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Swedish Chemicals Agency

Legislation for risk management at marketing of chemicals

– the first step of the supply chain

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Publisher: Swedish Chemicals Agency
Order address: CM-Gruppen, Box 11063, 161 11 Bromma, Sweden
Phone: +46 8 50 59 33 35, Fax: +46 8 50 59 33 99, E-mail: kemi@cm.se

Preface

Many countries all over the world are to start or on the way to further develop their legislation and institutions for modern chemicals risk management. Often this is done in connection with implementation of the UN programme “Strategic Approach to International Chemicals Management”, SAICM (UN 2006), the Stockholm Convention on Persistent Organic Pollutants (UN 2001) and the Globally Harmonized System of Classification and Labelling of Chemicals, GHS (UN 2003). Development of legislation on pesticides may be based on the Guidelines for Control of Pesticides of Food and Agricultural Organisation on United Nations, FAO(UN 1989).

The main aim of the report is to give ideas to and to facilitate and guide development, managing and enforcement of horizontal chemicals legislation for management of chemical risks. The target groups are legislators and authorities primarily in developing countries and countries with economies in transition. The report may also be seen as a general guidance for other actors as enterprises, NGOs etc.

In a previous report (Swedish Chemicals Agency, 2007), some basic features of chemicals control, product and trade orientated risk management of special significance to the first step in the supply chain i.e. marketing of chemicals, were discussed in general terms. Chemicals control has a focus on development and dissemination of knowledge on hazards and risks of chemicals and on limitations on sale and use of high risk chemicals, both essential steps at management of chemical risks. The emphasis was put on the importance of an effective legal and institutional infrastructure and of clear allocation of responsibilities and tasks to enterprises in trade and industry that introduce chemicals on the market. The role of public institutions and the importance of an efficient enforcement were discussed.

This report has the previous report as the starting point and discusses legislative issues more in depth. It specifies the most important components of legislation regulating risk management at marketing of, trade of chemicals, gives a rationale for them, makes some comments on specific issues to consider and illustrates possible legal text by examples.

The report was written by Bengt Bucht at the International Secretariat of the Swedish Chemicals Agency, KemI, after thorough discussions within the Secretariat and with legal expertise at KemI. KemI has, as part of its international activities, developed a special programme for support to other countries, in specific developing countries and countries with economies in transition.

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Introduction

Many areas in chemicals risk management

Risk management of chemicals concerns many areas in the society. It is in most countries in general regulated in several pieces of legislation as on environment, waste, work environment, consumer safety, rescue services, transport, trade, pesticides, cosmetics, additives in food and feed stuff etc. Often different ministries are responsible for the various pieces.

Dividing up regulation of risk management of chemicals in several types of legislation is appropriate for many reasons. This is especially true as regards legislation which regulates practical handling of chemicals as use, storage, transport, waste handling etc. Depending on type and way of handling and amount of chemicals handled, emissions and exposure and therefore type and level of risk as well as means for appropriate risk management may differ considerably. This makes it quite rational to have separate legislation for risk management in areas like environment, work environment, transport etc.. A single piece of legislation fully covering all types of chemicals risk management of all chemicals in use, if at all possible, necessarily would become very comprehensive and complex and less transparent. The number of substances in practical use is estimated to some tens of thousands, the number of mixtures in the range of 100 000 or even larger. The ways of use are countless. Therefore, one single comprehensive legislation would become difficult to grasp and understand for enterprises and for governmental institutions and therefore less efficient.

The legislation discussed in this report aims at regulating a specific product and trade orientated type of preventive risk management, measures to take before or when chemicals are introduced on the market. These measures are horizontal in nature being the first steps common to all risk management irrespective of type of use.

SAICM (the UN programme “Strategic Approach to International Chemicals Management”), the Stockholm Convention on Persistent Organic Pollutants (POPs), 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 and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) have either heavy or full (GHS, PIC) focus on risk management measures to be taken by suppliers before or when introducing chemicals on the market. These international agreements, therefore, provide important starting points, a base for development of national legislation on marketing of chemicals.

Report structure

The report discusses an appropriate design and content of a general, product orientated legislation for chemicals risk management for control of supply of chemicals. It addresses the main actors concerned with chemicals control; legislators, appropriate government institutions as well as enterprises and their associations. A special focus is given to the important role of the primary suppliers, the manufacturers and importers. The previous report (KemI 2007) discusses more closely issues like allocation of responsibilities to enterprises and to government institutions why the discussion here is made as short as possible.

Firstly are discussed advantages and disadvantages with one comprehensive general chemicals law compared to splitting the various building blocks that are needed to control supply of chemicals into several laws. The following chapter discusses the distribution of specific regulations between a basic law and secondary legislation.

The main chapter and its subchapters discuss design and content of general chemicals legislation regulating marketing of chemicals. Focus is given to regulations regarding the most important responsibilities and tasks of enterprises and of governmental institutions. These regulations constitute the main building blocks of legislation for efficient management of risks at marketing of chemicals. It is, however, appropriate that a horizontal general legislation regulating marketing, in general terms to some extent regulates basic demands on chemicals risk management at all “down-stream” handling in the supply chain.

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 contents of detailed secondary law. It is recommended that detailed responsibilities and requirements are regulated in secondary legislation. The final design and content of legislation and the exact wordings to be used are to the national legislators to decide on.

In Annex 1, the examples of legal texts are put together to illustrate a possible design and content of a comprehensive and coherent general legislation covering risk management before or when chemicals are introduced on the market. Annex 1 is however as this report as a whole, only to be seen as a guide for countries wishing to develop legislation on chemicals. At shaping the final overall design of a national legislation and the final texts of each regulated issue, prevailing legal, administrative and other traditions of each country obviously are to be taken into consideration.

There are certainly more issues that may be regulated in a general chemicals legislation. Furthermore, there is a need for non-binding guidelines in order to facilitate for enterprises to comply with law and detailed regulations. As the aim with this report is to present, as simply as possible, a starting point, a base for development of national legislation, this need for further guidelines is not addressed. When the legislative process is well on the way, it will not be difficult to introduce more elements in the system as further regulations and guidelines.

Design of general chemicals legislation

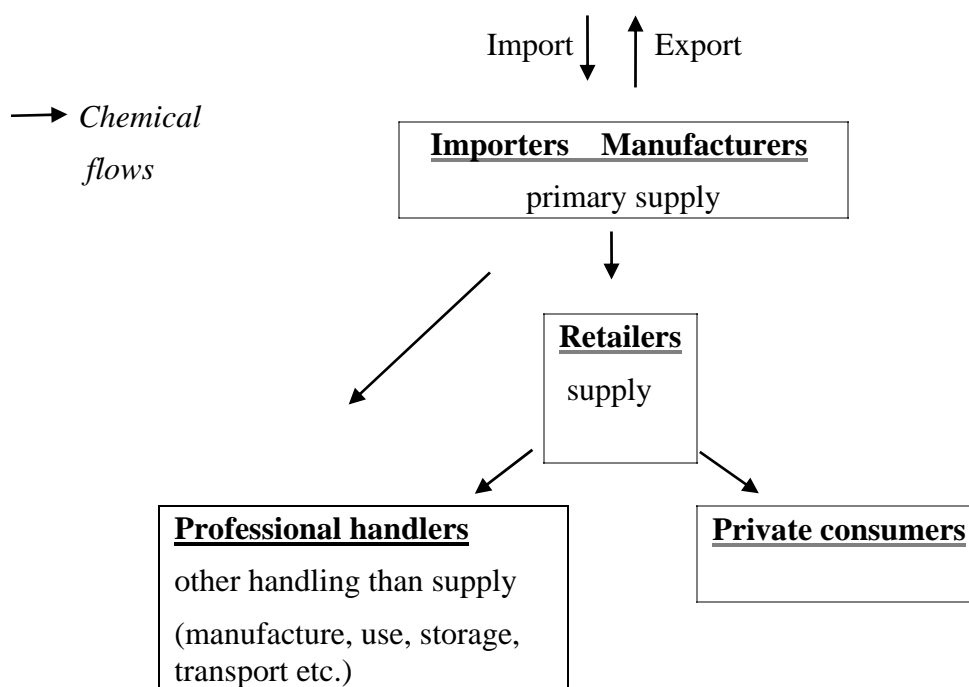
Product and trade orientated risk management

The word chemical is in the following in general 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.

The various measures at product orientated risk management of chemicals early in the supply chain (fig. 1), before or when chemicals are introduced on the market, here called chemicals control, have very much in common. They all aim at improved control of the flow of chemicals to the market and to later use.

These measures, mainly build-up and dissemination of knowledge on hazards, risks and safe handling and limitation of flows to the market of high risk chemicals, are the first general steps of risk management and prerequisites for efficient risk management at later steps of the supply chain irrespective of type of use or other handling. This makes the role of the primary suppliers, importers and manufacturers, of particular interest.

Figure 1. Supply chain – the base for risk management



The main steps of this product and trade orientated, preventive and precautionary risk management are;

- identification and assessment of inherent hazardous properties of and possible risks with chemicals,
- dissemination of hazard, risk and safety information to users, and
- limitation of sale and use of chemicals that are judged to cause unacceptable risks.

These measures are essential for managing of risks wherever they occur and should mainly be the responsibility of enterprises importing or manufacturing chemicals, i.e. those enterprises that introduce chemicals on the market.

In case risks may not be eliminated by proper choice of chemicals, users and other handlers in later stages of the supply chain need information on all hazardous properties of and general risks with chemicals which they purchase. Such information is needed to assess possible particular risks and need for risk prevention measures at their specific handling. Therefore, suppliers of chemicals, especially manufacturers and importers, have to identify and assess all hazardous properties and possible risks, to human health, to environment and to property due to fire or explosion, before they are able to

1. decide to market a chemical or not and
2. convey full information on hazards and possible risks to users on chemicals marketed.

Classification and labelling of chemicals are based on their inherent properties, labelling being a hazard statement. In addition, exposure and risk related information is given in safety data sheets (SDS).

When making choices of chemicals, users likewise have to take into account all types of hazards of and risks with possible alternatives in order to optimize the choice from risk point of view. The same is true for legislators e.g. when reflecting on bans or restrictions. It should, therefore, be an advantage to regulate these rather few early measures for risk elimination and reduction in an integrated way in a comprehensive horizontal type of legislation on chemicals.

Rationale for separate general legislation on chemicals

There are some main reasons to regulate the flow of chemicals to the market, i.e. chemicals risk management at supply of chemicals, separately from other legislation.

One main reason for a separate legislation is that chemicals legislation, as mentioned above, is horizontal, covering protection of environment, workers, consumers and property. And that it is the first preventive step of chemicals risk management. As indicated above, efficient control of the flow of chemicals to the market, the aim of chemicals legislation, is needed for chemicals risk management at all handling of chemicals, irrespective of where it occurs or for what purpose. Appropriate risk and safety information by labelling and SDS and bans and restriction on trade of very hazardous chemicals are prerequisites for efficient risk management at use and other handling of chemicals for various specific reasons as occupational health and safety or environmental protection.

Measures like classification, labelling, SDS and bans and restrictions may, obviously, have marked effects on international trade in chemicals. Almost by definition, national measures may cause barriers to trade, why they must be carefully designed to comply with international trade agreements that countries may have ratified. Opposite to much of traditional legislation on e.g. environment, work environment etc., a high degree of international harmonization of chemicals legislation is most important, which also justifies a legislation separate from other legislation.

In order to facilitate compliance with the legislation and an efficient enforcement and monitoring of compliance, the various pieces of legislation regulating responsibilities and tasks of suppliers of chemicals should be easy to find and understand for all actors, enterprises as well as authorities. A horizontal, trade and product orientated legislation preferably should therefore be coherent and concentrated to the extent possible. This is a third reason to deal with it separately.

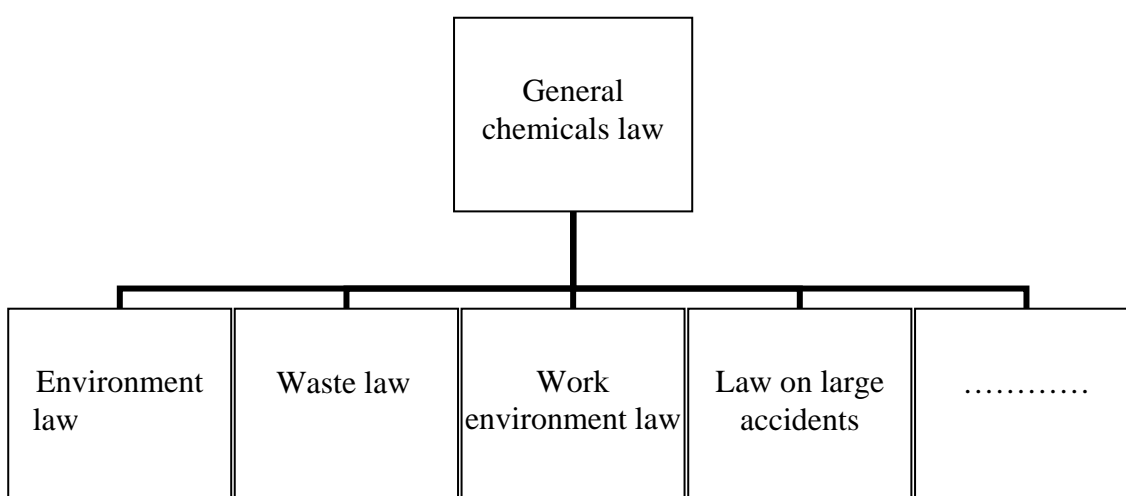
As mentioned in the introduction, enterprises that market chemicals, have to assess and classify them with regard to all types of hazard and to provide them with information (labels and SDS) taking into account all types of hazards, risks and use. Furthermore they have to comply with possible bans and restrictions. Regulating these obligations of suppliers in many laws and regulations issued by several ministries and authorities would greatly complicate the legislation as well as its implementation and enforcement. This would be disadvantageous and costly to governmental institutions as well as to enterprises.

For highest possible efficiency, national implementation of international agreements should be done in a coherent and co-ordinated manner, not by creating specific legislation for each agreement. There are no obvious advantages with separate laws, on the contrary. This is especially true as regards implementation of trade orientated parts of SAICM, the Stockholm and Rotterdam conventions, and GHS. It may also be so as regards other international agreements on chemicals, which regulate trade. Implementation co-ordinated

with other, national regulations on marketing of chemicals within the framework of a general legislation on chemicals makes legislation more transparent and efficient..

In order to avoid omissions, gaps and contradictions and to be workable and efficient, the legislation on risk management of chemicals in the early steps of the supply chain should be as coherent and concentrated as possible. It seems reasonable to have one separate piece of legislation primarily regulating risk management at supply of chemicals. This general chemicals legislation should have a horizontal approach and cover protection of environment, workers, consumers and property. It would then be 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 at transport, on large accidents etc. (fig.2).

Figure 2. General chemicals law and examples on sector specific legislation



The general, comprehensive chemicals legislation may in practise with advantage be formulated as a separate Chemicals Law. This solution makes the legislation to clearly stand out from other legislation on chemicals risk management. It will give more focus on the importance of preventive risk management at marketing of chemicals to the benefit of risk management in later steps of the supply chain. General chemicals legislation, however, also may be organised as a specific, separate part of some existing legislation as 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 risk perspective than protection of environment only. Accordingly, the aim and purpose of the law must be formulated to allow regulation of protection of health and property as well.

Allocation of regulations between primary and secondary legislation

A basic general primary national law on chemicals, to which secondary legislation may be attached, is essential for effective regulation of chemical hazards and risks. As discussed and illustrated above, primary legislation makes it possible to “organize” general responsibilities, obligations and tasks, i.e. roles, of both enterprises and government institutions. Such a law will set the framework for the legislation. Details concerning responsibilities, obligations and tasks may preferably be issued as secondary legislation e.g. ministerial regulations or even at lower level. Specific regulations needed on e.g.

classification and labelling are too scientific, technical and detailed, and are revised too frequently to be decided upon by parliaments, in many cases even by governments.

Secondary legislation is needed to regulate specifics regarding e.g. testing and assessment of and information on chemicals. Among the most important regulations to elaborate are the ones for classification, labelling and safety data sheets guiding the crucial 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 may also be regulated as secondary legislation. Further pieces of secondary legislation may concern specifics on authorization, licensing, and registering to establish the specific obligations of legal and private persons and the procedures for and organisation of processes and routines needed. Annex 2 illustrates a possible allocation of regulations between a primary law and secondary legislation.

Government institutions to manage and otherwise be responsible for that specific piece may be stated in each piece of secondary legislation. In case that decision making is not delegated to the government these responsibilities must be established in the primary law.

Many international conventions and agreements on chemicals give a good guidance on the content and formulation of specifics of legislation. The internationally agreed Globally Harmonised System of Classification and Labelling of Chemicals (GHS) may, preferably unchanged as regards contents, be referred to as the accepted national standard for classification, labelling and safety data sheets. Any remaking of this international standard will make national chemicals control more complex and resource demanding for authorities and enterprises. Deviations from the standard may cause unnecessary barriers to trade.

The Stockholm and Rotterdam conventions on persistent organic pollutants and on prior informed consent for certain chemicals in international trade respectively, lay a good foundation for elaboration of national legislation on bans and restrictions and information at export and import of chemicals. OECD has issued several documents on chemicals control e.g. on testing and concerning exchange of data. FAO has issued guidelines on authorization of pesticides (plant protection products).

In general, application of international standards and other agreements contribute to a cost-efficient national control of chemical risks. In lack of international guiding documents, legislation in e.g. Canada, EU, US or other countries with modern chemicals legislation may give ideas on framing of laws and regulations.

Content of general chemicals legislation

Aim and scope of a general legislation on chemicals

Broad coverage of risks

It is an advantage to make clear the aim of the legislation already in the very beginning. Not only risks due to toxic properties of chemicals to health and to the environment need to be considered at risk management. As chemicals, in case of less careful handling, may cause risk to property as well, physicochemical properties affecting flammability and explosiveness also are to be taken into account. The aim of a comprehensive general chemicals law, therefore, should be to protect human health, environment and property from harm at use or other handling of chemicals. As regards human health the law should encompass protection of consumers, workers as well as of the general public.

Substances, mixtures

The term chemicals is in this report as usually in most prevailing national legislation and international agreements in general used as a generic term for chemical substances and mixtures of substances. It should be noted that chemicals not only may be chemically synthesized but may also be extracted from natural inorganic, organic or biological sources. The term handling of chemicals therefore encompasses handling of all chemicals irrespective of their origin.

Articles

Risks caused by chemical substances in articles are given increasing attention internationally. As the largest flows of chemical substances into the society go by articles, articles may give rise to considerable chemical risks both to health and to the environment. Leakage of metals like cadmium, mercury and lead from articles, at use or as waste, are typical examples. Others are organic substances used as flame retardants, preservatives and dyes in wood, textiles, electronics etc. Bans and restrictions of substances like POPs and heavy metals therefore concern use of them in articles as well. At time being there are few other regulations regarding articles. However, development is on way to find means for conveying hazard, risk and safety information for articles like already agreed upon internationally for substances and mixtures (GHS). Some simple regulations for that purpose already exist e.g. in EU. General responsibilities for careful handling of chemicals as expressed in chemicals legislation of course may be valid for substances in articles as well(c.f. below).

Focus on supply of chemicals

A general chemicals law should preferably have focus specifically on stages before or when chemicals are introduced on the market especially on manufacture and import. As 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 governmental institutional set up for implementation and enforcement. Regulation of export is needed to implement some of the international agreements.

Other laws normally regulate use, transport and other later stages of the supply chain with regard to e.g. workers health and safety, environment protection, risks for large accidents, fires, explosions etc. In consequence, these laws, in order to avoid duplication and uncertainty, should not encompass regulations on marketing of chemicals. However, some parts of a general chemicals law may preferably encompass also these later stages as e.g. regulations on bans and restrictions and on need for general precaution at use or other handling.

Possible legal text

General 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 and to protect property from harm caused by chemicals.

The law lays down provisions on chemicals which shall apply to the manufacture, import, marketing and use of chemical substances on their own, in mixtures or in articles.

Comment: The protection of property from physicochemical hazards (fire, explosion etc.) may instead 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 in what way chemicals incorporated in articles are covered.

Secondary chemicals legislation

In each piece of secondary legislation the specific purpose is to be expressed.

Demarcations towards other legislation

In many countries, marketing of certain types of product groups already are regulated in specific laws. Typical examples are pesticides, pharmaceuticals, additives in food and feeding stuff, drugs and cosmetics, and radioactive substances. These chemicals may, in case already satisfactorily regulated, at least partly be exempted from a general chemicals law e.g. as regards regulations on hazard assessment, classification and hazard communication. It should, however, be noted that these specific laws normally only are valid for the final formulations of the products comprised and thus do not cover handling of chemicals used as raw materials used at manufacture of them. Raw materials, therefore, in any case should fall under a general chemicals law. Another limitation with these specific laws to pay attention to is that they normally do not regulate environmental risks caused of use of the products.

Pesticides used in agriculture (often named plant protection products) are by tradition in many countries since long regulated in specific legislation. FAO (Food and Agriculture Organisation of the United Nations) has published guidelines to assist Governments wishing to develop a legal framework for the control of pesticides. This product group, however, has very much in common with many chemicals for e.g. industrial, office and consumer use concerning methods for hazard assessment and communication as regards both health and environment, or with regard to risk management in general. Therefore, it may well be brought in under the umbrella of a general chemicals law. In any case countries will benefit from a close co-ordination of legislation and co-operation between institutions managing these various types of chemicals including pesticides.

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, may not be covered. Likewise, legislation on drugs, cosmetics and food and feed additives has a limited focus, protection of health of humans/animals, while protection of the environment is normally not covered. These limitations of the specific legislations are to be paid attention to and possibly to take care off at elaboration of a general chemicals legislation.

Furthermore, there may be issued (or planned) specific laws for protection of workers and environment, for waste, for transport and for other handling in practise of chemicals 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 e.g. for protection of workers and environment. If needed, these latter laws should take precedence in case of conflicting provisions.

Possible legal text

General 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, drugs, cosmetics, food and feeding stuffs or additives in food and feeding stuff.

Comments: If the legislator chooses to regulate classification etc. in other secondary legislation, the exemptions under 3. should be included there. There may be a need for other exemptions, such as cases where chemicals are only imported for transit to other countries. Some rules may not be necessary for chemicals imported or manufactured for own use. It may be necessary to clarify that waste is not regarded as a chemical.

Secondary chemicals legislation

If found necessary, appropriate specific further derogations may be introduced in detailed secondary legislation on classification, labelling, SDS, limitations, reporting, etc.

Definitions

It is most 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 standard will greatly enhance understanding and compliance of regulations and facilitate international sharing of risk and safety information to the benefit of safe use of chemicals and of import and export.

Possible legal text

General chemicals law

Definitions

1. *Substance* –
2. *Mixture* –
3. *Chemical* –
4. *Hazardous chemical* -
5. *Article* -
6. *Pesticide* -
7. *Plant protection product* -
8. *Biocide* -
9. *Handling (including import and export)* -
10. *Marketing* –
11. *Use* -
12. *Manufacturing/manufacturer* -
13. *Import/importer* -
14. *Supplier* -
15. *Downstream user* –
16. *Distributor* –

Comment: There is need for clear definitions of the objects of the legislation (substance, mixture, article etc.), activities which are regulated (handling, marketing, use) and persons/legal entities which are subject to the requirements (importer, manufacturer, supplier, distributor, user etc). A distinction needs to be made between professional (downstream) users and consumers. Points 6-8 are only needed if pesticides are regulated in the law.

Secondary chemicals legislation

Further specific definitions needed may be introduced in each piece of secondary legislation

Responsibilities and obligations of enterprises and others handling chemicals

Public institutions for managing general 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. In modern legislation on chemicals control, therefore, the main responsibility to provide for a safe use of chemicals is allocated to the enterprises in the supply chain, which manufacture, market (importers included), use and otherwise handle chemicals. Private consumers must take their share of responsibility. Exporters are to comply with regulations implementing international agreements.

Risks to health and to the environment may only be managed and harm avoided provided that actors in the supply chain search for and convey information on hazardous properties, risks and safe use to those handling chemicals. An appropriate information flow through the chain makes possible a preventive approach in risk management. Risks may be eliminated or reduced to acceptable levels before negative effects occur. Therefore, classification and labelling of chemicals together with safety data sheets (SDS) are the most important tools for efficient control of chemical risks. Initially, special attention may be devoted to ensure adequate labelling of chemicals, labelling being a less complex tool than SDS especially as regards small and medium sized enterprises (SMEs),.

A chemicals law should therefore clearly state a general responsibility of actors in the supply chain to ensure a safe use of chemicals which enter the market. The manufacturers and importers, being the primary suppliers, are the key actors. They should have the main responsibility to identify and assess the hazards and risks of chemicals and to provide for appropriate risk and safety information to make possible handling of chemicals at a high level of protection in later steps of the supply chain.

Importers may obtain information to identify hazards and risks from their suppliers abroad. Lot of information on hazardous properties of chemical substances is available in literature and data bases. Testing of chemicals should normally not be necessary but may be needed in case a manufacturer is producing a new substance or if the information available from suppliers or other sources is not satisfactory. Testing requirements may explicitly be stated in the law to ensure that it really takes place when needed.

Professional actors in the supply chain should have an adequate internal organisation and other qualifications for chemicals control 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 as regards hazard and risk assessment, information and risk management. Enterprises may hire own expertise or make use of external consultants. The latter solution is often applied by small and even medium sized enterprises. It should be noted that an enterprise handling chemicals, even when hiring a

consultant must be kept responsible for the result of assessment, classification, labelling, SDS etc.

It is a general finding that implementation of regulations on classification and labelling is an excellent means for enterprises (as well as authorities) to get experience of chemicals control as a whole and to raise competence. This is an excellent reason for countries to initially strongly focus on classification and labelling when introducing legislation on chemicals control.

Possible legal text

General chemicals law

General obligations of actors in the supply chain

Manufacturers and importers shall

- *identify and assess hazardous properties of and possible risks with chemicals they 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 risk and on safety measures,*
- *update the information whenever new knowledge has become available.*

Suppliers/distributors/downstream users shall

- *convey down the supply chain the information provided by manufacturers/importers,*
- *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 an general obligation in the law, however, to apply the protective measures that have been identified even in 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 an adequate organisation and other qualifications needed to comply with this law.

Comment: Particularly important for importers and manufacturers as their role in chemicals control is crucial.

Secondary chemicals legislation

Hazard and risk information:

Detailed regulations on classification, labelling and SDS may easiest be issued by adopting and implementing the GHS system. Transposal to national regulations should to the extent possible be done without deviations e.g. by reference to GHS. This simplifies work of government and authorities and of enterprises and facilitates international co-operation on chemicals control.

Information on request:

Specification of which type of information and documentation on the enterprise and on chemicals handled that is to be provided at request. If needed, specification of authorities with right to get information at request and for what purposes.

Qualifications:

In secondary legislation responsibilities of enterprises as regards routines requested at supply, purchase and use of chemicals may be specified (e.g. registering of customers, inventories and listing of chemicals handled etc.). Qualifications of enterprises as regards e.g. specific level of education of personnel should be avoided. Appropriate level of qualifications of an enterprise varies with 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 knowledge needed for chemicals control.

Limitations on trade and use

Bans and restrictions

Some chemicals, mostly chemical substances, are, due to their inherent hazardous properties or effects found on health or environment, judged to cause unacceptable risk at any use or at certain types of use. Many governments therefore have introduced bans or restrictions for trade and use of certain chemicals, normally substances, others may wish to do so.

The international community has by the Stockholm Convention 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. National implementation of those parts of the convention that regulate trade or use in general may preferably be done as part of general chemicals legislation. Other parts concerning emission regulation and waste may preferably be implemented by environmental legislation. If found appropriate from national points of view countries may ban or restrict additional chemicals substances, which are judged to cause unacceptable high risk.

By way of the Rotterdam Convention, the international community has agreed on a system for prior informed consent and information exchange at export or import of chemicals that are banned or severely restricted in countries which have ratified the convention. The number of chemicals covered is considerably higher than in the Stockholm Convention. This system gives importing countries information on import of chemicals that are banned or severely restricted in other countries and a possibility to stop or to regulate import, trade and use. However, a simple copying of bans and restrictions in other countries should be avoided. Decisions made in a specific country are based on prevailing risks and needs, which may differ considerably from country to country.

Possible legal text

General chemicals law

Bans or restrictions

In case it is found necessary for the protection of health, environment or to protect property the Government may ban or restrict import, marketing, use export or other handling of a dangerous chemical, including its use in articles.

Comment: Bans or restrictions may need to be notified under WTO rules. Substances or mixtures/mixtures which are highly carcinogenic, mutagenic or toxic for reproduction (CMR) according to GHS criteria are often banned for consumer use.

Secondary legislation

Specification of bans and restrictions. Implementation of parts of international agreements like the Stockholm convention that limit trade and use of chemicals. Regulations on further national bans and restrictions.

Authorisation

Countries with less developed chemicals control may be tempted to solve the present situation with heavy actions of central authorities like introduction of general authorization procedures. It should then be observed that an authorization procedure may be, in fact often is, most resource demanding for enterprises as well as for authorities. Therefore, they necessarily, as done in industrialised countries, are to be restricted to very few types of high risk chemicals.

By tradition pesticides used in agriculture, plant protection products, are controlled this way, as they intentionally have negative effects on health and/or environment. Quite commonly corresponding authorization is requested for similar groups of chemicals like insecticides, wood, textile and leather preservatives, rodenticides and disinfectants (often commonly called biocides) used in health care, in industry, in offices, in homes etc. These types of chemicals have intended biological effect and are often used in ways that may give rise to high exposure to workers, consumers, general public and to the environment. The use of them is therefore often combined with special risks, which is the rationale for authorization.

In some cases like in EU (REACH) authorization in addition is introduced for some other chemicals with serious effects on health and/or the environment like substances with a high degree of carcinogenicity, mutagenicity, effect on reproduction, persistence or bioaccumulative effect.

Hazard assessment and classification, information requirements especially regarding hazard communication on labels and SDS but also basic risk management regarding these types of chemicals do not basically differ from corresponding measures for other chemicals. It may therefore be rational to regulate the authorization procedure of these types of chemicals in a general chemicals law and to organise a common use of resources for various assessments and other deliberations to make. Thereby the legislation on chemicals will be simpler, more transparent and less costly, to the benefit of enterprises as well as of authorities.

Pesticides used in agriculture may in many countries since long be regulated in a specific law, why countries despite the advantages with a common legislation might prefer not to change their legislation on these pesticides. Regulations for authorisation of biocides, another type of pesticides used in industry, health care and in homes, on the other hand

often may be new, or need to be revised and enlarged to cover the full need, why it may be more appropriate to incorporate them into a general chemicals law.

An authorization should be time limited, e.g. last for five to ten years. The reason for time limited authorization is that knowledge on hazards and risks of chemicals successively increases. Countries may face serious problems with old, in time unlimited authorizations, when they due to new knowledge find a need to review and reassess old pesticides, 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. It keeps alive the pressure on applicants to keep their toxicological and other data updated.

Possible legal text

General chemicals law

Authorisation

The following chemicals may not be manufactured, imported, marketed or used without authorization from designed authorities:

- *pesticides,*
- *chemicals with the following serious effects on health and the environment: (to be decided countrywise).*

Authorization 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.*

Authorization 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 enterprise 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 legislation

Detailed regulations on requirements and procedure for authorisation of pesticides may be based on the FAO Guidelines for Legislation on the Control of Pesticides. Responsibilities of enterprises as regards e.g. documentation on 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 designation of authorities to receive applications.

Registers

Many countries have introduced or may plan registers on chemicals and/or on enterprises handling chemicals. Countries that have a system for authorisation of pesticides normally use information achieved through that system to establish a register on authorized pesticides and responsible enterprises. Registers may vary considerably as regards level of ambition and complexity. They may be simple lists on names and addresses of enterprises and their main activities including chemicals handled. They may be complex computerized systems encompassing qualified demands on testing combined with

extensive reporting of test and other data. Normally establishment of such registers does not imply any kind of authorisation or other explicit decision on acceptance of registered chemicals.

Simple registers

In most cases developing countries (DCs) and countries with economies in transition (CETs) in order to get hold on chemicals used in a country may benefit considerably from quite simple types of registers. Thus, an inventory of primary suppliers may be used as a base for a register of enterprises which manufacture and import chemicals for use on the domestic markets or for export. Customs and tax authorities may assist at such inventories. If found appropriate, the system might be combined with a simple general licensing system for importers and manufacturers to get even better hold on those key enterprises.

Such a simple register/data base will be valuable for e.g. planning and inspection purposes. It may, if successively supplemented with reporting on types and uses and contents of the chemicals handled, give an overview of the chemicals flow to the domestic market and use and therefore be even more valuable for planning and other measures. This further information collection may be based on the article above on reporting. However, as strongly emphasised in the previous report, 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 enterprises) for registering and control of data, for updating etc. Absence of updating quickly makes data unreliable.

A stepwise build-up extended in time and adapted to resources available is therefore to recommend e.g. as follows:

1. registering of importers and manufacturers that introduce chemicals on the domestic market,
2. registering of data on import and manufacture of pure substances (technical quality) of particular interest for a country (possibly incl. volume data/classification),
3. registering of import and manufacture of mixtures in certain groups of chemicals (lubricants, paints, glues etc.) of particular interest for a country (possibly incl. volume data/classification),
4. registering of hazardous components in classified mixtures (in certain groups, group by group, possibly percentages of components) etc.

Qualified registers

Industrialized countries/regions like US, Australia, Japan and EU, have introduced notification systems and registers for new (all) chemical substances encompassing vast responsibility for notifiers to test substances and to present toxicological and other data to authorities before placing new substances on the market. The EU system REACH includes data reporting for existing substances as well. The aim with these systems is primarily to ensure adequate knowledge on hazards and risks of chemicals used. They are extremely demanding as regards financial and human resources (incl. expertise) and not to recommend for DCs or CETs at early stages of development of chemicals legislation and control. Possibly, countries with own manufacturing of substances that are not manufactured and therefore not registered elsewhere, certainly very few, might introduce a limited notification system for these substances only. In general, countries should take

advantage of existing elaborate systems like the ones mentioned and rely on the qualified knowledge these systems generate.

Possible legal text

General chemicals law

Registering

Chemicals that are manufactured and imported professionally must be registered with the designated authority. Registrations shall be updated regularly as required according to implementing provisions. The register will be kept by the authority designated by the Government.

A registration shall include

- identity of enterprise/person making the registration,*
- identity of the chemical,*
- type of the chemical [, group, volumes marketed, contents of mixtures, etc],*
- [known dangerous properties/classification*
- further toxicological information, risk assessment data]*

Comment: Registering should normally be kept as simple as possible, especially when introducing a system. Registering of items within square brackets[] may, if found necessary and possible with regard to the resources needed, be regulated in later steps. Further information can be required by the authorities according to the article on reporting below.

Secondary legislation

Responsibilities of enterprises and procedures and routines for registering including designation of authorities to receive information are to be specified.

Licensing

Licensing of legal and natural persons is a possibility to ensure authorities knowledge on enterprises, appropriate qualifications of enterprises and appropriate handling of chemicals. Licensing of suppliers of very hazardous chemicals is quite common often combined with licensing of users of such chemicals, enterprises or private persons. Opposite to registers as described above, licensing calls for an active contribution of authorities encompassing assessment of an application and a decision to give or deny a license.

Licensing concerning chemicals should focus on primary and other suppliers. By requiring suppliers to register their customers, authorities will get a possibility to trace and control users. Licensing of users may, if found appropriate, preferably be regulated in legislation on protection of workers and environment or other specific legislation. General licensing of users should be avoided taking into account the great number of users compared to suppliers. It would lead to great administrative burdens for authorities and enterprises and be less cost effective.

Licenses may preferably be issued for a certain period and restricted to supply of well defined categories e.g. very hazardous chemicals as chemicals of high acute toxicity, high corrosiveness and highly flammable and explosive chemicals. Licensing may, if found appropriate, be extended to other chemicals of high concern e.g. carcinogens, mutagens etc. Focus should primarily be on the qualifications of the applicant to handle chemicals in

general at this high level of hazard e.g. on the need of expertise required. Such a procedure, focussing on categories of chemicals rather than on a single specific chemical, reduces the administrative burden of authorities and of enterprises while maintaining the allocation of responsibility at the applicant. In some cases, however, it may be more appropriate to introduce short time permits as a means of control. For instance, a simple permit may be to prefer in cases of need for occasional handling of a specific very hazardous chemical.

Possible legal text

General chemicals law

Licensing

Legal and natural persons manufacturing or importing chemicals must in the following cases obtain a license for marketing or for their own use.

- *Import of very hazardous chemicals,*
- *Professional supply or other transfer of very hazardous chemicals,*
- *Other handling of very hazardous chemicals.*

A license will be given if the person is qualified to handle chemicals with such properties, has undertaken the necessary safety measures and keeps records of all transactions which can be accessed by the authorities.

Licenses shall be reviewed periodically.

Comment: Safety measures can include storage and accessibility requirements. Licenses can be made general for professionals and more restrictive for use and import by non-professionals.

Secondary legislation

Designation of authorities to issue licenses and of procedures and routines for licensing including documentation, possibly qualifications of enterprises, requested of enterprises.

Reporting

Government institutions designed responsibility and tasks for implementation, management and enforcement, of legislation need access to information to fulfil their duties. Actors in the supply chain, therefore, should have the responsibility to provide on request designed public institutions with information they need for fulfilling their tasks as regulatory, enforcing authorities or authorities designed other tasks associated with the chemicals legislation.

When enterprises that manufacture or market a chemical get new information on hazard and risk of the chemical, they should be obliged to report this information to designed authorities in case it influences given licenses, permits or authorizations or influences the classification of the chemical due to serious health effects.

Possible legal text

General chemicals law

Reporting

- Legal and natural persons professionally handling chemicals shall provide upon request the designated authorities with such information about the chemical and its handling that is needed for assessment of risks for health or the environment and of risk reduction measures.

- *Legal and natural persons that manufacture, import or market a chemical shall report to designed authorities any new information on hazards and risks which they are aware of*

1. *if the information may influence given licenses, permits or authorizations,*
2. *if the information may influence classification due to carcinogenic or mutagenic effects or effects on reproduction or other serious effects of equivalent concern.*

Secondary legislation

Specification of documentation to be reported to authorities and of procedures and routines of reporting processes including designation of authorities to receive reports.

Confidentiality

The authorities will obtain information from operators, e.g. as part of licensing and reporting procedures, that must be kept confidential. Enterprises that give information to government 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 is, as seen above, regulated in regulations on labelling and SDS. In the GHS system it is e.g. stated that components in chemicals classified as hazardous that contribute to the hazard are to be revealed. Obviously, enterprises should not have the right to claim that this type of information should be kept confidential by authorities. Authorities may have legitimate reasons to make public also other information in case that is needed for protection of health and environment.

Possible legal text

General 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).

Responsibilities and tasks of government institutions

Issues concerning government institutions for chemicals control were discussed in depth in the previous report and are therefore only briefly dealt with here.

The chemicals legislation discussed here is complex. It has a high scientific/technical content and is subject of continuous change due to new knowledge rising on properties and effects of chemicals and concomitant risks.

Due to the steadily rising knowledge and to the increasing trade in chemicals and articles, no country can manage chemical risks by their own. The need to share knowledge, experiences and not at least costs has made chemicals risk management a highly international issue regulated in many international conventions and agreements.

All countries have a need of well developed government institutional set up with appropriate capacity and capability to keep up with new knowledge and other

development, for participation in international work and for domestic work including implementation, enforcement and supervision of legislation.

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

Efficient management and supervision of the law and other means for enforcement are most important for getting compliance with legislation. Tools needed are e.g. injunctions, prohibitions, possibility to connect such orders with a prospective fine, access to premises etc. If those tools for supervision are already in place in general national law they should be activated for the purpose of the chemicals law. Regulations issued by the government could distribute the supervision power to authorities.

There is, furthermore, a need to promote safe use of chemicals by information and other general advice to enterprises and to the common public on risks and use of chemicals. Co-operation with important stakeholders as representatives of trade and industry, environmental NGOs, trade unions etc., is most important. In countries in early stages of development of modern chemicals control, it might be appropriate to establish special support programmes for SMEs provided that they are constructed in a way which does not transfer responsibility from enterprises. In general, advisory and other support of government institutions should be carried through in a way not to reduce the responsibility of those handling chemicals to organise an adequate risk management in each specific case.

It is most important to concentrate the tasks for government management and enforcement of legislation on chemicals to a few designated institutions with clearly-defined and separate mandates. Concentration and clear boarder lines between areas of responsibility reduce risk of indistinct or overlapping responsibilities. Routines for work are to be established. Cost-efficiency of the work of the institutions is promoted and the very important contacts between these institutions and enterprises needed for successful implementation are facilitated.

Possible legal text

General chemicals law

Management and supervision

The designated authorities for management and supervision shall be responsible for ensuring that the law and regulations issued according to the law are followed.

The Authorities for management and supervision shall

- ensure that they are updated nationally and internationally about the development as regards risks caused by chemicals,*
- participate in international co-operation,*
- enforce the law and regulations and take the measures needed to ensure compliance,*
- monitor and report on compliance with the legislation and decisions based on the legislation.*

Authorities for management and supervision have the right to get information from legal and natural persons handling chemicals which is needed for their tasks according to the legislation.

Authorities for management and supervision have the right to get access to premises where chemicals are handled and to issue the orders needed to make legal or natural persons to comply with the legislation.

Authorities designed by the government shall, in addition these tasks, contribute to a safe use of chemicals by general advice and information.

Secondary legislation

In secondary legislation the governments may introduce instructions that specify the mandates and responsibilities of authorities and underpin the need of co-operation between them and with stakeholders.

Delegation

The high scientific/technical content of chemicals legislation and the frequent needs to make changes due to new information on hazards, risks, uses, exposure and risks, makes it necessary to delegate power for implementation from parliaments and governments to the lowest level possible. The basic law must therefore encompass a regulation on implementation provisions which makes possible for designated institutions to issue secondary legislation for implementation. Some countries may by tradition like to make delegation in specific administrative laws. Which ever way is used it is most important to clearly separate between responsibilities and tasks of institutions designed.

Possible legal text

General chemicals law

Implementing provisions

The Government/Ministry/designated authority may issue further detailed implementing provisions about the obligations in this law.

Secondary legislation

In secondary legislation the government may, when found appropriate and necessary, designate responsibility to authorities.

Penalties, sanctions

In order to get desired effect of a law, it is most important that sanctions are applied in case of non-compliance. Injunctions and prohibitions connected with prospective fines were mentioned above. Such reparative means of coercion have effect only case by case and only for the future. Furthermore they tender to transfer responsibility from the companies to the authorities. There is a need for repressive means of coercion to deal with non-compliance in already passed time, e.g. penal provisions and/or administrative sanction charges.

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

Most countries address penal provision only to natural persons, but do often combine them with provisions on confiscation of property which has been the subject of offences

and of the gains 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 chemical 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 sentence to prison.

If there is no fast-track in the penal process available for minor offences, administrative sanction charges may be introduced for certain frequently appearing, ready investigated violations. Such charges contribute to efficient supervision and could be useful as a general tool on other supervision areas too. Law provisions on sanction charges could consequently take place in a general law e.g. on supervision.

Possible legal text

General chemicals law

Penalty provisions and confiscation

A sentence (e.g. a fine or a term of imprisonment not exceeding X months) shall be imposed on any person who, whether deliberately or through gross negligence

- handles a chemical without taking protective measures needed to avoid damage to humans or the environment,*
- omits to classify a hazardous chemical before placing it on the market,*
- omits to transfer discoveries on possible hazardous effects he has been made aware of, despite he was obliged to it due to this law,*
- infringes provisions on classification and labelling of chemicals by serious wrong-classification or wrong-labelling.*

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

Administrative sanction charges:

- A sanction charge shall be paid by any economic operator who in his business activities:*
 - neglects to comply with rules issued pursuant to this law;*
 - commences an activity for which a permit must be obtained pursuant to this law or to rules issued in pursuance thereof.*

This shall only apply to infringements for which the Government has imposed a sanction charge pursuant to 2.

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

- The Government shall issue rules concerning infringements for which sanction charges are payable and the amounts to be paid for various infringements. The minimum sanction charge shall be 000 and the maximum charge shall be 000000.*
- Supervisory authorities shall decide matters relating to sanction charges.*

- A person who is liable for payment of a sanction charge pursuant to a decision taken by supervisory authority may appeal against the decision to an administrative court.

Entry into force and application. Transitional periods

The coming into force of a complex and demanding legislation like the one presented here cannot be made too fast. That goes for the basic law as well as for secondary legislation. It is appropriate for the provisions of the legislation to enter into force in a stepwise, staggered way to smooth the transition to the system. A gradual entry into force allows enterprises as well as authorities and stakeholders to get appropriate time for preparation for new duties.

Possible legal text

General chemicals law

Entry into force and application

1. *This law enters into force --/--/----*
2. *Article x enters into force --/--/----*
3. *Articles y, z enter into force --/--/----*
4. *etc.*

Comment: Articles (c.f. Annex 1) with general responsibilities may preferably come into force before articles with specified requirements which are very demanding for actors and therefore require longer time for preparation.

Secondary legislation

At issuing of secondary legislation the same approach as for the law may be applied for entering into force of the regulation as a whole and of individual articles.

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Annex 1.

A possible framing of legislation on chemicals as a comprehensive single law

Aim and scope

Article 1

Purpose

The purpose of this law is to ensure a high level of protection of human health and the environment when chemicals are handled and to protect property from harm caused by chemicals.

The law lays down provisions on chemicals which shall apply to the manufacture, import, marketing and use of chemical substances on their own, in mixtures/mixtures or in articles

Article 2

Scope

- 1 This law shall apply without prejudice to workplace and environmental legislation.*
- 2 This law shall not apply to radioactive substances.*
- 3 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, drugs, cosmetics, food and feeding stuffs or additives in food and feeding stuff.*

Definitions

Article 3

The following definitions are applied in this law and in secondary legislation to the law:

- 1 Substance –*
- 2 Preparation/Mixture –*
- 3 Chemical –*
- 4 Hazardous chemical -*
- 5 Article -*
- 6 Pesticide -*
- 7 Plant protection product -*
- 8 Biocide -*
- 9 Handling (including import and export) -*
- 10 Marketing –*
- 11 Use -*
- 12 Manufacturing/manufacturer -*
- 13 Import/importer -*

14 Supplier -

15 Downstream user –

16 Distributor –

General responsibilities and obligations for enterprises and others handling chemicals

Article 4

General obligations of actors in the supply chain

1 *Manufacturers and importers shall*

- identify and assess hazardous properties of and possible risks with chemicals they 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 risk and on safety measures,

2 *update the information whenever new knowledge has become available.*

3 *Suppliers/distributors/downstream users shall*

4 *convey down the supply chain the information provided by manufacturers/importers,*

5 *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.

Article 5

Hazard and risk information,

1. *Chemicals are to be classified according to criteria set in GHS.*

2. *Labelling of chemicals shall be done according to the requirements set in GHS.*

3. *Safety Data Sheets (SDS) are to be produced and provided to professional users for all substances and mixtures according to the requirements set in GHS.*

Article 6

Information on request

Legal and natural persons handling chemicals professionally are obliged on request to provide supervision authorities with all the information they possess relating to their relevant activities.

Article 7

Qualifications

Legal and natural persons professionally handling chemicals must have access to the expertise needed to take on their responsibilities according to this law.

Limitations

Article 8

Bans or restrictions

In case it is found necessary for the protection of health, environment or to protect property the Government may ban or restrict import, marketing, use export or other handling of a dangerous chemical, including its use in articles.

Article 9

Authorisation

The following chemicals may not be manufactured, imported, marketed or used without authorization from designed authorities:

- 1. pesticides,*
- 2. chemicals with the following serious effects on health and the environment: (to be decided).*
- 3. Authorization may be granted if*
- 4. the effects on health and the environment are acceptable when the chemical is used for the intended purpose,*
- 5. the chemical is needed for the purpose specified in the application and cannot be replaced by safer alternative chemicals or technologies.*

Authorization 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.

Registering, licensing, reporting

Article 10

Registering

Chemicals that are manufactured and imported professionally must be registered with the designated authority. Registrations shall be updated regularly as required according to implementing provisions. The register will be kept by the authority designated by the Government.

A registration shall include

- 1 identity of enterprise/person making the registration,*
- 2 identity of the chemical,*
- 3 data on the chemical [, group, volumes marketed, contents of mixtures, etc],*
- 4 [known dangerous properties/classification,*
- 5 further toxicological information, risk assessment data]*

Article 11

Licensing

Legal and natural persons manufacturing or importing chemicals must in the following cases obtain a license for marketing or for their own use.

- 1. Import of very hazardous chemicals,*
- 2. Professional supply or other transfer of very hazardous chemicals,*
- 3. Other handling of very hazardous chemicals.*

A license will be given if the person is qualified to handle chemicals with such properties, has undertaken the necessary safety measures and keeps records of all transactions which can be accessed by the authorities.

Licenses shall be reviewed periodically.

Article 12

Reporting

- 1. Legal and natural persons professionally handling chemicals shall provide upon request the designated authorities with such information about the chemical and its handling that is needed for assessment of risks for health or the environment and of risk reduction measures.*
- 2. Legal and natural persons that manufacture, import or market a chemical shall report to designed authorities any new information on hazards and risks which they are aware of*
 - a. if the information may influence given licenses, permits or authorizations,*
 - b. if the information may influence classification due to carcinogenic or mutagenic effects or effects on reproduction or other serious effects of equivalent concern.*

Confidentiality

Article 13

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.

Implementation, delegation

Article 14

Management and supervision

The designated authorities for management and supervision shall be responsible for ensuring that the law and regulations issued according to the law are followed.

The Authorities for management and supervision shall

- 1 ensure that they are updated nationally and internationally about the development as regards risks caused by chemicals,*

- 2 *participate in international co-operation,*
- 3 *enforce the law and regulations and take the measures needed to ensure compliance,*
- 4 *monitor and report on compliance with the legislation and decisions based on the legislation.*

Authorities for management and supervision have the right to get information from legal and natural persons handling chemicals which is needed for their tasks according to the legislation.

Authorities for management and supervision have the right to get access to premises where chemicals are handled and to issue the orders needed to make legal or natural persons to comply with the legislation.

Authorities designed by the government shall, in addition these tasks, contribute to a safe use of chemicals by general advice and information.

Article 15

Implementing provisions

The Government/Ministry/designated authority may issue further detailed implementing provisions about the obligations in this law.

Sanctions

Article 16

Penalty provisions and confiscation

A sentence (e.g. a fine or a term of imprisonment not exceeding X months) shall be imposed on any person who, whether deliberately or through gross negligence

- 1 *handles a chemical without taking protective measures needed to avoid damage to humans or the environment,*
- 2 *omits to classify a hazardous chemical before placing it on the on the market,*
- 3 *omits to transfer discoveries on possible hazardous effects he has been made aware of, despite he was obliged to it due to this law,*
- 4 *infringes provisions on classification and labelling of chemicals by serious wrong-classification or wrong-labelling.*

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

Article 17

Administrative sanction charges:

1. *A sanction charge shall be paid by any economic operator who in his business activities:*
 - a. *neglects to comply with rules issued pursuant to this law;*

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

This shall only apply to infringements for which the Government has imposed a sanction charge pursuant to 2.

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

2. The Government shall issue rules concerning infringements for which sanction charges are payable and the amounts to be paid for various infringements. The minimum sanction charge shall be 000 and the maximum charge shall be 000000.

3 Supervisory authorities shall decide matters relating to sanction charges.

4. A person who is liable for payment of a sanction charge pursuant to a decision taken by supervisory authority may appeal against the decision to an administrative court.

Entry into force and application

Article 18

- 1. This law enters into force --/--/----*
- 2. Article x enters into force --/--/----*
- 3. Articles y, z enter into force --/--/----*
- 4. etc.*

1. Annex 2.

Primary law and secondary legislation

PRIMARY LAW with general obligations and responsibilities	General obligations of enterprises - duty of care - testing, - assessment - hazard and risk information - qualifications	Limitations on sale and use of chemicals	Registering of enterprises and of chemicals	Licensing of enterprises	Reporting to authorities	Delegation
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SECONDARY LEGISLATION with detailed regulations	Testing and assessment * Classification Labelling SDS * Qualifications	Bans and restrictions * Authorisation of pesticides * Authorisation of biocides * Other authorization	Registers on importers and producers * Simple registers on chemicals * Advanced registers on chemicals	Licensing of suppliers of very hazardous chemicals	Regular reporting to authorities * Reporting at new findings on hazards	Instructions for authorities
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SWEDISH CHEMICALS AGENCY • P.O. Box 2 • 172 13 Sundbyberg • SWEDEN
Phone: +46 8 519 41 100 • Fax: +46 8 735 76 98