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Capacity Building for Chemicals Control

Organisation, responsibilities and tasks of
governmental institutions and trade and industry

Swedish Chemicals Agency

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Publisher: Swedish Chemicals Agency
Order address: Phone: +46 8 50 59 33 35,
Fax: +46 8 50 59 33 99, E-mail: kemi@cm.se

PREFACE

This report was written by Bengt Bucht at the International Secretariat of the Swedish Chemicals Agency (KemI). The report summarises some of his main observations and experiences from work on chemicals risk management in industrialised countries, as well as in developing countries and countries with economies in transition. Some basic features of chemicals control of special significance to the first step in the supply chain, the placing of chemicals on the market, are discussed. The main emphasis is put on the need for an effective legal and institutional infrastructure and for clear allocation of responsibilities and tasks to public institutions and enterprises in trade and industry that place chemicals on the market. The importance of this preventive chemicals control, mainly to be carried out by the primary suppliers, producers and importers, and its relationship to traditional risk management for protection of the environment, occupational health and safety and consumer protection are discussed. The main aim is to make clear some important issues to take into account in the development of modern chemicals control, primarily in developing countries and countries with economies in transition.

Swedish Chemicals Agency

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GENERAL COMMENTS

Scope of the report

Chemicals control in this report is defined as control of consumer, industrial and agricultural chemicals in relation to measures for risk management before or when placing chemicals on the market. These measures are to be seen as the first preventive steps in sound management of chemicals as defined in SAICM (see below). Control of other chemicals such as pharmaceuticals, food and feed additives and narcotics, which in general are regulated in specific legislation, is not discussed. 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. However, the correlation between these types of legislation and legislation on the placing of chemicals on the market, specific chemicals legislation, is emphasised. Chemicals is used as a generic term for chemical substances and preparations.

The report summarises some main general points of view and experiences as expressed in international agreements and in various national programmes on chemicals control.

Chemicals control – an internationally prioritised issue

Management of chemical risks is one of the high-priority issues at the international level in programmes on environmental protection as well as in programmes on public health and occupational health and safety. This has long been the case for industrialised countries and for international organisations such as various UN institutions and the OECD. Interest in improved risk management is steadily increasing in developing countries and countries with economies in transition. Risks due to the use of pesticides in agriculture are fairly well known although often not dealt with in an appropriate way. Risks due to the increasing use of chemicals in industrial production, agriculture and households may still be underestimated, although exporting countries increasingly face demands for clean production methods and clean products from customers in countries with a greater awareness of the need for chemicals control.

It is a commonly held opinion that the risks caused by the extensive use of chemicals are still a great threat to human health and the environment, not just at present 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 levels of toxic metals in water and soil as well as in the air are a cause for concern, as are the levels of persistent organic chemical substances. Acute health effects such as poisoning and skin and eye burns continue to be dangers faced by workers, farmers and children, particularly in developing countries.

The increasing production, trading and use of articles and goods (electronics, clothing, cars, building materials etc.) lead to high flows of chemicals into society and therefore also to increasing exposure of humans and the environment to chemicals. Due to the increasing international trade in chemicals and other goods and to the long-range transport of pollution, chemical risks often originate outside the country where the adverse impacts occur.

International co-operation is therefore necessary to achieve effective management of chemical risks.

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.

The UN, the OECD and the European Union (EU) have recently all strengthened their chemicals programmes. UN environmental ministers decided in 2006 on a global chemicals strategy, the Strategic Approach to International Chemicals Management (SAICM). Several other UN agreements on the management of chemical risks have been reached following the 1992 Rio Conference, such as the Rotterdam Convention (1998) and the Stockholm Convention (2001). 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. In the EU a new chemicals policy has been launched (2006) and a Regulation on Registration, Evaluation and Authorisation of Chemicals, REACH, enters into force in 2007, leading to the revision of legislation in order to make the efforts to manage chemical risks more stringent and more efficient. Agreements preceding the Rio Conference and to some extent encompassing chemicals include, for example, ILO Convention 170, the Montreal Protocol, the Chemical Weapons Convention and the Basel Convention.

National efforts for improved preventive chemicals control

Effective preventive chemicals control simplifies and improves the cost-effectiveness of risk management later in the supply chain such as exposure and emission control in transport, storage, use, waste management etc. Therefore, countries with modern, well developed chemicals risk management usually have special legislative and administrative programmes on chemicals control i.e. risk management steps before or when placing chemicals on the market. At national level, governments and their subordinated authorities as well as enterprises are allocated specific responsibilities under this legislation. Mostly, however, the 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 encompass regulations on testing, hazard assessment, classification, labelling and packaging of chemicals, safety data sheets, programmes on risk assessment and on risk management such as restrictions on the placing on the market and use of chemicals. These are all important steps in a risk prevention strategy, which reduce and facilitate risk management in storage, transport, use and waste handling. Other types of traditional legislation on the management of chemical risks such as on protection of the environment and occupational health and safety and on transport regulate risks in the handling of chemicals in greater detail.

The primary, and therefore in a sense most important, regulations on chemicals control encompass classification, labelling and safety data sheets and bans and restrictions. They guide the flow of information in the supply chain to ensure that enterprises and other users have good knowledge of contents, hazards and safe use of chemical products and goods and that highly hazardous chemicals are not placed on the market 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 placing on the market. 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 the ones 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 but also, most importantly, they lay down and make clear the responsibilities and obligations of enterprises and public institutions. Enterprises and other actors handling chemicals including private consumers are normally allocated main responsibility for ensuring that use of chemicals does not affect humans and environment in an unacceptable way. Every actor in the supply chain, such as the producer, importer, retailer, user or waste handler, has specific responsibilities.

Fig. 1 shows in simplified form the main responsibilities of various actors in the supply chain as often found in legislation. According to specific chemicals legislation regulating the placing of chemicals on the market, the producers and importers, being the primary suppliers, are allocated main responsibility for practical implementation of the regulations. They are obliged to make sure that they have appropriate information on chemical products and on goods to be placed on the market with regard to composition (chemical substances) and hazardous properties and to provide customers/users with adequate information on risks and safe use. Primary suppliers have to search for toxicological data, test chemicals if necessary, assess their hazardous properties, decide whether to produce or import a certain chemical or not, and finally provide chemicals placed on the market with appropriate 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. 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 product chain is essential for the desired result to be achieved.

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

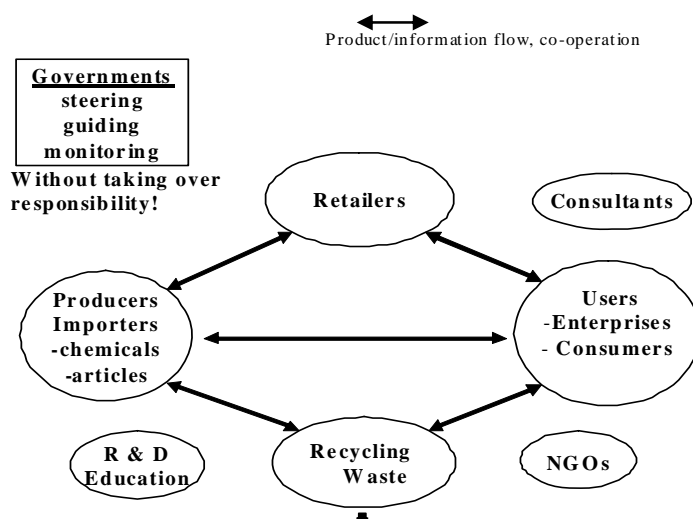
Type of legislation	Primary target groups in supply chain	Typical responsibilities regulated
Legislation on chemicals (“chemicals legislation”)	Suppliers: Exporters } primary Importers } suppliers Producers Retailers	Responsibilities in placing on the market (supply): - Data retrieval (testing, literature, ..) - <i>Hazard</i> 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) - <i>Risk</i> 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 authorities in general is to guide the activities of the actors in the supply chain by issuing legislation, providing general information on chemical risks and on responsibilities of enterprises, enforcing legislation and monitoring compliance with legislation by supervising enterprises. This is to be done in a way that avoids public institutions taking over responsibility from the actors in the supply chain, those who handle chemicals.

To some extent, public institutions can make hazard and risk assessments and decide on risk management. This may be the case in connection with international and national programmes for the classification and labelling of substances, new and existing substances, authorisation of biocides and plant protection products and specific regulatory activities such as bans or restrictions on certain very hazardous chemicals. However, public institutions should not and cannot 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 how to organise safe use. The reason is obvious. Due to the very extensive, varying and ever changing use of chemicals, 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).

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



Appropriate legislation and capability and capacity of enterprises and ministries and authorities are key factors

In addition to ensuring an adequate and effective legislation on chemicals control, a main and even greater challenge for countries is to develop the capability and the capacity of enterprises to assume their responsibility under the legislation. This is primarily a task for trade and industry. For governments it is most important to ensure that institutions in the public sector will have capability and capacity to fulfil their tasks, to steer and monitor the activities of the actors in the product chain. Capability and capacity means technical and financial resources, human resources with regard to numbers and qualifications, organisational issues in trade and industry as well as within enterprises, organisational issues in the public sector as a whole and within institutions etc. There is a need for an institutional infrastructure for effective control of chemical hazards.

Capability and capacity of enterprises

Organisation and expertise needed

In countries with less developed chemicals control (developing countries, newly industrialised countries, countries with economies in transition), many if not most enterprises handling chemicals (producers, importers, traders and users) may lack much, often most, of the capability and capacity needed for effective chemicals control. They will therefore not be able to ensure that the chemicals placed on the market or used are assessed, classified, labelled and provided with safety data for safe use. They will not be able to guarantee that their chemicals do not contain banned substances or organise safe use. This means that they cannot ensure that risks to health and the environment will be avoided in use and other handling of the chemicals.

The 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 the enterprises. Often enterprises even lack a general understanding of the responsibilities they have and of the consequences of these. There are most probably deficiencies in organisational structures within the companies with regard to the necessary allocation of resources and responsibilities needed for effective control and management of chemical risks.

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 hiring external expertise in the person of consultants. Normally a combination of these alternatives can be used. In any case, enterprises have to organise their internal work on chemicals control. Clear responsibilities must be laid down and effective routines established within the company for tasks such as control of the purchase of chemicals, data retrieval, assessments, classification, labelling, SDS, etc. Obviously, smooth and effective co-operation between actors in the supply chain simplifies the work of enterprises (cf. Fig. 2).

Good chemicals control promotes business

Enterprises acting on international markets are facing increasing demands for safe, clean products, clean production and good information for customers, who want to protect their own workers and customers and the environment. Customers in industrialised countries demand that their foreign suppliers apply stringent rules and routines on chemicals control. They increasingly demand that international standards on environmental management systems are complied with. It is obvious that enterprises in countries with inadequate chemicals control at national level and in enterprises will face increasing problems with competitiveness on international markets.

Federations in industry and trade have an important role to play

The experiences of countries with well-developed chemicals control clearly show the great importance of an infrastructure in trade and industry for successful management of chemical risks and for business. Governments and authorities in most cases do not have the capacity to discuss with individual enterprises when preparing regulations. There is a need for speaking partners such as federations, which may represent groups of enterprises. Enterprises, not least small and medium-sized ones (SMEs), benefit from being members of federations. In addition to providing a channel to and from governmental institutions, federations may provide assistance to enterprises such as information on regulations and what these require of enterprises, advice on problem solving, assistance with training etc.

In developing countries and in other countries that are improving their systems for chemicals control, existing organisations in trade and industry usually do not have the capacity needed to ensure effective assistance to the enterprises or co-ordination of the views and efforts of the enterprises on issues concerning chemicals control. Often federations in trade and industry, if they exist at all, are small with a fairly low level of coverage.

Capability and capacity of public institutions. Role of legislation

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

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

The management of chemical risks, chemicals control, is a truly horizontal issue encompassing health, environmental and safety aspects. It concerns the health and safety of consumers and workers as well as protection of environment and property. This means that several governmental institutions have an interest in this issue, and accordingly that there is a great need for integration. Integration is needed to obtain coherence, concentration, co-ordination, co-operation, continuity and cost-efficiency in efforts made to achieve the ultimate goal, good risk management of chemicals.

Coherence and concentration of legislation

For several reasons there will always be several pieces of legislation regulating chemical risks. Efforts to regulate all types of chemicals risks, for the environment, workers, consumers and all steps in the supply chain (Fig. 1) in a single piece of legislation will undoubtedly lead to problems. Such legislation will be very wide-ranging, extensive and heterogeneous and therefore not easy to comprehend and to apply for enterprises or governmental institutions. When introducing specific chemicals legislation regulating the placing of chemicals on the market, countries therefore often develop it as a complement to existing legislation on protection of the environment, occupational health and safety and consumers. However, in order to avoid omissions, gaps or contradictions, the number of pieces of legislation should be reduced to a minimum.

In order to be workable and efficient, legislation on the risk management of chemicals must be as coherent as possible and concentrated into a few basic laws. It seems reasonable to have one separate piece of legislation primarily regulating placing on the market of chemicals covering all the horizontal issues, as a complement to other pieces regulating the use of chemicals such as 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 risk and to provide them with information (labels etc.) on risks and on safe use taking into account all types of risk. Regulating these tasks 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 enterprises. It goes without saying

that the 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 this basic legislation on chemicals as far as regulations on guidance of placing on the market are concerned.

Co-operation, co-ordination and concentration of institutions

There is obviously built-in tension in chemicals control. On the one hand, the strong interlinks between various parts of the specific chemicals legislation regulating placing on the market necessitate coherent management of them for the highest cost-effectiveness, preferably concentrated in one ministry and one central management institution. On the other hand, chemicals control is an issue for many parts of society. The horizontal character of chemicals control makes it 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 complement and support each other without contradictions.

Co-operation and co-ordination is a responsibility of all institutions managing legislation on chemicals. Clearly defined and transparent terms of reference for institutions are crucial for fruitful co-operation. The co-operation and co-ordination required will primarily be reached by regular contacts between institutions managing the specific legislation on the placing of chemicals on the market as well as between them and other institutions. These contacts cannot be replaced by other forms of communication. However, as chemicals risk management is a horizontal issue, it may be appropriate to organise special routines or even, as is done in some countries, a specific forum for discussions on policies and strategies on chemicals control and chemicals risks management in general as well as for information purposes. Such a forum should, however, not replace existing institutions nor contravene their terms of reference (cf. below).

International co-operation and co-ordination

Due to the international trading of chemicals, articles and goods and the long-range transfer of 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, nor can it fail to respond to risks caused by chemicals that are exported as such or as components in various types of articles and goods, whether they be textiles, electronics, cars, construction materials or other products or whether they be contaminants in food. In countries with well-organised chemicals control the way to manage problems with chemicals is through extensive international co-operation, normally by participation in the large chemical programmes run by UN organisations and the OECD.

Well organised and effective national chemicals control is crucial for states to accept transfer of chemicals from one country to the other 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 but from which countries also benefit. Participation in international co-operation on chemicals facilitates national legislative work, keeping track on flows and uses of chemicals and monitoring of compliance with regulations.

Continuity

By establishing appropriate institutions for managing chemical risks and by allocating appropriate resources to them, not only is the capacity, so too is the continuity needed for effective 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 are demanding on resource, even for small countries. The chemical programmes needed for example on classification and labelling, risk assessment and risk management such as bans and restrictions on chemicals of high concern are comprehensive and are need to be run continuously, as do authorisation systems for example for plant protection products and biocides. Regulations issued are not everlasting, far from it. 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, coherence, concentration, co-ordination, co-operation and continuity, it will be possible for countries to obtain good cost-efficiency in the management of chemical risks. Governments will, through coherent legislation, concentration of tasks in a few institutions and co-ordination and co-operation between these, use available 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. All this means reduced costs for enterprises.

DEVELOPMENT, IMPLEMENTATION AND ENFORCEMENT OF MODERN LEGISLATION FOR CHEMICALS CONTROL

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 control.

Basic parts of chemicals control

Basically, chemicals control aims at four main goals:

1. To obtain knowledge of the intrinsic hazardous properties of chemicals.
Test methods and criteria for assessment of hazardous properties of chemicals are developed and agreed upon in international co-operation. Normally national legislation refers to these international agreements. The responsibility to test, assess and classify chemicals rests with the enterprises that place chemicals on the market, producers and importers being the primary suppliers. Testing is not necessary if corresponding information on toxicity can be found in the literature, databases or, as may be the case for importers, can be obtained from the supplier abroad. In some specific cases authorities may have complementary tasks as regards assessment and classification.

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 (risk) labelling and other types of risk information and safe use such as Safety Data Sheets. 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 need for specific safety measures and use instructions.
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 partly done by public institutions as part of pre-market approval regimes (pesticides and other chemicals of special concern) and as bans and restrictions (other chemicals of high concern). In all other cases the choice is entirely up to the enterprises 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 express 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 by the basic national legislation on chemicals.

- a) Responsibilities and obligations of enterprises as regards for example:
 - assessment of hazards and risks of chemicals to be placed on the market or used,
 - information to customers and users on hazards and risks and how to avoid these,
 - safe 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 regulations and injunctions, if needed restrictions and bans and sanctions in the event of violations of legislation,
 - supervision including the right to obtain information needed and the right to admission to sites and other facilities
 - confidentiality of data.

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

With the exception of pesticides (plant protection products and biocides) and to some extent other chemicals of high concern, modern legislation on industrial, agricultural and consumer chemicals does not require pre-market approval before chemicals are placed on the market. It is therefore important that the basic legislation on chemicals states the general responsibilities of suppliers and users of chemicals for risk prevention and management. The suppliers, in

specific cases producers and importers, should be responsible for searching for knowledge on hazards and risk caused by the chemicals they intend to place on the market, for not providing unnecessarily hazardous chemicals for a specific purpose and for appropriate information to the users on hazards and risks and on safe handling for risk management. The users should be responsible for the measures to be taken for safe use of chemicals taking into account possible ways of reducing risks by substituting hazardous chemicals with less hazardous alternatives.

The basic legislation must state the rights and duties of governments, ministries and public authorities as well, such as in issuing of secondary legislation, monitoring of compliance etc. The responsibilities and roles of those handling chemicals in relation to the authorities may be clarified by appropriate clauses in the legislation stating the responsibilities of various actors.

Rights and obligations for public institutions are to be stated

The enterprises not only have to supply customers and users with information on hazards and on proper use of chemicals, they must also be obliged, when necessary, to provide the authorities with data on the chemicals placed on the market as well as other information needed for the authorities to work effectively. The authorities must have clearly stated legal rights to obtain such information 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. Inspectorates must, when considered necessary to make enterprises comply with the legislation, have the right to issue injunctions including bans on sale or use.

Sanctions needed for compliance

Effective implementation of the legislation in practice necessitates sanctions in the event of violations. It is therefore to be ensured that the legislation on chemicals 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 a prerequisite for efficiency

It is essential for legislative work at all levels that stakeholders concerned (producers, importers, users, NGOs, the public etc.) are already consulted by legislators at early stages in preparatory work on specific legislation or on any other action 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 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 for 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.

Organisation of public institutions

In the following priorities concerning institutional issues are further discussed. The general comments given above on infrastructure issues are highly relevant to this section. In Section 3 below more detailed reflections on institutional issues are presented along with some recommendations.

Co-ordination and co-operation are essential

Chemicals control is, as already mentioned, a horizontal discipline of a preventive nature. Before introducing a new chemical for use, all types of possible risks are to be evaluated in order to avoid unforeseen effects. Risks to health, the environment, property in normal use and in (major) accidents are all to be taken into account when preparing classification, labelling and safety data sheets as well in decisions on bans and restrictions or on authorisation for example of pesticides. If not, a means to effectively avoid one type of risk may result in another. The replacement of unhealthy and flammable solvents with chlorinated fluorocarbons, CFCs, resulted in new serious risks to health and environment due to destruction of the ozone layer. In the case of asbestos, this effective chemical introduced for heat and fire protection was later found to pose a lethal danger to workers. Although it is not possible always to foresee all risks, one of the main aims in modern chemicals control is to ensure that all available knowledge on hazards and risks is taken into account.

The horizontal nature of the preventive chemicals control, as described above, calls for an appropriate institutional set-up (ministries and subordinated bodies) and strong co-ordination of the work in institutions selected to be responsible for various aspects of chemical safety. Good co-operation is to be ensured both vertically and horizontally. It may be organised in various ways e.g. by establishing some kind of co-ordinating body at ministerial level (cf. Chapter 3 below). 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. The National Profiles based on the UNITAR/IOMC National Profile Guidance Document (1996) may be a useful instrument for such analyses and assessments.

Bodies for legislative work, scientific/technical assessments and supervision

Allocation and delegation of responsibility - a prerequisite for effective work

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 placing on the market of chemical products and goods, it is cost-effective to concentrate responsibilities for issuing regulations, implementation and enforcement on as few institutions as possible. The more scattered the responsibilities are, the more duplication of resources is needed and the more public institutions have to spend resources on inter-institutional co-ordination. Split responsibilities will make legislative work, implementation and enforcement more burdensome. Furthermore, split responsibilities will make difficult for enterprises to identify responsible institutions and in general make implementation of legislation unnecessarily complicated and costly.

It might be preferable to designate one ministry and subordinated institutions to be responsible for chemicals legislation regulating placing on the market, including overall responsibility for national co-ordination and international contacts. As management of legislation on chemicals, biocides and plant protection products has much in common, countries may find 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 appropriate expertise is essential to meet these demands.

Allocation and delegation of responsibilities may be done 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 might be considered (cf. Chapter 3 below).

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

As mentioned, the management of modern chemicals legislation demands considerable scientific and technical support, in particular for hazard and risk assessment. Countries may respond to this demand either by incorporating expertise for this support in ministries or governmental authorities responsible for legislation or, more commonly, by utilising external expertise at appropriate scientific institutions, for example at universities (cf. Chapter 3 below).

Supervision - important for effective chemicals control

Legislation on chemicals control in industrialised countries allocates considerable responsibility to enterprises handling chemicals. Except for chemicals of special concern such as plant protection products and biocides, the present legislative systems applied internationally contain very little in the way of detailed central control. Therefore, it is of the utmost importance that the 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. Chapter 3 below).

Like other public institutions, inspectorates should not provide specific advice to enterprises on how to solve a problem. They should not “take over” responsibility for managing chemicals from enterprises. This is, as mentioned above, neither possible with regard to capacity and capability of public institutions, nor is it appropriate with regard to the balance regarding allocation of responsibilities between enterprises and authorities to be stated in the legislation. This balance is easily distorted if the authorities tell the enterprises precisely what to do in order to solve a problem. Furthermore, such actions take the initiative away from enterprises and give it to the authorities, something which is to be avoided on all accounts.

Some specific issues

In the following section some main, strategic elements of chemicals control are commented on. The choice of issues reflects the most common problems and issues as discussed in many countries, not least countries with still less well developed chemicals control.

Classification/labelling/safety data sheets to ensure information flow

Basic primary national legislation on chemicals to which secondary legislation may be attached is essential for effective regulation of chemical hazards and risks. Primary legislation makes it possible to “organise” responsibilities and tasks of both enterprises and governmental institutions. As already mentioned, the most important secondary regulations

seem to be the ones on classification, labelling and safety data sheets. Correct classification in combination with labelling and safety data sheets is the basis for assessing risks in use and other handling and for taking measures to eliminate risks. Implementation of these regulations is therefore essential to reduce hazards in the use of chemicals. Issuing and enforcement of them should be given the highest priority in every country when developing modern chemicals control. Implementation of these regulations in practice provides very valuable experience and knowledge of issues such as data finding, identification of chemical substances in preparations, hazard and risk assessment, and how to organise chemicals control in general. Such experience is essential both for enterprises and authorities in their work on other parts of chemicals legislation as well as on other legislation concerned with chemical hazards.

Responsibilities must be made clear

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 the requirements. They should, however, abstain from acting as consultants to the enterprises. The main task for the authorities is, as mentioned above, to direct and monitor the chemicals control to be carried out by the actors in the product chain. It should be up to enterprises and their federations to produce more detailed manuals or other means to facilitate and organise the work at enterprises. The allocation of responsibilities is to be borne in mind in every action by the authorities. If authorities take over tasks from enterprises, the result will be a 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 have neither the resources nor qualifications for an extensive, adequate service to the enterprises. Altogether, the result will be impaired risk assessment and risk management.

An efficient supervision carried out as post-market control (see below), market surveillance, 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 post-market monitoring ensures fair competition among enterprises, with all running the risk of sanctions if they fail to comply and none gaining advantages.

Availability of data bases and expertise is essential

Assessment of hazardous properties of chemicals for classification and labelling and for preventive measures including possible restrictions on use necessitates access to evaluated information on effects on health and the environment of chemical substances. This type of information many chemicals is available internationally in public sources such as databases and handbooks. Governments may, by technical means such as information on 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, public institutions especially authorities, being used as intermediaries or consultants for the enterprises in searching for data on specific substances is to be avoided. It should be the duty of every enterprise to search for the data

needed without assistance from authorities in order not to distort the allocation of responsibility. If necessary and found appropriate, enterprises may make use of commercial consultants or their federations to obtain the expert support they need both with regard to data retrieval and for assessment of the data.

Many countries may, when introducing chemicals control, face serious problems due to lack of appropriate expertise in enterprises and lack of consultants. These problems are, however, temporary and certainly will be reduced 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. Ways for governments to ensure that a country has the expertise needed may be to introduce courses of training for example in toxicology, risk assessment and management and legislation at appropriate university institutions or other scientific institutions. The availability of consultants will rise when enterprises learn that non-compliance will lead to consequences. An effective inspection regime promotes development of a market for consultants.

Data collection to the extent needed

As mentioned several times, systems for control of chemicals in industrialised countries to a large extent allocate responsibility for safe use to enterprises and other institutions handling chemicals. The rationale for this is that in a modern society with its huge flows of chemicals and other goods, it is not possible for public authorities to follow the flows and uses of them in detail. The flows are very complex 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 and biocides, the authorities will be in a position to assess risks and to regulate in detail use for proper management of risks. Systems for pre-market authorisation of pesticides provide good knowledge on the use of these products.

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

Centralised data collecting on chemicals used in a country is valuable but should be limited to the extent really needed. Data collection programmes can easily be developed too far by making use of large resources to small or no benefit. A comprehensive inventory with the aim of establishing a complete database on chemicals in use in a country is a very large and resource-demanding exercise, especially as the usefulness of a database is dependent on regular updating. It is therefore not recommended that countries in early stages of developing modern chemicals control make such full inventories or establish advanced chemicals registers.

A first fairly simple data collection step would be to identify enterprises importing and producing chemicals and to establish a database of them. This might be accomplished by a licensing system for producers and importers. 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 on new and existing chemical substances, the main rationale being the need to improve the information on hazardous properties of chemicals as a basis for risk assessment and evaluation of nationwide risk reduction measures possibly needed such as restrictions or bans. New substances are normally defined as substances not in use in a country at a specified date, existing substances being identified by way of an inventory. Such legislation implies regulatory and administrative systems with heavy duties on enterprises in trade and industry as regards 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 burdens” 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.

Running systems for new/existing substances is too resource demanding for it to be realistic for most countries to establish entirely their own regimes. 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 the ones 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 assessed and regulated in other countries it should be possible to rely on hazard data gathered and evaluated internationally, when found necessary complemented by domestic exposure data to assess the possible need for national risk reduction measures.

Education and training of personnel a must

Training in legislation, in information retrieval, human toxicology and ecotoxicology, assessment of chemicals, classification, labelling and production of safety data sheets is essential. 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 the governments. In both cases the opportunities to make use of internationally available funding, expertise and training programmes should be analysed. As mentioned above, the needs of education may be met by developing appropriate courses at universities or other scientific institutions.

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

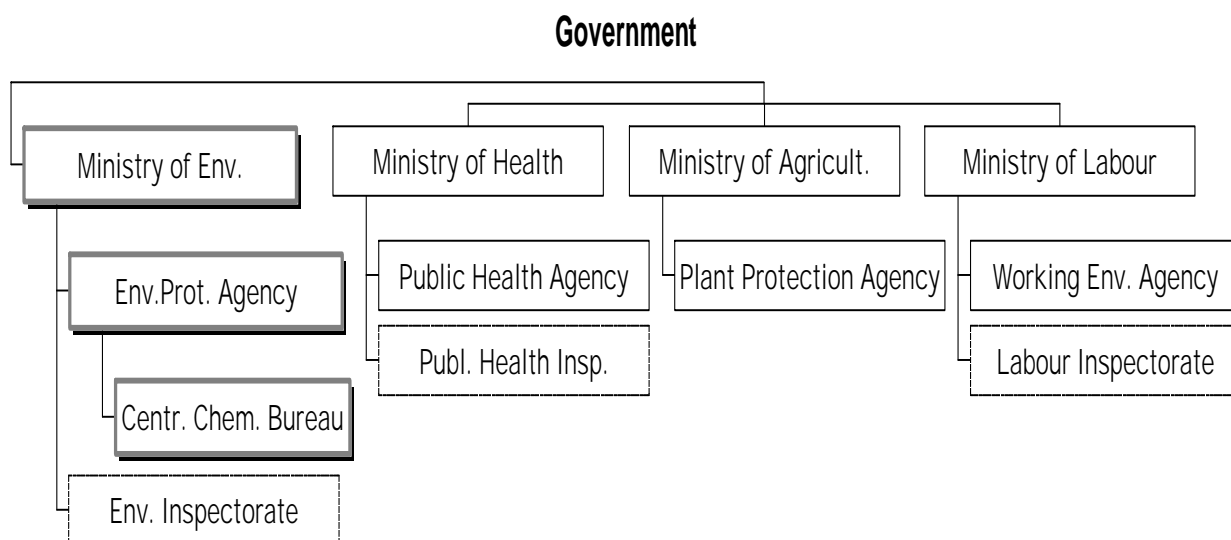
The management of chemical risks should preferably be organised at three main levels: the policy level, the implementation/management level and the enforcement level.

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.

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



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 state 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 placing chemicals on the market.

When appointing the main responsible ministry for chemicals control, familiarity with legislation for managing chemical risks is a factor which merits attention. This is why countries often allocate responsibility for chemicals legislation at political level to ministries

of the environment, ministries of health or, as regards pesticides, 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. Issues concerning chemicals control therefore run a lower risk of not being given adequate priority compared to other ministries. Furthermore, modern chemicals control at international level very much focuses 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. Risk assessment, classification, labelling and safety data sheets are basically the same, and such co-ordination is consequently found to be both practical and cost-effective.

Chemicals legislation should empower governments and ministries to issue new and revise old secondary legislation. Detailed regulations should preferably be issued as ministerial regulations, or even at a lower level. As mentioned, the chemical regulations are too scientific and technical and detailed, and are revised too frequently, to be decided upon by parliaments, in many cases even by governments.

Irrespective of how the main responsibility for the chemicals legislation will be allocated, several ministries are 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.

A co-ordinating body may be useful

Although 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 be facilitated by a specific body with representation from the ministries (and authorities) concerned. Such a body may advantageously be connected to the ministry designated as holding the main responsibility. The role of the special body should be advisory and consultative. Care should be taken not to allocate power and tasks which are normally held by ministries/authorities to an advisory 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 in international work on chemicals.

When establishing a co-ordinating body, countries may, as already mentioned, make use of experiences gained when establishing National Profiles. Many countries already established a multi-stakeholder co-ordinating committee during that work. It should be quite easy to re-organise this committee into a permanent body for ministerial co-ordination.

Co-operation on and co-ordination of collection, dissemination, retrieval and storage of data might be yet other issues to discuss in a co-ordinating body. Several public institutions will have interests in these issues, and it is consequently it is of great importance to find cost-effective solutions that satisfy all parties. It is, however, important in all these cases, that the ministries and other institutions in charge have the main responsibility for advice and other service to government.

Implementation and management level

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

As mentioned several times, the legislative work on chemicals is highly scientific and technical and demanding on resources. Ministries in charge therefore normally need support in technical and scientific issues from subordinated institutions, which have the expertise needed. The daily work on implementation and management of the various parts of chemicals legislation is even more demanding with regard to scientific and technical capability and capacity. Obviously, there is a need to find ways of organising the support to ministries as well as the daily management of chemicals legislation.

It is quite common in developing countries and countries with economies in transition for responsibility for existing pieces of legislation on chemicals control to be dispersed among many ministries and subordinated institutions. Existing resources added together can often be considerable. With regard to the discussion above including cost-effectiveness it may, especially for countries with scarce resources, 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 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.

If a central institution is not established, it should be ensured that appropriate resources will be available for support to the ministries and for daily management, e.g. by networking between managing institutions in charge 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 with a view to achieving the co-ordination and co-operation needed.

Qualified scientific and technical support is necessary

Even if a central managing institution with qualified personnel is established, it will need support for more qualified scientific assessments of hazard and risk. Such assessments are common in administrative systems for control of industrial and consumer chemicals, biocides and of plant protection products. In many countries these assessments are made with support from appropriate scientific institutions at universities or institutes.

The scientific risk (health and environment) and other assessments needed for the type of chemicals control discussed in this paper and for occupational health and safety, environmental protection and food safety control may well be done by one or more common

scientific institutions, despite the main responsibility for the various legislations resting with several ministries/authorities. Hazard and risk assessments for example of industrial chemicals, consumer chemicals, biocides, plant protection products and food additives have so much in common that it would be a waste of scarce scientific resources not to co-ordinate the scientific work to avoid duplication of and dilution of resources and expertise. If common institutions for assessments are established, countries may find it appropriate to link training in toxicology to this institution or these institutions (cf. above).

Enforcement level

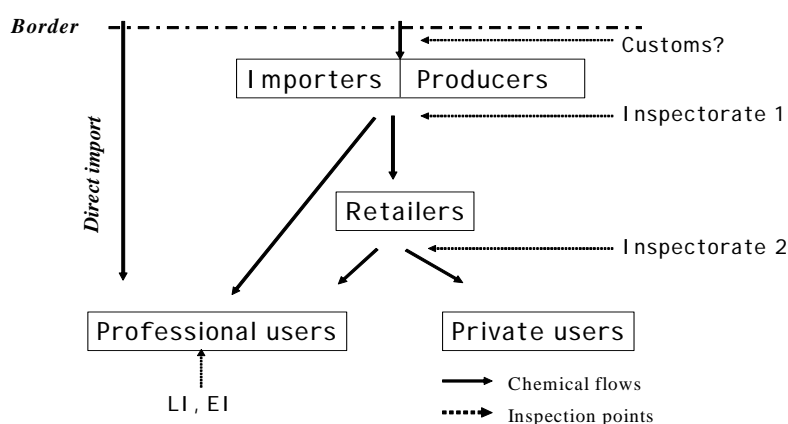
Organisation of supervision is vital

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 exercise their duties.

Supervision of producers and importers with regard to their responsibilities as primary suppliers of chemicals (toxicological 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 taken 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.

Fig 4. Organisation of supervision/enforcement. An example



LI = Labour Inspectorate
EI = Environmental Inspectorate

It seems appropriate to make use of existing inspectorates as far as possible, provided they have the capability, capacity and experience needed. 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 of transferring transfer resources from “old” to new areas can be considered. Regardless of choice of inspectorates to supervise the various actors, it is to be ensured through appropriate statutory instruments that enterprises do not run the risk of being checked by more than one inspectorate with regard to compliance with specific chemicals regulations.

The role of customs as an institution for pre-market surveillance can easily be overestimated in view 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., is to be done as post-market surveillance by random inspections of suppliers. However, customs may well play a role in some specific cases such as checking that licences for import or other documents are in order, for example in implementation and enforcement of the Rotterdam Convention on banned and severely restricted chemicals. Customs can obviously alert chemicals inspectorates in the event of suspected violations of legislation.

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 provided that 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 in developing countries be considerable existing resources for work on chemicals risk management, although these are dispersed between several ministries, which may work somewhat in isolation from 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 a more cost-efficient use of existing as well as new resources, reducing 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 to 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 of other costs following emissions, for example pollution of watercourses and soils due to accidents or long use of chemicals.

Enterprises

The costs to enterprises in trade and industry may be considerable as well, 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, however, be partly purchased from consultants, which may reduce the costs especially for small and medium-sized enterprises.

However, 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 in many cases may already be recouped in one year or a few years.

Possible alternatives for financing the work of public institutions

The ways of financing chemicals control will always be in issue for national deliberations. 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 costs for governmental efforts to organise an efficient control of chemicals are caused by the chemicals placed on the market and used. Many countries already 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 a specific enterprise, it will be possible to quantify and price the efforts of authorities.

SUMMARISING CONCLUSIONS

The management of chemical risks is increasingly brought into international and national focus. As chemicals are distributed internationally by trading as well as by long-range transport of pollutants, no country can any longer manage the risks on its own. Therefore, efforts towards sustainable use of chemicals are increasingly made in international co-operation. 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 a modern legislation and modern systems for chemicals control many countries will face new and in a way revolutionary challenges. This is true as regards the development of legislation at primary and secondary level. An appropriate and well-balanced legislative system is an 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 is to be allocated to enterprises.

Most probably, however, the main challenge will be to establish an institutional infrastructure to manage the legislation. There is a need to ensure that countries do have an appropriate 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 to monitoring of compliance with the legislation. In both cases there is a need for special expertise. The costs of running institutions can at least partly be financed by fees or special taxes on enterprises.

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 carry through the necessary improvements and reinforcements. Enterprises and their federations need to make corresponding analyses and improvements.

The horizontal nature of chemicals control is very 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.

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SWEDISH CHEMICALS AGENCY • P.O. Box 2 • SE-172 13 Sundbyberg • +46 8 519 41 100 • Fax +46 8 735 76 98
E-mail kemi@kemi.se • www.kemi.se