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for Asia-Pacific Prosperity

Survey for Review of Chemical Management Regulatory Systems Worldwide - Summary

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EXECUTIVE SUMMARY

Background

Russia continues to put efforts into the implementation of self-funded project "Survey for Review of Chemical Management Regulatory Systems Worldwide" ("Survey") (CD 02 2017S), which had been endorsed at SOM1 2017 and was to be completed by December 2018. The aim of the Survey is to provide information about chemical regulatory systems in place worldwide to all interested stakeholders.

The Survey contributes to the promotion of trade relations between economies, facilitates the identification of the possible non-tariff barriers and sharing good regulatory practices. It corresponds to the APEC priority area Strengthening Regional Economic Integration and Quality Growth and supports a goal «to facilitate trade by expanding and supporting regulatory cooperation and mutual recognition in the Region».

The Survey includes a brief chemical legislation overview, information on IT and laboratory infrastructure, etc. A block of information on the CBI protection rules was also added to the Section "Availability of data" following discussions at the 19th CD.

The gathered information and comments are consolidated and included into the final version of the project Survey. A full text of the Survey, containing chapters that were updated by the Economies is expected to be published by Russia itself (not as an APEC Publication). The electronic version of the full text of the Survey is available online: http://ciscenter.org/upload/iblock/93d/Chemical-regulations.pdf.

This Executive Summary was developed to facilitate communication of Survey results. It provides concise information on some major chemicals management systems, chapter by chapter.

Russia is grateful to Economies that have contributed to the Project.

Executive Summary Structure

Each chapter of the Executive Summary focusses on a few regulatory approaches and identifies main regulators. Information provided identifies approaches to new and existing chemicals and mixtures. As many Economies separately address the regulation of some chemical categories such as pesticides, biocides, POPs, mercury, etc., these are *not* addressed in the Executive Summary. As an exception, a list of the multilateral environmental agreements relevant to chemicals and waste is provided in the Table X.1.

Table X.2 provides a high level description of the main chemicals management legislative tools used for the control of regulated objects, regulators and brief description of the identified acts. Voluntary industry initiatives are identified in Table X.3 of each chapter. Information on IT and laboratory infrastructure is provided in Table X.4, accompanied by web-links. Only official international or governmental chemical data bases and portals were included. Questions concerning confidential business information (CBI) protection were addressed in this Table. The Table X.4 also contains facts on the GLP laboratory system and response on emergency situations involving chemicals, including poisoning.

Chapter 1. Australia

Regulated objects: chemical ingredients (new and existing) and chemical products according to their use covering: 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. This ES only contains an overview of the industrial chemicals regulation (ICNA Act[1]).

Regulators: Office of Chemical Safety (OCS) administering National Industrial Chemicals Notification and Assessment Scheme (NICNAS); Australian Competition and Consumer Commission (ACCC); Therapeutic Goods Administration Advisory Committee on Chemicals Scheduling (ACCS), Defence Export Control Office; Civil Aviation Safety Authority (CASA); Australian Maritime Safety Authority (AMSA); Safe Work Australia; The Department of Home Affairs; State/Territory Governments; Environmental Protection Authority (EPA); Local Councils.

Table 1.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: The Stockholm Convention on Persistent Organic Pollutants, The Montreal Protocol on Substances That Deplete the Ozone Layer, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, Vienna Convention for the Protection of the Ozone Layer, United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; United Nations Convention on Psychotropic Substances, 1971; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988; Convention for the Protection of the Natural Resources and Environment of the South Pacific Region (Noumea Convention), 1986
Signed, not ratified: The Minamata Convention on Mercury
Other relevant agreements: Convention on the Organisation for Economic Co-Operation and Development (OECD), 1960 (accession)

Table 1.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
ICNA Act	Industrial chemical *as defined in the Part 1, Section 7 of the Regulation*	NICNAS	*New chemical substances* An industrial chemical that is not listed on the Australian Inventory of Chemical Substances (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. Manufacturers or importers of new industrial chemicals may need to notify NICNAS if the chemical

[1] Industrial Chemicals (Notification and Assessment) Act 1989. The ICNA Act, which establishes the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), will be replaced by the Industrial Chemicals Act 2019 and the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019 on 1 July 2020. From this time, the Australian Industrial Chemicals Introductions Scheme (AICIS) will replace NICNAS.

Table 1.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			is not listed on the AICS, some additional conditions apply.
GHS implementation			
Model WHS Regulations	workplace hazardous chemicals (substances, mixtures and articles)	Safe Work Australia, the Commonwealth and state/territory governments	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 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. A five year transitional period was provided to industry to prepare for the implementation of GHS labelling. Safe Work Australia has a suite of training tools and information sheets about the GHS and the requirements under the model WHS Regulations. Safe Work Australia has published a new database of GHS classification and labelling information called the Hazardous Chemicals Information System (HCIS). Please refer to the Table 1.4 for more information on HCIS.

Table 1.3

Non-regulatory Mechanisms: industry voluntary initiatives
• ICCA member: Responsible Care overseen by the Chemistry Australia Limited • Industry groups (International Fragrance Association, Accord) initiatives

Table 1.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
AICS	https://www.nicnas.gov.au/chemical-inventory/Public-Inventory	The legal device that distinguishes new from existing chemicals. It is a database of chemicals (not products) and has a public and confidential section. Public section contains more than 40 000 substance entries.
HCIS	http://hcis.safeworkaustralia.gov.au/	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. HCIS 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)	https://www.legislation.gov.au/Details/F2018L01344 Version of October 2018 (SUSMP No. 22)	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.
Confidential business information (CBI) protection		
In carrying out its functions and duties under 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. To list a chemical confidentially on the AICS, the certificate holder must submit an application, including justification for requesting a confidential listing. 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.		
Laboratory infrastructure (GLP)		
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. 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.		

Table 1.4

Chemical management system infrastructure
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).
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. *Poisons Information Centre* 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.

Chapter 2. Canada

Regulated objects: Substances (CEPA 1999[2], CMP[3]). Certain groups of chemicals of concern are addressed by over 50 regulations under CEPA 1999, and where appropriate, regulations under other federal acts, and those of other governmental jurisdictions within Canada. Please refer to the Government of Canada website to view the full list of CEPA regulations[4].

Regulators: federal, provincial, territorial, and municipal governments. CEPA 1999 is jointly administered by the Minister of Environment and Climate Change (addressing risks posed by chemicals entering the environment) and the Minister of Health (addressing the risks posed by chemicals on human health). The CMP Stakeholder Advisory Council is a multi-stakeholder group that contributes to the implementation of the CMP, meeting a minimum of twice per year (April 2016 until March 31, 2021). Members represent national indigenous organizations, consumer groups, environmental NGOs, health NGOs and industry.

Table 2.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: The Stockholm Convention on Persistent Organic Pollutants, The Montreal Protocol on Substances That Deplete the Ozone Layer, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, The Minamata Convention on Mercury, Vienna Convention for the Protection of the Ozone Layer, UNECE Protocol on Heavy Metals (Protocol to the UNECE Convention on Long-Range Transboundary Air Pollution (LRTAP)) UNECE Protocol on Persistent Organic Pollutants (POPs) (Protocol to the UNECE Convention on Long-Range Transboundary Air Pollution (LRTAP)) United Nations Framework Convention on Climate Change (UNFCCC) United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988
Other status: United Nations Convention on Psychotropic Substances, 1971 (accession), The Rio Declaration on Environment and Development/Agenda 21
Other relevant agreements: Convention on the Organisation for Economic Co-Operation and Development (OECD), 1960; Organization for Economic Cooperation and Development (OECD) Decisions related to Wastes; Organization for Economic Cooperation and Development (OECD) Decisions related to the Chemicals Programme; The Strategic Approach to International Chemicals Management (2006); the North American Agreement on Environmental Cooperation; the Great Lakes Water Quality Agreement (GLWQA); bilateral cooperation activities (including United States, European Union, Australia) For full summary see: https://www.canada.ca/en/environment-climate-change/corporate/international-affairs/partnerships-organizations/participation-international-environmental-agreements.html#X-201502091434394

[2] The Canadian Environmental Protection Act, 1999 (CEPA 1999)
[3] Chemicals Management Plan (CMP)
[4] Government of Canada. Current, proposed and repealed regulations. https://pollution-waste.canada.ca/environmental-protection-registry/regulations

Table 2.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
CEPA 1999	Substance *as defined in the Article 3(1)*	Environment and Climate Change Canada and Health Canada	Provides the legislative framework for risk assessment and management of existing and new substances in Canada. The Domestic Substances List (DSL) is an inventory of existing substances that were reported to be in use or commerce in Canada from 1984-1986. For more information on the DSL refer to the Table 1.4. ***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. ***Existing substances*** The Government of Canada created the 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. Prior to this, under CEPA 1988, the Federal Government conducted assessments of substances on the Priority Substances List (PSL). The first PSL, established in 1989, comprised 44 substances or mixtures; the second PSL, established in 1995, included 25 other substances or mixtures. Both lists were compiled from substances nominated through stakeholder consultations. These assessments were comprehensive and rigorous, and produced 67 assessment decisions, which were followed by regulatory action where indicated. 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

Table 2.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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. 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). As of December 2017, the Government of Canada had addressed 3,331 of the 4,300 chemicals identified as priorities for attention by 2020-2021, including draft and final assessments. It 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).
GHS implementation			
			Canada is currently undertaking stakeholder consultations in order to implement the GHS (Globally Harmonized System of Classification and Labelling of Chemicals). 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) [5] is the cornerstone of workers' right-to-know

[5] The Workplace Hazardous Materials Information System (WHMIS). http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index-eng.php

Table 2.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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.

Table 2.3

Non-regulatory Mechanisms: industry voluntary initiatives
• ICCA member: Responsible Care overseen by the Chemistry Industry Association of Canada

Table 2.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
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.[6] The CEPA Environmental Registry and CMP 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. Canada's Single Window is an online reporting system created by the federal government, which is also used by provincial governments 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. 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.		
The Domestic Substances List (DSL)	https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/domestic.html	An inventory of existing substances that were reported to be in use or commerce in Canada from 1984-1986. 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.

[6] Government of Canada. Chemicals Management Plan. https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan.html

Table 2.4

Chemical management system infrastructure		
Mercury and the environment	https://www.canada.ca/en/environment-climate-change/services/pollutants/mercury-environment.html	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.
Cosmetic Ingredients Hotlist	https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients/hotlist.html	The federal government also maintains a list of substances that are restricted and prohibited in cosmetics called the Cosmetic Ingredients Hotlist. This administrative list is intended to help manufacturers avoid these substances, in order to satisfy the requirements for sale in Canada.
Pollution prevention plans	https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/plans-policies/pollution-prevention.html	Information submitted by facilities subject to Pollution Prevention Planning Notices under CEPA 1999 is made publicly available.
IPCS INCHEM	http://www.inchem.org	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 website.
National Pollutant Release Inventory (NPRI)	https://www.canada.ca/en/services/environment/pollution-waste-management/national-pollutant-release-inventory.html	CEPA 1999 provides the legislative basis for annual industrial reporting to Canada's 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. Online training modules for facilities along with sector specific guidance to improve the accuracy of the information reported were developed. For 2016, the

Table 2.4

Chemical management system infrastructure		
		last reporting year for which information is available, over 7000 facilities reported to the NPRI on more than 300 listed substances.
Chemicals Management Plan information sheets	https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/chemicals-glance.html	Chemicals Management Plan information sheets are a series of short fact sheets about chemical substances and microorganisms that are being (or have been) assessed in Canada for their possible risks to human health and the environment.
Confidential business information (CBI) protection		
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 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. 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.		
Laboratory infrastructure (GLP)		
The Standards Council of Canada (SCC) has established a GLP Compliance Monitoring Authority (GLP MA) recognized by the OECD. Health Canada's Pest Management Regulatory Agency (PMRA) in its role as the regulatory authority for pesticide registration in Canada, the New Substances program, 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. 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.		
Response on emergency situations involving chemicals, including poisoning		
Canada's *Emergency Management Act*, 2007 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, 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		

Table 2.4

Chemical management system infrastructure
Environmental Emergencies Team 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. 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. Risk related to marine transportation 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.

Chapter 3. Chile

Regulated objects: chemicals and wastes, which can be defined as «hazardous substances»[7], POP's, hazardous wastes, mercury, hazardous chemicals and pesticides.

Regulators: Ministry of Health and Health Services; Ministry of Agriculture; Ministry of Labor; Ministry of Economy; Ministry of Environment; Ministry of Defence; Ministry of Transport and Telecommunications; Ministry of Interior; Ministry of Finance; Ministry of Foreign Affairs; Ministry of Mining; The National Emergency Office (ONEMI); The Agricultural and Livestock Service, SAG;
Chile's National Environmental Commission (CONAMA); National Customs; The Ministry of Defense is the General Directorate of Territory Maritime and Merchant Marine (DIRECTEMAR); National Standards Body: Instituto Nacional de Normalización; National Metrology Institute: Instituto Nacional de Normalización; Accreditation Bodies: Instituto Nacional de Normalización (INN). Other important participants: The Chemical Industry Association of Chile (ASIQUIM).

Table 3.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: The Stockholm Convention on Persistent Organic Pollutants, The Montreal Protocol on Substances That Deplete the Ozone Layer, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, GATT/WTO, Vienna Convention for the Protection of the Ozone Layer, United Nations Convention on Psychotropic Substances, 1971; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
Signed, not ratified: The Minamata Convention on Mercury, United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol
Other relevant agreements: Convention on the Organisation for Economic Co-operation and Development, the Union of South American Nations (UNASUR), the Southern Common Market (MERCOSUR), Free trade agreements provisions (with China, Japan, USA, Canada, Mexico, Korea, European Free Trade Association (EFTA), EU, Chile)

Table 3.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Existing and New Chemicals, Registration, Permit			
The Sanitary Code	Chemicals and waste, including the manufacturing, importation, distribution, transportation, sale, possession and disposal	the Ministry of Health and Health Services	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. 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

[7] Circular No. 2/C 152 (1982), Part II, Section b

Table 3.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			90 is that the importation and manufacture of these substances requires the authorization of health services.
Law 18.164 on Customs Destinations, published September 17, 1982	Toxic or dangerous substances, and substances used in food or cosmetics	the National Customs service	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. It 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	Dangerous substances to health	Ministry of 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 (ASDigital). 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. The one that keeps records of disinfectants is the Public Health Institute of Chile, who authorizes these products prior to their commercialization. Individuals and businesses can begin the registration process via the online system. Exempt Resolution is in the process of being updated.
Supreme Decree N° 43 of July 27, 2015	Dangerous substances	Ministry of Health	Regulation of storage of dangerous substances, applicable to hazardous substances classified in Chilean Standard /NCh N°382: 2013.
Exempt Resolution N° 1521 of December 26, 2016	Dangerous substances	Ministry of Health	Approves the facility declaration system that store dangerous substances, established in the supreme decree Nº 43, of 2015, of the Ministry of Health.

Table 3.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Decree-Law No. 1 of November 8, 1989	Substances hazardous to health, pesticides	Health Services	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	Dangerous substances		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. In process of being updated.
Decree No. 144 of May 10, 1985	Organic solvents harmful to health, their mixtures		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 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 of June 17, 2005	Toys		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 of June 30, 2007	Pesticides		Decree No. 157 is Regulation on Pesticide for Sanitary and Domestic Use of July 22, 2005. 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. There are also fixed Standards for Agricultural Pesticide Evaluation (Res. No. 3670/1999).
Restricted, Prohibited, or Banned Chemicals			
NCh (Chilean norm) 382 of 2004	Dangerous substances		Supreme Decree Nº 43, of 2015

Table 3.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Decree No. 374/97 promulgated August 25, 1997	Lead in paints		Specifies the maximum lead in paints
Decree No. 754/98 of December 12, 1998	Toluene		Prohibits toluene in adhesives and glues
Decree N°1/2013/MMA y Res. Ex. 1139/2004/MMA	Dangerous chemicals generally		Sets Pollutant Release and Transfer Register (RETC)
PNSQ	Dangerous chemicals generally		National Chemical Safety Policy
"Regulation on basic sanitary and environmental conditions in workplaces". - S.D. N° 594/1999	Dangerous chemicals		Applicable to the manufacturing and disposal of the dangerous substances
Law No. 3.557/2009	Dangerous chemicals		Agricultural Protection Provisions. Applicable to the usage of the dangerous substances. …
S.D. No. 148/2004	Hazardous Waste		Regulation on hazardous waste management on basic sanitary and environmental conditions in workplaces

GHS implementation

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. These regulations exclude 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,

Table 3.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
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. 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: 2015 of the Chilean National Standards Institute has established standards for the content and order of sections of Safety Data Sheets and hazard labels. (Required by Supreme Decree No.43 Ministry of Health of 2015). This standard was updated under Rev.5 of the UN GHS. 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. 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 wellbeing 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.			

Table 3.3

Non-regulatory Mechanisms: industry voluntary initiatives
• ICCA member (The Chemical Industry Association of Chile (ASIQUIM)): Responsible Care, Product Stewardship

Table 3.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
List of Dangerous Substances to Health		This list contains the chemical substances identified as dangerous to health by the Government of Chile. There are the indicated in the Resolution 408/16 of the Ministry of Health and classified according to NCh 382: 2013. On the other hand, the Ministry of Agriculture has regulated and prohibited pesticides.
Several occupational exposure limit lists are in force, including list of substances considered carcinogenic by the Government of Chile; list of substances prohibited from the workplace by the Government of Chile except for the qualified cases made by the sanitary authority.		
Confidential business information (CBI) protection		
–		
Laboratory infrastructure (GLP)		
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.		

Table 3.4

Chemical management system infrastructure
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.
Response on emergency situations involving chemicals, including poisoning
On the web-site ASIQUIM Information about authorities related to emergencies can be found: contacts of emergency consultants, authorities related to emergencies, technical information and MSDS. Chronic poisoning occurrences are registered in Peru from the following chemicals: lead, mercury, arsenic, copper and aluminum. The General Directorate of DIGERD develops, organizes, and maintains an emergency response on the national, regional and local level. Depending on the sort of chemicals hazardous properties, which may cause emergency situation, the Chilean citizens may call relevant emergency consultants. Responsibility for emergency situations is divided among different ministries and other institutions relevant to emergency response actions. 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 On the web-site the access to MSDS is available. MSDS were provided by the companies associated with ASIQUIM.

Chapter 4. Hong Kong, China

Regulated objects: Ozone depleting substances; non-pesticide hazardous chemicals; Mercury and its compounds and mercury-containing products; and hazardous chemical wastes.

Regulators: Environmental Protection Department (EPD) of Hong Kong, China (HKC)

Table 4.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Montreal Protocol on Substances that Deplete the Ozone Layer Vienna Convention for the Protection of the Ozone Layer 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 Minamata Convention on Mercury The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal

Table 4.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
(1) & (2) Ozone Layer Protection Ordinance [OLPO]	Ozone depleting substances listed in the Schedule of OLPO	EPD	The Ordinance prohibits the manufacturing of substances that deplete the ozone layer and imposes controls on the import and export of these substances through registration and licensing provisions.
(3) & (4) Hazardous Chemicals Control Ordinance [HCCO]	Non-pesticide hazardous chemicals	EPD	Any person importing*, exporting*, manufacturing or using Scheduled Chemicals controlled under the HCCO must hold a valid permit issued by EPD. *In addition, for every shipment of Scheduled Chemicals entering or leaving HKC, an import/export licence is also required under the Import and Export Ordinance, to be issued by EPD under delegation from the Trade and Industry Department.
(5) Mercury Control Ordinance *(exact name of the Ordinance to be confirmed)*	Mercury, mercury compounds, mercury-added products and manufacturing processes using mercury	EPD	The new legislation will mainly control the following: (i) Restrict the import and export of mercury; (ii) Prohibit the manufacturing, import and export of specified mercury-added products by a specified phase-out date, and further prohibit their sale and supply after a period from the specified phase-out date; (iii) Prohibit the use of mercury or mercury compounds in specified manufacturing processes; and (iv) Control the storage of mercury and mercury compounds.
(6) Waste Disposal Ordinance [WDO] and	Hazardous chemical wastes	EPD	Part IVA of the WDO provides for the control on import and export of waste (including chemical waste) in HKC. The control enables HKC to manage its import and export of waste in an environmentally sound manner. This ties in with the requirements of the Basel

Table 4.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Waste Disposal (Chemical Waste) (General) Regulation [CWR]			Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. Proper labelling of chemical waste is required under the CWR and the requirement is compatible with that under the International Maritime Dangerous Goods (IMDG) Code.
GHS implementation			
–			

Table 4.3

Non-regulatory Mechanisms: industry voluntary initiatives
–

Table 4.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
(1) & (2) Database of ozone depleting substances	https://www.epd.gov.hk/epd/english/application_for_licences/guidance/wn6_licen1_1.html	Contains about 91 chemicals being controlled under OLPO.
(3) & (4) List of non-pesticide hazardous chemicals	https://www.epd.gov.hk/epd/english/laws_regulations/comp_guides/cg_hazardous_chemical.html	List of non-pesticide hazardous chemicals controlled under the HCCO.
(6) List of hazardous chemical wastes	https://www.epd.gov.hk/epd/english/environmentinhk/waste/guide_ref/guide_cwc_sub1.html	List of hazardous chemical wastes (on page 13 (Appendix A)).
Confidential business information (CBI) protection		
–		
Laboratory infrastructure (GLP)		
The Government Laboratory follows the international standard ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories” to implement a quality system for the laboratory’s operation.		
Response on emergency situations involving chemicals, including poisoning		
EPD has developed a spill response plan named “Maritime Hazardous And Noxious Substances (HNS) Spill Response Plan” to deal with spill of HNS at sea, in order to fulfill the “Protocol on Preparedness, Response and Co-operation to Pollution Incidents by Hazardous and Noxious Substances, 2000” (2000 OPRC-HNS Protocol) prepared by the International Maritime Organization (IMO). The Government Laboratory provides Fire Services Department and Environmental Protection Department with analytical and advisory services for handling incidents involving chemicals.		

Chapter 5. Japan

Regulated objects: Poisonous and deleterious substances (the Poisonous and Deleterious Substances Control Act: PDSCA) from the viewpoint of health and hygiene, Chemicals at workplace (Industrial Safety and Health Law (ISHL) for ensuring the safety and health of workers, New and existing industrial chemical substances (Chemical Substance Control Law, CSCL), Chemical substances released and transferred in waste (the PRTR system and Promotion of Chemical Management)

Regulators: the Ministry of the Environment (MOE), the Ministry of Economy, Trade and Industry (METI), the Ministry of Health, Labor and Welfare (MHLW)

Table 5.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
The Stockholm Convention on Persistent Organic Pollutants, The Montreal Protocol on Substances That Deplete the Ozone Layer, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, The Minamata Convention on Mercury, The Vienna Convention for the Protection of the Ozone Layer, United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, United Nations Convention on Psychotropic Substances, 1971

Table 5.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Chemical Substance Control Law, CSCL	control both new and existing industrial chemical substances, prevent pollution by chemical substances	MOE, METI, MHLW	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 certain chemical substances as Class I Specified Chemicals to prohibit their manufacture/import or as Priority Assessment Chemicals for their further assessment.
Industrial Safety and Health Law (ISHL)	ensure the safety and health of workers, regulate chemicals at workplaces	MHLW	Designate 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.
PRTR and SDS Law		MOE, METI	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 and the other is SDS system which provides information concerning the properties and the handling of the specified chemical substances by business operators.

Table 5.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Poisonous and Deleterious Substances Control Act (PDSCA)	control of poisonous and deleterious substances from the view point of health and hygiene	MHLW	PDSCA 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 prescribed standards for the transportation, storage or disposal of Poisonous Substances or Deleterious Substances and comply with specific requirements on storing, labeling or transferring.
GHS implementation			
CSCL, ISHL, PRTR and SDS, PDSCA No specified law to implement GHS		MOE, METI, MHLW	Decided to introduce GHS into these existing laws. To ensure consistency among laws, adopted JISs (Japan Industrial Standards) as tool to implement GHS. Now two JISs exist and mentioned by laws: JIS Z7252 (Latest Version JIS7252-2019) providing chemical classification criteria; JIS Z7253 (Latest Version JIS7253-2019) stipulating format and content of SDSs and labels. Both standards are based on 6th revised edition of GHS. It should be noted that SDSs are mandatory and labels are mandatory or mandatory to make an effort. 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. 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. 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. https://www.meti.go.jp/policy/chemical_management/int/ghs_auto_classification_tool_ver4_EG.html MHLW and MOE have conducted GHS classifications on hundreds of substances. The classifications can be

Table 5.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			downloaded via site of the National Institute of Technology and Evaluation (NITE).

Table 5.3

Non-regulatory Mechanisms: industry voluntary initiatives
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.

Table 5.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
ASEAN-Japan chemical safety database (AJCSD)	http://www.ajcsd.org/	In order to enhance transparency and reduce compliance risk on the chemical safety through sharing and disclosure of national regulatory information of the Member Economies of ASEAN, ASEAN-Japan chemical safety database (AJCSD) started it full operation in April 2016 operated by the National Institute of Technology and Evaluation of Japan (NITE). Database contains Regulatory information of ASEAN Economies and Japan, hazard and risk information, GHS classification results and sample SDSs.
Confidential business information (CBI) protection		
–		
Laboratory infrastructure (GLP)		
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).		
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.		

Chapter 6. New Zealand

Regulated objects: chemicals and substances, and, particularly, hazardous substances (explosives, pesticides, and industrial chemicals) (HSNO Act[8], HSW legislation[9]).

Regulators: Environmental Protection Authority (EPA), Ministry of Business Innovation and Employment (MBIE), WorkSafe NZ, Ministry of Environment.

Note: 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. In June 2011 ERMA NZ was disestablished and its functions were incorporated into the new EPA.

Table 6.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: The Stockholm Convention on Persistent Organic Pollutants, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, Vienna Convention for the Protection of the Ozone Layer, The Montreal Protocol on Substances That Deplete the Ozone Layer, United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, United Nations Convention on Psychotropic Substances, 1971, United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
Signed, not ratified: The Minamata Convention on Mercury
Other relevant agreements: Convention on the Organisation for Economic Co-Operation and Development (OECD), 1960; The Convention to Ban the Importation into Forum Island Economies of Hazardous and Radioactive Wastes and to Control the Transboundary Movement and Management of Hazardous Wastes within the South Pacific Region (Waigani Convention), Organisation for Economic Coordination and Development Decision C(2001)107/FINAL (OECD Hazardous Waste Decision), bilateral cooperation activities.

Table 6.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
HSNO Act	Substance *as defined in the section 2(1) of the Act*	EPA	Hazardous Substances and New Organisms (HSNO) Act 2017 as amended by the Hazardous Substances and New Organisms Amendment Act 2015 is aimed 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. 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

[8] Hazardous Substance and New Organisms (HSNO) Act 2017
[9] Health and Safety at Work Act 2015, Health and Safety at Work (Hazardous Substances) Regulations 2017

Table 6.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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. 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/assinging-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.
HSW Act and Regulations	hazardous substance *as defined in the section 2(1) of the HSNO Act*	MBIE, WorkSafe NZ	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. On 1 December 2017, many requirements for managing hazardous substances in workplaces moved out of HSNO and into the new HSW Regulations 2017. These regulations bring together workplace requirements for hazardous substances (other than for

Table 6.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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. 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. Guidance on the HSW Act and regulations are available at the WorkSafe NZ's website.
GHS implementation			
The Hazardous Substances (Minimum Degrees of Hazard) Notice 2017	hazardous substances	EPA	The thresholds for the HSNO hazardous properties are set out in the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017. The HSNO Classification system is unique to the economy. The classification systems comprise: - numbered classes, indicating the intrinsic hazardous property; - numbered subclasses, indicating the type of hazard; and - lettered categories 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; - 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. EPA is currently working to update the current HSNO hazardous substances classification system to GHS Rev. 6 or later within the next three years. Further details on the thresholds and classification systems are given in the User Guide to the HSNO Thresholds and Classifications re-published by the EPA in January 2012.
EPA Notices	hazardous substances	EPA	The EPA can set hazardous substance rules (EPA Notices) under the HSNO Act. EPA Notices are tertiary instruments, are

Table 6.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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. *Hazardous Substances (Classification) Notice 2017* Prescribes the criteria for each hazard classification. *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. It 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, 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*

Table 6.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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. 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* 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.

Table 6.3

Non-regulatory Mechanisms: industry voluntary initiatives
• Responsible Care® NZ, RCNZ (formerly NZ Chemical Industry Council (NZCIC)): 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.

Table 6.4

Chemical management system infrastructure
Informational resources

Table 6.4

Chemical management system infrastructure		
Data base	*Web link*	*Brief description*
NZIoC	https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/	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 Economies. They are: 1. Non-hazardous substances are not required to be listed; 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 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 a set of the specific information. EPA updates the NZIoC regularly with new chemicals that have been notified and verified.
Approved Hazardous Substances with Controls database	https://www.epa.govt.nz/database-search/approved-hazardous-substances-with-controls/	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.
CCID	https://www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid/	Chemical Classification and Information Database 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.
Hazard Substances Toolbox	https://www.hazardoussubstances.govt.nz/	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.
Confidential business information (CBI) protection		
–		
Laboratory infrastructure (GLP)		

Table 6.4

Chemical management system infrastructure
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/). 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.
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.

Chapter 7. Peru

Regulated objects: selected chemical and chemical product groups, such as: 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; a number of substances that are considered to be precursors in the manufacture of illicit drugs used in household and artisan; chemicals related to explosives and pyrotechnic products and chemicals susceptible to be used for the manufacture of chemical weapons; POPs; hazardous wastes; mercury; ODS.

Regulators: Ministry of Health (MINSA), Ministry of Environment (MINAM); Ministry of Interior (MININTER); Ministry of Production (PRODUCE); Ministry of Energy and Mines (MINEM); Ministry of Agriculture and Irrigation (MINAGRI); Ministry of Transport and Communications (MTC); National Institute of Quality (INACAL) [under the Ministry of Production]; National Superintendence of Customs and Tax Administration (SUNAT) [under the Ministry of Economy and Finance]; among others.

Table 7.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: 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, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, The Minamata Convention on Mercury, GATT/WTO, Vienna Convention for the Protection of the Ozone Layer, United Nations Convention on Psychotropic Substances, 1971; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
Signed, not ratified: United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol
Other status: The Montreal Protocol on Substances That Deplete the Ozone Layer (acceptance), The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (acceptance)
Other relevant agreements: Other relevant agreements: Andean Community (CAN), the Union of South American Nations (UNASUR), the Southern Common Market (MERCOSUR), Free trade agreements provisions (with Cuba, China, Japan, USA, Canada, Mexico, Singapore, Thailand, Panama, Costa Rica, Korea, European Free Trade Association (EFTA), EU, Chile, Venezuela, Honduras), Pacific Alliance (PA)

Table 7.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Legislative Decree N° 1126 (July November 1, 2012), regulated through	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	SUNAT	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 regulates the complete commercial chain: imports, production, manufacture, preparation, packaging, re-packaging, retail, transport, storage, distribution, transformation, use, and services related to these substances. A *"User's Certificate"* that allows for the use of the products registered in a "Unified Registry" database

Table 7.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Supreme Decree No. 044-2013-EF and complementary rules			may be obtained (valid for 2 years), in this case the company must keep special records and present monthly statements on all activities performed with the substances.
GHS implementation			
Currently GHS is not implemented. 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. It also requires storage and project personnel must be trained on handling.			

Table 3.3

Non-regulatory Mechanisms: industry voluntary initiatives
• ICCA member (CIQ-SNI): Responsible Care since 1996

Table 4.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
Control of Chemical Raw Materials and Supervised Product	http://orientacion.sunat.gob.pe/index.php/empresas-menu/insumos-quimicos/normas-legales-insumos-quimicos http://orientacion.sunat.gob.pe/index.php/empresas-menu/insumos-quimicos	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	http://orientacion.sunat.gob.pe/index.php/empresas-menu/insumos-quimicos/normas-legales-insumos-quimicos http://orientacion.sunat.gob.pe/index.php/empresas-menu/insumos-quimicos	Contains 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

Table 4.4

Chemical management system infrastructure		
Prohibited Carcinogenic Substances	https://web.ins.gob.pe/es/salud-ocupacional-y-proteccion/normatividad http://www.imarpe.pe/imarpe/archivos/Reglamento_Cancer_ocupacional.pdf	Contains the prohibited carcinogenic substances as established by Peru's Regulation of Occupational Exposure Limits of Chemicals
Prevention and Control of Occupational Cancer	https://web.ins.gob.pe/es/salud-ocupacional-y-proteccion/normatividad http://www.imarpe.pe/imarpe/archivos/Reglamento_Cancer_ocupacional.pdf	Contains the carcinogenic substances with which contact or exposure should be avoided / limited
Confidential business information (CBI) protection		
Currently Peru does not have a general regulation for industrial chemicals. Nevertheless, the Law N° 27806, Law on Transparency and Access to Public Information, in article 15°B establishes some exceptions to the right of access to public information, such as the information protected for the industrial and technological secret.		
Laboratory infrastructure (GLP)		
The Peruvian National Institute of Quality (INACAL) under the 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.		
Response on emergency situations involving chemicals, including poisoning		
The Ministry of Health is responsible for care of emergencies and disaster. The General Directorate of Disaster Risk Management and National Defense in Health (known ins Spanish as Dirección de Gestión del Riesgo de Desastres y Defensa Nacional en Salud - DIGERD) of the Ministry of Health (MINSA) 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 DIGERD develops, organizes, maintains an emergency response on the national, regional and local level. The Ministry of Environment (MINAM) is responsible for declaring environmental emergencies in coordination with the competent authorities.		

Chapter 8. Russia

Regulated objects: chemical products (chemical substances and mixtures).

Regulators: Ministry of industry and trade of Russia (Minpromtorg), Ministry of Natural Resources and Environment of Russia (Minprirody), The Ministry of Foreign Affairs of Russia (MFA), Ministry of Economic Development of Russia (MEDT), The Ministry of agriculture of Russia (Minselkhoz), The Ministry of health of Russia (Minzdrav), Ministry of Transport of Russia (Mintrans), Ministry of Energy of Russia (Minenergo), Ministry of Labour and Social Protection of Russia (Mintrud), Ministry of construction, housing and utilities of Russia (Minstroy), Ministry of Russia for Civil Defence, Emergencies and Elimination of Consequences of Natural Disasters (EMERCOM), Federal Environmental, Industrial and Nuclear Supervision Service (Rostechnadzor), Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor), Federal Service for Accreditation (RusAccreditation), Federal Customs Service (FCS), the Ministry of the Internal Affairs of Russia (MIA).

Table 8.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: The Stockholm Convention on Persistent Organic Pollutants, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, The Montreal Protocol on Substances That Deplete the Ozone Layer, United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, United Nations Convention on Psychotropic Substances, 1971, United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
Signed, not ratified: The Minamata Convention on Mercury
Other status: The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (accession), Vienna Convention for the Protection of the Ozone Layer (acceptance)
Other relevant agreements: Kyoto Protocol to the United Nations Framework Convention on Climate Change, Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter1972 (London Convention), supplemented by the 1996 Protocol, Agreement on common principles and rules of technical regulation in the Economies of the Eurasian Economic Commission, multilateral and bilateral cooperation activities.

Table 8.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
FL No 52-FZ of March, 30, 1999	Environmental factors	Rospotrebnadzor	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.

Table 8.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Prohibition or restriction of the use of certain chemicals			
RF Government Decree No. 681 of June 30, 1998 RF Government Decree of June 3, 2010 No. 398	Narcotic drugs, psychotropic substances and their precursors	Minzdrav, MIA	Lists of narcotic drugs, psychotropic substances and their precursors, whose handling in Russia is prohibited or restricted, and for which control measures are in effect according to the national legislation and international treaties. List of precursors (list IV) whose handling in Russia 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.
RF Government Decree of March 24, 2014 No. 228	Substances that deplete the ozone layer	Minprirody	RF Government Decree "On measures of state regulation of consumption and handling of substances that deplete the ozone layer" contains the list of ozone depleting chemicals, the handling of which is subject to state regulation. 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 Russia.
Technical regulation (TR) of the Customs Union (CU) 009/2011	Substances	Rospotrebnadzor	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 CU "On the safety of perfume and cosmetic products". Annex 2 includes a list of substances permitted for use in specific applications of perfumery and cosmetic products, taking into account some limitations.
TR CU 013/2011	Metal-containing additives	Federal Agency on Technical Regulating and Metrology Federal Service for Supervision of Transport	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" in Russia, metal-containing additives (containing manganese, lead and iron) are not allowed to be used in motor gasoline and diesel fuel.
TR EAEU 037/2016	Hazardous substances		The ban on the use of lead, mercury, cadmium and chromium in electronic engineering will be in effect in Russia 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. According to this TR "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 came into force on March 1, 2018; however, a

Table 8.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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.
New chemicals notification			
EAEU TR 041/2017	New substances		The procedure of pre-market notification for new substances is stipulated in the EAEU TR "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 the applicant shall submit to the relevant authority information on the substance, incl. a chemical safety report (SDS). 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.
Compliance confirmation in the form of certification and declaration			
Federal Law of December 27, 2002, No. 184-FZ	Products	Federal executive authorities	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 RF with the requirements of TR, provisions of standards, sets of rules or terms of contracts may be voluntary or mandatory. Voluntary confirmation of compliance shall be carried out in the form of voluntary certification. 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. Mandatory confirmation of compliance is carried out as: − adoption of a declaration of compliance (compliance declaration); − mandaroty certification. Mandatory confirmation of compliance is performed only in cases stipulated by the relevant TR and exclusively for compliance with its requirements. A single list of products subject to mandatory assessment (attestation) of compliance within the CU with the issuance of common documents (compliance certificate and compliance declaration) according to uniform forms was approved by the Decision of the CU Commission. Products not included in the single list can be subject to mandatory assessment (attestation) under

Table 8.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			the national legislation of the states - members of the CU. The Government of Russia 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.
State registration			
Decision of the Commission of the CU of May 28, 2010 No. 299	Potentially hazardous chemicals	Rospotreb-nadzor	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 CU "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 or imported for the first time on the CU 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. More details on the list of goods under supervision (control) can be found on the official website of the Eurasian Economic Commission[10]. State registration 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. 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 whose received at the first stage of registration), etc.

[10]Eurasian Economic Commission official website 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#

Table 8.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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 CU 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 CU territory. For products that are not subject to mandatory state registration, it is possible to voluntarily formalize an expert opinion of Rospotrebnadzor. A separate procedure of state registration is provided for pesticides and agrochemicals. This service is provided by the Minselkhoz.
GHS implementation			
GOST 30333-2007 GOST 31340-2013 R 50.1.102-2014 R 50.1.101-2014	Chemical substances and mixtures	Minpromtorg Federal Agency on Technical Regulating and Metrology	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. In accordance with GOST 30333 the SDS is an integral part of technical documentation for chemicals (substance, mixture, material, industrial waste). In particular, the SDS is included in 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 Russia 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 4th rev. 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;

Table 8.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			GOST 32421-2013 Classification of chemicals which hazard is caused by physical and chemical properties. Test methods of explosives.

Table 8.3

Non-regulatory Mechanisms: industry voluntary initiatives
• Russian Chemists Union (RCU): Responsible Care • Association "CIS Center": GPS

Table 8.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
The development of a register of substances and mixtures handling in Russia is stipulated by the TR "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		
SanPiN 1.2.2353-08 SanPiN 1.2.2834-11	http://www.pravo.gov.ru/proxy/ips/?docbody=&nd=102122725&rdk=1 http://www.pravo.gov.ru/proxy/ips/?docbody=&prevDoc=102122725&backlink=1&&nd=102146704	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 Russia
SanPiN 2.2.0.555-96	http://51.rospotrebnadzor.ru/documents/10156/134103/СанПиН+2.2.0.555-96+Гигиенические+требования+к+условиям+труда+женщин	Annex 2 of SanPiN 2.2.0.555-96 “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)
Single list of goods subject to sanitary-and-epidemiologic supervision (control) at the customs border and on the customs territory of the CU	http://www.eurasiancommission.org/ru/act/texnreg/depsanmer/regulation/Documents/perechen-73.pdf	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: – 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

Table 8.4

Chemical management system infrastructure		
Register of state registration certificates	See Footnote 1	Chemical Classification and Information Database 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.
Register of compliance certificates and compliance declarations	http://fsa.gov.ru/index/staticview/id/294/	Register of compliance certificate and compliance declaration, including the Russian national part of the register is available on the official website of the RusAccreditation.
State catalog of pesticides and agrochemicals	http://opendata.mcx.ru/opendata/	State catalog of pesticides and agrochemicals allowed for use on the territory of Russia is available on the official website of the Ministry of Agriculture of Russia. The catalog is valid until the next edition
ARIPS "Hazardous Substances"	http://www.rpohv.ru/db/arips/	Automated distributed data retrieval system (ARIPS) "Hazardous Substances" maintained by FBUZ "Russian Register of Potentially Hazardous Chemical and Biological Substances" 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 Russia there is no list of chemicals classified according to the GHS criteria, therefore the classification results presented in ARIPS are not officially approved.
GISP		State information system of industry (GISP) was created in accordance with the Federal Law No. 488-FZ "On Industrial Policy in Russia". GISP is focused on the development of a system of industrial balances
Register of Safety Data Sheets (SDS)	http://ciscenter.org	The Register of SDS is maintained by the Association "CIS Center" 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 in line with interstate standard GOST 30333-2007.
Confidential business information (CBI) protection		
Commercial secrets are secured by the provisions of the Federal Law No. 98-FZ of July 29, 2004, on Trade Secrets. The right to classify information as information constituting a commercial secret belongs to a holder of such information, this may relate to the information on chemicals composition. It should be noted that in line with the Article 5 of this FL the regime of commercial secrecy may not be established with regard to data on pollution of the environment, the condition of fire safety, safety of food products and other factors adversely affecting the safe functioning of production facilities, security of each citizens and security of population as a whole. CBI protection provisions are also envisaged in the second-tier documents to the TR "On the Safety of Chemical Products".		
Laboratory infrastructure (GLP)		

Table 8.4

Chemical management system 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. Russia 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. 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'.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 Russia. 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. At the present time, there are 10 laboratories in Russia that carry out research in accordance with GLP principles and one of it has an official international recognition since 2013.
Response on emergency situations involving chemicals, including poisoning
Article 4 of the Federal Law of Russia "On protection of the population and the territories against emergency situations of natural and technogenic nature" 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.

Chapter 9. Singapore

Regulated objects: hazardous chemicals[11], Chemical Weapon Convention (CWC) scheduled chemicals and unscheduled discrete organic chemicals (DOCs) [12], toxic chemicals, their precursors, psychotropic substances, controlled drugs[13], petroleum and flammable materials, which are regulated under our domestic legislations.

Regulators: 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.

Table 9.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, The Minamata Convention on Mercury, The Stockholm Convention on Persistent Organic Pollutants
Other status (accention): The Montreal Protocol on Substances That Deplete the Ozone Layer, Vienna Convention for the Protection of the Ozone Layer; United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988; The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Other relevant agreements: bilateral cooperation activities

Table 9.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
WSH Act	hazardous chemicals *as stated in in the 5th Schedule of the Act*	MOM	Workplace Safety and Health Act 2006. 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	hazardous chemicals	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

[11] List of controlled hazardous substances. http://www.nea.gov.sg/docs/default-source/anti-pollution-radiation-protection/chemical-pollution/hazardous-substances/hs--table-1;
[12] Controlled Chemicals by Singapore Customs. https://www.customs.gov.sg/businesses/chemical-weapons-convention/controlled-chemicals
[13]Psychotropic substances and controlled drugs listed in the respective regulations under the Health Products Act and Misuse of Drugs Act. http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview.html

Table 9.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			workplace safety and health risks, and establish safe work procedures if the risks cannot be eliminated.
WSH (General Provisions) Regulations	hazardous chemicals	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 (Major Hazard Installations) Regulations	hazardous chemicals	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 (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.
Fire Safety Act and Fire Safety Regulations	petroleum and flammable materials	SCDF	Fire Safety Act (Chapter 109A) and Fire Safety (Petroleum and Flammable Materials) contain the requirements for controlling the import, storage, transport by road, conveyance by pipelines of petroleum and flammable materials in Singapore.
EPMA	hazardous substances	NEA	Environmental Protection And Management Act (Chapter 94A) 2002 Revised Edition is the main Act for pollution control. It consists of 14 parts and 3 Schedules. It specifies what are scheduled premises and list out the conditions to the licence (Part III); specifies requirements of the Air Pollution Controls (Part IV); the Water Pollution Controls (Part V); the Land Pollution Controls (Part VI); the Hazardous Substances Controls (Part VII); the Noise Controls. Part IX specifies the conditions for Licences and Industrial Plant Works. Part X contains the description of the Environmental Pollution Control Measures. Enforcements (Part XI), Compensation, Damages, Fees, Costs and Expenses (Part XII) are also specified. First Schedule defines Scheduled Premises. Second Schedule contains the List of Hazardous Substances and exemptions. The Third Schedule includes the Subject Matters of Regulations.
EPM (HS) Regulations	hazardous substances	NEA	Environmental Protection & Management (Hazardous Substances) 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.
GHS implementation			

Table 9.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
Under the Work Safety and Health (General Provisions) Regulations 2011 the seller or agent of the seller of hazardous substances must provide SDS in accordance with Singapore Standard SS 586 Part 3, and any occupier of a workplace must label the containers of hazardous substances in accordance with SS 586 Part 2. Other standards and Guidelines are also in force (SS 532: 2016, SS 508: 2013, SS 508 - 2: 2013, Guidelines On Quantitative Risk Assessments (QRA) (Last amended on Apr 2010)).			
WSH (General Provisions) Regulations	Hazardous chemicals	MOM	Workplace Safety and Health (General Provisions) Regulations Part IV Special Provisions relating to Health, Safety and Welfare.
SS 586:2014	hazardous chemicals and dangerous goods		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. Part 1 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. Part 2 provides standard hazard communication elements including labels and safety data sheets. Part 3 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.

Table 9.3

Non-regulatory Mechanisms: industry voluntary initiatives
• Singapore Chemical Industry Council Limited (SCIC): Responsible Care, Chemical Industry Manpower Advisory Committee (CHIMAC), ICCA-HPV program (a global initiative on High Production Volume (HPV) chemicals), ICCA-LRI program (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) • Singapore Environmental Council (SEC): The Singapore Green Labelling Scheme (SGLS)

Table 9.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*

Table 9.4

Chemical management system infrastructure		
TradeNet	http://www.tradenet.gov.sg/trdnet/index_home.jsp	Electronic database of goods moving across Singapore's borders administered by Customs.
List of controlled substances		Hazardous Substance (HS) Permit issued by the NEA
List of Explosive Precursors	https://www.police.gov.sg/e-services/apply/licenses-and-permits/~/media/spf/files/e-services/list_of_15_eps.pdf	Explosive precursor (EP) license issued by the SPF
Controlled chemicals under CWC	https://www.customs.gov.sg/businesses/chemical-weapons-convention/controlled-chemicals	Chemical Weapon Convention (CWC) license issued by the Singapore Customs
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		Petroleum and Flammable (P&FM) license issued by the SCDF
Confidential business information (CBI) protection		
–		
Laboratory infrastructure (GLP)		
Singapore is accepted into the Organisation for Economic Co-operation and Development (OECD) Mutual Acceptance of Data framework. Enterprise Singapore (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. The Singapore Accreditation Council (SAC) (https://www.sac-accreditation.gov.sg/), 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.		
Response on emergency situations involving chemicals, including poisoning		
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. 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		

Table 9.4

Chemical management system infrastructure
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. In Singapore there is an Incident Management Center otherwise known as the Asia Chemical Transportation Emergency Center (ASCTEC) [14]. It offers communication services entailing the storage, maintenance and dissemination of material safety data sheet (MSDS) information, technical consultation. It also provides 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.

[14] Incident Management Center Singapore. http://www.alertdisastercontrol.com/emergency/hazardous-material-control/

Chapter 10. Chinese Taipei

Regulated objects: chemical substances: new chemical substances (new substance shall be registered 90 days prior to production or import) (TCSCA[15] and OSHA[16]) and designated existing substances (TCSCA).

Regulators: Environmental Protection Administration of Chinese Taipei, EPA; Occupational Safety and Health Administration, Ministry of Labor (MOL)

Table 10.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Measures to comply voluntarily with major MEAs: Vienna Convention and Montreal Protocol (committed to comply with control measures set to the industrialized nations (non-Article 5 Economies)); Stockholm Convention (Chinese Taipei Implementation Plan for Persistent Organic Pollutants (POP)); Basel Convention (Waste Import and Export Management and Basel Convention Implementation Plan); Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction; Minamata Convention.

Table 10.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
TCSCA	Chemical substances (both new and existing) *as defined in the Article 7-1 and Regulation of New and Existing Chemical Substances Registration*	EPA	Adopts 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[17]. Followings are other important supporting documents. - Approval Regulation for Class 4 Toxic Chemical Substances of Chinese Taipei. - Regulation on Commission on New Chemical Substances and Existing Chemical Substances Registration Dossier Review of Chinese Taipei. - Toxic Chemical Substances Labeling and Safety Data Sheets Regulations of Chinese Taipei. - Standard on Toxic Chemical Substances Handling Application Fee and Chemical Registration Fee.

[15] EPA (2013). Toxic Chemical Substances Control Act of Chinese Taipei.
[16] MOL (2013). Occupational Safety and Health Act of Chinese Taipei.
[17] EPA (2014). Regulation of New Chemical Substances and Existing Chemical Substances Registration of Chinese Taipei.

Table 10.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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. 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. Registration Platform is available for registrants (TSCA Chem Reg). 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. If a substance has been announced as Class 1, 2, 3, or 4 toxic chemical substance, enterprises who handle it will need to

Table 10.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			apply for permits, registration or approval and comply with relevant management measures.
OSHA	New chemical substances *as defined in the Article 13*	MOL	Producers or importers shall not manufacture or import new substances prior to submitting hazard information and obtaining registration approval from Chinese Taipei. Three types of registration is available: standard, simplified and low volume registrations. Chemical Risk Assessment is required for >=1t/y CMR substances and >=10t/y regular new substances. New substances manufactured or imported into Chinese Taipei prior to 11 Dec 2014 need to go through small quantity registration process, the certificate is valid for 1 year only. OSHA CSNN Registration Platform is available. In addition to the new chemical substances registration, three measurements were adopted to protect workers' safety and health in workplace: *Chemical control banding (CCB) - Article 11 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 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 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 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.
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;			

Table 10.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
– Regulations for the Labeling and Hazard Communication of Hazardous Chemicals of Chinese Taipei (effective on December 31, 2008) ("MOL Regulation"); – Management Measures on Toxic Substances Labeling and Material Safety Data Sheet of Chinese Taipei, 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 it. The latest version of January 2015 is based UN GHS Rev. 4. The revised Regulation of Labeling and Hazard Communication of Dangerous and Harmful Substances of Chinese Taipei 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* 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.			

Table 10.3

Non-regulatory Mechanisms: industry voluntary initiatives
• TCIA • TRCA • TCIA and TRCA are ICCA observers: Responsible Care

Table 10.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
TCSI	http://csnn.osha.gov.tw/content/home/Substance_Query_Q.aspx	The Inventory is the only chemical substance inventory of Chinese Taipei. The Inventory lists over 100,000 chemical substances, 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. 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 by the identification number, serial number or chemical name.
CHEMical Information System and Tool - CHEMIST 3.0	https://tcscachemreg.epa.gov.tw/Epareg/content/login/DownloadList.aspx?enc=C124AE6A01053E7F0BB471DDF8210136B03FA862EEB559E6	On 5 Oct 2015, Chinese Taipei EPA issued the offline chemical registration 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.
Confidential business information (CBI) protection		
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.		
Laboratory infrastructure (GLP)		
TAF is the Good Laboratory Practice (GLP) Compliance Monitoring Authority (CMA) in Chinese Taipei, officially designated by the Chinese Taipei 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, as well as the Advisory Documents of the Working Group on GLP. 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. 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. TAF represents as the GLP compliance monitoring authority in Chinese Taipei under the program "OECD GLP National Compliance Monitoring System".		
Response on emergency situations involving chemicals, including poisoning		

Table 10.4

Chemical management system infrastructure
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. Chinese Taipei EPA is also operating an emergency response call center and providing three incident response teams in handling of chemical accidents.

Chapter 11. The United States of America

Regulated objects: chemical substances (new and existing) and mixtures (TSCA[18]). Chemical substances regulated under other U.S. statutes include: pesticides; foods and food additives; drugs; cosmetics; tobacco and tobacco products; nuclear materials; and munitions.

Regulators: U.S. Environmental Protection Agency (EPA); U.S. Consumer Product Safety Commission (CPSC); Department of Transportation (DOT); Occupational Safety and Health Administration (OSHA); Food and Drug Administration (FDA) and state departments at the state level (incl. Department of Ecology, Department of Toxic Substances, Department of Environmental Protection).

Table 11.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: The Montreal Protocol on Substances That Deplete the Ozone Layer, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, The Minamata Convention on Mercury, Vienna Convention for the Protection of the Ozone Layer, United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988
Signed, not ratified: The Stockholm Convention on Persistent Organic Pollutants, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Other relevant agreements: Convention on the Organisation for Economic Co-Operation and Development (OECD), 1960; the North American Agreement on Environmental Cooperation; the Great Lakes Water Quality Agreement (GLWQA); bilateral cooperation activities

Table 11.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
TSCA	Chemical substance *as defined in the Sec. 2602, Chapter 53 of the 15 U.S.C.*[19]	EPA	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. 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 EPA and listed by EPA on the TSCA Inventory of Chemical Substances upon notification of commencement of commercial manufacture, including import. ***New chemical substances***

[18] Toxic Substance Control Act, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), 2016. https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act
[19] http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim

Table 11.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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. 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 a premanufacture notice (PMN) before initiating the activity. 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. 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 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. If EPA determines that a new chemical or significant new use presents unreasonable risk, 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

Table 11.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			limit the manufacture, processing or distribution in commerce to take effect on the expiration of the applicable review period. ***Existing chemical substances*** EPA evaluates the safety of existing chemicals via a three-stage process (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 [20], 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 during risk evaluation. This includes risks to subpopulations who may be at greater risks than the general population, such as children and workers. 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. 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

[20] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#updates

Table 11.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			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.
GHS implementation			
Hazard Communication Standard	Hazardous Chemicals as defined by 29 CFR 1910.1200	OSHA	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.*

Table 11.3

Non-regulatory Mechanisms: industry voluntary initiatives
• EPA: Sustainable Futures Program, Presidential Green Chemistry Challenge Awards, Safer Choice Program to encourage the development of safer chemicals, products, and practices • ICCA member (American Chemistry Council): Responsible Care

Table 11.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
The TSCA Inventory	https://www.epa.gov/tsca-inventory	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 USA 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 chemicals, was published in 1982. The TSCA Inventory now lists about 85,000 chemicals. The Chemical Data Reporting (CDR) rule under TSCA (formerly known as the Inventory Update Rule (IUR)) 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.
ChemView	https://chemview.epa.gov/chemview	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.
Toxics Release Inventory	https://www.epa.gov/toxics-release-inventory-tri-program	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.)

Table 11.4

Chemical management system infrastructure		
		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.
Confidential business information (CBI) protection		
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Laboratory infrastructure (GLP)		
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.		
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.		

Chapter 12. EC

Regulated objects: chemical substances (REACH[21] and CLP[22] Regulations); mixtures (CLP Regulation, REACH Regulation [safety data sheets preparation and communication]). There are several legal acts in place regulating distinct chemical groups.

Regulators: European Chemicals Agency (ECHA), European Commission (EC), competent authorities of the EU Member States (competent authorities).

Table 12.1

Multilateral environmental agreements (MEAs) relevant to chemicals and waste
Signed, ratified: The Stockholm Convention on Persistent Organic Pollutants, The Montreal Protocol on Substances That Deplete the Ozone Layer, The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, Vienna Convention for the Protection of the Ozone Layer, United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; United Nations Convention on Psychotropic Substances, 1971; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
Signed, not ratified: –
Other status: The Minamata Convention on Mercury (approval)

Table 12.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
REACH	Substances (both new and existing), including those contained in mixtures *as defined in the Title 1, Chapter 1, Article 3 of the Regulation*	ECHA, EC, competent authorities	Regulation introduces mandatory registration of all substances that are manufactured in the EU or/and placed on the market of the EU (in the volume greater than 1t/y per legal entity, exemptions apply), registration process was phased. Up to the 1 June 2018 all chemical substances subject to registration had to be registered. Registrants (manufacturers, importers/only representatives) have many responsibilities under REACH: the responsibility to provide ECHA substance hazard and exposure data, including corresponding test protocols; assess risks arising from the uses of their substances and suggest appropriate risk management measures, communicate them to the users. Nomenclature of the data required depends on the hazardous chemical properties and production/import volumes.

[21] 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
http://data.europa.eu/eli/reg/2006/1907/2014-04-10

[22] 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
http://data.europa.eu/eli/reg/2008/1272/oj

Table 12.2

Key procedures for control of the regulated objects			
Legal act	Regulated objects	Regulator	Legal act brief description
			ECHA received registration dossiers and checks their compliance. Selected substances undergo evaluations by competent authorities to concerns for human health or for the environment. Competent authorities and ECHA's scientific committees assess whether the risks posed by selected hazardous substances can be controlled. Competent authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorisation. ECHA administrates various databases, providing access to nonconfidential data from the registration dossiers (please refer to the Table 1.4 of the ES).
GHS implementation			
CLP	Substances and mixtures *as defined in the Title I, Article 2 of the Regulation*	ECHA, EC, competent authorities	Regulation sets obligations for the manufacturers, importers and downstream to classify substances and/or mixtures before placing them on the market. Where a substance or mixture is classified as hazardous, suppliers shall ensure that the substance or mixture is labelled and packaged in accordance with the Regulation requirements, before placing it on the market. Manufacturers, importers must notify a substance to the Classification and Labelling (C&L) Inventory within one month from being placed on the market (including substances, contained in mixtures) in the following cases: (a) substances subject to registration in accordance with REACH Regulation or (b) hazardous substances that are placed on the market either on their own (regardless volumes) or in a mixture above the specified concentration limits, where relevant, which results in the classification of the mixture as hazardous. CLP Regulations established a list of substances with their harmonised classifications and labelling elements at the EU level (Part 3 of Annex VI). ECHA has established and maintains a classification and labelling inventory in the form of a database, containing information obtained through the notification process and partially from the REACH registration dossiers (please refer to the Table 1.4 of the ES).

Table 12.3

Non-regulatory Mechanisms: industry voluntary initiatives
• ICCA member: Responsible Care, Global Product Strategy (GPS) and Product Stewardship (PS) • Chemicals Health Monitor Project • Chemical Leasing Award • CHEM Trust • European Technology Platform Sustainable Chemistry • The Endocrine Disruption Exchange, Inc. (TEDX)

Table 12.4

Chemical management system infrastructure		
Informational resources		
Data base	*Web link*	*Brief description*
EC Inventory	https://echa.europa.eu/information-on-chemicals/ec-inventory	Contains the following lists: EINECS (European INventory of Existing Commercial chemical Substances), ELINCS (European LIst of Notified Chemical Substances), NLP (No-Longer Polymers). Substances on those lists were deemed to be «existing» in the EU market. Those substances were subject to phased registration under the REACH Regulation. Contains 106 000 substance entries.
Substances Infocards and Brief Profiles	https://echa.europa.eu	Contains high-level aggregated information on chemicals for broad public ("first-tier" information). It includes information from REACH registrations and C&L notifications from industry as well as data gathered by the competent authorities within harmonised C&L, authorisation and restriction. Infocards are generated automatically based on the information available in ECHA and are not manually verified. Infocards contain substance C&L; hazard and safe use information, chemicals of very high concern, chemicals with restricted use. Users may choose to see additionally substance brief profile, that includes data on phys-chemical, environmental and human health ("second tier"). Source data is also accessible ("third tier").
Registered substances	https://echa.europa.eu/information-on-chemicals/registered-substances	ECHA grants access to non-confidential part of the REACH registration dossiers. Contains more than 21 000 substance entries (as of July 2018).
C&L Inventory	https://echa.europa.eu/information-on-chemicals/cl-inventory-database	C&L information obtained via CLP notification and REACH registration processes, as well as harmonized C&L. Contains more than 142 000 substance entries (as of July 2018).
Community rolling action plan (CoRAP)	https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table	If a substance is on this list, it means that competent authorities of a Member State have evaluated or will evaluate it over the coming years. Contains more than 350 substance entries (as of July 2018).
Candidate List of substances of very high concern for	https://echa.europa.eu/candidate-list-table	Official list of candidate substances for the REACH authorization process. Contains more than 190 substance entries (as of July 2018).

Table 12.4

Chemical management system infrastructure		
Authorisation		
Authorisation List	https://echa.europa.eu/authorisation-list	List of substances included in Annex XIV of REACH ("Authorisation List"). Contains 43 unique substance entries (as of July 2018).
For compliance with REACH and CLP requirements the following IT-tools are available: IUCLID system (system to store and manage chemical data), REACH-IT (system to provide for interaction of registrants/notifiers with ECHA), Chesar (tool to support hazard and risk assessments), QSAR Toolbox (software application to fill the gaps in the (eco)toxicity property data by computer modelling). The use of some of these tools is mandatory for the purposes of REACH and CLP compliance. Detaild information is available at the ECHA website.		
Confidential business information (CBI) protection		
REACH registrants and CLP notifiers have an opportunity to flag out information that falls under the criteria of the Article 119(2) of the REACH Regulation as confidential. The request is fee-based and has to be fully justified. For information falling under the Article 119(1) confidentially status can not be obtained.		
Laboratory infrastructure (GLP)		
GLP is implemented by the Directives 2004/10/EC[23] and 2004/9/EC[24]. GLP laboratories are operating in Belgium, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Netherlands, Italy, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland and the UK. Detailed information on GLP implementation in the EU is available at the EC website via the following link http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en		
Response on emergency situations involving chemicals, including poisoning		
Member states have individual responsibility for providing emergency response. The ECHA website contains information on the poison centers that provide assistance in the treatment, incl. related to chemical poisoning. https://poisoncentres.echa.europa.eu		

[23] Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 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. *OJ L 50, 20.2.2004, p. 44–59.* *http://data.europa.eu/eli/dir/2004/10/oj*

[24] Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP). *OJ L 50, 20.2.2004, p. 28–43.* *http://data.europa.eu/eli/dir/2004/9/oj*