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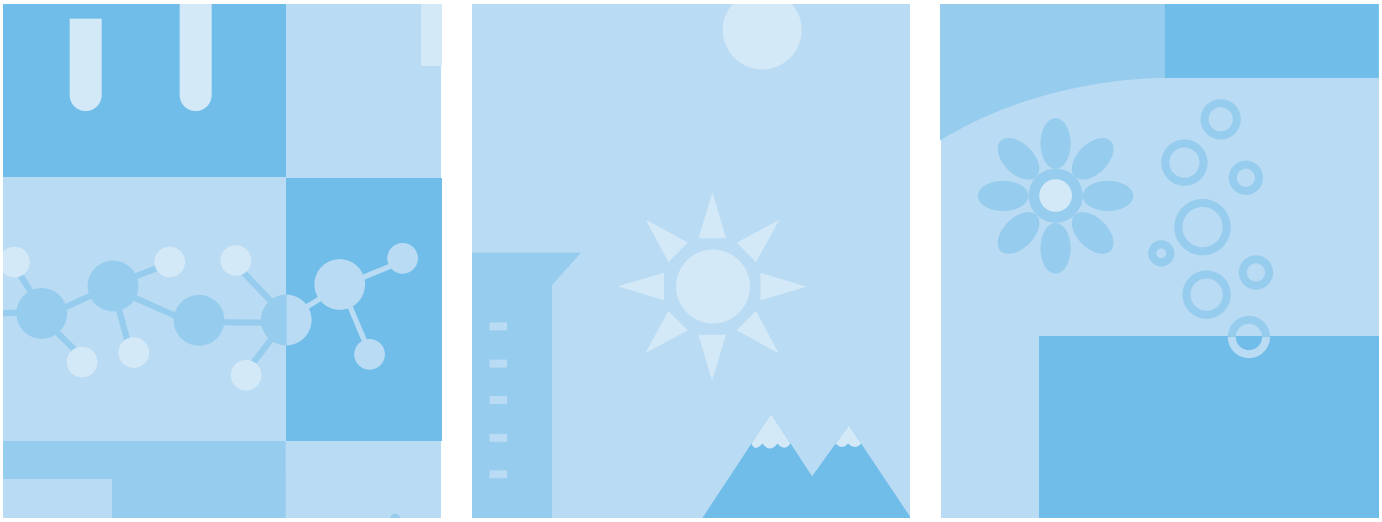
Capacity Building for Sound Management of Chemicals

Organisation, responsibilities and tasks of governmental institutions and enterprises



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Swedish Chemicals Agency

Capacity Building for Sound Management of Chemicals

Organisation, responsibilities and tasks of governmental institutions and enterprises

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Order address: CM Gruppen, P.O. Box 11063, SE-161 11 Bromma, Sweden
Phone: +46 8 5059 33 35, Fax +46 8-5059 33 99, E-mail: kemi@cm.se
The report is available as a downloadable pdf on www.kemi.se

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Sammanfattning

Många länder är i färd med att bygga upp eller förbättra sina nationella system för kemisk riskhantering. Ofta sker detta som ett led i implementering av SAICM (Strategic Approach to International Chemicals Management), ett program som antogs 2006 vid en FN-konferens i Dubai. I rapporten diskuteras förutsättningar för utveckling en effektiv kontroll av kemiska risker som är av särskild betydelse för utvecklingsländer och länder med ekonomier i förändring. Stor vikt läggs vid uppbyggnad av en nationell infrastruktur i form av lagstiftning och offentliga institutioner. Diskussionen koncentreras till utveckling av en effektiv kontroll av utflödet av kemikalier på marknaden med fokus på tillverkare och importörer. Ansvarsfördelningen mellan regering och myndigheter å ena sidan och företag i industri och handel å den andra behandlas. En praktisk vägledning ges för uppbyggnaden av ett program för utvecklingsarbetet med konkreta mål och åtgärdsplaner.

Executive summary

Introduction

The use of chemicals is very important for economic development and in improving people's living conditions. It is a commonly held opinion, however, that the risks posed by the extensive use of chemicals also represent a great threat to human health and the environment, not just today but for coming generations too. The need for chemicals risk management has therefore received ever greater attention. It is now one of the high-priority issues in environmental protection programmes as well as in programmes relating to public health and occupational health and safety in many countries and in international organisations such as various UN institutions and the OECD.

Industrialised countries are still improving their systems for chemicals risk management, not least as regards measures prior to or on the marketing of chemicals, chemicals control. Chemicals control is viewed as the first preventive step towards effective risk management. It simplifies and reduces costs of risk management in use or other handling.

Developing countries and countries with economies in transition have shown sharply increased interest in improved chemicals risk management, particularly in the past decade. Although risks due to the use of pesticides in agriculture are fairly well known in these countries, they are often not dealt with in a way that provides sufficient safety for the health of workers and for the environment. Risks due to the increasing use of chemicals in industrial production, agriculture and households may still be unknown, underestimated or even ignored. The chemicals control part of risk management is less well developed. The level of awareness of adverse effects of chemicals is often quite low.

Basic features of chemicals risk management

Chemicals risk management aims at four main goals:

1. To obtain knowledge of the intrinsic hazardous properties of chemicals.
2. To disseminate information on hazardous properties of chemicals placed on the market and on safe use.
3. To make informed choices of chemicals in order to avoid hazards.
4. To organise safe use of chemicals.

These goals are to be attained by activities of government and by the actions of those handling chemicals in practice as suppliers, users, waste handlers etc., i.e. the actors in the supply chain through whom chemicals are introduced to the market, transported, stored and used.

The key areas of modern legislation on the marketing of chemicals, chemicals control, encompass regulations on testing, hazard assessment, hazard communication, risk assessment and hazard management. The primary, and therefore in a sense most important, regulations on chemicals control, risk management in the first steps of the supply chain before or when chemicals are supplied, encompass:

1. **Hazard communication** through classification, labelling and safety data sheets based on hazard assessment. These measures guide the flow of information in the supply chain to ensure that enterprises and other users are provided with adequate information on hazards and contents of chemicals and their safe transport, storage, use and disposal.
2. **Risk management** in the form of bans and restrictions to ensure that highly hazardous chemicals are not marketed or used.

The main responsibility rests with enterprises

Modern legislation on chemicals risk management specifies the responsibilities and obligations of enterprises and public institutions. Enterprises and other actors handling chemicals are normally allocated the main responsibility for ensuring that the use of chemicals does not affect human health or the environment in an unacceptable way.

Each actor in the supply chain, (producer, importer, retailer, user, waste handler etc.) has specific responsibilities. According to specific chemicals legislation regulating marketing of chemicals, the producers and importers in a country, the primary suppliers, have the main responsibility. They are obliged to provide customers/users with adequate information on hazards and guidance on safe use. The users have to take account of aspects of risk in their choice of chemicals and organise safe use to avoid risks. Exporters may have still other responsibilities. Enterprises in the supply chain have to fulfil their regulated tasks without any specific support from public institutions.

Role of government

In market economies, governments and their institutions control the responsibilities and work of actors in the supply chain by legislation and by enforcement and monitoring of compliance. Due to the great number of chemicals on the markets and in use and the complexity of their use, it is not possible for governments to control or manage the marketing or use of chemicals in detail.

Establishment of a basic infrastructure in the form of legislation and an institutional organisation with clear responsibilities for the government and its institutions in relation to those of enterprises is the first step in developing chemicals risk management. An adequate legal and institutional infrastructure makes it possible to organise transparent and cost-saving implementation and enforcement of national regulations on chemicals, including implementation of international agreements. Without such an infrastructure, countries run an obvious risk of scattered legislation and unclear institutional responsibilities and as a consequence ineffective and unnecessarily costly management.

There is a need to have institutions for actions at:

1. Policy level: Legislative actions.
2. Management level: Day-to-day management of legislation.

3. Enforcement level: Enforcement and monitoring of legislation.

It is very important that institutions in the public sector have the capability and capacity to fulfil their tasks, to control and monitor the activities of the actors in the supply chain.

Sound chemicals management reduces societal costs and promotes business

Introduction of chemicals risk management in supply of chemicals, chemicals control, will mean improver risk management in general. It will, among other things, mean reduced health care costs due to fewer accidents with chemicals and fewer illnesses and other adverse health effects of chemicals. Furthermore, improved chemicals control means a reduction in costs of remediation of environmental damage and of other costs following emissions, for example pollution of watercourses and soils due to accidents or prolonged use of chemicals. The costs to governments of managing chemicals will be reduced.

It is an often heard argument that enterprises cannot afford to improve their chemicals risk management; it would be too costly and remove them from markets. Such arguments are, however, in most cases far from representing the truth.

It is well known that enterprises acting on the global markets face increasing demands for safe, clean products (chemicals and other products), clean production and good information. Customers want to protect their own workers, their own customers and the environment. In more and more countries, enterprises using chemicals in their production demand that their suppliers (foreign or domestic) apply stringent rules and routines for chemicals control as for other chemicals risk management. Enterprises which cannot meet these demands due to inadequate chemicals risk management will face increasing problems with competitiveness, particularly in international markets.

Investments in improved chemical control will therefore pay off in the form of improved business opportunities. Furthermore, measures for the preventive chemicals control such as making use of less hazardous chemicals and improved information on risks and safe use will be repaid in the form of less need for costly technical risk reduction measures for exposure and emission control. Improved control of very commonly used chemicals also results in more cost-effective processes with reduced use of chemicals and less waste. Costs of initial investments may in many cases be recouped in a very short time.

Aim and contents of the report

This report summarises some main observations and experiences from work on chemicals risk management in industrialised countries, in international organisations as well as in developing countries and countries with economies in transition. Basic features of special significance for chemicals control, the preventive first steps of risk management in the supply chain before and at marketing of chemicals, are discussed. The main emphasis is on the need for a legal and institutional infrastructure and for clear allocation of responsibilities and tasks to public institutions and enterprises which market chemicals. The importance of preventive chemicals control, for many countries a new approach, and its relationship to traditional risk management for protection of the environment, occupational health and safety and consumer protection are discussed. Practical guidance is given for the development of a possible programme with objectives and an action plan for improved chemicals management. The main aim is to make clear some important issues to take into account in the development of modern chemicals risk management, primarily in developing countries and countries with economies in transition.

The report, which is a revised and extended version of a previous report (KemI PM 1/07), has been written, like the previous one, by Bengt Bucht in collaboration with colleagues in the International Secretariat of the Swedish Chemicals Agency (KemI).

Scope of the report

The report focuses on an important part of chemicals risk management, here referred to as chemicals control, which during the past decade has received increasing attention internationally. Chemicals control is defined in this report as control of consumer, industrial and agricultural chemicals for risk management before or when chemicals are marketed. It comprises the first preventive steps in sound management of chemicals as defined in the Strategic Approach to International Chemicals Management (SAICM), decided upon by UN environmental ministers 2006. Effective chemicals control is essential for cost-efficient risk management in later steps of the supply chain such as transport, storage, use and waste handling. Chemicals such as pharmaceuticals, food and feed additives and narcotics, which in general are regulated in specific legislation, are not discussed here. Risk management in the use of chemicals as regulated in legislation on the environment, occupational health and safety, transport etc., is discussed only in general terms. The correlation between traditional regulations on protection of the environment and workers and regulation of the marketing of chemicals, for many countries a new form of legislation, is emphasised. 'Chemicals' is used as a generic term for chemical substances and mixtures of substances.

The report summarises some general points of view and experiences as expressed in international agreements and in various national programmes on chemicals management. Experience gained from projects supporting developing countries and countries with economies in transition in the development of modern chemicals management is also taken into account. The aim is to give guidance to countries for planning and establishment of a step-by-step programme for the introduction of chemicals control for sound chemicals risk management and for the implementation of SAICM and other international agreements on chemicals.

A second report (Swedish Chemicals Agency 2008) "Legislation for Risk Management on Marketing of Chemicals", KemI PM 4/08, is intended to inspire and facilitate the development of specific legislation on chemical risks management at the first steps in the supply chain before chemicals are taken into use.

General comments

Chemicals risk management – an internationally prioritised issue

Chemicals risk management is internationally one of the high-priority issues in programmes relating to environmental protection as well as in programmes relating to public health and occupational health and safety. This has long been the case for many industrialised countries and for international organisations such as various UN institutions and the OECD. Industrialised countries are still improving their systems for chemicals management, not least as regards measures before or on marketing of chemicals (chemicals control).

Interest in improved risk management is steadily increasing in many countries, not at least in developing countries and countries with economies in transition. However, although risks due to the use of pesticides in agriculture are fairly well known in these countries, they are often not dealt with in a way that provides sufficient safety for the health of workers and for the environment. Risks due to the increasing use of chemicals in industrial production, agriculture and households may still be unknown, underestimated or ignored. The level of awareness of the adverse effects of chemicals is often quite low. Exporting countries, however, increasingly face demands for clean products and clean production methods from customers in countries with a higher level of awareness of the need for chemicals control.

The use of chemicals is very important to economic development and improving people's living conditions. It is a commonly held opinion, however, that the risks posed by the extensive use of chemicals also represent a great threat to human health and the environment, not just today but for coming generations too. The increasing incidence of allergies, cancer, effects on reproduction and other chronic toxic effects are examples of possible adverse consequences of the use of chemicals, which have made the need for strengthened chemicals control obvious. It is recognised that the level of toxic metals and persistent organic chemicals (POPs) in water, soil and air is a cause for concern. Acute and delayed health effects due to chemical exposure notably affect workers, farmers and children, particularly in many developing countries.

The increasing production, trading and use of articles and goods (electronics, clothing, cars, building materials etc.) cause high flows of chemicals into society and therefore also increasing exposure of humans and the environment to chemicals. Due to the increasing international trade in chemicals and articles containing hazardous chemicals and the long-range transportation of pollution, chemical risks often originate outside the country where the adverse impacts occur. International co-operation is therefore necessary to achieve effective chemicals risk management.

As regards the effects of chemicals, there are still, despite great efforts to improve the situation, unacceptable gaps in knowledge, and we therefore cannot assess chemical risks in an adequate way in order to take preventive measures. This was strongly emphasised at the United Nations Conference on Environment and Development, Rio 1992, in the Agenda 21 programme that was adopted. The intensified international co-operation on chemicals management implementing Agenda 21 has further addressed the management of chemicals risks.

Several UN agreements on chemicals risk management have been reached following the 1992 Rio Conference, such as the Rotterdam Convention (1998) and the Stockholm Convention (2001). Agreements preceding the Rio Conference which encompass chemicals risk management include, for example, ILO Convention 170, the Montreal Protocol, the Chemical Weapons Convention and the Basel Convention. The UN, the OECD and the European Union (EU) have recently all strengthened their chemicals programmes. At the International Conference on Chemicals Management in Dubai 2006 governments decided on a global chemicals strategy, the Strategic Approach to International Chemicals Management (SAICM). The OECD chemicals programme is developing continuously. UN organisations and the OECD have jointly developed a Globally Harmonised System for Classification and Labelling of Chemicals (GHS), first published in 2003 as an important tool for all countries. In the EU a new chemicals policy has been launched (2006) in order to make the efforts to manage chemical risks more stringent and more efficient, and a Regulation on Registration, Evaluation and Authorisation of Chemicals (REACH), entered into force in 2007. REACH replaced several other pieces of legislation. The GHS was implemented in Community law in 2008 through a regulation on classification, labelling and packaging of mixtures (CLP). REACH and GHS both aim at improved chemicals control.

Preventive chemicals risk management

Effective chemicals control and preventive risk management early in the supply chain, make possible cost-effective risk management later in the chain such as exposure and emission control in transport, storage and use and in management of chemical waste. Countries with modern, well developed chemicals risk management have therefore usually introduced a legal

and institutional infrastructure with special legislative and administrative programmes on chemicals control i.e. risk management steps before or when marketing chemicals. At national level, governments and their subordinated authorities as well as enterprises are allocated specific and separate responsibilities under this legislation. Mostly, however, responsibility to ensure safe handling of chemicals with regard to health, environment and safety rests with the enterprises. As legislation and programmes for chemicals control are subject to continuous change, countries, governments and trade and industry, in order to keep up to date, have to allocate resources for work at national level as well as for participation in international co-operation.

The key areas of modern legislation on chemicals control, this preventive risk management, encompass regulations on testing, hazard assessment, hazard communication and hazard management in the form of restrictions on marketing and use of chemicals. These are all important steps in a risk prevention strategy, a “new approach”, which reduces the need for and facilitates traditional risk management in storage, transport, use and waste handling. The better the control of chemicals before and on their marketing, the more cost-effective risk management in later steps of the supply chain will be. Risks may be avoided by choice of chemicals or managed by appropriate handling.

The primary, and therefore in a sense most important, regulations on chemicals control encompass:

1. Hazard communication through classification, labelling and safety data sheets. These measures guide the flow of information in the supply chain to ensure that enterprises and other users are provided with adequate information on hazards and contents of chemicals and their safe transport, storage, use and disposal.
2. Risk management in the form of bans and restrictions to ensure that chemicals which pose risks that could not be handled adequately in the supply chain are not marketed or used.

There are specific regulations in many countries on biocides and plant protection products or other chemicals of high concern requiring, for example, authorisation before marketing and use. Regulations on the exporting and importing of banned or severely restricted chemicals implement international agreements. Other regulations on chemicals control are supportive in nature, such as those for animal testing and good laboratory practice.

The main responsibility rests with enterprises

The main parts of modern legislation on chemicals control do not just encompass specific requirements on chemicals, they also, and most importantly, lay down and make clear the responsibilities and obligations of enterprises and public institutions. Enterprises and other actors handling chemicals are normally allocated the main responsibility for ensuring that the use of chemicals does not affect human health or the environment in an unacceptable way.

Fig. 1 shows in simplified form the main responsibilities of various actors in the supply chain as often specified in legislation. Every actor in the supply chain (producer, importer, retailer, user, waste handler etc.) has specific responsibilities (Fig. 2). According to specific chemicals legislation regulating marketing of chemicals, the producers and importers in a country, the primary suppliers, have the main responsibility. They are obliged to provide customers/users with adequate information on hazards and guidance on safe use. Primary suppliers have to search for toxicological data, test chemicals if necessary, assess their hazardous properties and decide whether to produce or import a certain chemical or not. Chemicals marketed have to be provided with adequate classification, labelling, safety data sheets (SDS) and packaging to make safe use possible. The users have to search for data, take account of aspects of risk in

their choice of chemicals and organise safe use to avoid risks. Exporters have certain information duties (Rotterdam Convention). Enterprises have to fulfil these tasks without any specific support from public institutions. It is obvious that extensive co-operation between the actors in the supply chain is essential for the desired result to be achieved.

Figure 1. Chemicals control. Supply chain risk management – two main types of legislation

Type of legislation	**Primary target groups in supply chain**	**Typical responsibilities regulated**
Legislation on chemicals ("chemicals legislation")	Suppliers: Exporters } primary Importers } suppliers Producers Retailers	Responsibilities in placing on the market (supply): - Data retrieval (testing, literature, ..) - *Hazard* assessment, classification - Information to customers through e.g. labelling, SDS - Packaging in supply - General bans and restrictions in supply and use - Substitution with less hazardous chemicals - Licences import/export/ trade - Authorisation (pesticides, biocides, others) - Registration of chemicals Measures to make possible safe use and other handling – Risk prevention
Legislation on: - Environment - Work environment - Major accidents - Transport	Handlers: Users All other handlers (including suppliers)	Responsibilities in handling (use, transport, storage etc.): - Data retrieval (primarily from suppliers) - *Risk* assessment - Specific bans and restrictions on use - Substitution with less hazardous chemicals - Information to workers, instructions, training - Safe handling - Exposure control - Emission and waste control - Licences/permits for production, use, other handling Measures to organise safe use in handling prevalent at each specific enterprise - Risk management/reduction

Role of public institutions

The main role of governments and public authorities in general is to steer and guide the activities of the actors in the supply chain by legislation, by general information on chemical risks and on responsibilities of enterprises, and by enforcement and monitoring of compliance with legislation. However, public institutions must never take over responsibility from the actors in the supply chain.

Public institutions will only make hazard and risk assessments and decide on risk management to a limited extent. This is the case for instance in the authorisation of biocides and plant protection products and the prohibition and restriction of certain very hazardous chemicals. Public institutions should not and cannot even in those cases be made responsible for supplying specific information on chemicals on the market such as contents, toxicological data, hazard assessment, classification, labelling and SDS, nor for detailed advice on safe use. They should not act as consultants. The reason is obvious. Due to the very extensive, varying and ever-changing use of chemicals, the experience in developed countries is that governments and authorities do not have the capacity and capability required for such tasks. Modern chemicals legislation therefore allocates these tasks to the enterprises, especially the primary suppliers (producers and importers).

It should be up to enterprises and their federations to produce more detailed manuals or other means of facilitating and organising the work on classification, labelling, SDSs etc. at enterprises. The allocation of responsibilities should be borne in mind in every action by the authorities. If authorities take on tasks that should be allocated to enterprises, the result will be less effective work by both enterprises and authorities. The enterprises will learn to wait for the authorities to tell them what is expected. They will passively respond to signals from authorities rather than be proactive. The authorities will neither have the resources nor the qualifications needed to provide extensive service to the enterprises, and the result would be poorer risk assessment and risk management.

Figure 2. Chemicals control. Decentralised risk control – shared responsibilities of actors in the supply chain.

Co-ordination and co-operation and capability and capacity of enterprises and government institutions are key factors

In addition to ensuring adequate and effective legislation on chemicals risk management, an even greater challenge for countries is to develop the capability and the capacity of enterprises to assume their responsibility under this legislation. This is primarily a task for trade and industry. For governments it is most important to ensure that institutions in the public sector have the capability and capacity to fulfil their tasks, to steer and monitor the activities of the actors in the supply chain. Capability and capacity means technical and financial resources, human resources (manpower and expertise) and efficient organisation (between and within

enterprises; between and within public institutions). There is a need for an efficient institutional infrastructure for effective control of chemical hazards.

Capability and capacity of enterprises

Organisation and expertise needed

Enterprises marketing chemicals need an internal organisation with clear responsibilities, expertise and routines for tasks such as control of the purchase of chemicals, data retrieval, hazard assessment, classification, labelling, SDS, and to a certain degree risk assessment. Users need to organise data retrieval, risk assessment, information to and safety instructions for employees etc. Smooth and effective co-operation between actors in the supply chain simplifies the work of enterprises (cf. Fig. 2). Enterprises may meet the demands for expertise by making use of the expertise of their suppliers of chemicals, by hiring their own experts or by engaging external expertise (consultants). Normally a combination of these alternatives is used.

Sound chemicals management promotes business

Enterprises acting on the global markets are facing increasing demands for safe, clean products (chemicals and other products), clean production and good information from customers who want to protect their own workers, their own customers and the environment. Customers in more and more countries are demanding that their suppliers (foreign or domestic) apply stringent rules and routines to chemicals control as they do to other chemicals risk management. They increasingly demand that suppliers comply with international agreements and standards including those on environmental management systems. It is obvious that enterprises with inadequate chemicals risk management will face increasing problems as regards co-operation with customers and consequently with competitiveness on international markets.

Federations in trade and industry can play an important role

Experience clearly shows the great importance of an infrastructure in trade and industry for successful chemicals risk management and for business. Governments and authorities in most cases do not have the capacity to hold discussions with individual enterprises when preparing regulations. There is a need to hold talks with partners such as federations, which may represent groups of enterprises. Enterprises, in particular small and medium-sized ones (SMEs), benefit from being members of federations. In addition to providing a channel to and from governmental institutions, federations can provide assistance to enterprises such as information on regulations and what these require, advice on problem solving, assistance with training etc.

Capability and capacity of public institutions. Role of legislation

Establishment of a basic infrastructure in the form of primary legislation and an institutional organisation with clear responsibilities is the first step in developing chemicals control. An adequate legal and institutional infrastructure makes it possible to organise transparent and cost-saving implementation and enforcement of national regulations on chemicals, including implementation of international agreements. Without such an infrastructure, countries run an obvious risk of scattered legislation and unclear institutional responsibilities and as a consequence ineffective and costly risk management.

The six C's: coherence, concentration, co-ordination, co-operation, continuity and cost-efficiency

Chemicals risk management in the early steps of the supply chain, chemicals control, is a truly horizontal issue. It concerns the health and safety of consumers and workers as well as protection of the environment and property. Several governmental institutions obviously have

an interest in this issue, and accordingly there is a great need for integration to achieve coherence, concentration, co-ordination, co-operation, continuity and cost-efficiency in efforts made.

Coherence, concentration and co-ordination of legislation

It would be very complicated to regulate all types of chemicals risks, to the environment, workers, consumers and all the steps in the supply chain (Fig. 1) in a single piece of legislation. Such legislation would be very wide-ranging, extensive and heterogeneous and therefore not easy for enterprises or governmental institutions to comprehend and apply. When they introduce specific chemicals legislation regulating marketing of chemicals, countries therefore often develop it as a complement to traditional legislation on protection of the environment, occupational health and safety and consumer protection. However, in order to avoid omissions, gaps or contradictions, the number of separate statutory instruments should be reduced to a minimum. The instruments should be well co-ordinated.

Thus, in order to be workable and efficient, legislation on chemicals risk management should be as coherent as possible and concentrated into a few basic laws. It seems reasonable to establish separate chemicals legislation on chemicals control primarily regulating marketing. This specific chemicals legislation will complement other statutory instruments on the use of chemicals such as regulations on occupational health and safety and environmental protection. The rationale behind this is obvious. When placing chemicals on the market, enterprises have to assess and classify them with regard to all types of hazards to workers, consumers and the environment. They have to provide all customers, whether they be enterprises or private consumers, with information (labels, SDS) on all types of inherent hazards and directions on safe use. Regulating these obligations of enterprises 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 to governmental institutions as well as to enterprises. For the same reasons, national implementation of international agreements such as the Stockholm, Rotterdam and Basel Conventions as well as the Montreal Protocol should preferably be made within the framework of the specific chemicals legislation as far as regulations on marketing are concerned.

Co-operation, co-ordination and concentration of government institutions

Chemicals risk management, in specific chemicals control, is a horizontal discipline of a preventive nature. Before a new chemical is introduced for use, all types of possible hazards have to be evaluated in order to avoid or reduce risks in use. Hazards to health, the environment and property and related risks during intended or foreseeable use but also as a result of (major) accidents have to be taken into account when preparing classification, labelling and safety data sheets. They also have to be considered before decisions on bans, restrictions or authorisation for example of pesticides. If not, a means of effectively avoiding one type of risk may result in another. The replacement of unhealthy and flammable solvents with chlorinated fluorocarbons (CFCs), for instance, resulted in new serious risks to health and environment due to destruction of the ozone layer. Asbestos, introduced as an effective chemical for heat and fire protection, was found to represent a serious human health hazard. Although it is not always possible to foresee all risks, one of the main aims of modern chemicals risk management is to ensure that all available knowledge on hazards and possible risks is taken into account before marketing and use of chemicals.

The horizontal nature of chemicals risk management calls for an adequate institutional set-up (ministries and subordinated bodies) and strong co-ordination of the work of institutions selected to be responsible for various aspects of chemical safety. Good co-operation has to be ensured both vertically and horizontally.

There is obviously built-in tension in chemicals risk management. On the one hand, the strong interlinking of various parts of the specific chemicals legislation regulating marketing necessitates coherent management for the greatest cost-effectiveness, preferably concentrated in one ministry and one central management institution. On the other hand, chemicals risk management is a horizontal issue of interest to many parts of society. It is therefore necessary to have smooth co-operation and co-ordination between ministries and other institutions concerned. They must share a common view on chemical risks and on how to manage them, and they need to ensure that the various pieces of legislation and the actions of institutions complement and support each other without contradictions.

International co-operation and co-ordination

Due to the international trading of chemicals, articles and goods and the long-range transportation of chemical pollutants, there is a need for international co-operation on measures to avoid risks. No country can any longer manage national chemical risks on its own. Countries cannot fail to respond to risks posed by chemicals that are exported as such or as components in various types of articles and goods, whether they are textiles, electronics, cars, construction materials or other products or whether they are contaminants in food. In countries with well-organised chemicals control the way to manage problems with chemicals is through extensive international co-operation such as by participation in the large chemical programmes run by UN organisations and the OECD, and by implementation of international agreements. Enterprises co-operate with trading partners abroad and in their international organizations.

Well organised and effective national chemicals control is crucial to gain acceptance for the transfer of chemicals from one country to another without extensive and costly border control or extra market surveillance. Control of chemical hazards is an issue of internationally shared responsibility, which no country can dissociate itself from and from which all countries benefit. International co-operation on chemicals facilitates national legislative work, gathering of information on the properties of chemicals, tracking flows and uses of chemicals and monitoring of compliance with regulations. The possibility of making use of data produced in other countries saves resources (manpower and money) for both government institutions and enterprises.

Continuity

Adequate institutions with adequate resources for managing legislation on chemicals are essential for effective chemicals risk management.

For institutions in the public sector it is most important to have the legislative, scientific and technical capability and capacity needed for development, implementation and management of legislation, including regulatory work and supervision of compliance with the regulations. These tasks, despite enterprises not having the main responsibility for chemicals risk management, are demanding on resources, even for small countries. The programmes needed for example on hazard and risk assessment and on risk management (for example in the form of classification and labelling, bans and restrictions on chemicals of high concern and authorisation of plant protection products and biocides) are comprehensive. They need to be run continuously and revised regularly. Regulations issued are far from being everlasting. They are very much moving targets, and most of them need to be continuously revised to adapt to new knowledge on hazards and risks posed by chemicals.

Cost-efficiency

By integration, as outlined above, and by coherence, concentration, co-ordination, co-operation (national and international) and continuity, it will be possible for countries to achieve good cost-efficiency in chemicals risk management. Governments will use resources

in a more efficient way. Enterprises will find it easier to comprehend the legislation, understand it and comply with it. Their contacts with governmental institutions will be simplified. Altogether this means reduced costs for enterprises.

Development, implementation and enforcement of modern legislation for chemicals risk management

This section presents comments of importance on some main issues concerning legislation. They have been found to be especially relevant with regard to the present situation in countries with a less developed infrastructure for chemicals risk management in general and for chemicals control in particular.

Basic parts of chemicals risk management

Chemicals risk management basically aims at four main goals:

1. To obtain knowledge of the intrinsic hazardous properties of chemicals.

Are developed and agreed upon in international co-operation. National legislation normally refers to these international agreements. The responsibility to test, assess and classify chemicals rests with the enterprises that place chemicals on the market, primarily with producers and importers as the primary suppliers. Testing is not necessary if reliable information on toxicity can be found in the literature, databases or can be obtained from suppliers abroad.

2. To disseminate information on hazardous properties of chemicals placed on the market and on safe use.

This step is guided by regulations on hazard labelling and other types of hazard (risk) information and safe use such as Safety Data Sheets (SDS). Labels and SDSs are to be drawn up by those who place chemicals on the market, based on the outcome of the classification made and on assessment of the need for specific safety measures and directions for use.

3. To make informed choices of chemicals in order to avoid hazards.

The choice of chemicals to be placed on the market or used for some chemical groups is done in a few cases by public institutions as part of authorisation regimes (pesticides and other chemicals of special concern) and as bans and restrictions (other chemicals of high concern). In all other cases, enterprises have to make appropriate choices when placing chemicals on the market or using chemicals. Attention should be paid to options for substituting hazardous chemicals with less hazardous ones or with non-chemical alternatives in order to minimise risks.

4. To organise safe use of chemicals.

The task of organising safe use of chemicals chosen is the responsibility of enterprises or others handling chemicals. To some extent, public institutions can regulate the use of particularly hazardous chemicals in more detail. In other cases regulations normally only specify general demands for precautionary measures. The choice and design of the precise measures is the responsibility of the user.

Some basic legal requirements of importance

There are some important issues which are to be covered and made clear by the specific national chemicals legislation. They are briefly discussed below. Legal issues are discussed in more depth in report KemI PM 4/07.

a) **Responsibilities and obligations of enterprises** as regards for example:

- assessment of hazards and risks of chemicals to be marketed or used,
- information to customers and users on hazards and risks and how to avoid
- them,
- safe storage, use or other handling, including of waste,

b) **Responsibilities, obligations and rights of governmental institutions** as regards for example:

- roles and tasks of ministries, agencies and other public institutions
- legislative actions including restrictions and bans
- supervision including the right to obtain information needed, the right
- to admission to sites and other facilities and to issue injunctions
- and bans in the event of violations of legislation
- confidentiality of data
- sanctions.

Allocation of responsibility between enterprises and public institutions is to be made clear

The responsibilities and roles of those handling chemicals in relation to the authorities have to be clarified by appropriate clauses in the legislation.

Enterprises

The specific chemicals legislation must state the general responsibilities of suppliers and users of chemicals for risk prevention and management.

The suppliers, in particular producers and importers, should be responsible for

a. searching for knowledge on hazards and risk posed by the chemicals they intend to place on the market,
b. not providing unnecessarily hazardous chemicals for a specific purpose,
c. conveying appropriate information to the users on hazards and risks and on safe handling for risk management,
d. supplying requested information to authorities

The users should be responsible for the measures to be taken for safe use of chemicals, taking into account the options for reducing risks by substituting hazardous chemicals with less hazardous alternatives.

Public institutions

The legislation must state the rights and duties of governments, ministries and public authorities regarding issuing of secondary legislation, monitoring of compliance etc. The authorities need legal rights to obtain information they need for their tasks and to gain access to the premises of enterprises for inspections. In order to ensure legitimate confidentiality, the legislation must regulate the handling of the information which the authorities obtain from

enterprises. Competent authorities also need legal tools to enforce compliance as well as the right to issue obligations and bans in specific cases.

Sanctions needed for compliance

Implementation of legislation in practice necessitates sanctions in the event of violations. It therefore has to be ensured that the chemicals legislation (like any other legislation) contains the necessary clauses on sanctions. Legislation which is not monitored with regard to compliance and which does not lead to sanctions in the event of violations will not be effective.

Stakeholder participation is crucial to efficiency

It is essential for legislative work at all levels that stakeholders concerned (producers, importers, users, NGOs, the public etc.) are consulted by legislators in early stages of preparatory work on legislation or other actions to solve a problem. By doing so it is ensured that relevant views on the prevailing problem and on ways of solving the problem are put forward and taken into account. Stakeholder participation makes it easier to find the optimal legislative or other solution to a problem. It will, in addition to increasing the technical quality and effectiveness of regulations and other decisions on risk management, increase the transparency of the decision-making process. Stakeholder participation and transparency are two prerequisites to ensure the trust that is needed between legislators, enterprises, NGOs, the public and others. It increases acceptance of decisions and makes implementation and enforcement easier and more effective.

NGOs such as trade unions and environmental organisations, by fulfilling a “watchdog” function, have an important role to play in promoting efficient chemicals control, primarily by general awareness raising and by keeping pressure on enterprises as well as on governments/authorities. However, NGO’s should carefully design their actions in order not to interfere with the responsibility of authorities or enterprises or otherwise distort the allocation of responsibility as dictated by law. They can preferably, by whatever means is found appropriate, act for strengthened legislation and push for improved implementation and enforcement by authorities and improved performance on the part of enterprises. As for the authorities, the main goal should be to make chemicals control work in the supply chain.

Some specific issues

In the following section some main, strategic elements of chemicals control, i.e. the first stages of risk management in the supply chain, are commented on. The choice of issues reflects the problems most commonly discussed in many countries, not least countries where chemicals risk management is still less well developed.

Classification/labelling/safety data sheets - the main pathway for information

Correct classification of chemicals according to their hazardous properties and labelling and safety data sheets based on this classification are the basis for assessing risks at use and other handling and for taking measures to eliminate risks. Establishment, implementation and enforcement of regulations on these issues is therefore essential to reduce risks in the use of chemicals. They should be based on the internationally agreed globally harmonised system on classification and labelling of chemicals (GHS), (cf. KemI PM 04/08). Issuing and enforcement of these should be given the highest priority in every country when developing modern chemicals control. Implementation of these regulations in practice provides, as a “spin-off”, very valuable experience and knowledge of issues such as data finding, identification of chemical substances in mixtures of substances, hazard and risk assessment, and how to organise chemicals control in general. Such experience is essential for both

enterprises and authorities in their work on other parts of chemicals legislation as well as on other legislation concerned with chemical risks.

Classification, labelling and supply of safety data sheets are obligations for enterprises, in particular importers and producers, the primary suppliers. Governments and authorities may publish general advice to make it easier for the enterprises to understand and fulfil these obligations.

Effective supervision, combined with sanctions in the case of non-compliance, is in general the most cost-effective way for the authorities to ensure that the enterprises comply with the regulations, that they assess, classify and label chemicals, produce safety data sheets, etc. Properly planned and implemented regular inspections ensure fair competition among enterprises, with all of them running the risk of sanctions if they fail to comply and none of them gaining advantages.

Availability of data on chemicals and of expertise is essential

Assessment of hazardous properties of chemicals necessitates access to evaluated information on effects on health and the environment of chemical substances. This type of information for many chemical substances is available internationally in public sources such as databases and handbooks. Governments may, by technical means such as information and links to websites, facilitate access to sources of this information for both enterprises and public institutions concerned.

Public institutions may give advice to enterprises on how to find information in databases and handbooks and how to use these. However, authorities responsible for legislation should not act as intermediaries or consultants for the enterprises in searching for data on specific substances. It should be the duty of every enterprise to search for the data needed without assistance from the authorities, in order not to distort the allocation of responsibility. If necessary and found appropriate, enterprises may make use of their suppliers, commercial consultants or their own federations to obtain the expert support they need both with regard to data retrieval and for assessment of the data.

Countries may, when introducing chemicals control, face serious problems due to lack of information on effects of chemicals, lack of adequate expertise in enterprises and lack of consultants. Experience shows that these problems are temporary and will certainly decrease with time provided authorities, by supervision, monitor compliance with legislation, demand that enterprises take necessary measures and, in the event of non-compliance, apply sanctions when needed. Legal pressure and pressure from users will lead to improved performance of suppliers as regards availability and quality of data and information. Likewise, the availability of consultants will rise when enterprises learn that non-compliance will lead to consequences. An effective inspection regime thus promotes development of a market for consultants.

Availability of expertise on legislation, in information retrieval, human toxicology and eco-toxicology, assessment of chemicals, classification, labelling and production of safety data sheets is essential for every country. Training of personnel in enterprises should primarily be a duty for the enterprises and their federations, while training of personnel in the public sector needed for development and enforcement of legislation is an issue for governments.

Ways for governments to ensure that a country has the qualified expertise needed for public institutions and enterprises may be to introduce courses of education for example in toxicology including hazard and risk assessment at appropriate university institutions or other scientific institutions.

Data on flows and use of chemicals

In a modern society with its massive flows of chemicals and other goods, it is not possible for public authorities to follow the flows and uses of chemicals in detail. The flows are very complex, the numbers of chemicals huge, and there are countless users. Only in a few exceptional cases, mainly chemicals of special concern such as the small chemical groups plant protection products, biocides and some very hazardous chemicals, the authorities will be in a position to obtain knowledge on flows and uses. Prevailing systems for authorisation of these groups, when adequately run, provide quite detailed knowledge on flows and uses.

There is, however, a need for the public institutions responsible to also gain some basic knowledge of the flows of chemicals other than the small groups mentioned. Less detailed knowledge on flows of chemicals is valuable, for example, for monitoring compliance with the legislation and thereby ensuring that enterprises properly assess hazards and classify and label chemicals. It is also valuable in setting priorities, to target the risk management at the most important risks posed by chemicals.

Centralised data collection on chemicals used in a country may be valuable but should be limited to the extent that is really needed. Data collection programmes can easily be developed too far, demanding large resources from authorities as well as from enterprises, with little or no benefit. A comprehensive inventory with the aim of establishing a complete database of chemicals in use for most countries would be a very large, resource-demanding and less successful exercise, especially as the usefulness of a database is dependent on regular updating. It is therefore not recommended that countries in early stages of improving chemicals management make such full inventories or establish advanced chemicals registers.

A first fairly simple but nevertheless quite useful data collection step would be to identify enterprises importing and producing chemicals and to establish a database of these. This might be accomplished by a licensing system for producers and importers or by other means. As already mentioned, these enterprises are the key actors in chemicals control with main responsibilities according to chemicals legislation. Later on, depending on the resources available, it may be possible to extend the database to include more information on chemicals placed on the market.

Regimes for central risk assessment and risk management of substances

Some industrialised countries have established specific regulations and systems on new and existing chemical substances. New substances are normally defined as substances not in use in a country at a specified date, with existing substances being identified by means of an inventory. The systems are not general authorisation systems. The main rationale is the need to improve the information on hazardous properties and risks of chemicals. The information produced by enterprises enables governments to evaluate the need for nationwide risk reduction measures in the form, for example, of restrictions or bans.

Legislation of the kind mentioned implies regulatory and administrative systems with heavy duties on enterprises in trade and industry in relation to testing, assessment and reporting. Authorities need to allocate resources for the evaluation of data reported. In the EU the old systems for new and existing substances have recently been combined into one system (REACH), jointly run by the Member States and the European Commission in order to “share the burden”, especially with regard to evaluation of assessments made by enterprises and considerations on the need for risk reduction measures. The United States and some other countries have similar regimes. Industrialised countries cooperate on these issues within the OECD Chemicals Programme, again to share the burden and avoid obstacles to trade.

Advanced domestic systems for new/existing substances are too heavy on resources to be realistic for most countries. This is certainly true for developing and newly industrialised countries and for countries in economic transition. It may, however, be possible for individual countries to introduce limited national regimes which make use of those that exist internationally without duplication of effort. If national hazard data gathering regimes are to be introduced it may be wise to limit them to substances that are not dealt with in other countries. For substances tested, assessed and regulated in other countries it should be possible to rely on test and hazard data gathered and evaluated internationally, when necessary complemented by domestic exposure data to assess the possible need for national risk reduction measures. The OECD documents on Good Laboratory Practice (GLP) and Mutual Acceptance of Data (MAD), when applied, provide a guarantee of high and reliable quality of experimental data.

Organisation of public institutions

The discussion above underlines the importance of efficient and well co-ordinated public institutions from the highest policy level down to the scientific/technical level.

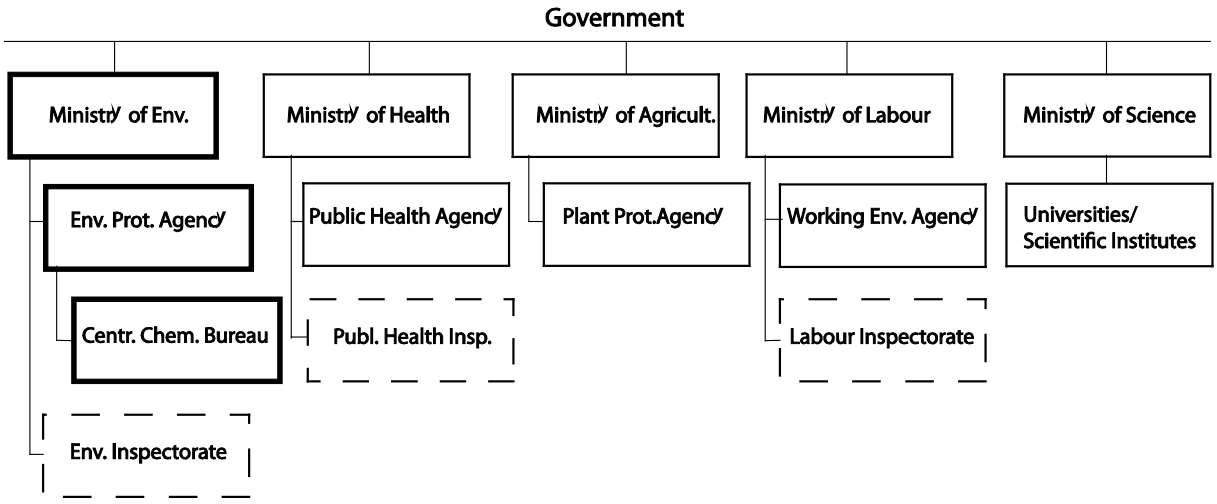
The management and enforcement of chemicals legislation may preferably be organized at three main levels: the policy level, the implementation/management level and the enforcement level.

Policy level: preparative and executive legislative actions, international co-operation on policy issues, co-ordination/co-operation between ministries.

Management level: support legislative work, daily scientific/technical expert implementation work, co-ordination/co-operation between implementing institutions.

Enforcement level: enforcement and monitoring, co-operation/co-ordination between institutions for enforcement and supervision.

Figure 3. Organisation of public institutions for chemicals control. An example.



This chapter examines institutional issues of high priority for further development in more detail, and gives some recommendations. As the comments and recommendations made are necessarily of a general nature, modifications may be needed to “translate” them to the conditions prevailing in a specific country.

Delegation and clear allocation of responsibility for enhanced effectiveness

It is necessary to allocate to appropriate bodies clear responsibilities, tasks and resources for policy issues, legislative work, expert assessments and supervision and control. Existing public bodies can often be used as a basis. As chemicals control includes health and environmental aspects and in particular addresses marketing of chemical products and goods, it is cost-effective to concentrate responsibilities for issuing regulations, implementation and enforcement on as few institutions as possible. This makes it possible to avoid duplication of resources and spending of resources on inter-institutional co-ordination. Split responsibilities will make legislative work, implementation and enforcement burdensome. Furthermore, split responsibilities will make it difficult for enterprises to identify responsible institutions and in general make implementation of legislation unnecessarily complicated and costly.

It may be preferable to designate one ministry and subordinated institutions to be responsible for chemicals legislation regulating the first steps of the supply chain, marketing of chemicals, including management, enforcement and supervision of legislation, overall responsibility for national co-ordination and international contacts. As management of legislation on industrial and consumer chemicals, biocides and plant protection products has much in common, there are advantages in a high degree of co-ordination between these areas.

The need and opportunities to delegate power should be addressed. Modern legislation on chemicals is highly scientific and technical in nature and regularly amended, often demanding prompt response and action. Adequate delegation of power from parliament and government to institutions with capability for rapid action and adequate expertise is essential to meet these demands.

Responsibilities can be allocated and delegated by legislation and by specific instructions for the public institutions. It might be necessary to amend some basic national legislation in order to obtain well-balanced allocation and delegation of power. Establishment of a special institution for the daily management of chemicals legislation and programmes on chemicals could be considered (cf. below).

Scientific and technical assessments – need for enhanced capacity and for co-ordination

Management of modern chemicals legislation demands considerable scientific and technical support to competent authorities, in particular for hazard and risk assessment. Countries can respond to this demand either by incorporating expertise for this support in managing institutions responsible for legislation or by utilising external expertise at appropriate scientific institutions, for example at universities. Normally both options are used.

Supervision for effective chemicals control

Legislation on chemicals in industrialised countries allocates considerable responsibility to enterprises handling chemicals. Except for chemicals of special concern such as plant protections products and biocides which are authorised before marketing and use, the present legislative systems applied internationally contain very little in the way of detailed central control. It is therefore of the utmost importance that countries have effective means of monitoring compliance with the legislation and, as mentioned above, an effective system for sanctions in the event of violations. The allocation and delegation of responsibility to appropriate inspectorates is to be stipulated very clearly in the basic legislation and in instructions. The task of monitoring compliance with chemicals legislation should be carried out by a few authorities with the supply chain as the basis for the allocation of responsibilities (cf. below).

Policy level

Allocation of responsibilities at ministerial level to be made clear

The horizontal character of the chemicals legislation with several ministries involved has been emphasised several times above, as has the need to clarify and separate the responsibilities of public institutions. It should be noted that the term chemicals control here, as in the paper as a whole, primarily refers to measures including legislation to direct and regulate risk management steps before or when marketing chemicals.

When appointing the main responsible ministry for chemicals control, familiarity with legislation for managing chemical risks is a factor which merits attention. This is the reason why countries often allocate responsibility for chemicals legislation at political level to ministries of the environment, ministries of health or, as regards pesticides in agriculture, to ministries of agriculture. Ministries of the environment (or equivalent) may be preferable owing to the fact that issues of risk assessment and risk management in general, as well as chemicals, are more frequent and more dominant in these ministries (pollution of air, water and soil, waste problems) than in other ministries. There is therefore a risk of issues concerning chemicals control not being given adequate priority. Furthermore, modern chemicals control at international level is increasingly focused on environmental hazards or environmentally mediated hazards.

In some countries the responsibilities for managing the legislation and systems for plant protection products and legislation on other chemicals are allocated to the same ministry. Methodology and expertise needed for hazard and risk assessment, classification, labelling and safety data sheets are basically the same, and such co-ordination is therefore found to be both practical and cost-efficient.

Irrespective of how the main responsibility for the specific chemicals legislation is allocated, several ministries have to contribute, and good co-ordination and co-operation between ministries is consequently needed. It is necessary for ministries involved each to have a person or persons on their staff with the capacity to handle legislative and other policy issues concerning chemicals.

Central implementation and management level

A cost-effective institutional set-up for implementation and management of chemicals legislation to be organised

Due to the highly scientific and technical type of legislation, ministries in charge need support in technical and scientific issues from subordinated institutions with the expertise needed. The daily work on implementation and management of the various parts of chemicals legislation is even more demanding with regard for example to chemical and toxicological capability and capacity. There is obviously a need to find ways of organising the support to ministries as well as the daily management of chemicals legislation.

With regard to the discussion above and to cost-effectiveness it may be advantageous to concentrate tasks such as support to ministries and the daily management of chemicals legislation in a central managing institution for chemicals control. Activities such as preparation of the technical parts of proposals for regulations on chemicals and operating systems for classification and labelling, new and existing chemicals, authorisation of biocides and plant protection products, data and information retrieval and dissemination to a great extent require the same kind of expertise (lawyers, chemists, toxicologists and others), and the same type of routines and methods irrespective of the type of chemical. It is therefore logical and practical to amalgamate existing units/activities in ministries and at authority level as far

as possible and thereby to make possible effective use of resources and facilitate co-ordination.

A central managing institution (Central Chemicals Bureau in Fig 3.) for chemicals control is, if established, preferably attached to an existing governmental agency with scientific and technical tasks and qualifications as regards chemicals risk assessment and management (cf. below). Depending on local conditions such an institution may also, however, be set up within a ministry.

Support to ministries and daily management might also be organised by networking between managing competent institutions in various ministries. Such a solution with dispersed responsibilities will, however, most probably be less cost-effective than a special institution and will be complicated to manage to achieve the co-ordination and cooperation needed.

Enforcement level

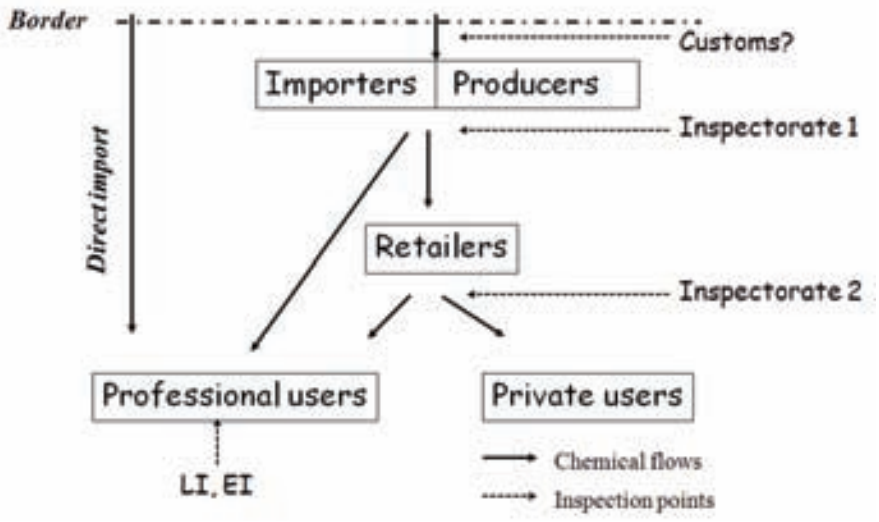
Organisation of supervision is vital

As mentioned, it is very important to allocate the task for inspections to specific inspectorates and to clarify their roles. Detailed regulations and instructions that specify roles and tasks are essential to enable inspectorates to fulfil their duties.

Supervision of producers and importers with regard to their responsibilities as primary suppliers of chemicals (hazard assessment, classification, labelling, safety data sheets, notification, restrictions on sale etc.) is a task requiring specific skills and qualifications for inspectors, for example in toxicology and hazard assessment. Supervising retail sale is a simpler type of control. Supervision of users is also complex, requiring yet other types of inspector skills and qualifications, for example for assessment of exposure and of risk, control of technical safety measures etc.

Allocation of responsibilities for supervision of chemicals legislation should preferably be based on the three main levels in the supply chain, producers/importers, retailers and users, taking into account the differences in their respective responsibilities and therefore the different type of expertise needed by inspectors. Neither traditional labour inspectors nor environment inspectors normally have the expertise and skills needed for a chemicals inspector.

Figure 4. Organisation of supervision and enforcement. An example.



LI = Labour Inspectorate
EI = Environmental Inspectorate

It seems appropriate to make use of existing inspectorates as far as possible, provided they are able to develop the capability and capacity and expertise needed for inspectors. Many countries have old structures for supervision in the field of public health, which may have dealt with chemical hazards and the trading of chemicals. Often institutions for supervision of users in the areas of occupational health and safety, labour inspectorates and environmental inspectorates have been established. Ways to transfer resources from "old" to new areas may be considered. It has to be ensured through appropriate statutory instruments that there is no risk of enterprises being checked by more than one inspectorate with regard to compliance with specific chemicals regulations.

The role of customs as an institution for monitoring of compliance with legislation can easily be overestimated if account is not taken of the need for skilled, highly qualified chemical inspectors and the often time-consuming task of verifying possible non-compliance with chemicals legislation. In most cases, as already mentioned, the monitoring of compliance with regulations on chemicals, such as those on classification, labelling, bans etc., has to be done by the way of regular, random inspections of suppliers. However, the customs authorities may well play a role in some cases. Besides checking that licences for import, export or other documents are in order, the role of customs will be of importance for example in implementation and enforcement of the Rotterdam Convention on banned and severely restricted chemicals. Customs can obviously also alert chemicals inspectorates in the event of suspected violations of legislation.

Guidance for countries improving chemicals risk management and implementing international agreements on chemicals

Many countries are on the way to improving management of chemicals and to implementing SAICM (Strategic Approach to International Chemicals Management), a policy framework to foster the sound management of chemicals adopted at the International Conference on Chemicals Management (ICCM) on 6 February 2006 in Dubai, United Arab Emirates. This may be done by running projects which directly or indirectly concern chemicals risk management in general. The projects may also encompass implementation of other international agreements on chemicals. Others have not yet started the process. UN organisations have published various documents to assist countries. Countries that have elaborated National Chemicals Management Profiles usually make these the foundation for further efforts towards improved chemicals management.

National Profiles (NPs), as published on the website of UNITAR (United Nations Institute for Training and Research), irrespective of country reveal that in countries with less developed chemicals control a number of governmental institutions are in charge with chemicals management guided by quite many laws and other official documents. Lack of specific legislation on chemicals and low efficiency and weak co-ordination of existing legislation and of institutions is often seen as a major problem. The NPs indicate that countries may have a fairly good superficial understanding of the need to improve the prevailing situation but that they are less knowledgeable on methods of improvement.

In the following some specific guidance and advice is given which may be applicable to countries that wish to strengthen, or are on the way to strengthening their management of chemicals in specific risk management before or on marketing of chemicals, chemicals control. The views presented are based on extensive experience of chemicals risk management in industrialised countries and a number of bilateral and regional support

projects conducted by Swedish Chemicals Agency in, as well as on other contacts with, such countries. The guidance and advice must necessarily be quite general and is based on similarities found in conditions in various countries. There are, also are differences between countries, which are to be taken into consideration.

In the publication “Legislation for Risk Management at Marketing of Chemicals”, KemI PM 4/08, the most important components of legislation regulating risk management on marketing of and trading in, chemicals are specified and discussed. A rationale for these is given and some comments on specific issues to consider are made. A possible statutory text is also presented. Legislative issues are therefore not discussed here in detail.

A road map for establishing modern chemicals management

Introduction of a new or improvement of an existing system for chemicals management may preferably follow a step-by-step process.

1. Thorough review of existing legislation and institutions.
2. Analysis of legislative gaps, overlaps or other problems.
3. Analysis of gaps and overlaps as regards responsibilities, roles, tasks and capacity of government institutions.
4. Analysis of capacity, efforts and achievements regarding chemicals management of enterprises supplying and using chemicals.
5. Identification of necessary improvements regarding legislation and institutions.
6. Identification of necessary improvements regarding enterprises.
7. Setting up of objectives and time-limited goals for work on legislation, institutions, awareness raising and other improvements needed for an adequate and satisfactory management of chemicals risks.
8. Setting up of an action plan with short and long-term perspectives towards objectives and goals set.
9. Carrying through of action plan.

A main challenge for all countries embarking on programme to improve domestic chemicals management is to raise understanding of how responsibilities of government institutions on the one hand and enterprises, state or private, on the other are to be shared and allocated for adequate and cost-effective management. This is obviously of particular importance for countries with economies in transition (CETs). However, other countries also have to pay attention to the fact that in market economies enterprises, not governments, are the main actors for sound management of chemicals. If this understanding does not exist, attempts to improve the present situation may be less successful. The legislation developed will not be adequate. Attempts to improve and strengthen institutional capacity will fail and may even be contradictory in the light of the aims and goals of the programme.

In the sections that follow, some issues and challenges of specific relevance are briefly discussed, followed by examples of programme objectives and goals and action plans. Some issues dealt with above are briefly discussed again to emphasise their importance.

Chemicals legislation to regulate marketing of chemicals as a complement to other legislation on chemicals management

With the exception of pesticides, chemicals management in many countries by tradition may be regulated with regard to health and safety of workers and of consumers, and more recently

also with regard to environmental emissions. However, a focus primarily on the use of chemicals and less on their marketing may mean that chemicals enter the market without there being basic knowledge of their effects on health, environment and safety. Use of them will not be safe. This will be the case if the primary suppliers (producers and importers) and users do not face clear legally stated responsibilities for managing chemical risks. Many very hazardous chemicals that are banned or restricted in industrialised countries may therefore still be freely sold and used in countries lacking efficient control of marketing of chemicals.

A second main problem may be a lack of labelling and safety data sheets in the domestic language with information on hazards and risk and with instructions for safe use of chemicals. Furthermore, this lack of information to accompany every chemical on the market is a leading reason for a low general level of awareness of chemical risks. Another important weakness at present may be that enforcement and monitoring of compliance with legislation in place is weak.

The roles and responsibilities of government institutions in many countries may not be adequate to meet the needs of a modern market economy. The discussion in many National Profiles tends to overestimate the role of authorities and underestimate the responsibility of enterprises in trade and industry.

New legislation on chemicals, as discussed above, in order to be efficient should not regulate all chemicals risk management but focus on the marketing step in the supply chain. It should, however, regulate marketing from all aspects of risk for protection of the environment, workers and consumers. International agreements may, to the extent they concern marketing of chemicals (relevant parts of the Stockholm and Rotterdam Conventions, the Montreal Protocol, SAICM, the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) etc.), preferably be implemented by comprehensive new chemicals legislation in order not to split regulations.

When specific legislation on chemicals is established there will be a need to review existing legislation on environment protection, waste and protection of workers and consumers, transport etc. These types of legislation are needed to regulate risk management in use and other practical handling of chemicals including waste. However, present domestic legislation on these areas is to be modified and improved, gaps are to be plugged, and the legislation is to be well adapted to new chemicals legislation. The aim should be for the different pieces of legislation to complement each other in order to cover the whole supply chain.

Changed roles of governmental institutions and of enterprises to be understood and accepted

As mentioned, it is of the utmost importance to recognise and understand the implications of a market economy on roles and responsibilities of government institutions and of enterprises. In addition to state them in legislation, there will be a need to inform government institutions, enterprises and other interested parties such as NGOs and the public in general of the changes. Not only are boarder lines between responsibilities of government institutions and enterprises to be made clear, it is just as important to make clear and separate responsibilities and tasks of various government institutions.

Government management of legislation

Policy level

It is often appropriate, as discussed or planned in many countries, to designate ministries of the environment or health (equivalent) and subordinated institutions to be responsible for new domestic chemicals legislation regulating the placing on the market of chemicals. This responsibility should include overall responsibility for national co-ordination and for

international contacts in the area of this legislation. If other solutions are chosen, it has to be ensured that environmental and health issues will be prioritised to the extent needed.

As mentioned, countries need both specific chemicals legislation regulating marketing of chemicals and traditional legislation on chemicals management to protect the environment, workers protection etc. However, it must be emphasised again that ministries and authorities should share a common view on chemical risks and on how to manage them in order to co-operate well. As chemicals legislation partly regulates the market, ministries responsible for trade and for industry are very important actors alongside ministries of the environment, health and agriculture. Clearly defined and transparent terms of reference, instructions, with clear and separate roles for and responsibilities of institutions are crucial for fruitful co-operation and for avoiding conflicts, i.e. for cost-efficient chemicals management

The daily co-ordination needed at policy level is preferably a task for the main ministry designated to manage the specific chemicals legislation. It may, however, be facilitated by a specific body with representation from other ministries (and authorities) concerned. Such a body may advantageously be connected for co-ordination to the managing ministry. The role of this body should be advisory and consultative only. Care should be taken not to allocate power and tasks which are normally held by ministries/authorities to such a body. Subject to this proviso, such a body may be very useful for discussion and consultation on issues such as policies and strategies concerned, for example, with legislation and organisation, monitoring of compliance and co-ordination of national positions and contributions to international work on chemicals. Co-operation on and co-ordination of collection, dissemination, retrieval and storage of data might be other issues to discuss in a co-ordinating body. Several public institutions will have interests in these issues, and it is consequently of great importance to find cost-effective solutions that satisfy all parties.

A country-wise analysis and assessment of infrastructure issues, as referred to above, will provide a firm basis for the organisation of a co-ordination body and for decisions on its responsibilities and tasks. Previous work done on National Profiles based on the UNITAR/IOMC National Profile Guidance Document (1996) may be useful for such analyses and assessments. Many countries already established a multi-stakeholder committee during that work. It should be quite easy to reorganise this committee into a permanent body for ministerial co-ordination. This body should, however, not include external actors such as representatives of trade and industry, NGOs etc. on a regular basis. Government institutions have a need to freely discuss government policies and strategies. Furthermore, there is a need to keep the responsibilities of competent institutions separate from those of enterprises and others.

Central management level

It is quite common in many countries for the responsibility for existing pieces of legislation on chemicals control to be unclear and scattered between a number of ministries and subordinated institutions. Existing resources when added together may be considerable although not used in the most cost-effective way. Cost-effectiveness may be raised by combining, by concentrating tasks concerning daily management of the chemicals legislation in a special central managing institution for chemicals control as discussed above. Note that this institution will have more and larger responsibilities and tasks for management of legislation than seem to be anticipated for government management in many of the present NPs that discuss establishment of such an institution. Note also what has been emphasised above as regards the need to delegate power from parliament and government.

A new central institution for managing chemicals legislation may preferably be connected to an existing governmental agency or institution subordinated to the ministry allocated main

responsibility. It is an advantage if this institution already has scientific and technical tasks and qualifications as regards chemicals risk assessment and management. In some countries personnel and other resources needed for this managing institution may be transferred from institutions with tasks remaining from old outdated systems for chemicals management. This may be possible as in a new market-oriented system which is to be established, enterprises, not governments, will largely be responsible for hazard and risk assessment, classification, labelling and SDS etc.

Qualified scientific assessments of hazard and risk, as organised in many countries, may be made by scientific institutions at universities or institutes contracted to assist managing authorities. Training in toxicology (human and eco-toxicology) that is needed to meet the needs for expertise of authorities and enterprises, may be linked to these institutions. Opportunities for making use of internationally available funding, expertise and training programs should be analysed.

Hazard and risk assessments made by international bodies should be utilised by every country in order to save resources for other important tasks. From 2011 the European Chemicals Agency will publish on its website information on chemicals gathered on registration or notification under EU regulations. This information as well as corresponding information from countries with well developed chemicals management will be of great assistance to institutions in DCs and CETs. On the OECD website there is a gateway with links to this type of information.

Enforcement level

As a consequence of allocating great responsibility to enterprises in legislation it is of the utmost importance that countries establish an efficient system for monitoring how enterprises comply with the legislation for enforcement and inspection.

Organisation of responsibilities for enforcement and supervision of the chemicals legislation may, as mentioned, preferably be based at the three main levels in the supply chain, producers/importers, retailers and users. Note should be taken of the different demands on the skills of inspectors and on methodology and therefore on training.

Responsibility of enterprises

In some countries, for example countries that have had or have centralised economies, enterprises are used to and familiar with strong interference by government institutions with regard to chemicals management. In other countries, due to weak legislation and/or weak enforcement of legislation, enterprises may not be aware of how responsibilities should be/are allocated between government institutions and enterprises in trade and industry. As a consequence, enterprises handling chemicals (producers, importers, traders, transporters, users, waste handlers etc.) may lack capability and capacity adapted to new, expanded responsibilities. They may not be able to ensure that the chemicals marketed, used and otherwise handled are assessed, classified, labelled and provided with safety data and instructions for safe handling. They may not be able to ensure that their chemicals do not contain banned substances or to organise safe handling in order to avoid risks to health, environment and property. In many countries a large proportion of the enterprises will certainly face these problems, possibly with the exception of subsidiaries of international companies.

Enterprises may lack expertise with adequate understanding, qualifications and skills in toxicological hazard assessment according to modern standards and in applying the legislation and what this means for them. There are most probably weaknesses in organisational

structures within the companies with regard to the allocation of resources and responsibilities needed for effective chemicals risk management.

It many countries federations in trade and industry do not have the capacity needed to ensure effective assistance to their member enterprises. Federations, if they exist at all, are often small with a fairly low level of coverage and less familiar with chemicals risk management.

The most important way of making enterprises take responsibility will, besides appropriate legislation, be the establishment of an efficient system for enforcement including monitoring of compliance with regulations. Efficient supervision encompassing use of sanctions in case of violations of regulations is a cost-efficient way for the authorities to ensure that enterprises assess, classify and label chemicals, produce safety data sheets, etc. Properly planned and executed regular inspections of suppliers (and users) of chemicals ensures fair competition amongst enterprises, which all run the risk of sanctions in the case of non-compliance, with no-one gaining advantages. Furthermore, experience shows some interesting spin-off effects of effective enforcement as the development of more effective federations and of consultancies to offer expert assistance to enterprises.

Public institutions at central level as well as local inspectorates should not provide specific advice to enterprises on how to solve their problems. They should not “take over” responsibility for chemicals management from the enterprises and thereby distort the allocation of responsibility stated in the legislation. The pressure on enterprises must be kept strong in order not to create a risk of enterprises becoming passive and to build the capacity they need for taking responsibility.

There will be a great need, especially when introducing a new system, for information and other general support to enterprises on their new responsibilities and tasks. Governments have to institute mechanisms and ensure resources for such information, taking into account the fact that the changes and development needed may take substantial time. Governments have to ensure a regular and constructive dialogue with enterprises in trade and industry and with their associations.

Information on risks and safe use of chemicals. Awareness raising

The awareness of chemical risks in enterprises handling chemicals, of workers and consumers and in society in general is dependent on good availability to information on risks in general and the risks of specific products. Information on risks and safe use of chemicals on the market and in use is, as mentioned, the responsibility of enterprises.

Due to non-existent or less adequate information on hazards and risks of chemicals, governmental institutions may be tempted to initiate their own programmes to compensate for present poor information from suppliers. For reasons mentioned above, this should be avoided. The most powerful tool to ensure adequate flow of information on hazards and safe use of chemicals on the market is introduction of legislation on classification, labelling and safety data sheets It is fairly easy for countries to develop such legislation by making use of the new internationally agreed information system, GHS. This can be done as normally with international standards, by copying them into national legislation. In doing so, governments should avoid making changes or additions to GHS. Fully harmonised classification and labelling make life easier for governmental institutions and for enterprises.

Introduction of a system of regulations on labelling and safety data sheets will be of the utmost importance in raising awareness of chemical risks. No government information can ever substitute for the risk and safety information to follow each chemical placed on the market, nor the awareness raising effect of that information.

Countries can institute programmes and campaigns for general information on chemical hazards and risks to the public, enterprises and other interested parties. Use of websites may be one tool for this purpose, especially for information to enterprises and NGOs. Furthermore, it may be appropriate to introduce chemical risks into curricula at appropriate levels of education. Except for initiatives for increased awareness and understanding of chemical risks in general, there will be a need in most countries to educate students for example in toxicology and eco-toxicology to make it possible for government institutions and enterprises to gain the expertise needed.

Priority chemicals

Great attention is paid to the need to act on priority chemicals in NPs as well as at international meetings and workshops on chemicals. Existing problems are often due to previous lack of awareness and information on risks and measures for safe handling, and chemicals have consequently been used in a careless way, causing contaminated sites and accumulation of chemical waste. In many countries the focus seems, however, to be on the role of government as regards risk assessment and management, and less attention is paid to the responsibilities of enterprises.

There is certainly a need to solve some very urgent problems caused by inappropriate use of chemicals in the past, as well as to avoid future problems. Some problems may be solved quite easily and should therefore initially be the ones to focus on. However, unless weaknesses of legislation and lack of resources of government as well as of enterprises are not solved, efforts to come to grips with priority chemicals may become less effective.

Many problems may only be solved provided countries as discussed above establish new and revise old legislation to make the responsibilities of enterprises clear and to obtain a legal basis for actions. It is most important to persuade enterprises to take their responsibility not only for their present and future handling of chemicals including of chemical waste but for solving problems with priority chemicals as well. This will make it possible for governments to allocate and organise their limited resources to be able to focus their efforts on the most urgent problems where government interference is needed. The government should thus focus on the most hazardous substances and on cases when the total exposure from many enterprises gives rise to problems. In the latter case a small emission from a single enterprise may not warrant risk reduction actions.

If, due to changes in industrial infrastructure, it is no longer possible to find enterprises that can be made responsible for example for remedying environmental damage or destruction of toxic chemicals, other means, for example through environmental funds, may be used. The possibility of making use of facilities abroad for the destruction of waste should be investigated.

A possible programme with objectives and an action plan for improved chemicals management

The work on chemicals management that many countries have started or are on the way to starting when appropriately planned and carried through will be a decisive step towards sound management of chemicals, towards implementation of SAICM and other international agreements.

In order to make the most of the work, a long-term programme for cost-efficient and coherent management of chemicals may be established. Such a programme should look at all aspects of chemicals management and respect the demands on legislation and roles and responsibilities of government and enterprises in trade and industry the market economy implies. However,

the main focus in a programme should initially be on the early steps in the flow chain, before or on marketing of chemicals. As said above, effective control of the marketing of chemicals is crucial to efficient risk management in use or other handling. It seems appropriate to set long term objectives for such a programme with

A. Long term programme objectives (10- year perspective)
B. Programme goals (5-year perspective)
C. C.Action plan in
    a. short perspective (1-3 years)
    b. long perspective (1-10 years)

The time periods may vary considerably, and even be outside these ranges, depending on prevailing conditions in a country.

Some suggestions on how such a programme might look like are presented in Annex 1. These suggestions may be analysed and discussed and reflected on, taking account of prevailing domestic conditions.

Mechanisms of financing

Costs and gains

Public sector

The costs to governments of establishing the institutional infrastructure needed for effective chemicals control may be considerable if there are no existing resources for such control. The highest costs in most cases possibly relate to the need for adequate capacity both in numbers and qualifications of personnel and to other expenses for the extensive tasks with regard to legislative work, scientific and technical assessments, surveillance and supervision. Other costs relate to data retrieval and processing and to other technical support.

There may, however, even be considerable existing resources in many countries for work on chemicals risk management, although these are dispersed between several ministries, which may partly work independently of each other. By concentrating responsibility for chemicals control issues in a few institutions and by improved co-ordination and co-operation it will be possible, as discussed above, to obtain more cost-efficient use of resources and thereby to reduce the need for new resources.

The gains for society from improved chemicals control are not easy to quantify in monetary terms, although they may be substantial. They include, for example, reduced costs of health care due to fewer accidents with chemicals, fewer acute health effects such as poisoning, skin corrosion or burns, reduced risk of chronic effects such as allergies, cancer etc. Furthermore, improved chemicals control means a reduction in costs for remediation of environmental damage and in other costs following emissions, for example pollution of watercourses and soils due to accidents or long-term use of chemicals.

All governments wish, for economic and other reasons, to take part in the increasing international trade in chemicals and other products. The prospects of doing so successfully are increasingly dependent on how well a country, both its governmental institutions and its trade and industry, performs as regards chemicals risk management in general and implementation of international agreements on chemicals in particular.

Enterprises

The costs to enterprises in trade and industry of efficient chemicals control may seem high, especially in a short-term perspective. Enterprises have to organise their internal administrative systems for chemicals control, recruit personnel including experts to run the systems, educate existing personnel, establish routines for retrieval, assessment and dissemination of data and for risk management, etc. The services needed may be partly purchased from consultants, which may reduce the costs, especially for small and medium-sized enterprises.

On the other hand, as already mentioned, good chemicals control has positive effects on the competitiveness of enterprises. Investments in improved chemical control may therefore pay off in the form of improved business opportunities. Furthermore, investments in preventive chemicals control in enterprises such as making use of less hazardous chemicals and improved information on risks and safe use will pay back in the form of less need for costly technical risk reduction measures for exposure and emission control. In addition, better control of chemicals used very often also results in more cost-effective processes with reduced use of chemicals and less waste. By applying the concepts of Clean Products and Clean Production as parts of improved chemicals control, costs of initial investments may in many cases be recouped in one year or a few years.

Possible alternatives for financing the work of public institutions

Ways of financing chemicals control will always be an issue for national deliberation. The work of public institutions on chemicals control may be financed traditionally through the government budget and regular taxes. However, alternative ways may be available, such as applying special taxes to enterprises or their products or charging special fees. This seems quite logical as the costs of governmental efforts to organise efficient control of chemicals are due to activities of enterprises as regards chemicals they market and use.

Many countries apply fees to make national authorisation systems for plant protection products possible. Other systems that may be entirely or partially financed by fees are licensing regimes and authorisation or other administrative systems for biocides or other chemicals of concern. Inspectorates may be at least partly financed by fees for inspections. In cases like these, when there is a clearly defined activity of authorities towards enterprises, it will be possible to quantify and price the efforts of authorities. Environmental funds may be still another way to fund activities. UNEP Chemicals is drawing up Guidance on Economic Instruments.

Countries may apply for external funding for development projects to strengthen the infrastructure (legislation and institutions) for chemicals risk management, from international organisations (UN) and from countries offering bilateral support.

Summarising conclusions

Chemicals risk management is increasingly brought into international and national focus. As chemicals are distributed internationally by trading as well as by long-range transportation of pollutants, no country can manage the risks on its own. Efforts towards sustainable use of chemicals including risk assessment of chemicals are therefore increasingly made in international cooperation. However, in order to make these efforts successful, all countries need a national infrastructure, legislation and institutions, in proportion to the scale of chemicals produced, imported, used and exported.

When adapting to modern systems for chemicals control many countries will face new and in some way revolutionary challenges. This is true as regards the development of legislation at primary and secondary level. An adequate and well-balanced legislative system is essential to establish effective chemicals control. The legislation must clearly state the responsibilities of governmental institutions and enterprises in trade and industry. The main responsibility for avoiding chemicals risks has to be allocated to enterprises.

It is most important, for legislative work and other actions to solve problems with chemicals, that legislators and authorities already consult stakeholders in early stages of work on new or changed legislation as well as before taking other action.

A second main challenge will be to establish an institutional infrastructure to manage the legislation. There is a need to ensure that countries do have an adequate institutional set-up with the capacity and capability needed to manage the legislation as such as well as the various administrative systems for chemicals control based on the legislation. The greatest needs for capability and capacity arise with the tasks connected with day-to-day management of the legislation at agency level and with monitoring of compliance with the legislation. In both cases there is a need for special expertise. The costs of running institutions can be at least partly financed by fees or special taxes on enterprises.

Decision makers in all parts of society have to be aware of the increasing international demands on enterprises in trade and industry. Enterprises in countries with adequate chemicals control will be more competitive on international markets.

In order to get the priorities right, it is recommended that governments analyse in depth the implications of modern chemicals control for their legislation as well as for institutional capabilities and capacities to manage appropriate legislation, and then establish a programme to implement the necessary improvements and reinforcements. Enterprises and their federations need to make corresponding analyses and improvements.

The horizontal nature of chemicals control is demanding with regard to effective and smooth co-ordination of the work in the public sector at ministerial policy level, central executive level and enforcement level. Even in countries with scarce resources there may be good opportunities to meet new challenges without too great an additional allocation of resources by simply reallocating existing resources, clarifying responsibilities and establishing efficient co-operation between and co-ordination of activities of public institutions. To some extent, it may be necessary to establish new structures for efficient and cost-effective management of the tasks faced.

The costs of improved chemicals risk management will be balanced by benefits such as fewer accidents, less illness and other adverse health effects, fewer adverse effects on the environment, lower health care costs and less need for remediation of environmental effects of chemicals. Risk management at government level and in enterprises will be more cost-efficient. Enterprises producing, exporting, importing and using chemicals will raise their competitiveness when applying chemicals risk management at an internationally accepted level.

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Annex 1

An outline of a national programme for improved chemicals management

The long-term objectives for the programme given below (A.) are ultimate goals for chemicals risk management. They are formulated to express the general status of important preconditions for and parts of successful risk management in a country in a 10-year perspective encompassing all relevant actors.

In order to reach these goals governments must set short-term goals for their own activities (B.). They are expressed below as goals to be reached in a 5-year period.

Finally, an action plan (C.) with checklists of activities of governments and government institutions that may be needed to reach the short-term goals and the long-term programme objectives are presented.

In addition to goals and activities of governments and their institutions, other stakeholders have to set their own goals and implement activities. They are not included below.

A. Programme objectives to be reached in a 10-year perspective

1. Chemicals on the domestic market may be used or otherwise handled without causing harm to health, environment or property.

a. Chemicals are thoroughly investigated with regard to their effects on health, environment and safety before being placed on the market (assessment may be based on internationally available data).

b. Chemicals placed on the market are accompanied by information on risks and use that is needed for safe handling during their life cycle.

c. Use and other handling of chemicals is organised in a safe way to avoid adverse effects on health, environment and property.

d. Chemical waste is handled in a safe way.

e. Chemicals causing known risks of priority concern for the country are identified and action is taken to manage risks.

f. Chemicals with unacceptable effects are banned or restricted.

g. International standards are complied with, international agreements are implemented.

h. The general awareness of chemical risks among the population is satisfactory. Relevant information on chemical risks is available for concerned parties. Chemical risks are an integral part of curricula in various types of education. Concerned parties take part in the formulation of legislation and other important government activities.

2. There is a legal and institutional infrastructure that works well for chemicals management. Legislation on chemicals management is well co-ordinated.
    a. Government institutions work efficiently and are well co-ordinated at the
        i. Policy level
        ii. Central management level
        iii. Enforcement and supervision level
    b. Co-operation and dialogue with interested parties such as trade and industry and NGOs is well established. The co-operation is open and fruitful. Trade, industry and NGOs participate as far as possible in government work with legislation and in other government activities.
3. Domestic enterprises (private and state-owned) in trade and industry comply with regulations.
    a. Enterprises are well aware of their own responsibilities.
    b. Enterprises have either established their own resources required to take their responsibility or are able to make use of external resources.
    c. Primary suppliers (importers and domestic producers) gather information on toxic (eco and human) and other properties of chemicals to the extent needed to assess their hazardous properties and risks and need for precaution.
    d. Chemicals on the market and in use are properly classified and labelled. Safety data sheets are of good quality.
    e. Enterprises strive for marketing and use of chemicals which give rise to the least possible risk by applying principle of substitution.
    f. Enterprises which buy chemicals for use or which trade in, store and transport chemicals receive adequate information on hazards and risks and on safe use through labelling and safety data sheets. They organise use and other handling of chemicals to avoid adverse effects on health, environment and property.
4. Awareness, information, education. Public participation
    a. The awareness of chemical risks among the domestic population and the capability to avoid risks is raised by better availability to information on risks in general (responsibility of government) and of specific products (responsibility of enterprises).
    b. Chemical risks are on the curricula of schools at all levels from primary schools to universities in an appropriate way.
    c. Curricula for education in toxicology/applied toxicology (human and eco) are developed at appropriate scientific institutions.
    d. Domestic NGOs play an important role in awareness raising and as information sources.

B. Short-term programme goals for governments and their institutions to be reached in a 5-year perspective

Development of legislation

1. A domestic comprehensive legislative system for chemicals management is in place.
    a. Chemicals legislation regulating supply of chemicals.
    b. Sector legislation regulating in detail risk management concerning
        i. Environment
        ii. Work environment
        iii. Plant protection in agriculture
        iv. Transport

v. Major accidents
vi. …..

c. Chemicals legislation and sector legislations are well co-ordinated.
d. All legislation is adapted to international standards and legislation and implements international agreements that have been ratified.

Development of institutions

2. Cost-efficient domestic government management of legislation is in place. Institutions are established/reorganised to ensure efficient management of chemicals legislation.
    a. Ministries involved, main responsibility allocated to one of them.
        i. Environment
        ii. Health incl. workers and public health
        iii. Agriculture
        iv. Industry
        v. ……
    b. Government institutions for legislative and other central management issues.
        i. Central chemicals management.
        ii. Central pesticides management.
        iii. Central environment protection issues.
        iv. Central issues on public health and workers health and safety.
        v. Customs issues.
        vi. …..
    c. Government institutions for supervision (inspection of compliance with legislation).
        i. Inspection of primary suppliers.
        ii. Inspection of retailers.
        iii. Inspection of use and other handling.
    d. Government institutions have the required capacity and capability for their tasks.
        i. Human and financial resources are adequate.
        ii. Staffs are well educated and trained for their tasks.
        iii. Education and training programmes are developed.
    e. Government institutions have clear and separated mandates. They are well co-ordinated and co-operate smoothly.
    f. Government institutions recognise and act in accordance with the legally stated sharing of responsibility between government and trade and industry.
3. Government institutions take part in international co-operation and co-operate with corresponding institutions in other countries, regionally and otherwise as found appropriate.

C. Action plan

Short-term activities for government institutions to be started and to the extent possible implemented within 1-3 years

Development of legislation

1. Review of existing legislation regulating chemicals risk management.
2. Analysis of deficiencies in existing legislation especially as regards regulations steering marketing of chemicals.
    a. Gaps in legislation
    b. Overlapping legislation

c. Needs for restructuring/improvement

3. Development of legislation.
    a. Chemicals law incl. sanctions. Legislation on placing on the market (trading) of chemicals should be concentrated on this law and regulate
        i. General responsibilities of enterprises.
        ii. General responsibilities and rights of government institutions.
        iii. Mandates/areas of responsibility of government institutions.
    b. Secondary legislation to Chemicals Law.
        i. General government "ordinance" under the Law regulating
            - Limitations of chemicals - bans and restrictions
            - Authorisation of biocides
            - Classification, labelling safety data sheets (implement GHS)
            - Registering (when needed, c.f. Annex 3)
            - Licensing (when needed)
            - Reporting
            - Storage
            - ……
        ii. Detailed government regulations on i. 1-8
    c. Sector legislation.
        i. Revise and supplement legislation on environment, labour protection etc. to adapt to the new chemicals legislation and to plug present gaps in sector legislation.

Development of institutions

4. Review of existing government institutions for management of legislation on chemical risks.
5. Analysis of imperfections as regards government institutions especially as regards marketing of chemicals
    a. Lacking responsibilities
    b. Overlapping responsibilities
    c. Unclear responsibilities
    d. Lacking co-ordination or co-operation
    e. Lacking resources
    f. Needs for reorganisation
6. Development/reorganisation of institutions.
    a. Ministries.
        i. Decide on the ministry responsible for the new chemicals legislation.
    b. Central institutions.
        i. Central chemicals institutions in which management of chemicals legislation is concentrated.
            - Organise as appropriate central management of new chemicals legislation, preferably subordinated to the ministry responsible for the legislation.
                a. As a new separate institution, or
                b. as part of the competent ministry, or
                c. as part of an existing institution.
        ii. Central institutions for environment protection, worker safety and health and plant protection products.
            - Strengthen/reorganise as found appropriate present central institutions.

        - Ensure co-ordination and co-operation with a new central chemicals managing institution.
    c. Institutions for supervision/inspection.
        i. Establish a chemicals inspectorate for supervision of primary suppliers, taking into account the needs for specific qualifications of inspectors and inspection methodology.
            - As a part of the central managing institution, or
            - as part of an existing institution for inspection, or
            - as a separate institution
        ii. Ensure co-ordination and co-operation between chemicals inspectorate and environmental, labour and plant protection inspectorates.
    d. Develop the capacity and capability of ministries and of institutions at central level and of inspectorates.
        i. Ensure sufficient funding of institutions.
        ii. Hire personnel with the qualifications required.
        iii. Establish work routines.
        iv. Develop and run education and training courses.
        v. Ensure offices.
        vi. Ensure other facilities (computers, software, etc.).
        vii. Start development of a database (register) of chemicals on the market.
        viii. Ensure availability of qualified scientific expertise for management institutions by co-operation for example between a central chemicals institution and appropriate scientific toxicological and eco-toxicological institutions. The same scientific institutions may serve several government agencies.
    e. Develop general co-ordination of and co-operation between institutions at all levels.

Long-term activities for government institutions to be implemented within a period of 10 years

Activities to make enterprises take their responsibility

1. Implement and enforce legislation in order to ensure that enterprises comply with it. Make use of information, inspections and sanctions.
2. Develop constructive dialogue with associations in trade and industry

Awareness, information and education

1. Implement awareness-raising and information campaigns.
2. Make general information on chemicals and the work of government institutions available to citizens, NGOs and other interested/concerned parties as far as possible.
3. Inform on international open databases (OECD, EU and others) on toxicology, risk assessment and risk management for use by enterprises, government institutions, NGOs etc.
4. Make efforts to introduce chemical risks into the curricula of public institutions for education.
5. Make efforts to develop education of toxicologists (human and eco-toxicology) to cover needs in public institutions and enterprises. Initiate a special project. Look at opportunities for regional co-operation between universities in neighbouring countries.

Priority chemicals

1. Finalise identification process of chemicals which cannot be handled safely.

2. Start early risk management actions, to the extent needed, with the highest priorities first.

Continuous development

1. Further develop legislation as found appropriate.
2. Further develop institutions and their national and international co-operation.
3. Enhance implementation and enforcement of legislation.
4. Enhance awareness raising, information and educational activities.
5. Apply further risk management activities related to priority chemicals.

www.kemi.se

Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg
Phone: +46 8 519 41 100, Fax: +46 8 735 76 98, E-mail: kemi@kemi.se