de/cd/1488">http://www.bfr.bund.de/cd/1488</a>
Greece	General Chemical State Laboratory <a href="http://www.gcsf.gr/index.asp?a_id=136">http://www.gcsf.gr/index.asp?a_id=136</a>
Hungary	National Institute of Pharmacy <a href="http://www.ogyi.hu">http://www.ogyi.hu</a>
Ireland	Irish National Accreditation Board <a href="http://www.inab.ie">http://www.inab.ie</a>
Italy	Italy GLP Monitoring Authority <a href="http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=italiano&amp;tema=Dispositivi%20medici%20e%20altri%20prodotti&amp;area=buona%20pratica%20laboratorio">http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=italiano&amp;tema=Dispositivi%20medici%20e%20altri%20prodotti&amp;area=buona%20pratica%20laboratorio</a>
Netherlands	Health Care Inspectorate <a href="http://www.igz.nl/english/">http://www.igz.nl/english/</a>
Norway	Norwegian Accreditation <a href="http://www.akkreditert.no/">http://www.akkreditert.no/</a>
Poland	Bureau for Chemical Substances and Preparations <a href="http://www.chemikalia.gov.pl/index.php?id_language=2">http://www.chemikalia.gov.pl/index.php?id_language=2</a>
Portugal	Instituto Nacional da Farmacia e do Medicamento <a href="http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH">http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH</a>
Slovak Republic	Slovak National Accreditation Service (SNAS) <a href="http://www.snas.sk/index.php?l=en&amp;p=19&amp;ps=69">http://www.snas.sk/index.php?l=en&amp;p=19&amp;ps=69</a>
Slovenia	National Chemicals Bureau <a href="http://www.uk.gov.si/en/areas_of_work/good_laboratory_practice/">http://www.uk.gov.si/en/areas_of_work/good_laboratory_practice/</a>
Spain	Agencia Española de Medicamentos y Productos Sanitarios <a href="http://www.agemed.es">http://www.agemed.es</a> Entidad Nacional de Acreditacion <a href="http://www.enac.es">http://www.enac.es</a>
Sweden	Swedish Board for Accreditation and Conformity Assessment <a href="http://www.swedac.se/sdd/System.nsf/(GUIview)/index_english.html">http://www.swedac.se/sdd/System.nsf/(GUIview)/index_english.html</a>
European Commission	DG Enterprise <a href="http://ec.europa.eu/enterprise/sectors/chemicals/specific-chemicals/laboratory-practice/index_en.htm">http://ec.europa.eu/enterprise/sectors/chemicals/specific-chemicals/laboratory-practice/index_en.htm</a>

## 10. Information sharing

### 10.1. Implementation of the GHS

European occupational safety and health directives transposed into the national legislation of the Member States set minimum standards of protection for workers. The Framework Directive (89/391/EEC) lays down the obligation of the employers to evaluate the risks to the safety and health of workers, among others those arising from the chemical substances or preparations used. It contains

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the general principles of prevention, the elimination of risks and accident factors, the informing, consultation and balanced participation and training of workers and their representatives.

SDSs are a well-established and effective mechanism for transmitting appropriate safety information along the supply chain on substances and mixtures which meet specific classification criteria. The requirements for SDSs were already in place before the REACH Regulation entered into force but the Regulation further developed these requirements.

The original requirements introduced by REACH have been further adapted to take into account the rules of the GHS for safety data sheets and the implementation of the CLP Regulation.

The content and format of an SDS within the EEA is defined in Annex II to the REACH Regulation. The SDS follows a 16-Section format, which is internationally agreed, and to be provided in the official language of the Member State(s) where the substance or mixture is placed on the market.

The SDS is normally first compiled by the manufacturer or importer or Only Representative (or by someone on their behalf), but the requirements of REACH in relation to the provision of SDSs apply at each stage of the supply chain. A supplier of a substance or mixture, which fulfills specific conditions, must provide an SDS for it, regardless of his position in the supply chain. When compiling their own SDSs, each of the actors along the supply chain should check the adequacy of the SDS received from his supplier and use all the relevant information to compile his own SDS.

Each actor remains responsible for the accuracy of the information in the SDS they provide.

It should be kept in mind that the compilation of a good SDS requires extensive knowledge in different fields, as the SDS itself covers a wide range of aspects concerning the substance or mixture properties, occupational health and safety, transport safety and environmental protection. REACH indicates that the SDS should be compiled by a “competent” person, but no specific definition of “competent” in this context is given in the Regulation.

REACH establishes specific criteria for when an SDS must be provided for a substance or a mixture. An SDS must be provided for a substance or mixture that meets the criteria for classification as hazardous on the basis of the criteria established by the CLP Regulation.

Furthermore, the obligation to provide an SDS also applies to substances which are considered to be PBT or vPvB according to Annex XIII to REACH or are included in the Candidate List of substances for possible inclusion in the Authorisation List.

When the substance or mixture does not meet the criteria for classification as hazardous, the supplier is not obliged to provide an SDS for this substance or mixture. Nevertheless, if a mixture contains classified substances, substances that are PBT or vPvB or a substance included in the Candidate List above a certain threshold specified in the REACH Regulation or substances which have Community workplace exposure limits, the customer is entitled to request an SDS and the supplier has the obligation to provide it. Only a downstream user (industrial or professional user) or a distributor has the right to request an SDS for a mixture meeting the above mentioned criteria.

When hazardous substances or dangerous mixtures are also offered or sold to the general public, an SDS does not need to be supplied. To rely on this exemption however, the supplier must provide “sufficient information to enable the user to take all necessary measures as regards the protection of human health, safety and the environment”. REACH does not specify how this safety information should be provided, hence the supplier can choose the most suitable means according to the case and the recipient (e.g. by labelling or with product inserts).

For some mixtures REACH provides a general exemption from the need to supply information covered by Title IV “Information in the supply chain”, including the provision of SDSs. The mixtures which benefit from such an exemption are such that are in the finished state, intended for the final user, and that belong to specific categories for which other pieces of legislation exist and an overlap with

REACH requirements should be avoided (e.g. medicinal products, cosmetic products and food and feeding stuffs).

Certain substances are not in the scope of the REACH Regulation (radioactive substances, substances under customs supervision, non-isolated intermediates, products during carriage by rail, road, inland waterway, sea or air, etc.) and therefore again the SDS-related obligations do not apply.

The SDS must be provided free of charge, no later than when the substance or the mixture is first supplied. It can be provided on paper or electronically. In every case, it is a duty of the supplier to actually deliver the SDS to the recipient. This means, for instance, that to only make it available on a web page is not sufficient.

SDSs for substances or for mixtures containing substances that have been registered under REACH are required to include:

- *Registration numbers where appropriate*
- *Exposure Scenarios including any risk management measures required, in an Annex to the SDS for hazardous substances registered at >10 tonnes/year. Any actor required to prepare a CSR including exposure scenarios has to attach the relevant exposure scenario(s) to the SDS.*

An exposure scenario describes how a substance can be manufactured or used in a safe way and should refer to the uses identified in the SDS itself. In practice, the exposure scenario(s) extend(s) the information given in the main body of the SDS.

Downstream users and other actors who need to supply an SDS for a substance or mixture, but are not required to prepare a CSR, have to consider and include relevant safe use information sourced from exposure scenario(s) received from their supplier(s) when compiling their SDS(s).

They can either attach the relevant exposure scenarios to the SDS, integrate relevant exposure information in the body of the SDS (i.e. Sections 1 – 16 of the SDS) or append safe use information for the mixture derived from the exposure scenarios of the component substances.

By contrast with the case for an SDS, the format of the exposure scenario is not fixed by the legal text. One available supporting tool to generate a suitable format is the Chemical Safety Assessment and Reporting tool, Chesar, which generates exposure scenarios ready to be annexed to the SDS.

Certain situations require the update and re-issue of the SDS:

- *as soon as new hazard information or information that may affect the risk management measures becomes available*
- *once an authorisation under REACH has been granted or refused*
- *once a restriction under REACH has been imposed*

When any of the above three situations apply, suppliers must provide updated safety data sheets to all the former recipients to whom they have supplied the substance or mixture to within the preceding 12 months.

There is a lot of information for downstream users of chemicals on the ECHA website. One can find this information using interactive map prepared by ECHA and on webpage Downstream Users of Chemical Co-ordination group (DUCC).

Suppliers must label a substance or mixture contained in packaging according to CLP before placing it on the market either when:

- *A substance is classified as hazardous.*
- *A mixture contains one or more substances classified as hazardous above a certain threshold.*

CLP defines the content of the label and the organisation of the various labelling elements. The label includes:



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- *The name, address and telephone number of the supplier*
- *The nominal quantity of a substance or mixture in the packages made available to the general public (unless this quantity is specified elsewhere on the package)*
- *Product identifiers*

A hazard label must contain the following elements applicable to the substance or mixture placed on the market:

- *name, address and telephone number of the EU supplier(s),*
- *product identifiers e.g. chemical name and CAS/EC no. of the substance/trade name of a mixture along with the chemical name(s) of all substances responsible for classification of the mixture (excluding skin and eye irritants),*
- *hazard pictogram(s): A hazard pictogram is an image on a label that includes a warning symbol and specific colours intended to provide information about the damage a particular substance or mixture can cause to our health or the environment. The pictograms are in line with UN GHS.*

Pictograms are in the shape of a red diamond with a white background, and will replace the old orange square symbols which applied under the previous legislation. Since 1 December 2010, some substances and mixtures have already been labelled according to the new legislation, but the old pictograms can still be on the market until 1 June 2017. Until then, one may find detergents, lamp oils or other products labelled with either the orange or white pictogram at the local supermarket in the EU or on the shelves of the hardware store.

- *hazard statement(s) In addition to the pictograms, the label contains an explanation of what it means (hazard statement). The same pictogram might have multiple hazard statements associated with the effects that the substance or mixture might cause. There are also precautionary statements on the label, which indicate how to handle the product safely and what measures you should take if you are exposed to the product by accident. The label also contains a "signal word" that indicates the severity of the damage a product may cause: 'Danger' for more severe damage and 'Warning' for less severe.*
- *nominal quantity (when the chemical is supplied to the general public), and*
- *supplemental information.*

### *10.2. Response on emergency situations involving chemicals, including poisoning*

EU Member States are mainly individually responsible for responding to public health and other major emergencies within their borders. The EU's role in the field of public health, as established by the Treaty on the Functioning of the EU, is limited to complimenting the national policies of the EU Members, coordinating their actions, and facilitating communication and the exchange of data between the European Commission and the EU Members.

The European Centre for Disease Prevention and Control (ECDC) plays a vital role in the surveillance, identification, assessment, and communication of current and/or emerging threats to human health in the EU. The ECDC has assumed operation of the Epidemiological Surveillance Network and the Early Warning and Response System (EWRS), both of which were established in 1998 to enhance the EU's ability to respond to public health emergencies.

The EU has also established two committees to assist the Commission when a scientific opinion is needed: (a) the Scientific Committee on Emerging and Newly Identified Health Risks, and (b) the Scientific Committee on Health and Environmental Risks.

Alert notifications are sent either by the Commission or the national authorities to the EWRS when a serious cross-border threat is unusual or unexpected for the specific place where it originated and has the potential to lead to significant morbidity and mortality in humans (or grows larger), affects more than one Member State, and may require a coordinated response at the Union level.

A new decision, Decision No. 1082/2013 on Serious Cross-Border Threats to Health, expands the list of sources of danger to health to include not only communicable diseases but also biological, chemical, and environmental events, or events of unknown origin that may pose a risk to EU citizens.

Article 2 of Decision No. 1082/2013/EU on Serious Cross-Border Threats to Health, issued in 2013, recognizes the following categories of serious cross-border threats to health, which may trigger public health measures, including threats of chemical origin and threats of environmental origin.

EU Members have the right to maintain or introduce additional measures and procedures to tackle serious threats to health due to biological, chemical, environmental, or unknown origin within their borders.

### B I B L I O G R A P H Y & R E F E R E N C E S

1. *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance).* <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20150601>
2. *Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).* <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A02008R1272-20150601>
3. *The 6th Adaptation to Technical Progress (ATP) amends Annexes III, IV and V to the CLP Regulation in accordance with Annexes I, II and III to Regulation (EC) No 605/2014. The amended Annexes III and IV shall apply in respect of substances from 1 December 2014 and in respect of mixtures from 1 June 2015. The amendment to Annex V shall apply from 1 April 2015. See article 2 of this Regulation for derogations to these dates.* <http://sportedu.ru>
4. *Seventh adaptation to technical progress. Commission Regulation (EU) No 2015/1221 of 24 July 2015 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.* <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1221&from=EN>
5. *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.* <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20140425&from=EN>
6. *Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals.* <http://sportedu.ru>
7. *Commission delegated regulation (EU) No 1078/2014 of 7 August 2014 amending Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals.* <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:EN:PDF>
8. *Guidance on the compilation of safety data sheets, ECHA, version 3.1, november 2015.* [http://echa.europa.eu/documents/10162/13643/sds\\_en.pdf](http://echa.europa.eu/documents/10162/13643/sds_en.pdf)
9. *Guidance on Information Requirements and Chemical Safety Assessment. The Guidance consists of two major parts: Concise guidance (Part A to F) and supporting reference guidance (Chapters R.2 to R.20).* <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

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11. *Guidance for downstream users. Version 2.1 October 2014.* [http://echa.europa.eu/documents/10162/13634/du\\_en.pdf](http://echa.europa.eu/documents/10162/13634/du_en.pdf)
12. *Guidance for identification and naming of substances under REACH and CLP. Version: 1.3 February 2014.* [http://echa.europa.eu/documents/10162/13643/substance\\_id\\_en.pdf](http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf)
13. *Guidance on registration. May 2012 Version 2.0 Guidance for the implementation of REACH.* [http://echa.europa.eu/documents/10162/13632/registration\\_en.pdf](http://echa.europa.eu/documents/10162/13632/registration_en.pdf)
14. *Guidance on data sharing. Version 2.0 April 2012.* [http://echa.europa.eu/documents/10162/13631/guidance\\_on\\_data\\_sharing\\_en.pdf](http://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf)
15. *Guidance on the preparation of an application for authorisation. Version 1 January 2011.* [http://echa.europa.eu/documents/10162/13637/authorisation\\_application\\_en.pdf](http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf)
16. *Guidance on the preparation of socio-economic analysis as part of an application for authorisation. Version 1 January 2011.* [http://echa.europa.eu/documents/10162/13643/sea\\_authorisation\\_en.pdf](http://echa.europa.eu/documents/10162/13643/sea_authorisation_en.pdf)
17. *Guidance on the communication of information on the risks and safe use of chemicals. Version 1 December 2010.* [http://echa.europa.eu/documents/10162/13639/risk\\_communications\\_en.pdf](http://echa.europa.eu/documents/10162/13639/risk_communications_en.pdf)
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21. *OECD Guidelines for the Testing of Chemicals.* [http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals\\_chem\\_guide\\_pkg-en](http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en)
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23. *NEW FORMAT FOR SAFETY DATA SHEETS, CEFIC, 31 July 2015.* <http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/A-new-format-for-SDS-31-July-2015.pdf2>
24. *The ESCOM Package → Version 2.0 now available!. Key process for the successful implementation of REACH. CEFIC.* <http://www.cefic.org/Industry-support/Implementing-reach/escom/>
25. *Principles for Balanced Transparency of Regulatory Data in the European Union. CEFIC. September 2014.* [http://www.cefic.org/Documents/PositionPapers/Cefic\\_Position-Paper-Inter-association-Transparency-principles\\_Sept%202014.pdf](http://www.cefic.org/Documents/PositionPapers/Cefic_Position-Paper-Inter-association-Transparency-principles_Sept%202014.pdf)
26. *How to prepare a downstream user chemical safety report. ECHA/NA/15/27.* [http://echa.europa.eu/view-article-/journal\\_content/title/how-to-prepare-a-downstream-user-chemical-safety-report](http://echa.europa.eu/view-article-/journal_content/title/how-to-prepare-a-downstream-user-chemical-safety-report)
26. *CSR/ES roadmap. A cross-stakeholder plan of actions to 2018.* [http://echa.europa.eu/documents/10162/15669641/csr\\_es\\_roadmap\\_en.pdf](http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf)
27. *Welcome To The CEFIC ERICards Database.* [http://www.ericards.net/psp/ericards.psp\\_search?p\\_lang=1](http://www.ericards.net/psp/ericards.psp_search?p_lang=1)

**T h e R e p u b l i c o f T u r k e y**

Composed by Russian Federation  
NOT Reviewed by Turkey

## 1. Regulated objects

Under legislation of Turkey the regulated objects are substances and mixtures. According to the article 4 of Chemical Inventory and Control Regulation a substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. A mixture means a mixture or solution composed of two or more substances.

## 2. Participants of regulatory system

The responsible agencies in the field of chemicals management in Turkey are The Ministry of Environment and Urbanization (the main authority that is responsible for the regulations on chemicals and environmental protection), Ministry of Forestry and Water Affairs, , Ministry of Health, Ministry of Agriculture and Rural Affairs, Ministry of Labor and Social Security, Ministry of Transportation, Ministry of Industry and Trade, Undersecretariat of Foreign Trade and Undersecretariat of Customs and others. Their powers and responsibilities are outlined in the table 3.17.1. below.

**Table 3.17.1. - Institutional framework of Turkey**

<b>Government Institution</b>	<b>Duties with regard to chemicals management</b>
The Ministry of Environment and Urbanization (MoEU) ( <a href="http://www.csb.gov.tr">http://www.csb.gov.tr</a> )	collecting data regarding the chemicals supplied to the market; setting the classification, packaging and labeling rules; ensuring the preparation of safety datasheets; carrying out restriction and prohibition procedures; performing risk assessments; management of hazardous waste handling activities; setting the environmental standards adapted to the circumstances of Turkey; monitoring the pollutants persistent in air, water and soil; establishing laboratories to perform all types of analyses, measurements and controls; and carrying out inspections; KKDIK drafting
MINISTRY of HEALTH (MoH) ( <a href="http://disab.saglik.gov.tr">disab.saglik.gov.tr</a> )	activities relating to the market offer of biocidal products and detergents, provide services for the protection of public health as well as laboratory-based services
MINISTRY of FOOD, AGRICULTURE and LIVESTOCK (MFAL) ( <a href="http://www.tarim.gov.tr">www.tarim.gov.tr</a> )	control and inspect plant protection products and chemical fertilizers
MINISTRY of LABOUR and SOCIAL SECURITY (MLSS) ( <a href="http://www.csgb.gov.tr">www.csgb.gov.tr</a> )	developing labor health and safety standards and norms for the workplaces where chemicals are used and identifying the vocational training needs establishes methods and principles concerning the necessary measures to ensure the efficient and continual prevention of the major industrial accidents in the facilities in which PCDD/Fs can be formed as by-products of processes (together with the Ministry of Environment and Urbanization)
MINISTRY of TRANSPORT MARITIME AFFAIRS and COMMUNICATION (MoTMAC) ( <a href="http://www.ubak.gov.tr">www.ubak.gov.tr</a> )	regulating and implementing the principles and procedures governing the transportation of chemicals, within the framework of the management of chemicals

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Government Institution	Duties with regard to chemicals management
MINISTRY of CUSTOMS and TRADE (MCT) (www.gtb.gov.tr)	performing the necessary activities under the Chemical Weapons Convention and taking the necessary legal and administrative measures to protect consumer rights.
Undersecretariat of Customs (UoC)	control the entry and exit of chemicals subject to customs procedures and to prevent their illegal trading.
Undersecretariat of Foreign Trade (UoFT) (www.ekonomi.gov.tr)	establish the general principles and procedures governing the import/export of chemicals as well as market regulation and supervision
Ministry of Forestry and Water Affairs (former MINISTRY of ENVIRONMENT and FORESTRY (MoEF) ) <a href="http://www.ormansu.gov.tr/">http://www.ormansu.gov.tr/</a>	Drinking water quality monitoring

Other important participants of the regulatory system are Research Centers and Institutes. TUBITAK Marmara Research Center (MRC), which was founded in 1972, aims at becoming World leader in science and technology manufacturing using its research, development and innovation capabilities seven Institutes exist, each with broad area of competence. These Institutes are: Environment and Clean Production Institute, Energy Institute, Genetic Engineering and Biotechnology Institute, Food Institute, Chemistry Institute, Materials Institute and Earth and Marine Sciences Institute.

Major Chemicals Industry Institutions in Turkey with their main area of activities are listed in the table 3.14.2. below.

**Table 2 - Major Chemicals Industry Institutions in Turkey**

Industry Institution	What They Do
Türkiye Kimya Sanayicileri Derneği – TKSD (Turkish Chemical Manufacturers Association) (www.tksd.org.tr)	TKSD holds discussions and negotiations with government authorities and the representatives of the Turkish chemical industry both nationally and internationally.
Kimyagerler Derneği – KİMYAGER (The Chemist Society) (www.kimyager.org)	KİMYAGER organizes seminars and panels in universities and within industrial entities in order to create a highly skilled workforce in the industry.
Türkiye Kimyagerler Derneği - TKD Turkish Chemical Society (www.turchemsoc.org)	TKD has been in operation since 1919. The society has many objectives including supporting cooperation between foreign and Turkish institutions and providing up-to-date information on every subject within chemicals industry.
TMMOB Kimya Mühendisleri Odası – TMMOB Chamber of Chemical Engineers (www.kmo.org.tr)	The Chamber consists of 12 representatives in various cities in Turkey and aims to protect natural resources, create growth in agricultural production, protect the rights of consumer and contribute to the development of chemical engineering.
Türk Plastik Sanayicileri Araştırma, Geliştirme ve Eğitim Vakfı - PAGEV Turkish Plastics Industry Foundation (www.pagev.org.tr)	PAGEV follows the latest developments in plastics production techniques throughout the world. Its main aim is help the sector conform to world standards and to contribute to the development of local plastics production.
Boya Sanayicileri Derneği - BOSAD The Association of Paint Industry	BOSAD mission is to contribute to the development of the Turkish paint and coatings industry, to increase national

Industry Institution	What They Do
(en.bosad.org)	paint consumption, to provide consumers with modern and eco-friendly products, and to contribute to the EU integration process on a sectorial basis.
Gübre Üreticileri ve İthalatçıları Derneği - GÜİD Association for Fertilizer Producers and Importers (www.guid.org.tr)	GÜİD raises awareness of problems within fertilizer production as well as covering issues regarding import and export by organizing seminars and fairs in Turkey. Moreover, it ensures proper adaptation of the sector to the regulations published by EU and local regulations.
Temizlik ve Kozmetik Ürünleri Sanayicileri Derneği - KTSD The Association of Cosmetics and Cleaning Products Industrialists (www.ktsd.org.tr)	KTSD's mission is to support the development of the cosmetics and cleaning products industry in Turkey as well as to ensure consumers' access to healthy, reliable and high-quality products by raising overall awareness.
Plastik Sanayicileri Federasyonu - PLASFED Turkish Plastics Industrialists' Federation (www.plasfed.org.tr)	PLASFED's mission is to inform the industry about subjects that include regulations, taxes, technology, employment, personnel, health and safety. It oversees plastics production so it is sustainable and eco-friendly as well as creating public awareness for this process.

### 3 - 4 . Influences : National Priorities and International Activities

As a EU candidate country, Turkey national priorities are lying in the field of preparation for EU membership and correspondingly aligning current national legislation with EU legislative system.

In December 2008, Turkey enacted the Inventory and Control of Chemicals Regulation, a scaled-down version of the European Union's REACH regulation to establish an inventory of chemicals produced and imported into Turkey and to better control potential risks posed by those chemical substances.

At the same time with harmonization with EU legislation the government has launched a strategic action plan for the chemical industry in order to reduce the industry's import dependency. Import control system under the Regime on Technical Regulations and Standardization for Foreign Trade in Turkey plays an important role and has been subject to modifications since 2004 with the aim of harmonization of EU technical legislation. In this regard, the "Decree of Council of Ministers on the Regime on Technical Regulations and Standardization For Foreign Trade" and the legislation published based on the mentioned Decree was reviewed in order to enable the relevant EU legislation to be implemented in Turkey at the import stage. On the other hand, after the transposition of relevant product-specific EU directives into Turkey's legal order, Turkey started to perform import checks of certain product groups such as toys and personal protective equipments, machinery, low voltage equipment, pressure equipments according to the rules applicable in the new system. Furthermore, all products on the market no matter whether they are imported or not, are subject to market surveillance activities executed by responsible public authorities. As a result of these activities, products bearing serious risks should be withdrawn from the market. Below is a list of some related regulatory acts:

- *Communiqué On Inspection for Conformity to Standards on Import (Product Safety and Inspection: 2015/1)*
- *Communiqué on Import Inspection of Wastes that are under control relating to protection of environment (Product Safety and Inspection: 2015/3)*
- *Communiqué on Import Inspection of Chemicals that are under control relating to protection of environment (Product Safety and Inspection: 2015/6)*

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- *Communiqué on Import Inspection of Solid Fuels that are under control relating to protection of environment (Product Safety and Inspection: 2015/7)*
- *Communiqué on Import Inspection of Certain Products which are required to bear "CE" Marking (Product Safety and Inspection: 2015/9)*
- *Communiqué on Import Inspection of Toys (Product Safety and Inspection: 2015/10)*
- *Communiqué on Import Inspection of Batteries and Accumulators (Product Safety and Inspection: 2015/15)*
- *Communiqué on Commercial Quality Inspection on Export and Import for Certain Agricultural Products (Product Safety and Inspection: 2015/21)*
- *Communiqué on the Classification of the Firms with the Purpose of Risk Based Commercial Quality Controls of Exports (Product Safety and Inspection: 2015/22).*

The work on the international conventions and protocols regarding chemicals management is executed under the coordination of the Ministry of Environment and Urbanization. Turkey has joined the numerous international agreement and conventions whose objective is to protect human health and the environment (see table 3.17.3. below).

**Table 3.17.3. - Status of ratifications of some international conventions**

<b>Conventions</b>	<b>Status of Ratifications in Turkey (yes/no)</b>	<b>Ratification, Acceptance (A), Approval (AA), Accession (a)</b>	<b>Remarks</b>
The Stockholm Convention on Persistent Organic Pollutants	yes	14/10/2009	–
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	yes	22/06/1994	Entry into force: 20/09/1994
The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade	no	–	Date of signature: 11/09/1998
Vienna Convention for the Protection of the Ozone Layer and The Montreal Protocol on Substances That Deplete the Ozone Layer	yes	20/09/1991 (a)	On 16th September 2009, the Vienna Convention and the Montreal Protocol became the first treaties in the history of the United Nations to achieve universal ratification
Kyoto Protocol to the United Nations Framework Convention on Climate Change	yes	28/05/2009 (a)	Entry into force: 26/08/2009
Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction	yes	12/05/1997	Date of signature: 14/01/1993 Entry into Force: 11/06/1997
The Minamata Convention on	no	–	Date of signature:

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Conventions	Status of Ratifications in Turkey (yes/no)	Ratification, Acceptance (A), Approval (AA), Accession (a)	Remarks
Mercury			24/09/2014
The Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972 (London Convention)	no	–	

### 5. Parameters of regulation

To evaluate the current regulatory status as well as predict the direction of future development the regulatory bodies of Turkish Republic use different types of regulation indicators. The indicators that most clearly reflect the current state of the chemical industry are export/import volumes.

Located close to large and growing trade markets, Turkey has significant export potential. Turkey's export volume in the chemicals industry reached USD 17.5 billion in 2013, with Egypt, Iraq and Germany being the major chemical export markets. Turkey's goal for 2023 with regard to chemicals exports is USD 50 billion. The sector aims to account for a 9.17 percent share in Turkey's total exports. Quantitative targets for 2023 as regards exports in some of the sub-sectors of the industry include the following:

- *Organic and inorganic chemicals: USD 5.9 billion*
- *Paints and raw materials: USD 2.5 billion*
- *Soaps, detergents, cosmetics: USD 3.3 billion*
- *Plastics and rubber products: USD 23.3 billion*

The government has also launched a strategic action plan for the chemical industry in order to reduce the industry's import dependency. Currently Turkey is the 6th largest paint producer in Europe. The paints and coatings, plastics and rubber and inorganic chemicals sectors are significant suppliers to the construction, automotive and textile industries, which are already growing sectors in Turkey and the region, while demand for these industries is expected to grow by 4 percent and 5 percent respectively by 2018. Turkey's plastics sector is the 3rd largest in Europe after Germany and Italy, producing USD 30 billion/7.2 million tons of plastics per year. Turkey aims to be the top producer in the European plastic sector in 2016. Home and personal care giants have been active in Turkey for decades thanks to the rising middle-class and a population of 76 million.

The chemical industry, together with the sub-industries such as plastics and rubber, employs nearly 200.000 people and has about 6,2 thousand companies manufacturing various chemicals. Very small percentages of the existing companies have more than 150 employees. Most of the companies in the chemical industry, especially private sector companies, are located in Istanbul, Izmir, Kocaeli, Sakarya, Adana, Gaziantep and Ankara.

### 6. Key procedures for control of regulated objects

#### *Prohibition of certain chemicals*

By-law On Restrictions And Prohibitions Of Hazardous Substances And Mixtures No. 27092 was enforced on December 26, 2008. Last revision (No. 29182) was on November 27, 2014. It is similar to EU REACH restriction list but with a much narrower scope. Currently only a small number of chemicals are banned or restricted by this regulation:

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- a) *Banned (can not be manufactured, used or placed on the market)*
- 1) *Asbestos*
  - 2) *Polychlorinated terphenyls (PCT)*
  - 3) *Polychlorinated biphenyls (PCB)*
  - 4) *Polybromobiphenyls (PBBs)*
- b) *Restricted*
- 1) *Azo colourants & Azo dyes*
  - 2) *Some Phthalates (DEHP/DBP/BBP/DINP/DIDP/DNOP)*
  - 3) *Tris (2,3 dibromopropyl) phosphate*
  - 4) *Tris (aziridinyl) phosphine oxide*
  - 5) *Mercury, Cadmium and Nickel and their compounds*
  - 6) *Lead Carbonates, Lead Sulphates*
  - 7) *Arsenic Compounds*
  - 8) *Organostannic Compounds*
  - 9) *Pentachlorophenol*
  - 10) *PFOS*
  - 11) *Nonylphenol*

### *Notification of substances*

There are two Regulations which correspond to notification process of chemicals in Turkey Republic:

- *Chemical Inventory and Control Regulation (CICR) No. 27092 (Bis) which was published on December 26, 2008 and entered into force on January 1, 2009. It was amended on November 10, 2009 (No 27402) and May 23, 2010, Regulation No. 27589.*
- *SEA Regulation- By-Law on the Classification, Labelling and Packaging of Substances and Mixtures No. 28848 – CLP implementation of Turkey which was published on December 11, 2013 and comes into force on the date of publication.*

Under scope of the CICR, companies are required to notify the requested data to the Information System of the Ministry of Environment and Urbanization, for chemical substances manufactured in Turkey or imported to Turkey either itself or in mixtures in quantities 1 tonne per year. There are a few exemptions that could apply:

- *substances, which are subject to custom supervision in transit, provided that they do not undergo a treatment or processing;*
- *substances manufactured or imported for use in military purposes;*
- *substances that naturally occur in nature, which are not chemically modified;*
- *basic natural chemical substances about which sufficient information is available;*
- *chemicals listed in Annex-I Part 3 (Annex IV of REACH);*
- *polymers (OECD & REACH Polymer definition).*

Any imported substance which is not an exception has to be notified within 12+3 months from the first date of import in Turkey. The set of the data which should be submitted to the information system under the CICR notification depends on the tonnage thresholds:

- a) *1-1000 tons per year – only basic information needs to be provides:*
- 1) *Name of substance with EC and CAS number;*
  - 2) *Quantity of the substance manufactured or imported;*
  - 3) *Classification and labelling;*
  - 4) *Information on uses.*
- b) *More than 1000 tons per year – the scope of the information is relatively extensive:*
- 1) *Name of substance with EC and CAS number;*
  - 2) *Quantity of the substance manufactured or imported;*

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- 3) *Classification and labelling;*
- 4) *Information on uses;*
- 5) *Data on the physic-chemical properties;*
- 6) *Data on pathways and environmental fate;*
- 7) *Eco-toxicity properties;*
- 8) *Data on acute and sub-acute toxicity;*
- 9) *Data on carcinogenicity, mutagenicity and/or toxicity for reproduction;*
- 10) *Any other information relevant to the risk evaluation of the substance.*

Submitted data should be updated in the following cases:

- *Threshold changes of notified substances;*
- *Changes in the classification and/or use of notified substances;*
- *Changes in the LE details of the importers such as address or legal entity name.*

In contrast to CICR, SEA Regulation states that notifications shall be done for all hazardous substances by not considering the annual import volumes (even if it is imported 1 kg per year) in order to form a C&L inventory. Substances placed on the market before June 1, 2015 were to be notified C&L inventory before June 1, 2015. Substances placed on the market after June 1, 2015 are to be notified within one month at the latest after placing on the market for the first time. Notification can be made by manufacturers or importers or groups thereof that have a legal entity in Turkey. Companies that don't have a legal entity in Turkey may over take the notification obligation thorough their Legal representatives that are appointed with a letter of assignment (article 41). As there is no REACH implementation in Turkey available by now, derogation to notify to C&L inventory for registered substances does not apply as it was in EU.

C&L notifications should be made with the KKS-tool to the MoEU in the Turkish language. Notification submission system is similar to REACH IT C&L notification tool in means of fields to fill in.

The following information should be submitted under SEA notification:

- *Information for each manufacturer/importer/Turkish Representative of the substances (name, address, phone, fax, e-mail, contact person, place of manufacturing (if applicable));*
- *Information of the substance as stated on Art.39;*
- *Classification of the substances in accordance with Art.15;*
- *Reasons and justifications if there is lacking or non-conclusive data if the substance is not classified for some hazard classes;*
- *If applicable specific concentration limit values and M-factors;*
- *Labelling data and hazard statement of the substances.*

### *Registration of chemicals*

As a candidate for the European Union membership, Turkey started the process of introducing REACH into its own legislation in 2011. The implementation project ended in 2013 with a draft Regulation- KKDIK published by the Turkish Ministry of Environment and Urbanization. KKDIK it is abbreviation which corresponds to the first letters of REACH written in Turkish: Chemicals (Kimyasalların), Registration (Kaydı), Evaluation (Değerlendirilmesi), Authorisation (İzni), Restriction (Kısıtlanması). Now it is still in draft status, an additional round of consultations was open to interested stakeholders. The official release of KKDIK is expected in the first half of 2017.

According to the draft Regulation there is no separation of deadlines depending on the tonnage bands or the classification of the substances, like is the case in the EU, where REACH has three registration deadlines. All substances that are manufactured or imported in Turkey in quantity equal or more than 1 tons per year need to be registered between 01.01.2020 – 31.12.2022. After 31.12.2022, a

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substance needs to be registered before being manufactured or placed on the market. Also there will be a pre-registration period starting from 2019. Late pre-registration is under discussion.

The Safety Data Sheets will be prepared according to the KKDiK regulation as of 31.12.2022. The provisions of Annex 17 on Restrictions shall enter into force on 31.12.2018, 31.12.2019, 31.12.2021, 6 months after publication, respectively, as provided in the regulation.

### *Harmonization activities*

Turkey is a candidate country for EU membership following the Helsinki European Council of December 1999. Thus, all years after that date Turkey was focused on harmonization of current national legislation with EU legislative system and this process has had a significant progress. Current Turkish chemical regulation which was aligned with EU one is indicated in table 3.17.4. below.

**Table 3.17.4. - Harmonized legislative framework**

<b>Turkish regulation</b>	<b>EU-Dir/Regulation</b>
By-Law on Classification, Packaging and Labeling of Dangerous Substances and Preparations (26.12.2008/27092) – CPL By-law <sup>1)</sup>	Dangerous Substances Directive 67/548/EEC Dangerous Preparations Directive 99/45/EC
By-Law on the Classification, Labelling and Packaging of Substances and Mixtures (11.12.2013/28848) SEA Regulation – CLP By-law	Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation)
By-Law on the Preparation and Distribution of Safety Data Sheets □ (26.12.2008/27092) <sup>2)</sup>	Directive No. 91/155/EC - REACH Annex II
Regulation on Preparation and Distribution of Safety Data Sheets regarding Dangerous Substances and Preparations (15.12.2014/29204)	EU SDS regulation 453/2010/EC
By-law On Restrictions And Prohibitions Of Hazardous Substances And Mixtures (26.12.2008/27092; last rev. 27.11.2014/29182) <sup>2)</sup>	REACH Regulation Annex XVII
By-Law on Test Methods Applied for Determining the Physicochemical Toxicological and Ecotoxicological Properties of the Substances and Mixtures (11.12.2013/28848)	Directive No. 440/2008/EC
Chemical Inventory and Control Regulation (CICR) (26.12.2008/ 27092 amended 10.11.2009) <sup>2)</sup>	Council Regulation EEC 793/93
Regulation on Major Industrial Accidents – SEVESO (18.08.2010/27676)	Council Directive 96/82/EC on the Control Of Major-Accident Hazards
This By-Law will be repealed by the implementation of CLP Regulation in Turkey.	
This By-Law/Bis will be repealed by the implementation of REACH Regulation in Turkey.	

## 7. Non-regulatory Mechanisms

Voluntary initiatives of industry are emerging as important tools for addressing international and domestic environmental, social and ethical issues. One of such initiatives that is becoming more and more popular among the Turkish companies is the Responsible Care program. The Responsible Care initiative is the global chemical industry's commitment to sustainable development and openness in activities related to health, workplace safety and the environment. Chemical industry organizations in each country are responsible for the effective implementation of Responsible Care guidelines at the national level. In Turkey, this responsibility is fulfilled by the Turkish Chemical Manufacturers Association (TCMA). Being a member of CEFIC (European Chemical Industry Council) since 1992, TCMA has been conveying all the current developments on emerging policies at international level to its members along with successful implementation of the Responsible Care initiative since 1993.

## 8. Availability of National Data

One of the main objectives of Chemical Inventory and Control Regulation No.27092 is setting out the administrative procedures and principles concerning the creation and maintenance of national chemicals inventory. By the end of 2011 following the submission of notifications the ministry published two substance inventories, one for high production volume (HPV) substances produced in quantities above the 1,000 tonne/year threshold, the updated version of which includes 597 substances and another for low production volume (LPV) substances produced in quantities between 1 and 1,000 tonne/year, which contains 2,886 substances. In 2014 MoEU of Turkey published a list of prioritized substances consisting of 131 chemicals. Prioritization criteria were mentioned on Article 13 and 14 of the regulation.

Article 13 of CICR states:

- a) *The ministry shall prepare and publish a priority list of prioritised substances or groups of substances which require attention due to their potential hazards posed to human health and the environment, depending on the information provided by manufacturers and importers in accordance with Article 7 and 8.*
- b) *The following factors shall be taken into consideration for the preparation of the priority list:*
  - 1) *Effects of the substance on human health and the environment;*
  - 2) *Human and environmental exposure to the substance;*
  - 3) *Inadequacy of data on effects of the substance on human health and environment;*
  - 4) *Studies carried out by international organisations and under the international conventions, to which Turkey is a party;*
  - 5) *Other national legislation on dangerous substances.*
- c) *(3) If the substance has a chronic effect, in particular it is carcinogenic, toxic for reproduction and/or mutagenic, or it is well known for aggravating these effects or it causes such suspicion, those substances shall be paid special attention.*

Article 14 states: (1) the ministry shall perform a risk assessment for the substances in the priority list, as specified in paragraph 1 of Article 13. Depending on this primary risk assessment, the manufacturer or the importer who provided the information on the substance in accordance with Articles 7 and 8, with regard to written request within the scope of the procedure to be specified by the ministry, shall submit requested information or additional test results upon request within the period specified by the ministry, after the publication of the list.

MoEU reviewed the inventories under the light of the criteria mentioned on articles above to make an evaluation and prioritize the chemicals.

Another inventory which is also maintained by MoEU is C&L inventory. This inventory is formed on the base of notification under SEA Regulation via special IT system named KKS tool of Environmental Information System.

## 9. Laboratory infrastructure

Turkish Accreditation Agency (TÜRKAK) was designated as Good Laboratory Practices (GLP) Monitoring Authority since late 2008. The directive for GLP prepared by Ministry of Health (MoH), former Ministry of Environment & Forestry (MoEF) and Ministry of Agriculture & Rural Affairs (from the late 2011 it was reorganized as the Ministry of Food Agriculture and Livestock) published on the 9th March 2011 with Official Gazette number 27516. TÜRKAK also is a regulatory body that is responsible for laboratory accreditation in Turkey under law no 4457. For laboratory accreditation purposes ISO / IEC 17025 and ISO 15189 standard is taken as the basis. The requirements of this standard provide for the general requirements on a laboratory's quality management system and technical competence.

## 10. Information sharing

### *10.1. Globally Harmonized System of Classification and Labeling of Chemicals (GHS)*

On December 11, 2013 Turkey has published SEA Regulation (28848) that aims to align the country's application of the Globally Harmonized System (GHS) of classification and labelling of chemicals with the EU's CLP Regulation. Under SEA substances are to be classified and labelled according to criteria in the regulation as of 1 June 2015, and mixtures as of 1 June 2016. As a general principle, and similar to EU CLP, a two-year transition period for the products that were placed on the market prior to that date, will apply to prevent products having to be re-labelled.

Manufacturer, importer and distributor responsible with the placing on the market of the dangerous substance or preparation has to provides the professional user of this dangerous substance or preparation a safety data sheet. The latest Turkish SDS Regulation - Regulation on Preparation and Distribution of Safety Data Sheets regarding Dangerous Substances and Preparations is published in Official Gazette with number 29204 on December 15, 2014 and fully comes into force on June 1, 2016. It aligns the Turkish SDS format with EU SDS regulation 453/2010/EC and sets detailed requirements on the content and order of sections in Turkish SDSs.

SDS Requirements in Turkey:

- *Standard 16-section SDSs;*
- *Must be prepared in Turkish and provided free of charge;*
- *Must be authored by persons who has been certificated by the certification bodies that are accredited by TÜRKAK in terms of personnel certification scheme (TS EN ISO/IEC 17024) to author SDS. (According to reg. 29204 Article 5 (13));*
- *Certified author should be identified his contact details as well as certificate number in Sec 16 of the SDS;*
- *A copy of SDSs shall be submitted to the Ministry of Environment and Urbanization.*

### *10.2. Response on emergencies involving chemicals*

Two emergency numbers are available 24/7 in case of emergencies involving chemicals:

- *114: Poison Emergency;*
- *112: Medical emergency/ Ambulance.*

**114 UZEM (Presidency of Refik Saydam Hygiene Center – National Poison Solidarity Center)**

Information service for the public and health personnel on intoxication and poisoning via telephone line no. 114 is rendered. Calls to 114 across Turkey are forwarded to UZEM (Ulusal Zehir

Danışma Merkezi) Call Center within UZEM in Ankara by Türk Telecom. In the system, calls and applications received are responded, evaluated, analyzed and recorded in computerized medium by Operators via special UZEM software and Call Center application.

Calls to 114 and 0800 324 79 00, which are forwarded to Ankara by Türk Telecom, are sent to UZEM Call Center through PRI line. 114 UZEM Call Center Software integrated to call center, these received calls are responded and classified in computerized medium by specialist doctors and recorded in SQL database. The call center and its software functions in full integration. The system is comprised of two main Modules:

a) *Uzem Call Center Software*

- 1) *The whole process from receipt of call by the exchange to finalization of the case is recorded and controlled;*
- 2) *All calls are responded and managed on computer by exchange integration;*
- 3) *Statistical data can be produced for prospective planning purposes;*
- 4) *The Call Center Software operates with Micro-Medex Medicine Database Software, which is currently being used by the administration in case analysis.*

b) *114 Uzem Call Center and Voice Record System*

- 1) *Address Control From Phone Number: By the address database to be provided by the Türk Telecom, the address of the calling fixed number (where the phone number is displayed) is displayed on the monitor when the call is received;*
- 2) *Phone Number Control from Current Database: Operators are warned when a call was received in the past from the calling person or phone number;*
- 3) *Message and Voice Response System: When the calls received for the same reasons require the same answers, the caller is forwarded to voice response system, freeing Operators from giving the same answers for the same questions and saving their time;*
- 4) *Black List: In the event of "unfounded calls", the disturbing numbers are put in to black list for a period predetermined by the Administrator and their calls are rejected by the Exchange within this period;*
- 5) *Voice Records: All voice records of all phone calls are stored with their Application Number so as to enable easy access and examination in the event of a conflict. Voice record of the application could easily be attached to the file when forwarding received application to the administrator.*

**Türkiye Acil Sağlık Hizmetleri: 112 (Armakom 112 Emergency Operation Management System)**

In Turkey "112" has been known only as Ambulance Service Number since 1993. 112 Single Emergency Call Number Project was started in Turkey as MATRA Project in 2005 by The Turkish Ministry of Interior. The aim of the Project was to collect all of the emergency services under "112" Turkish Ministry of the Interior was politically responsible for the 112 provision nationwide. This responsibility includes all legislation, regulations, staff and financing.

Armakom Information Technologies was awarded the contract on establishment of 112 Emergency System in 40 provinces lacking automation systems and integration of all the systems across Turkey. Currently Armakom 112 Emergency Operation Management System is used by 80 cities local health authority and Ministry of Health of Turkey Armakom 112 Emergency Operation System that is developed by using state-of-the-art technologies is designed exclusively to meet the 112 Emergency requirements of Turkey in line with the long-track research and experiences.

The system provides effective solutions for crucial requirements such as prevention of unfounded calls, standard data entry, systematic operation management, regular data flow, performance management, control of mobile teams, address finding, and shortening length of access time.

The expandable technological infrastructure allows the system to be suitable for management of all emergency services under a single frame only by capacity expansion and installation of further software.

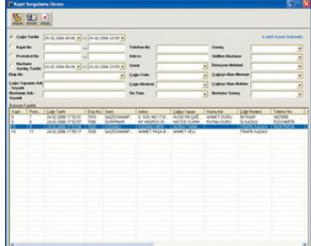
For the applications developed under the project efforts have been made for more than three years, meetings held with authorities from Command and Control Centers, and common requirements were identified.

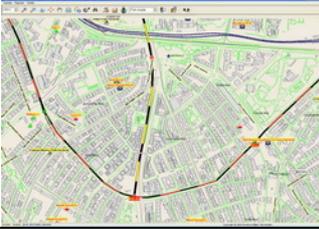
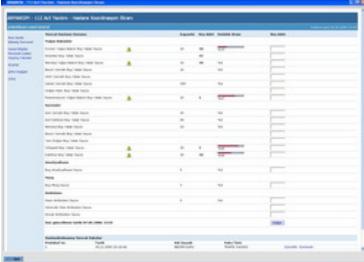
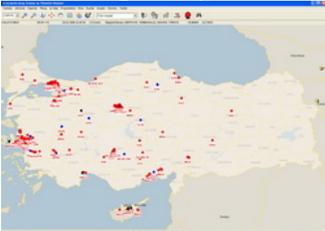
As the system has a modular structure, it can be activated as a whole or in phases. The main structure is delivered as ready for integration of other modules.

TÜBİTAK (The Scientific and Technological Research Council of Turkey) reviewed the project and decided to support it on 7th of December, 2004.

The system consists of the following modules represented in the table 3.17.5. below:

**Table 3.17.5. – Modules of the 112 Emergency Operation Management System**

Module name	Module description
<p>112 Emergency Operation Management Systems</p> 	<p>From receipt of a call to finalization of the event, the whole process is recorded and controlled. Constant and up-to-date monitoring of the status of calls, operators, hospitals, teams and ambulances is enabled. All calls are dealt and managed by computers through exchange integration. Standard data entry is provided and inadequate or erroneous entries are avoided. Forwards are made based on current status of teams and hospitals. In addition to standard reports, required statistical data is produced to make prospective planning</p>
<p>Call Center System</p> 	<p>An integrated call center application is developed specifically for 112 Emergency requirements where all call-related activities are computerized. The blacklist feature prevents "unfounded" calls, enabling a substantial decrease in the number of received calls. Calling telephone numbers are checked and previous duties are listed instantly. Where necessary connections are enabled, address data of fixed phone numbers can be attained automatically. Thousands of phone numbers for general dial purposes as well as fast dial buttons for users can be appointed. Moreover, number of holding calls can be viewed on-line</p>
<p>Voice Recording System</p> 	<p>Voice records are kept once the calls are received by exchange; wireless communications with teams are recorded. Voice recording is integrated with the whole system. The system provides search by many features like date, time, operator or phone number; moreover, it is also possible to access concerned voice records without making search by matching voice records for related duty with protocol numbers</p>
<p>Digital Maps and Digital Map Applications</p>	<p>Unknown addresses can be found on digital maps. It is possible to identify the address of the case when GPS coordinates are provided. The possibility to include important reference points to map facilitates address finding and directing. The scene can be marked on the map and submitted to teams</p>

Module name	Module description
	
<p>Ambulance Tracking and Directing with GPS and Mobile PC Data Communication System</p> 	<p>The special Arvento Mobile Data Device provides keeping track of ambulances 24/7 via GPS satellites and monitor their speeds, departure times, locations and periods of stop. Through 112 Emergency software, case addresses submitted to teams in writing and the scene are demonstrated on the map by sending coordinates. By means of mobile computers, it is possible to take picture of the scene and send it to Command and Control Center. The team is able to report their duty forms to the headquarter on-line. The hospital can be informed about current status of the patient in the ambulance on the way to the hospital. Written texting between headquarters and teams is possible</p>
<p>Hospitals and Coordination</p> 	<p>Availability of free bed and personnel on duty in hospitals can be monitored by internet connection between hospitals and Command and Control Center. By installing monitors in hospitals, case information can be communicated automatically when the ambulance is on the way to the hospital. This enables having the hospital informed in advance and making necessary preparations before the patient arrives at the hospital. Upon the patients admitted in the hospital cases are tracked on-line and retrospectively</p>
<p>Patient Transport System</p> 	<p>Appointments and duty plans required for patient transport are monitored on program. Patient transport vehicles are monitored with GPS satellites and kept under continuing control</p>
<p>Computer and Network Hardware</p> 	<p>Every hardware and software requirements for the system such as servers, computers, power supply and network infrastructure are projected turn-key upon on-site surveys. Hardware and software are used for back-up and security purposes. Periodic back-up of all records is enabled</p>
<p>Design and Technical Infrastructure of Command and Control Center</p>	<p>Solutions are provided under project for variety of issues like interior design, electricity and data infrastructure, operator and supervisor tables, wide monitoring units, etc.</p>

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