KEMI
Swedish Chemicals Agency

Guidance on national chemicals control

Legislation on chemicals placed on the market

GUIDANCE 3

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The Swedish Chemicals Agency's guidance series on national chemicals control

This guidance is part of a series developed by the Swedish Chemicals Agency. The guidance documents cover a wide range of issues that are important for the establishment of a system for preventive chemicals control. First versions of the documents were published during 2017 to 2020.

Control of chemicals placed on the market (brochure)

1. Sustainable financing of institutional capacity for chemicals control

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Link to the guidance documents and more information on guidance on national chemicals control: www.kemi.se/en/guidance-on-national-chemicals-control

KEMI
Swedish Chemicals Agency

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We also provide guidance regarding enforcement and inspections to municipalities and county administrative boards. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

Cover illustrations by Maja Modén

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Preface

Chemicals contribute in many ways to improving our standard of living, but some of them are hazardous and can have serious adverse effects on human health and the environment. It is therefore necessary to use different means to protect human health and the environment from the adverse effects from exposure to hazardous chemicals.

This guidance is part of a series of guidance documents developed by the Swedish Chemicals Agency. The series forms a complement to the UNEP Guidance on the Development of Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration (LIRA guidance) by giving more detailed guidance in different areas. This guide explains how countries can build a legal framework for chemicals placed on the market.

The Swedish Chemicals Agency has developed the guidance document with the financial assistance of the Swedish International Development Cooperation Agency, Sida. The views herein shall not be taken to reflect the official opinion of Sida.

Contents

Summary

The establishment of a national legal framework and related institutional capacity for the management of chemicals is one of the cornerstones for the sound management of chemicals and for achieving sustainable development.

The aim of this document is to give guidance to countries (governments and authorities) in their efforts to set up an efficient system for the sound management of chemicals with a special focus on the legal frameworks. The guidance focuses on legislation for preventive chemicals control directed towards the placing of chemicals on the market and gives examples of possible legal texts.

A primary national law on chemicals is essential for effective regulation of chemical hazards and risks. Primary legislation makes it possible to establish the general responsibilities, obligations, roles and, tasks of both companies and government authorities. Details concerning responsibilities, obligations, and tasks might preferably be issued as secondary legislation, e.g. as governmental/ministerial regulations or even at lower levels. Specific regulations needed are often too scientific, technical, and detailed, and are revised too frequently, to be decided upon by parliaments and in many cases even by governments.

A starting point in writing legislation for chemicals placed on the market is to ensure that information on the contents of the chemical substances and mixtures is gathered and disseminated in the supply chain. A fundamental means to provide the information to all actors in the supply chain is to make classification and labelling, preferably according to the Globally Harmonized System (GHS), mandatory. This will provide downstream users with the information they need to assess risks, make informed choices, and provide for safe handling.

Chemicals legislation can also limit free access to particularly hazardous chemicals through bans and restrictions or other means. The restriction requirements of international conventions could also be issued under the chemicals legislation, if not issued through specific ratification laws.

Other parts that might be covered by a chemicals legislation are authorisation, registration, reporting, confidentiality, and sanctions. Possible legal texts for these areas are also given in this guidance.

1 Introduction and scope

There are several benefits to having legislation regarding chemicals placed on the market. Such legislation is a central driver for the protection of health and the environment, and having good legislation in place can also facilitate trade between countries.

This document aims to guide countries in designing legislation on chemicals placed on the market and covers issues such as requirements on classification and labelling of chemical substances and mixtures and bans or restrictions of chemicals in various products. It also describes the importance of clearly defining the responsibilities of trade and industry and of government authorities in the law.

This guidance builds on the recommendations in the Swedish Chemicals Agency guidance on risk reduction of chemicals[1] and gives further guidance specifically on forming legal requirements.

Any country introducing new legal requirements will need to consider how these requirements shall be controlled. Provisions for enforcement should therefore be established in legislation and effectively implemented because laws are meaningless if they are not enforced. Legislation needed for enforcement often includes tools for inspection, like the right to get access to premises, the right to take samples, the right to issue sanctions, etc. Further guidance on enforcement can be found in the Swedish Chemicals Agency guidance on enforcement of legislation on chemicals placed on the market[2].

An additional source of information is the UNEP Guidance on the Development of Legal and Institutional Infrastructure and Measures for Recovering Costs of National Administration, often referred to as the UNEP LIRA-Guidance[3].

1.1 Guideline structure

This guideline discusses an appropriate design and content of a general, product-orientated legislation for chemicals placed on the market. It addresses the main stakeholders concerned with chemicals control, namely legislators, appropriate government authorities, and trade and industry. A special focus is placed on the important role of the primary suppliers, i.e. the producers and importers of chemicals.

In chapter 2, various types of legislation normally involved in chemicals management broadly is discussed. This is followed by a discussion on the specific need for control of chemicals placed on the market as well as ways to specifically regulate that area.

A presentation of benefits with placing some responsibilities in a primary law and placing other responsibilities in secondary legislation is found in chapter 3.

Chapter 4 and its subchapters discuss the design and content of legislation of chemicals placed on the market. Focus is placed on regulations regarding the most important responsibilities and tasks of companies and of governmental authorities. These regulations

[1] Swedish Chemicals Agency (2018). Guidance on national chemicals control: Risk reduction of chemicals. https://www.kemi.se/en/guidance-on-national-chemicals-control
[2] Swedish Chemicals Agency (2018). Guidance on national chemicals control: Enforcement of legislation on chemicals placed on the market. https://www.kemi.se/en/guidance-on-national-chemicals-control
[3] https://www.unenvironment.org/resources/report/lira-guidance

constitute the main building blocks of legislation for efficient management of chemicals. Each of the subchapters gives a short general background and a rationale for regulation. Examples are given of texts of general primary law followed by comments on the contents of detailed secondary law.

The legal texts put together gives an idea of a possible design and content of a comprehensive and coherent general legislation covering risk management before or when chemicals are placed on the market. When shaping the final overall design of a national legislation and the final texts of each regulated issue, prevailing legal, administrative, and other traditions of your country have to be considered.

2 Chemicals legislation and other related pieces of legislation

In this chapter various types of legislation normally involved in chemicals management are discussed. This is followed by a discussion on the specific need for control of chemicals placed on the market as well as ways to specifically regulate that area.

The word “chemical” is in the following used as a common term for chemical substances and mixtures of substances. For clarity, a distinction between substances and mixtures is made in some cases.

2.1 Many areas in sound chemicals management

It is estimated that more than 100,000 chemicals are available on the market[4], but the number used in significant volumes is much smaller. The number of registered substances in the EU-REACH system produced in volumes greater than one tonne/year was 21,551 as of 31 May 2018, which was the final date of the 10-year period for registration of phase-in substances produced in or imported into the EU market in such volumes.

Risk management of chemicals concerns many areas in the society. During their life cycle, chemicals are often regulated in several pieces of legislation such as on environment, health, work environment, consumer safety, rescue services, transport, and waste handling. Chemicals can also be regulated in different pieces of legislation depending on which type of chemicals they belong to, for example pesticides, cosmetics, medicines, or additives in food. Often different ministries are responsible for different chemicals.

Dividing regulations of chemicals into several pieces is appropriate for many reasons. Exposure to hazardous chemicals can occur in the workplace, through emissions to the outdoor environment, through major accidents at facilities, or during transportation, as well as in private homes. Further, some types of chemicals might warrant special attention because they are intended to have special properties, such as pesticides, which are intended to have some kind of hazardous properties. A single piece of legislation fully covering all types of management of chemicals in all steps of their lifecycle would become very comprehensive

[4] The Classification and Labelling Inventory at ECHA contained at the beginning of 2018 more than 135,000 substances. These include all substances subject to registration under REACH as well as all substances placed on the market that are classified as hazardous. https://echa.europa.eu/regulations/clp/cl-inventory

and complex. It could also become less transparent to certain actors in the supply chain if, for example, legislation on emissions of chemicals to the outdoor environment from facilities were to be found in another piece of legislation than the one regulating other emissions to the environment from such facilities.

Chemicals control focuses on the control of chemical substances and mixtures as well as other products that contain chemicals that are placed on the market. The legislation discussed in this guideline aims at regulating chemicals at this stage. These measures are the first steps of risk management irrespective of later type of use. As mentioned above, chemicals are also often regulated in several laws covering aspects like worker protection, emissions to the environment, etc. It is important that these different regulations are coordinated to avoid overlaps or the omission of important aspects.

2.2 Product-oriented risk management – focusing on the chemicals placed on the market

There are a number of reasons to continuously control the placing of chemicals on the market in countries in addition to measures controlling exposure to hazardous chemicals when they are used. In many countries some legislation is in place that can be used for reducing exposure to hazardous chemical agents in the workplace, exposure through emissions to the outdoor environment, exposure through major accidents at facilities, or during transportation. Regulating the placing of chemicals on the market and clarifying the responsibilities of the suppliers, especially the producers and importers of chemicals, is an area of legislation that is well established in a number of countries, whereas many other countries do not have this kind of legislation in place yet. Introducing such legislation allows for the control of chemicals when, or even before, they are placed on the national market and will help to reduce health and environmental problems that otherwise might occur later in the lifecycle of the chemical. This approach is often highly cost-effective compared to measures taken once chemicals are already spread in society or the environment.

The various measures of chemicals control early in the supply chain, when chemicals are placed on the market, all aim to improve control of the flow of chemicals onto the market and to provide possibilities to reduce exposure to hazardous substances during their subsequent use and disposal – i.e. preventive chemicals control.

These measures that

- build up knowledge on health and environmental hazards from chemical substances,
- disseminate information on hazards, risks, and precautionary measures accompanying the chemicals when supplied to professional users and private consumers, and
- phase out the most hazardous substances

are the first general steps of risk management and are prerequisites for efficient risk management at later steps of the supply chain irrespective of the type of use or other handling. This makes the role of the primary suppliers (importers and producers) of particular interest because they have to identify and assess all hazardous properties and reasonably foreseeable risks to human health and the environment before they place a chemical on the market.

Obligations to disseminate information on hazards and precautionary measures enable both professional and private users to choose less hazardous chemicals and to handle chemicals

safely. Based on this information, they can assess possible risks and the need for risk reduction measures specific to their handling and use of the chemical. Safety data sheets provide professional users with information on how to manage risks in the workplace, prevent emissions to the outdoor environment, ensure safe transportation, and ensure safe storage. Information about chemical contents in all sorts of products makes their recycling easier and supports safe waste management.

Bans and restrictions regulate access to chemicals that are too hazardous to remain freely and openly available. Such legislation can restrict the use of substances as such, in mixtures, in specified products, or for certain uses. Banned or restricted substances will not be present further down the supply chain and thus will not result in problems there.

There are a number of international agreements that provide important starting points and can form a basis for the development of national legislation regarding chemicals placed on the market.

- the UN programme Strategic Approach to International Chemicals Management, SAICM
- the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
- the Stockholm Convention on Persistent Organic Pollutants (POPs)
- the Minamata Convention on Mercury,
- the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
- the Montreal Protocol on substances that deplete the ozone layer

2.3 Rationale for separate and coherent legislation on chemicals placed on the market

There are some main reasons to regulate chemicals placed on the market in specific chemicals legislation separately from other legislation.

The main reason is that chemicals legislation supports all the other areas where chemicals are a concern, like in protecting the environment and worker and consumer health and safety. Efficient control of the flow of chemicals onto the market, which is the aim of chemicals legislation, is complementary to risk management in the handling of chemicals, irrespective of where or for what purpose.

As already mentioned, companies that place chemicals on the market should have the responsibility for assessing and classifying them with regard to hazard and for providing information (labels and safety data sheets (SDS)) that describes hazards, risks, and instructions for safe use. Furthermore, they should comply with possible bans and restrictions. Regulating these obligations of suppliers in many laws and regulations issued by several ministries and authorities can complicate the legislation as well as its implementation and enforcement. A chemical that is used in several sectors has the same intrinsic properties regarding health and environmental hazards irrespective of its use, and it will be confusing if the chemical is classified and labelled in different ways.

For efficiency, national implementation of international agreements should be done in a coherent and coordinated manner, avoiding specific legislation for each agreement. This is especially true with regards to the implementation of trade-orientated parts of the Stockholm-

and Rotterdam conventions, the Minamata Convention, the Montreal Protocol, GHS, and SAICM.

In order to avoid omissions, gaps, and contradictions and to be workable and efficient, the legislation on chemicals control in the first step of the supply chain should be as coherent and concentrated as possible. It is therefore reasonable to have one separate piece of legislation primarily regulating risk management in the supply of chemicals. This chemicals legislation should force all stakeholders placing chemicals on the market to take necessary precautions, to perform risk assessments, to classify and label, to provide SDS, etc. This will make such legislation an efficient complement to sector legislation on protection of the environment, on waste, on health and safety of workers, on consumer protection, on public health, on safety during transport, on large accidents, etc (fig.1).

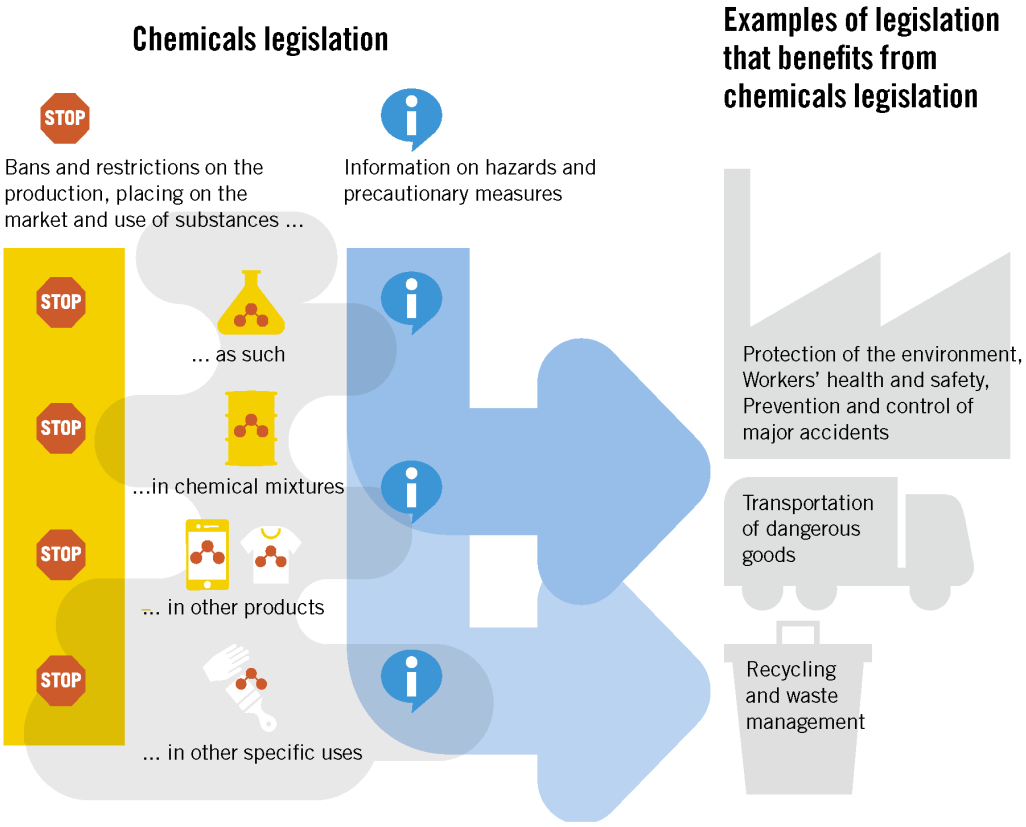

Figure 1. The obligations in the supply chain imposed by chemicals legislation. The yellow field to the left represents bans and restrictions as a means to regulate the use of the most hazardous substances. Information requirements on chemicals make it easier for professional users to comply with legislation on protection of the environment, workers' health and safety, major accidents, transportation, etc. The legislation also helps the consumer to make safe choices and handle chemicals correctly. Illustration by Maja Modén.

The chemicals legislation may be formulated as a separate Chemicals Law. This solution makes the legislation clearly stand out from other legislation covering risk management in other parts of the chemicals' life cycle. It will give more focus on the importance of preventive risk management when placing chemicals on the market to the benefit of risk management in later steps of the supply chain. Chemicals legislation can also be organised as a specific, separate part of some existing legislation, e.g., an Environment Protection Law. In the latter case, it is most important to make clear that this separate part regulates chemicals from a broader perspective than just protection of the environment. Accordingly, the aim and purpose of the law must be formulated to allow for regulation of the protection of health and the environment as well.

3 Allocation of regulations between primary and secondary legislation

A primary national law on chemicals, to which secondary legislation may be attached, is essential for effective regulation of chemical hazards and risks. Primary legislation makes it possible to establish general responsibilities, obligations, and tasks of both companies and government authorities. It provides a framework for the legislation, and details concerning responsibilities, obligations, and tasks may preferably be issued as secondary legislation, e.g. as governmental/ministerial regulations or at even lower levels. Specific regulations needed, e.g., on classification and labelling, are revised too frequently to be decided upon by parliaments or in many cases even by governments.

Secondary legislation is needed to regulate specifics regarding, e.g., testing, assessment, and information on chemicals. Among the most important regulations to elaborate are the ones for classification, labelling, and SDS guiding the flow of hazard, risk, and safety information from suppliers to users and others that handle chemicals. A high quality of this information flow is essential for efficient management of chemical risks. Bans and restrictions of supply and use of chemicals might also be regulated as secondary legislation. Further pieces of secondary legislation might concern specifics on authorisation and registration in order to establish specific obligations of legal and private persons and to organise needed processes.

The mandates for the government and authorities to develop and decide on legislation and to manage and be responsible for specific issues have to be stated in legislation. The mandates to the government need to be given in legislation decided by the parliament, and mandates to authorities needs to be given in legislation decided by the government if they have been given the power to make such further delegation.

Many international conventions and agreements on chemicals provide good guidance on the content and formulation of specifics of legislation. The internationally agreed upon GHS system might be accepted as a national regulation for the classification, labelling, and SDS and should as far as possible be referred to without adaptations. Any remaking of this international system will make national chemicals control more complex and resource demanding for authorities and companies. Deviations from the standard might also cause unnecessary barriers to trade.

The OECD has issued several documents on chemicals control, e.g. on testing and concerning the exchange of data. The FAO has issued guidelines on the legislation and authorisation of pesticides.

In general, application of international standards and other agreements contribute to a cost-efficient national control of chemical risks.

4 Content of legislation on chemicals placed on the market

This chapter and its subchapters discuss the design and content of legislation of chemicals placed on the market. Focus is given to regulations regarding the most important responsibilities and tasks of companies and of governmental authorities. These regulations constitute the main building blocks of legislation for efficient management of chemicals. Each of the subchapters gives a short general background and a rationale for regulation. Examples are given of texts of general primary legislation followed by comments on the contents of detailed secondary legislation.

4.1 Aim and scope of a legislation on chemicals placed on the market

This initial part of the legislation should cover the scope of the legislation.

4.1.1 Broad coverage of risks

It is an advantage to clarify the scope of the legislation in the beginning. The scope of a comprehensive general chemicals law should cover protection of both human health and environment from negative effects due to exposure to chemicals. As regards human health, the law should include protection of consumers, workers, and the public. Further, it is not only the risks due to toxic properties of chemicals to health and to the environment that need to be considered. Because chemicals might cause other risks due to physicochemical properties such as flammability and explosiveness, these also have to be taken into account.

4.1.2 Substances, mixtures, and articles

The law could cover chemical substances as such as well as in mixtures and in articles. A law only covering pure substances would be very narrow and have limited effect because most chemicals placed on the market are mixtures. Therefore, it is advisable to let the law cover both pure substances and mixtures at a minimum. However, nowadays the largest flows of chemical substances into society come through articles[5], and these might give rise to considerable chemical risks to both human health and the environment. Leakage of metals like cadmium, mercury, and lead from articles during use or as waste is a typical example. Others are organic substances used as flame retardants, preservatives, and dyes in wood, textiles, electronics, etc. By including articles in the scope of the law, it will be possible to

[5] In the EU regulation REACH, articles are defined as objects that during production are given a special shape, surface, or design that determines their function to a greater degree than does their chemical composition.

issue further provisions both on information and on bans and restrictions that also cover substances when they are present in articles. Development is ongoing to find means for conveying hazard, risk, and safety information for articles like those already agreed upon internationally for substances and mixtures (GHS). UN Environment is presently leading a Chemicals in Products (CiP) programme aiming to improve the access to information about chemicals in products (articles). Some regulations for this purpose already exist, for example, in the EU. Bans and restrictions can concern the use of chemicals in articles as well, and general responsibilities for the careful handling of chemicals as expressed in chemicals legislation might also be valid for substances in articles.

4.1.3 Focus on the supply chain

A law on chemicals placed on the market should preferably focus specifically on the stages before or when chemicals are placed on the market, especially on production and import. Because many countries import the vast majority of the chemicals used, it is most important to organise control of importers both with regard to legislation and the structure of governmental authorities that are responsible for implementation and enforcement. Some parts of a chemicals law, for example, regulations on bans and restrictions, can sometimes be limited to specific uses of a chemical and therefore use needs to be mentioned in the scope.

Other laws normally regulate later stages of the supply chain with regard to, for example, worker health and safety, environment protection, and risks for large accidents, fires, explosions, etc. These laws should not include regulations regarding placing chemicals on the market, if this area is covered by a specific law.

4.1.4 Possible legal text defining the aim and scope of the law

Chemicals law
Purpose § The purpose of this law is to ensure a high level of protection of human health and the environment when chemicals are handled. § The law lays down provisions on chemicals and shall apply to the production, import, placing on the market, and use of chemical substances as such, in mixtures or in articles.
Comment: The protection of assets from physicochemical hazards (fire, explosion, etc.) can be dealt with in specific legislation regulating measures to prevent accidents, but the classification, labelling, and SDS regarding such properties are part of the GHS system. The law applies basically to chemicals (substances and mixtures) and needs to define if and in what way chemicals incorporated in articles are covered.
Secondary chemicals legislation
Comment: Additional details may be needed to be introduced in each piece of secondary legislation.

4.2 Boundaries between legislation

In many countries, certain types of chemicals are regulated in specific laws. Typical examples are pesticides, pharmaceuticals, radioactive substances, and additives in food and in feedstuff, and cosmetics. These chemicals can be exempted from a general chemicals law, for example, as regards regulations on hazard assessment, classification, and hazard communication. It should be noted that these specific laws normally are valid for the final formulations of the products and thus do not cover handling of the chemicals used as raw materials to produce such products. Raw materials, therefore, should fall under a general chemicals law. Another limitation with these specific laws is that they normally do not regulate environmental risks caused by using the products. It is not advisable to try to exclude these chemicals by calling the law something like “Law on industrial chemicals”. This might narrow the scope too much and cause confusion as to whether chemicals used outside industrial facilities fall under the law or not. It is better to address chemicals broadly in the title of the law and then clearly state if some chemicals are not covered by the law.

Pesticides used in agriculture are often regulated in specific legislation. The FAO (Food and Agriculture Organization of the United Nations) has published several guidelines to assist governments wishing to develop a legal framework for the control of pesticides[6]. Radioactive substances are normally regulated in specific legislation limited to protection of the health of workers and the general public against danger from ionizing radiation. Other health hazards or environmental hazards, however, might not be covered. Likewise, legislation on drugs, cosmetics, and food and feed additives has a limited focus – the protection of human and animal health – and protection of the environment is normally not covered. The areas that are not covered of the specific legislations can be covered by a general chemicals legislation. Furthermore, there might be specific laws for protection of workers and the environment, for waste, for transport, and for other handling, including large-scale use. A general legislation on chemicals should, therefore, make clear that it is applicable in parallel to other laws for chemicals risk management. If needed, these other laws should take precedence in case of conflicting provisions.

[6] http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/en/

4.2.1 Possible legal text regarding boundaries between different laws

Chemicals law
Scope § This law shall apply without prejudice to workplace and environmental legislation. § This law shall not apply to radioactive substances. § The provisions on classification, labelling, and safety data sheets shall not apply to the following mixtures in the finished state intended for the final user: [pharmaceuticals, cosmetics, food and feedstuff or additives in food and feedstuff].
Comment: If the legislator chooses to regulate classification, etc., in other secondary legislation, the exemptions should be included there. There might be a need for other exemptions, such as cases where chemicals are only imported for transit to other countries. It might be necessary to clarify that waste is not regarded as a chemical unless the material is recycled.
Secondary chemicals legislation
Comment: If found necessary, appropriate specific further derogations may be introduced in detailed secondary legislation on classification, labelling, SDS, restrictions, reporting, etc.

4.3 Definitions

It is important to clearly define certain basic terms used in the legislation. Some of the main terms, which often are defined in international agreements as well as in national legislation on chemicals, are given below. Definitions given in GHS (Globally Harmonised System for Classification and Labelling of Chemicals) should preferably be used when regulating classification, labelling, and SDS. Application of this internationally accepted system will greatly enhance understanding and compliance of regulations and facilitate international sharing of risk and safety information.

4.3.1 Possible legal text about definitions

Chemicals law
Definitions 1. Substance - 2. Mixture - 3. Chemical - 4. Hazardous chemical - 5. Article - 6. Pesticide / Plant protection product - 7. Biocide - 8. Handling - 9. Placing on the market - 10. Use - 11. Production/producer - 12. Import/importer - 13. Supplier - 14. Downstream user - 15. Distributor -
Comment: There is a need to define the subjects of the legislation (substance, mixture, articles, etc.), activities that are regulated (handling, placing on the market, use), and persons/legal entities that are subject to the requirements (importer, producer, supplier, distributor, user, etc.). A distinction needs to be made between professional (downstream) users and consumers. Points 6 and 7 are only needed if pesticides are regulated in the law.
Secondary chemicals legislation
Additional definitions needed may be introduced in each piece of secondary legislation.

4.4 Responsibilities and obligations of companies and others handling chemicals

Public authorities managing chemicals legislation do not have capacity to monitor and regulate in detail the widespread and varying use of the tens of thousands of chemicals in practical use. The main responsibility to provide for safe use of chemicals is usually allocated to the companies in the supply chain that produce or import, place on the market, use, or otherwise handle chemicals.

Risks to health and to the environment may only be managed and harm avoided provided that producers and importers search for and distribute information on hazardous properties, risks, and safe use to those handling chemicals further down in the supply chain. Therefore, classification and labelling of chemicals together with SDS are the most important tools for

efficient control of chemical risks. Initially, special attention might be devoted to ensure adequate labelling of chemicals because labelling is a less complex tool than SDS, especially for small and medium sized companies.

Countries can as a risk reduction measure decide upon a specific classification for a number of substances. Such a list could contain the most hazardous chemicals and/or the most commonly used substances if they are hazardous. If such classifications occur in a country, they could be made obligatory for all companies that are placing those chemicals on the market.

A chemicals law should clearly state the general responsibility of actors in the supply chain to ensure the safe use of chemicals that are placed on the market.

Professional actors in the supply chain should have an adequate internal organisation and other qualifications for chemicals control that are needed to comply with specific regulations and to assume general responsibilities stated in chemicals legislation. This includes access to appropriate expertise for fulfilling their obligations with regards to hazard and risk assessment, information, and risk management. Companies may hire their own expertise or make use of external consultants. The latter solution is often applied by small and even medium sized companies. It should be noted that a company handling chemicals, even when hiring a consultant, must be held responsible for the result of the assessment, classification, labelling, SDS, etc.

4.4.1 Possible legal text describing responsibilities and obligations

Chemicals law
General obligations of actors in the supply chain § Producers and importers shall - identify and assess hazardous properties of and possible risks with chemicals they place on the market, - provide users and others handling the chemical with the result of the assessment and other available and relevant information on hazardous properties of the chemical, on risks, and on safety measures, and - update the information whenever new knowledge becomes available. § Suppliers/distributors/downstream users shall - forward down the supply chain the information provided by producers/importers, and - inform others in the supply chain of new information that they have identified concerning hazards or risks with the chemical. § In order to prevent or avoid harm to human health or the environment, all legal and natural persons handling chemicals have to take the necessary protective measures that they themselves have identified or been informed of according to this Article.
Comment: The detailed information requirements/formats are regulated separately (below). There must be a general obligation in the law, however, to apply the protective measures that have been identified even in the absence of specific regulations.
Hazard and risk information

§ Hazard assessment and classification of substances and mixtures shall be done in accordance with the criteria set in GHS. § Hazard communication in the form of labelling of substances and mixtures shall be done according to the requirements set in GHS. § Professional users shall be provided with information on appropriate precaution for use of substances and mixtures in the form of Safety Data Sheets (SDS) produced according to the requirements set in GHS
Comment: Information should always be in the national language/languages.
Qualifications § Legal and natural persons professionally handling chemicals must have the qualifications needed to comply with this law.
Comment: This is particularly important for importers and producers because their role in chemicals control is crucial.
Secondary chemicals legislation
Comment: Hazard and risk information: Detailed regulations on classification, labelling, and SDS might be easiest to issue by adopting and implementing the GHS system. Transposal to national regulations should to the greatest extent possible be done without deviations, e.g., by reference to GHS. This simplifies the work of government and authorities and of companies and facilitates international co-operation on chemicals control. Qualifications: Responsibilities of companies with regards to routines requested for the supply, purchase, and use of chemicals may be specified in secondary legislation (e.g. registering of customers, inventories, listing of chemicals handled, etc.). Qualifications of companies with regards to, for example, specific level of education of personnel should be avoided. The appropriate level of qualifications of a company varies with the type and amount of chemicals handled, and appropriate expertise in chemicals control may be achieved in many ways. It should be noted that a certain education in chemistry does not ensure the knowledge needed for chemicals control.

4.5 Limitations on trade and use

4.5.1 Bans and restrictions

Some chemicals are, due to their inherent hazardous properties or effects on health or the environment, judged to cause unacceptable risk for any use or for certain types of use. Many governments therefore have introduced bans or restrictions on the trade and use of certain chemicals.

The international community has through the Stockholm and Minamata Conventions and the Montreal Protocol agreed on a number of substances to be banned or severely restricted worldwide. The number of substances covered is steadily increasing. If not done by specific ratification laws, national implementation of those parts of the conventions that regulate production, trade or use in general may preferably be carried outunder the legislation on chemical products. Other parts concerning emission regulation and waste may preferably be

implemented in environmental legislation. If found appropriate from national points of view, countries may ban or restrict additional chemicals that are judged to cause unacceptable risk.

By way of the Rotterdam Convention, the international community has agreed on a system for prior informed consent and for information exchange for the export or import of chemicals that are banned or severely restricted in countries that have ratified the Convention. The number of chemicals covered is considerably higher than in the Stockholm Convention. This system gives importing countries information on the import of chemicals that are banned or severely restricted in other countries and gives the possibility to stop or to regulate the import.

4.5.2 Possible legal text for bans and restriction

Chemicals law
Bans and restrictions § In case it is found necessary for the protection of health or the environment, the government may ban or restrict production, import, placing on the market, use, export, or other handling of a chemical, including its use in articles.
Secondary chemicals legislation
Comment: Specification of bans and restrictions. Implementation of parts of international agreements like the Stockholm and Minamata Conventions that limit production, trade and use of chemicals. Regulations on further national bans and restrictions. Some countries have general bans on substances based on classification, e.g. substances or mixtures that are carcinogenic, mutagenic, or toxic for reproduction according to specific GHS criteria are in some countries banned for consumer use. Bans or restrictions may need to be notified under WTO rules.

4.5.3 Authorisation

An authorisation procedure is often very resource demanding for companies as well as for authorities. Therefore, such procedures are necessarily restricted to very few types of high-risk chemicals.

By tradition, pesticides used in agriculture are controlled in this way because they intentionally have negative effects on health and/or the environment. Quite commonly, corresponding authorisation is requested for similar groups of chemicals like insecticides, preservatives for wood, textile and leather, rodenticides, and disinfectants (often commonly called biocides) used in health care, industry, offices, homes, etc. These types of chemicals also have intended biological effects and are often used in ways that might give rise to high exposure to workers, consumers, the general public, and the environment. The use of such chemicals is therefore often combined with special risks, which is the rationale for demanding authorisation. For orientation in this area see another guidance from the Swedish Chemicals Agency.[7]

[7] Swedish Chemicals Agency (2020). Guidance on national chemicals control: Hazard and risk assessment and risk reduction of pesticides. www.kemi.se/en/guidance-on-national-chemicals-control

In some cases, like in EU REACH, authorisation is also required for some other chemicals with serious effects on health and/or the environment like substances with a high degree of carcinogenicity, mutagenicity, toxicity to reproduction, or persistence and bioaccumulation[8].

An authorisation should be time limited, e.g. it should last for five to ten years. The reason for time-limited authorisation is that knowledge on hazards and risks of chemicals is always increasing. Countries might face serious problems with old unlimited authorisations when new knowledge requires the need, for example, to review and reassess old pesticides, and possibly even withdraw them from the market. Such processes are very resource and time consuming, while an automatic reassessment procedure within a reasonable time period goes relatively smoothly. This puts pressure on applicants to keep their toxicological and other data updated and to search for safer alternatives.

4.5.4 Possible legal text for authorisation

Chemicals law
Authorisations § The following chemicals may not be produced, imported, placed on the market, or used without authorisation from designated authorities: - pesticides and - chemicals with the following effects on health and the environment: [to be decided by each country]. § Authorisation may be granted if - the effects on health and the environment are acceptable when the chemical is used for the intended purpose and - the chemical is needed for the purpose specified in the application and cannot be replaced by safer alternative chemicals or technologies. § Authorisation is only valid when the chemical is used for the purposes specified and may not be granted for a longer period than 5 (10) years.
Comment: Authorisation is given to an individual person or company but should apply for the whole supply chain where the chemical is used. It should include the necessary conditions about the use, including the information to be provided to users (if information in regular labelling and SDS is not sufficient).
Secondary chemicals legislation
Comment: Detailed regulations on requirements and procedures for authorisation of pesticides may be based on the FAO Guidelines for Legislation. Responsibilities of companies with regards, for example, to documentation on the properties and effects of mixtures and substances to be presented in the application are to be specified as well as procedures and routines for the application and authorisation processes, including the appointment of authorities to receive applications and decide on authorisations.

[8] More information available on the ECHA website, https://echa.europa.eu/substances-of-very-high-concern-identification-explained

4.6 Registers

Many countries have introduced or plan to introduce registers of chemicals and/or producers and importers of chemicals. Countries that have a system for authorisation of pesticides normally use information obtained through such a system to establish a register on authorised pesticides and responsible companies. Registers may vary considerably with regard to the level of ambition and complexity. They may be simple inventories with names and addresses of companies, including or not which chemicals they place on the market, or they may be complex computerised systems encompassing qualified demands on testing combined with extensive reporting of test data and other data. Normally the establishment of such registers does not imply any kind of authorisation or other explicit decision on the acceptance of registered chemicals.

4.6.1 Simple registers

The level of information in a register should always be based on the actual needs of the country. Countries may benefit considerably from requiring quite simple information to start with. An inventory of primary suppliers (e.g. producers and importers) could be a starting point. Customs and tax authorities may assist with such inventories. This information may as a next step be used as a base for a register of companies that produce and import chemicals for use in the domestic markets or for export.

Such a simple register/inventory can be valuable, for example, for planning and inspection purposes. It may, if successively supplemented with reporting on types, uses, and contents of the chemicals, give an overview of the chemicals flow to the domestic market and use and therefore be even more valuable for planning and other measures. However, countries have to be aware of the fact that every extension of such a data base with new information means increased work for authorities (and for companies) for registering and control of data, for updating, etc. A lack of updates quickly makes data unreliable.

A stepwise build-up of the register over time and adaptation to available resources is therefore to be recommend. More information can be found in the Swedish Chemicals Agency Guidance on access to information on primary suppliers and chemicals on the market[9].

4.6.2 Registers on properties of chemicals

In general, countries should if possible take advantage of existing elaborate systems in other countries and rely on the qualified knowledge these systems generate on properties of chemicals. However, countries with their own production of substances that are not produced, and therefore not registered, elsewhere need to consider introduction of a notification system for these substances.

[9] Swedish Chemicals Agency (2019). Guidance on national chemicals control: Access to information on primary suppliers and chemicals on the market. https://www.kemi.se/en/guidance-on-national-chemicals-control

4.6.3 Possible legal text for registers

Chemicals law
Registring § Chemicals that are produced and imported professionally must be registered with the appointed authority. Registrations shall be updated regularly as required according to implementing provisions. The register will be kept by the authority appointed by the Government. § A registration shall include; - identity of companies/persons making the registration, - identity of the chemical, - [further items could be added]
Comment: Registering should normally be kept as simple as possible, especially when introducing a system. Items to register could be added if found necessary and possible with regard to the resources needed. Further information can be required case-by-case by the authorities according to the article on reporting below.
Secondary chemicals legislation
Comment: Responsibilities of procedures and importers and detailed specifications on what to report and routines for registering, including appointing of authorities to receive information, are to be specified.

4.7 Reporting

Government authorities given responsibility and tasks for implementation as well as management and enforcement of legislation need access to information in order to fulfil their duties. Companies in the supply chain therefore should have the responsibility to provide appointed authorities with information they need for fulfilling their tasks as regulatory, or enforcing authorities or authorities designated for other tasks associated with the chemicals legislation.

4.7.1 Possible legal text for reporting

Chemicals law
Reporting on request § Legal and natural persons professionally handling chemicals shall provide the relevant authorities upon request with such information about the chemical and its handling that is needed for the assessment of risks to health or the environment and of risk-reduction measures. § Legal and natural persons that produce, import, or place on the market a chemical shall report to relevant authorities any new information on hazards and risks that they are aware of - if the information may influence given authorisations and - if the information may influence classification due to carcinogenic or mutagenic effects or effects on reproduction or other serious effects of equivalent concern.
Comment: The last bullet point can be relevant if there is a legally binding harmonised list of classifications in the country.

Secondary chemicals legislation
Comment: This can include specification of documentation to be reported to authorities and of procedures and routines of reporting processes, including the appointment of authorities to receive reports.

4.8 Confidentiality

The authorities will obtain information from operators, e.g. as part of reporting procedures, that must be kept confidential. Companies that give information to governments and to authorities on their activities and chemicals must be sure that the need for security and confidentiality of commercially important details will be provided for in a satisfactory way. However, confidentiality should not apply for basic information and information about health/environmental effects. It should be noted that professional users as well as consumers have a legitimate right to get information on hazards, risks, and safety measures. This right can be regulated in regulations on labelling and SDS. In the GHS system it is, for example, stated that components in chemicals classified as hazardous that contribute to the hazard are to be revealed. Obviously, companies should not have the right to claim that this type of information should be kept confidential by authorities. Authorities may have legitimate reasons to also make public other information that is needed for protection of health and the environment.

4.8.1 Possible legal text for confidentiality

Chemicals law
Confidentiality § Information obtained by the authorities according to this legislation that is commercially sensitive shall not be made public. This does not apply to information of general interest for the public relating to the protection of health and the environment.
Comment: A model for the detailed rules in such legislation can be found in the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, Aarhus Convention (UN 1998).
Secondary chemicals legislation
Comment: This can include regulations defining what commercially sensitive information can cover.

4.9 Responsibilities and tasks of government authorities

The chemicals legislation discussed here is complex. It has highly scientific and technical content and is subject to continuous change due to new knowledge arising on the properties and effects of chemicals and associated risks. Due to the steadily rising knowledge and to the increasing trade in chemicals and articles, no country can manage chemical risks on their own. The need to share knowledge, experiences, and costs has made chemicals risk management a highly international issue that is regulated in many international conventions and agreements.

All countries have a need for well-developed government institutional setups with appropriate capacity and capability. It is most important to concentrate the tasks for government management and enforcement of legislation on chemicals to one or a few appointed authorities. In the latter case, clearly defined and separate mandates are needed. Concentration and clear borders between areas of responsibility reduce the risk of overlapping responsibilities. Routines for work are to be established. Cost-efficiency of the work of the authorities is to be promoted, and the very important contacts between these authorities and companies that are needed for successful implementation and enforcement are to be facilitated.

The responsibilities and tasks of government authorities for management, and enforcement of chemicals legislation are to be developed in the light of the responsibilities and obligations of companies. They should, especially with regards to advisory activities, be designed in a way so as not to transfer responsibility of companies to authorities. The role of authorities should primarily be to steer and guide the work of companies through regulations and by monitoring of compliance.

However, authorities can have an important role in promoting the safe use of chemicals through information and other general advice to companies and to the common public on the risks and use of chemicals. Cooperation with important stakeholders as representatives of trade and industry, environmental NGOs, trade unions, etc., is important. In countries in the early stages of development of chemicals control, it might be appropriate to establish special support programmes for small and medium sized companies provided that they are constructed in a way that does not transfer responsibility from companies to authorities. In general, advice and other support from government authorities should be given in a way not to reduce the responsibility of those handling chemicals to organise adequate risk management in each specific case.

Efficient enforcement is most important for maintaining compliance with legislation. Inspectors need access to premises and information from the companies inspected and their rights need to be stated in the legislation. Tools needed for enforcement include, for example, injunctions, prohibitions, and possibility to connect such orders with a penalty of fine, etc. If such tools for enforcement are already in place in general national legislation, they should also be activated for the purpose of the chemicals law. Regulations issued by the government could distribute the enforcement power given to different authorities. Further guidance on enforcement can be found in Swedish Chemicals Agency Guidance on Enforcement of legislation on chemicals placed on the market[10].

[10] Swedish Chemicals Agency (2018). Guidance on national chemicals control: Enforcement of legislation on chemicals placed on the market. https://www.kemi.se/en/guidance-on-national-chemicals-control

4.9.1 Possible legal text for management responsibilities of authorities

Secondary legislation (depending on legal tradition)
§ The [name of authority] is the appointed authority for [specify management tasks] according to [title of the chemical law]. § The appointed authority shall: -ensure that it is updated nationally and internationally about the development as regards risks caused by chemicals, -provide support to the Government in matters on chemical safety [further possible general tasks]
Comment: In secondary legislation, the Government may introduce instructions that specify the mandates, responsibilities and both general and specific tasks of authorities.

4.9.2 Possible legal text for enforcement responsibilities of authorities

Chemicals law, separate law or secondary legislation (depending on legal tradition)
§ This law/regulation concerns enforcement according to [title of the chemicals law] § Enforcement shall be exercised by [names of relevant authority/authorities]. § The enforcement authority shall enforce the [title of the chemicals law] and regulations pursuant to the law and take all measures needed to ensure compliance. § The enforcement authority may order a person who pursues an activity or takes a measure that is governed by the provisions of these regulations to submit any information and documents to the authority that are needed for its tasks according to the legislation. § In order to perform its tasks pursuant to these regulations, the enforcement authority and persons engaged by the authority to perform a task shall be given access to properties, buildings, other structures, and means of transport for the purpose of carrying out investigations and taking other measures. Measures shall be carried out in such a way as to cause the least possible damage and intrusion. § The police authorities shall give any assistance that is necessary for the purposes of access and measures. § The enforcement authority may issue injunctions and prohibitions that are necessary in individual cases to ensure compliance with the provisions of these regulations, and other decisions issued in pursuance thereof. The measures taken must not be more intrusive than necessary in individual cases. § Injunctions or prohibitions may be made subject to a penalty of a fine. § The enforcement authority may decide that a decision taken by it shall take effect immediately even if it is appealed against. § The enforcement authority shall report infringements of the provisions of these regulations to the police or public prosecution authorities where there are grounds for suspicion that an offence has been committed.
Comment: The appointment of relevant enforcement authorities (the second paragraph) is normally done in secondary legislation.

4.10 Delegation

The high scientific and technical content of chemicals legislation and the frequent needs to make changes due to new information on hazards, uses, exposures, and risks makes it necessary to delegate power for implementation from parliaments and governments to the lowest level possible. The general law must therefore encompass implementation provisions that make it possible for appointed authorities to issue secondary legislation for implementation. Some countries might by tradition like to make such delegations in specific administrative laws. Whichever way is used, it is most important to clearly separate the responsibilities and tasks among the designated authorities.

4.10.1 Possible legal text for delegation

Chemicals law
Delegation § The Government/Ministry/appointed authority may issue further detailed implementing provisions with regard to the [specify] obligations in this law.
Secondary chemicals legislation
Comment: In secondary legislation, the government may, when found appropriate and necessary, designate responsibility to authorities.

4.11 Sanctions

In order for a law to have its desired effect, it is most important that sanctions are applied in case of non-compliance. Injunctions and prohibitions connected with penalty of fines were mentioned in section 4.9. Such reparative means of pressure have an effect only on a case by case basis and only apply to the future. Furthermore they tend to transfer responsibility from the companies to the authorities. There is also a need for repressive means of force to deal with non-compliance in already passed time, e.g. penal provisions and/or administrative sanction fees.

The possibility to apply sanctions is always dependent on the legal texts regulating the responsibilities of those handling chemicals. It should be clear for companies and others as well as for enforcement authorities what is required, and texts should as far as possible not allow for different interpretations. Penal provisions need to be even clearer to make it possible for courts to apply them.

Most countries address penal provisions only to natural persons, but they often combine them with provisions on confiscation of assets that has been used in the offences and that has been gained from such offences. In some countries there is also a possibility to fine the company in which the offence has been committed. If such provisions exist, they may be activated for the purpose of the chemicals law.

Penal provisions may, depending on national legal traditions, be specified in the chemicals law or in a general criminal law. In the same way, there is a need to assess which offences will be punished by penal provisions. Severe offences may be connected with a possibility for the court to issue prison sentences. The penal process can be combined with a separate

procedure for minor offences, and administrative sanction fees may be introduced for certain frequently appearing and readily investigated violations. Such fees contribute to efficient enforcement and could be useful as a general tool in other enforcement areas as well. Legal provisions on sanction fees could consequently be found in a general law, e.g. a law on enforcement.

4.11.1 Possible legal text for penalties and other sanctions

Chemicals law

Penalties:

§ Any person who, whether deliberately or through gross negligence, violates requirements regarding chemical products by:

- handling a chemical without taking protective measures needed to avoid damage to humans or the environment,
- fails to classify a hazardous chemical before placing it on the market,
- fails to transfer discoveries on possible hazardous effects one has been made aware of, despite being obliged to do so according to this law,
- infringes on the provisions on classification and labelling and Safety Data Sheets of chemicals through serious misclassification or mislabelling or
- makes substances, mixtures, or articles available on the market in contradiction to any bans or restrictions for that substance, mixture, or article.

shall be liable to a fine or imprisonment not exceeding [timeframe] for the offence

§ Chemical products that are involved in an offence may be confiscated or forfeited unless this is manifestly unreasonable. The same shall apply to the value of the assets or the proceeds of such an offence.

Administrative sanction fees:

§ A sanction fee shall be paid by any economic operator who in his or her business activities:

- neglects to comply with rules issued pursuant to this law or
- commences an activity for which a permit must be obtained pursuant to this law or to rules issued in pursuance thereof.

§ A sanction fee shall also be payable where the infringement did not occur deliberately or through negligence. However, the fee shall not be payable where this is manifestly unreasonable.

§ The Government shall issue rules concerning infringements for which sanction fees are payable and the amounts to be paid for various infringements. The minimum sanction fee shall be 000, and the maximum fee shall be 000000.

§ Enforcement authorities shall decide matters relating to sanction fees.

§ A person who is liable for payment of a sanction fee pursuant to a decision taken by an enforcement authority may appeal the decision to an administrative court.

4.12 Entry into force and application – Transitional periods

The coming into force of a complex and demanding legislation like the one presented here needs some time. This goes for the general law as well as for secondary legislation. It is appropriate for the provisions of the legislation to enter into force in a stepwise way so as to ensure a smooth transition to the system. A gradual entry into force provides companies as well as authorities the time needed to prepare for their new duties.

4.12.1 Possible legal text for implementation and the transitional period

Chemicals law
Entry into force and application § This law enters into force --/--/---- § Article x enters into force --/--/---- § Articles y, z enter into force --/--/---- etc.
Comment: Articles with general responsibilities should preferably come into force before articles with specified requirements, which are very demanding for stakeholders and therefore require more time for preparation.
Secondary chemicals legislation
Comment: Upon issuing a secondary legislation, the same approach as for the general law may be applied for entering into force of the regulation as a whole and of individual articles.

5 Further literature

FAO (2015). Guidelines on pesticides legislation. Food and Agriculture Organization of the United Nations. http://www.fao.org/3/a-i5008e.pdf

OECD Chemicals Programme http://www.oecd.org/chemicalsafety/

UN (1998). Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Rev. 2005. http://www.pic.int

UN (1998). UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, Aarhus Convention. https://unece.org/environment-policy/public-participation/aarhus-convention/introduction

UN (2001). Stockholm Convention on Persistent Organic Pollutants (POPs). http://www.pops.int

UN (2003). Globally Harmonized System of Classification and Labelling of Chemicals (GHS). https://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

UN (2006). Strategic Approach to International Chemicals Management (SAICM). http://www.saicm.org/

United Nations Environment Programme (2015). UNEP Guidance on the development of legal and institutional infrastructures and measures for recovering costs of national administration for sound management of chemicals. https://www.unenvironment.org/resources/report/lira-guidance

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