Test Version

Guidance on the Development of Legal and Institutional Infrastructures for Sound Management of Chemicals and Measures for Recovering Costs of National Administration

(LIRA-Guidance)

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Note on Development Status Terms

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the United Nations Environment Programme concerning the legal status of any country, territory, city or area, or of its authorities, or concerning the delimitation of its frontiers or boundaries. The designations “developed”, “developing” economies, “BRIICS” and “economies in transition” are intended for statistical convenience and do not necessarily imply a judgment about the stage reached by a particular country or area in the development process.

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Acronyms

BASA	Baseline Analysis and Solutions Assessment
CBA	Cost Benefit Analysis
CEiTs	Countries with Economy in Transition
COI	Costs of Inaction Initiative
DCs	Developing Countries
CiP	Chemicals in Products
DTIE	Division of Technology, Industry and Economics
DNA	Designated National Authority
FAO	Food and Agriculture Organization of the United Nations
GATT	General Agreement on Tariffs and Trade
GC	Governing Council
GHS	Globally Harmonized System for Classification and Labelling of Chemicals
GCO	Global Chemicals Outlook
GEF	Global Environmental Facility
HELI	Health and Environment Linkages Initiative
HESA	Health and Environment Strategic Alliance
ICCM	International Conference on Chemicals Management
ICM	Inter-Agency Coordination Mechanism
IISD	International Institute for Sustainable Development
ILO	International Labour Organization
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
IPCS	International Programme on Chemical Safety
ISO	International Standardization Organization
KemI	Swedish Chemicals Agency
MEAs	Multilateral Environmental Agreements
MSW	Multi-Stakeholder Workshop
NGO	Non-Governmental Organization
ODSs	Ozone Depleting Substances
OECD	Organization for Economic Co-operation and Development
PI	Partnership Initiative for the Integration of Sound Management of Chemicals into National Development Planning Processes
PIC	Prior Informed Consent
POPs	Persistent Organic Pollutants
SAICM	Strategic Approach to International Chemicals Management

(M)SDS	(Material) Safety data Sheet
SIDA	Swedish International Development Agency
SMC	Sound Management of Chemicals
SMEs	Small and Medium Enterprises
SPS	Sanitary and Phytosanitary Agreement
TBT	Technical Barriers to Trade
TEEB	The Economics of Ecosystems and Biodiversity
TRIPs	Trade Related Aspects of Intellectual Property Rights
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNITAR	United Nations Institute for Training and Research
WCO	World Customs Organization
WHO	World Health Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization

I. Introduction

A. The Benefits of Sound Management of Chemicals

Chemicals make up our physical world; they form the basis of life and they are the building blocks from which we make our products. Chemicals are an integral part of modern life with over 100,000 different substances used in a wide variety of products that build the world economy.

However, while chemicals sustain our global economy, they can also cause significant damage if mismanaged. A growing body of research is documenting the various risks and negative impacts harmful chemicals can have on the environment and human health. Such negative impacts result in significant economic costs for economic development at the sub-national, national, regional, and global levels[1].

There are very clear links between a precautionary approach to chemicals management and economic development. A knowledge-based, preventive approach to chemicals risks management throughout their lifecycle allows avoiding significant risks to human health and ecosystems, and associated economic costs for individuals, firms and society as a whole. In addition, improved management of chemicals creates business opportunities both directly and indirectly linked to chemicals production and use.

B. The Challenges to Achieving Sound Management of Chemicals

The 2002 World Summit on Sustainable Development (WSSD) defined that by 2020 chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment. Over the past decades, significant progress has been made in chemicals management at the national and international levels. Key instruments and processes have been established to address major chemicals management concerns. But these efforts have not been sufficient to protect the environment and health of the populations from chemicals risks.

Of particular significance in this regard is the fact that recent trends show changing patterns of global chemicals production and trade, with a progressive shift of portions of chemicals production and markets from OECD countries to developing countries (DCs) and countries with economies in transition (CEiTs). By 2020, DCs and CEiTs are expected to account for about a third of global chemicals production and consumption[2]. While they are attracting greater production and importing increasing quantities of both chemical products and consumer goods containing chemical substances, DCs and CEiTs generally lack the technical and financial capacity to manage chemicals soundly.

Acknowledging the need for faster progress in chemicals management, countries participating in the 2006 1st International Conference on Chemicals Management (ICCM1) that established the Strategic Approach to International Chemicals Management (SAICM) stated that "*fundamental changes are needed in the way that societies manage chemicals*" (Dubai Declaration on International Chemicals Management, para. 7). SAICM therefore calls for strengthened focus on improved cross-sectoral governance for the development of coherent preventive approaches for managing chemicals throughout their life-cycle at the international, regional, national and local levels.

In particular, SAICM emphasizes the need for enhanced coherence, consistency and cooperation to address the gaps, overlaps and duplication in national chemicals management activities. But SAICM also recognizes that the availability of secure, predictable *"financial resources provided by governments, private sector and bilateral, multilateral and global agencies or donors"* (Overarching Policy Strategy, Section V.19) is critical for improving chemicals management regimes in DCs and CEiTs. As such, if funding for chemicals management activities is to be sustainable, it is imperative that options for national-level funding are fully explored.[3]

In addition to national budget and international funding, bolstering private sector financial and technical participation in meeting the costs of full implementation and enforcement of national chemicals-related laws is thought to be a key feature of generating sustainable finance. Economic instruments – most particularly administrative cost recovery mechanisms are - recognized as one set of policy mechanisms that are ripe for further exploration in financing chemicals management.

C. About this guidance

1. The Guidance within UNEP Chemicals Mainstreaming Programme

In order to address these inter-related challenges as part of SAICM implementation, UNEP has developed a programme of five complementary initiatives:

- ⇨ The UNDP-UNEP Partnership Initiative for the Integration of Sound Management of Chemicals into National Development Processes (UNDP-UNEP PI)
- ⇨ UNEP-WHO Health and Environment Strategic Alliance (UNEP-WHO HESA)
- ⇨ UNEP Costs of Inaction Initiative (UNEP COI)
- ⇨ UNEP Global Chemicals Outlook (UNEP GCO)
- ⇨ UNEP Guidance on the Development of Legal and Institutional Infrastructures and Measures for Recovering the Costs of National Administration (UNEP LIRA-Guidance)

The approach underpinning UNEP Chemicals Mainstreaming Programme aims to raise awareness of the need and build capacity for improved integration of chemicals management into development agendas, and ultimately to mobilize sustainable financing for SMC[4].

The increasing emphasis on country-driven programmatic approach to economic and social development provides a strong rationale for the integration of Sound Management of Chemicals (SMC) priorities into national development planning processes. In this process, strengthened inter-sectoral collaboration amongst the broad spectrum of national institutions that regulate chemicals is required for coherent risk-reduction strategies to emerge. As well, improved demonstration of economic costs of chemicals mismanagement is required to convince finance policy-makers to invest in SMC at the national and international levels. Finally, the development comprehensive proposals, including realistic budgeting considerations, is required for being able to actually mobilize finance within the budget allocation process for the mainstreamed priorities.

As part of this approach, the Guidance addresses the development of such proposals with regard to legal and institutional infrastructures[5] for SMC. In line with SAICM, the scope of the Guidance includes "agricultural and industrial chemicals, with a view to promoting sustainable development and covering chemicals at all stages of their life-cycle, including in products"[6].

Since they provide the framework to implement chemicals management policy, these infrastructures can be seen as the backbone of national efforts towards SMC. Legislation defines the specific objectives to be reached; roles and responsibilities of the stakeholders involved; instruments and tools that can be used, and therefore distribution of costs between stakeholders. Institutional arrangements give operational reality to the policy by organizing the available resources (human, technical, financial) for decision making implementation, enforcement and compliance.

2. Managing the Placement of Chemicals on the Market for SMC

Comprehensive chemicals management frameworks include measures for managing chemicals at every step of their life-cycle – from production to disposal – as well as the promotion of innovative approaches for chemicals management by every stakeholder. This involves a significant body of national legislation and institutional frameworks. Most countries, and especially DCs and CEiTs, have yet been unable to establish complete supports for SMC. In general, chemicals risk management is partly covered (if at all), under several pieces of legislation (such as environment, waste, work environment, consumer safety, rescue services, transport, agriculture, trade, industry etc.) and splits various activities across different ministries.

Several guidance documents have been developed on comprehensive national policies and programmes for the sound management of chemicals[7]. However, tackling gaps and inconsistencies in the whole chemicals management legal framework at the same time would certainly prove very demanding, especially in the context of scarce capacity and resources characterizing most DCs. There is therefore a pressing need for prioritization.

A logical first step to facilitate chemicals control throughout supply-chains is the development of coherent legal and institutional infrastructures governing the placement of chemicals on the market. Regulating the placement of chemicals on the market is particularly in line with SAICM's approach to the sound management of chemicals, as:

- ⇨ Principles for the management of the marketing of chemicals apply generally to all chemicals, and involve relatively similar legal and institutional developments for all categories of chemical substances/flows;
- ⇨ Upstream chemicals management allows the adoption of preventive measures to manage chemicals negative impacts;
- ⇨ The focus on the clarification of mandates, powers, roles and responsibilities of key stakeholders, on requirements for information generation, dissemination and integrated management and on key bans and restrictions enables and facilitate management of later steps of the chemicals life-cycle;
- ⇨ The development of legal and institutional infrastructures governing the placement of chemicals on the market is a cost-effective solution for strengthening national chemicals management systems, as it involves few regulated entities (importers, distributors, producers/ manufacturers), and impacts the whole supply-chain.

3. Key principles underpinning this Guidance

In line with the UNEP Chemicals Mainstreaming approach, the following key principles should be kept in mind when working on the development and/or strengthening of legal and institutional infrastructures governing the placement of chemicals on the market in DCs and CEiTs:

- The review of legal and institutional infrastructures should be **part of an integrated, lifecycle chemicals management strategy**. Where no SMC policy is in place, the review of chemicals management legal and institutional infrastructures should provide the first step for the development of such a strategy;
- Legislation governing the placement of chemicals on the market and institutional arrangements for decision-making, implementation and enforcement should provide the **foundational capacity**[8] for lifecycle chemicals management;
- **Strong inter-sectoral and multi-stakeholders collaboration mechanisms** for SMC should be established;
- The review should follow a **sound planning process** in order to ensure the development of coherent, comprehensive and realistic action plans, as well as sustainable financing for the proposed developments.

4. Objectives

This guidance aims to provide practical, step-by-step support to policymakers for strengthening national legislation and institutional set-ups for achieving sound management of chemicals, including measures for financing necessary national administration supports.

The guidance includes a consideration of what structures countries typically need at a minimum, and which ones are useful to countries that are in the process of improving existing systems for better addressing chemicals management goals. Though of a general nature in order to accommodate for various national contexts, discussions contained within are tailored for the specific conditions of DCs and CEiTs.

Specifically, the objectives of this guideline are to:

I. Assist countries in reviewing their legal and institutional infrastructures in a step-by-step process, with a focus on the development and financing of an action plan for national strengthening SMC regimes;

II. Propose options for organizing the legal and institutional infrastructures governing the placement of chemicals on the market, including legislation and institutional arrangements given the national context;

III. Identify the main elements that should be considered when developing or strengthening legislation governing the placement of chemicals on the market, and discuss options for addressing these elements in line with the national situation;

IV. Provide tools for ensuring sustainable financing, including cost recovery measures and access to national budget allocation process.

The Guidance also provides practical tools (legislation template, case studies) for assisting users of these guidelines in meeting their development/ strengthening of a comprehensive chemicals management framework.

II. Reviewing Legal and Institutional Infrastructures Governing the Placement of Chemicals for SMC

The process proposed in these guidelines aims at the development and financing of an action plan for strengthening legal and institutional infrastructures governing the placement of chemicals on the market as part of a lifecycle chemicals management policy.

As a policy-driven process, the review should be based on sound planning. Three elements are therefore key for successfully strengthening the legal and institutional infrastructures governing the placement of chemicals on the market:

- ***Participatory:*** Participation of key stakeholders throughout the process is critical. This allows for all available information to be collected, and ensures broad political support for the proposed developments. In addition, the review process being a multi-disciplinary exercise, inclusion of experts from the various field of expertise involved (law, chemistry, economics, etc.) is required.
- ***Evidence-based:*** When developing an action plan for advancing the national chemicals management agenda, it is of utmost importance that country practitioners base their work on a sound analysis of the current country situation. Such analysis provides the basis for selecting and developing relevant policy options. As such, it also provides a strong justification for financing of the proposed developments.
- ***Targeted:*** In order to ensure agreement support for the proposed developments, the process should be transparent and in accordance with national procedures. In addition, the results need to be conveyed in formats and styles relevant to SMC decision makers. This notably involves the development of economic arguments, including the use of economic tools such as Cost Benefit Analysis (CBA).

A. Three National Contexts for Undertaking a Review of Legal and Institutional Infrastructures

The review of the national situation with regard to legal and institutional infrastructures for SMC should build on existing structures and information as far as possible. This will ensure efficient use of limited resources and ensure continuity. In particular, the process proposed in these guidelines intends to build on the work done as part of the development of the UNITAR National Chemicals Management Profile and of the UNDP-UNEP Partnership Initiative.

For the purpose of these guidelines, the three following types of pre-existing national contexts are therefore considered.

a) Countries where:
   - No inter-sectoral coordination mechanism exists;
   - No analysis of the national SMC situation has been performed.

   These countries will begin the process by establishing an inter-sectoral coordination mechanism as part of the project structure. In addition, in line with the approach of the guidance, preliminary investigations on the state of chemicals management in the national development context should be conducted. This is critical for positioning the strengthening of legal and institutional infrastructures governing the placement of chemicals on the market in the national development agenda, as a basis for the development of an integrated, lifecycle chemicals management policy.

b) Countries where:
   - Some inter-sectoral coordination mechanism has already been created;
   - An analysis of the main issues (and needs) for SMC has been conducted.

   This typically applies to countries having developed a UNITAR National Chemicals Management Profile. Mechanisms created as part of the project have sometimes been left aside of the policy-making process after the project completion; these mechanisms need to be revitalized and their

mandate extended. In addition, these countries have already conducted an analysis of their SMC situation and their major needs in this regard. Such analysis provides a valuable basis for the deeper assessment proposed in these guidelines. This assessment can therefore focus specifically on positioning the work into the national development agenda and on the detailed evaluation of needs and solutions for strengthening legal and institutional infrastructures governing the placement of chemicals on the market.

c) Countries where:
   - ⇨ A functional Inter-Agency Coordination Mechanism (ICM) and Multi-stakeholder Workshop (MSW) is in place;
   - ⇨ An analysis of the situation and needs with regard to SMC has been conducted;
   - ⇨ SMC priorities have been mainstreamed in the national development agenda.

   UNDP-UNEP Partnership Initiative country projects provide the foundation for strengthening national SMC systems. Countries having undertaken such projects have functional inter-sectoral collaboration mechanisms for SMC and have clearly identified SMC priorities in the national development context. These countries have a strong basis for positioning the strengthening of legal and institutional infrastructures governing the placement of chemicals on the market in an integrated lifecycle chemicals management policy, and can therefore directly start with a solution oriented assessment.

B. Main Phases of a Review Process

The process proposed in these guidelines involves five main phases. These phases are designed to allow countries in the three contexts described above to undertake such a review of legal and institutional infrastructures governing the placement of chemicals on the market for strengthening national SMC systems. Countries of contexts b) and c) from Section A can focus on the phases not performed already.

1. Mobilisation Phase

i Establishing an institutional structure

At first, an institutional structure should be established for the project. This structure should at least include a project director and a project coordinator. As well, inter-sectoral coordination mechanisms involving all the key stakeholders should be set up.

These include an Inter-Agency Coordination Mechanism (ICM) with participation of the key public bodies (a list of ministries/ agencies typically involved in chemicals management is presented in annex 2). The ICM should also include representatives from local authorities, and focal points/ Designated National Authorities (DNAs) of the chemicals Conventions. A consultative Multi-Stakeholders Workshop (MSW) should also allow for non-governmental stakeholders participation in the process.

Depending on the capacity and resources available for the project, multi-disciplinary Technical Task Teams can also be established for the technical work.

ii Initial review

The review of legal and institutional infrastructures governing the placement of chemicals on the market as a basis for sound management of chemicals requires an analysis of the state of these infrastructures as part of the broader national framework for lifecycle chemicals management. In line with the approach of the UNEP Chemicals Mainstreaming Programme, this also involves consideration of the integration of chemicals management policy into national development planning and knowledge of the budget allocation process, in order to ensure sustainable financing for the proposed developments.

Key questions to be considered in this regard include:
- ⇨ What current Knowledge of Chemicals Production, Imports and Uses and Related risks in the Country exists?
- ⇨ How is Chemicals Management integrated in the National Development Agenda?
- ⇨ What is the Prioritization of Chemicals Management Issues?

- ⇨ What is the Budget Cycle (and other policy cycles)?
- ⇨ Who are the Key Stakeholders for Chemicals Policy Making and Implementation?
- ⇨ What are the Experiences of Similar Processes in other Countries of the Region?

2. Baseline Analysis and Solutions Assessment

The goal of this phase is to evaluate the gaps and needs of the country with regard to the legal and institutional infrastructures governing the placement of chemicals on the market, and to assess the possible solutions for strengthening these infrastructures. It provides the evidence-base needed to develop efficient and cost-effective solutions as well as convincing arguments for mobilizing finance for these.
The phase is divided in two parts:
a) Collection and analysis of information on the country situation
b) Assessment of the possible solutions

i Basis for assessing the national situation

The analysis of the baseline situation with regard to legal and institutional infrastructures governing the placement of chemicals on the market should take into consideration at a minimum:

- ⇨ The existing legal framework for chemicals management, including all legislation related to chemicals, in order to determine if there are gaps and inconsistencies in legislation governing the placement of chemicals on the market.

  The analysis of the legal framework should include a review of:

  - The prime or source law (e.g. the constitution of the country) that gives authority to develop legislation in the area of SMC. The scope of the source law is therefore critical for the review, as it normally clarifies key elements such as: the definition of ministerial powers, the division of powers between levels of government, the extension of protections for private property, the extent of protection for human rights, the definition of groups with unique rights, the ownership of natural resource, etc.
  - Laws (primary legislation) applicable to chemicals management. Laws should clearly define the principles on which a specific policy rests, as well as the roles, responsibilities and obligations of government bodies, industry, enforcement bodies, and any other group or individuals to which the law applies. Analysis of the existing laws should include all laws that pertain to chemicals management. It should also include an analysis of major implementation gaps in existing laws.
  - Regulations (subsidiary legislation). The review should focus on assessing if there are any major gaps in regulations governing the placement of chemicals on the market, as regulations often are required to give operational reality to the laws. Where gaps in regulations are found, the adequacy of the legislative authority to fill these gaps should be evaluated.
  - Rules of procedures. These rules play a key role for implementation of chemicals law as they provide the standard procedure to be followed for enforcement of this law and allow the courts to impose government policy on chemicals. This is a separate requirement to consider as rules of procedure must adhere to more than just the chemicals legislation in being consistent with other aspects of constitutional law, civil rights law, due process in criminal law, etc. This aspect is oftentimes forgotten when reviewing/developing new legislation, resulting in difficulties for ensuring enforcement of the requirements.

- ⇨ The administrative structure and institutional arrangements in place for chemicals management at the three levels of national administration (policy, management, enforcement) to assess possible gaps, overlaps and inefficiencies in the organization of national administration. This analysis should in particular focus on:
  - Existing authorities at the three levels
  - Coordination and cooperation mechanisms

- Available capacity and expertise
- Information management systems
- Monitoring and Surveillance systems

⇨ The current situation with regard to financing of the infrastructures, including existing cost recovery measures. This will allow for the development of a resources mobilization strategy for the proposed developments. Attention should be paid to:

- Current sources of funding (national and international)
- Existing cost recovery measures
- Legal basis for financing mechanisms
- Organization of national administration for resources mobilization
- Revenue collection and allocation mechanisms

ii Assessment of possible solutions

The map of the gaps in the existing regime governing the placement of chemicals on the market would then serve as the basis for the second part of the BASA, the solutions (and opportunities) assessment. This part involves three distinct actions:

⇨ First, the main gaps and needs should be determined based on the results of the baseline analysis.

⇨ Second, possible solutions should be identified based on a clear problem statement and of the goal for the process of strengthening legal and institutional infrastructures governing the placement of chemicals on the market, including opportunities for developing cost recovery systems.

⇨ Third, an assessment of the possible solutions should be performed. Several tools can be used in this regard. The possible tools should be considered with regard to the targeted audience. In particular, Cost-Benefit Analysis can be very useful for development of strong justification for convincing finance policy-makers to invest in the proposed developments.

3. Design of Policy Options

The detailed assessment will allow selecting the most relevant solutions in the country situation, and possibly prioritizing these solutions for phased implementation. Prioritization should be as transparent as possible and rest on relevant arguments. Based on the conclusions of phase 2., the selected policy options should be designed, including the development of:

i. Legislative proposals
ii. Proposals for institutional arrangements
iii. Cost recovery measures, where appropriate

i Development of legislative proposals

The development of legislative proposals should include three main components:

⇨ Consolidation in a new law/ harmonization of existing laws governing the placement of chemicals on the market
⇨ Development of key regulations
⇨ Amendment of related sectoral legislation

ii Development of proposals for institutional arrangements

The development of proposals for institutional arrangements may include:

⇨ Reorganization of existing administration/ arrangements
⇨ Creation of new bodies/ arrangements
⇨ Development/ reform of information management system
⇨ Reorganization of human and technical capacity

iii Design of Cost Recovery Measures

The design of measures for recovering the costs of national administration should include:

⇨ Necessary legislative phases to enable chemicals management to use cost recovery measures

- ⇨ Key design elements for proposed cost recovery measures

4. Development of a Business Plan

A business plan for the implementation and enforcement of the proposed developments should then be developed, including:

- ⇨ An analysis of the cost of the proposed infrastructures (incremental and operational)
- ⇨ An analysis of the possible funding sources, including a realistic timeline for availability of funding from the different sources
- ⇨ Development of a resources mobilization strategy

Analysis of the costs of the proposed developments and of the funding sources is critical for ensuring sustainable financing of the infrastructures. It also provides the basis for convincing finance policy makers of the viability of the proposals and of the benefits of investing in preventive chemicals management for the country's development. To this end, the use of the results of targeted assessment tools (such as Cost Benefit Analysis) should be considered.

5. Approval and Financing of the Plan

Political-level adoption of the plan is critical for the successful financing and implementation of the proposed developments. In particular, legislative proposals might require parliamentary approval to be enacted and it is therefore crucial to inform parliamentarians of the rationale for and value of the proposed developments. In addition, the plan should be presented to finance policy-makers as part of the national budget allocation process in order to ensure the required financing for the proposals.

The activities of this phase may certainly be different from country to country given the unique political cultures, institutions and processes. With informing and raising awareness among policy-makers being key for ensuring approval and financing of the plan, the development of targeted information material should be considered.

C. Key Elements for Strengthening Legal and Institutional Infrastructures Governing the Placement of Chemicals on the Market

The guidance aims to assist the strengthening of legal and institutional infrastructures governing the placement of chemicals for SMC in countries facing various chemicals management situation. Particularly important to consider in this regard is the way chemicals enter the national market; through imports, manufacture, and/or illegal traffic. In addition, countries using the guidance may be at different stages of development of their national chemicals management infrastructures, and the measures adopted need to be targeted to their specific situation.

The table 1 below presents the elements to be considered for strengthening legal and institutional infrastructures governing the placement of chemicals on the market in four typical country situations related to the way chemicals enter the national market. These elements are organized in four categories representing the main components of legal and institutional infrastructures for chemicals management[9]:

- ⇨ Organizational structure
- ⇨ Knowledge-base
- ⇨ Protective measures
- ⇨ Compliance schemes

The key elements presented in the first column of the table are the fundamental elements forming the basis of a national SMC system. Once these are in place, the system can then be developed by adding elements from the three other columns according to the country's situation and needs.

Table 1: Key Elements of Legal and Institutional Infrastructures Governing the Placement of Chemicals on the Market in Four Typical Country Situations

Country Situation		**Import; illegal traffic**	**Import, some manufacturing; Illegal traffic**	**Import, manufacture; Illegal traffic**	**Import, manufacture**
		small amounts, pesticides; disinfection chemicals	pesticides; fertilizers; disinfection chemicals; fuels	Pesticides; fertilizers; disinfection chemicals; metals; inorganics; basic bulk chemicals; specialty chemicals; production chemicals; PBTs; CMRs; historical chemicals	Pesticides; fertilizers; disinfection chemicals; metals, inorganics, basic bulk chemicals; specialty chemicals; production chemicals; PBTs; CMRs
Key Elements	**Organizational structure**	- Clear Mandates at the three levels of national administration	- Clear Mandates at the three levels of national administration	- Clear Mandates at the three levels of national administration	- Clear Mandates at the three levels of national administration
		- Inter-Agency Coordination Mechanism (ICM) - Pesticide board	- Inter-Agency Coordination Mechanism - Pesticide board - Other technical committee(s)	- Inter-Agency Coordination Mechanism - Pesticide board - Other technical committee(s)	- Inter-Agency Coordination Mechanism - Pesticide board - Other technical committee(s)
		- Clear allocation of public and private sectors responsibilities - Companies at least responsible for generation and dissemination of information on chemicals properties, hazards, risks and safe handling of chemicals	- Clear allocation of public and private sectors responsibilities - Companies at least responsible for generation and dissemination of information on chemicals properties, hazards, risks and safe handling of chemicals	- Clear allocation of public and private sectors responsibilities - Companies at least responsible for generation and dissemination of information on chemicals properties, hazards, risks and safe handling of chemicals	- Clear allocation of public and private sectors responsibilities - Companies at least responsible for generation and dissemination of information on chemicals properties, hazards, risks and safe handling of chemicals

Knowledge-base	- Use of existing information (inter-sectoral, national/international) - Information collection based on instruments; Classification and labelling, registration/ authorization, licensing, verification and monitoring	- Use of existing information (inter-sectoral, national/international) Information collection based on instruments; - Classification and labelling, registration/ authorization, licensing, verification and monitoring	- Integrated Surveillance System for categories of very-high concern chemicals - Partnerships with Universities, Research Institutes	- Integrated Surveillance System for categories of high concern chemicals
	- Register of highest concern chemicals (pesticides, biocides) - Inventory of primary suppliers of substances of particular interest for the country (Info: supplier's name, chemicals supplied)	- Register of highest concern chemicals (pesticides, biocides) - Inventory of data on import and manufacture of pure substances (technical quality) of particular interest for a country; possibly incl. volume data/classification	- Register of highest concern chemicals (pesticides, biocides) - Inventory of import and manufacture of mixtures in certain groups of chemicals (lubricants, paints, glues etc.) of particular interest for a country; possibly incl. volume data/classification	- Register of highest concern chemicals (pesticides, biocides) - Inventory of hazardous components in classified mixtures; in certain groups, group by group, possibly percentages of components, etc.
	---	---	- Limited notification scheme for the "new" chemicals not produced and registered elsewhere	- Notification scheme for "new" chemicals
Protective Measures	- WHO Classification Labelling	- WHO Classification or GHS	- GHS	- GHS
	- Bans and restrictions; very-high concern chemicals (including MEAs-chemicals)	- Bans and restrictions; very-high concern chemicals (including MEAs-chemicals)	- Bans and restrictions; very-high concern chemicals (including MEAs-chemicals)	- Bans and restrictions; very-high concern chemicals (including MEAs-chemicals)
	- Registration/ authorization for very-high concern chemicals	- Registration/ authorization for high-concern chemicals	- Registration/ authorization for high-concern chemicals	- Registration/ authorization for high-concern chemicals
	- Licensing of primary suppliers/ of high volume/ very-high concern chemicals	- Licensing of primary suppliers of high volume/ high concern chemicals	- Licensing of primary suppliers of high volume/ high concern chemicals	- Licensing of primary suppliers of high volume/ high concern chemicals

		- Import/export licenses for high volume/ very-high concern chemicals - Control of illegal traffic	- Import/export licenses for high volume/ high concern chemicals - Control of illegal traffic	- Import/export licenses for high volume/ high concern chemicals - Control of illegal traffic	- Import/export licenses for high volume/ high concern chemicals - Control of illegal traffic
	Compliance scheme	- Inspections prioritized on very-high concern chemicals - Reference laboratory - Qualitative testing for monitoring and verification purpose - Reporting upon request	- Inspections prioritized on high concern chemicals - Reference laboratory - Quantitative testing for monitoring and verification purpose - Reporting upon request	- Inspections prioritized on high concern chemicals - Reference laboratory + district laboratories - Quantitative testing for monitoring and verification purpose - Regular reporting and upon request	- Comprehensive inspection system - Comprehensive laboratory network - Regular reporting and upon request

III. The Organization of Legal and Institutional Infrastructures Governing the Placement of Chemicals on the Market

A. Organization of Legal Requirements Governing the Placement of Chemicals on the Market

Depending on the country's legal tradition and system, specific legislation is comprised of various documents (laws, acts, decrees, regulations, bills, notifications, ordinances, guidelines, rules of procedure, etc). While each of these has its specificities, they can generally be grouped in two main categories: statutes enacted by the national legislating body (laws), and regulations (all subordinated enactments).

The decision on which elements to include at the level of law and which to include in subordinate enactments is to be made based on the national legal tradition and structure. However, a general principle is that the law should be kept as basic as possible, so as to ease parliamentary approval and leave flexibility to the responsible authority for its implementation. Technical details and requirements likely to be modified should be relegated to regulations.

1. Laws

For the purpose of this Guidance, law is defined as parliamentary level legislation – statute enacted by the national legislative body (i.e. the Parliament). The law on chemicals management will clearly define the principles on which a specific policy rests, as well as the roles, responsibilities and obligations of government bodies, industry, enforcement bodies, and any other group or individuals to which the law applies.

As they have to be passed by a legislature or some other national legislative body, laws can be difficult to amend over time. As several elements of the management of the placement of chemicals on the market are highly technical and might need to be updated regularly, including them in law can be impractical. Therefore, typically, the specific purposes of the legislation are introduced and the responsibilities are defined in a general way with further details included in secondary forms of law-making such as regulations. Box 1. lists some of the essential components of a law governing the placement of chemicals on the market.

Box 1. Main structural components of a law governing the placement of chemicals on the market

- ⇨ Clear indication of the **objectives** and **scope** of the law, and **definitions** of key terms used in the law.
- ⇨ **An organizational structure** which clearly delineates the roles and responsibilities of key stakeholders, establishes the authority and ability to control chemicals and co-ordinates related management efforts.
- ⇨ **A knowledge base** to collect, interpret and disseminate information used to support decisions about which chemicals are acceptable for use and under what conditions;
- ⇨ **The establishment of preventive and corrective measures** designed to ensure the proper importation, production and use of chemicals
- ⇨ A **compliance scheme** to monitor, enforce and promote observance of legislative provisions
- ⇨ Clear indication of the **effective date**

Adapted from: IPCS-IOMC (August 1998); p 41.

2. Regulations

For the legal regime to be implemented, there can be no gray or poorly defined areas of obligation. Regulations are used to give details which clarify responsibilities, requirements and obligations set out in the law, and therefore give operational effect to it.

As regulations normally do not need to be approved by the Parliament but rests on the authority attributed to ministries and/or agencies in law, they are more easily revised. This is particularly suited for defining specifics of highly scientific, technical issues, tools and instruments, as these tend to vary significantly depending on the chemical substance(s) considered and with evolving knowledge. Including such requirements in regulations allows for more flexibility.

Regulations should in any case be developed on the basis of the general law(s) they are based on (i.e. using the same definitions), and requirements established in regulations should be consistent with those of the law. Requirements not underpinned by the law can easily be challenged. In addition, regulations should be developed in the view of comprehensively addressing the issue, so that the system established remains in place if the law is repealed[10].

B. Advantages and Disadvantages of a Framework Law

Two main options can be envisioned when considering how best to tackle fragmentation in regulatory regimes, depending on the country situation (legal tradition, existing legal structure, etc.). One approach is to consolidate legislation governing the placement of chemicals on the market by gathering the general requirements into a single law – laying down an institutional structure and principles, and leaving the details to be developed into specific subsidiary instruments. A second choice is to harmonize the various requirements governing the placement of chemicals on the market by amending existing laws and regulations.

1. The Advantages of a Framework Law

Some countries seeking to better govern the placement of chemicals on the market have favored creating a unique framework law distinct from – but linked to – other related legislation (i.e. environmental protection, workers protection, etc.).

Several arguments can be made in favor of this approach:

- Organization of general principles, roles, responsibilities and obligations for managing the placement of chemicals on the market is relatively similar for all chemicals and relatively invariable in time, therefore not requiring frequent amendments or updates. Organizing these general requirements in a single law governing the placement of chemicals on the market provides an opportunity to improve coherence and concentration of the legislation governing the placement of chemicals.
- In turn, coherent general requirements regarding placement of chemicals on the market will facilitate implementation and enforcement, and therefore reduce the costs of enforcement and increase efficiency of the legislation. This also makes it easier for authorities and companies to implement and comply with the obligations set out.
- In addition, as these legal requirements mainly target primary suppliers, concentration in a single law will ease access to the law by concerned stakeholders, again facilitating compliance.
- Because of its market and trade focus, legislation governing the placement of chemicals on the market requires a high level of international harmonization (i.e. compliance with the international trade agreements the country has ratified). Having a law governing the placement of chemicals on the market separate from other chemicals management legislation is therefore more convenient.
- Several important aspects of the chemicals-related MEAs (i.e. Rotterdam, Stockholm and Basel Conventions, International Labour Organization (ILO) Convention 170 concerning Safety in the Use of Chemicals at Work, etc.) are related to chemicals access to the national market. Including these aspects into a single framework law governing the placement of chemicals on the market therefore contribute to a more coordinated implementation of these conventions.

2. The disadvantages of a Framework Law

However, concentration of requirements into a framework law governing the placement of chemicals on the market can also include several challenges:

- Gathering elements for governing the placement of chemicals on the market can lead to concentration of powers in one particular ministry, i.e. environment, which may not be the most appropriate solution in all contexts given the relative capacity of ministries/agencies to meet their responsibilities.
- More generally, concentration of measures governing the placement of chemicals on the market might involve the redefinition of mandates on which ministries base their actions. This can generate resistance from ministries potentially "losing" parts of their current mandate. However, for most countries this will not be a problem as there is no existing legislation in the field.
- Gathering requirements governing the placement of chemicals on the market into one framework law, with regulations attached, can also require revising and amending many different laws, and might therefore give rise to temporary increased work loads and costs;
- Implementing cost recovery/earmarking measures generally is regulated in other, fiscal or budgetary laws, and it is often not possible to bring these requirements into a general chemicals law;
- In some countries, framework law may be uncommon and therefore difficult to develop, distracting resources from more important objectives[11].

Whatever the choice, the structure of legislation governing the placement of chemicals on the market must be coherent and appropriate to the national context.

It is crucial, however, that measures governing the placement of chemicals on the market are underpinned by a coherent strategy in order to avoid gaps and inconsistencies. Such a strategy should preferably be part of a general lifecycle chemicals management policy. This will ensure coherence and comprehensiveness of chemicals management legislation throughout the life-cycle, and facilitate high-level political buy-in and the mobilization of required financing for implementation and enforcement (see Section I.C.3).

For ease of access by regulated entities and the general public, it is recommended that legal requirements governing the placement of chemicals on the market are gathered in a single document. Structured presentation of these requirements can for example be provided in a booklet, on a website, or in a CD-ROM, depending on the technical means available to the regulated entities[12]. Generally, these collections of legal requirements regarding a specific topic are provided in multiple formats in order to be broadly available for use by the regulated entities.

C. Organization of National Administration

1. Mandates of Public Bodies

Typically, many public bodies participate in the various activities involved with the management of the placement of chemicals on the market. Management activities include:

- Issuing specific regulations;
- Providing technical support for policy-making;
- Daily coordination and management of chemicals management programmes;
- Testing and verification of information on chemicals properties, hazards and risks;
- Decision making on the registration of products and the issuance of licenses;
- Maintaining and updating inventories;
- Conducting inspections;
- Monitoring;
- Issuing injunctions;

- Preparing reports for public disclosure.

A list of the sectoral ministries generally engaged in some aspect of chemicals management is presented in annex 2.

Clarity and coherence in the allocation of mandates between public bodies is key to the efficiency and cost-effectiveness of the regime. Clear legal mandates establish the basis for the overall organization of institutional arrangements for chemicals management, while provision of adequate powers to responsible authorities ensures their ability to fulfill their mandate.

Mandates for these activities are to be clarified at the three main levels: the policy level, the management and implementation level, and the enforcement level. Clarity of mandates at the policy level, based on a common view between the various ministries on chemicals risks in general and how to manage them, ensures that each ministry involved has a specific role to play in management and enforcement activities and is going to cooperate for these activities. At the management level, clarity of mandates and powers ensures that daily management of the legislation (including coordination of implementation activities and issuance of regulations) is efficiently and cost-effectively organized between participating agencies. Clear mandates at the enforcement level ensure that there are no gaps, duplication and overlaps in inspections and monitoring activities, so that compliance can be ensured cost-effectively.

One approach for revising the allocation of mandates of public bodies would be to concentrate these into as few public bodies as possible. Concentration avoids duplication and conflict over mandates, is cost-effective and easy to access. In order to avoid problems such as lack of capacity to undertake the wide variety of tasks involved in holding broad mandate for implementing chemicals management policy, an efficient allocation and use of resources should be assured. In addition, when legal reform entails taking mandates away from institutions to place them in one single body it can give rise to internal resistance to proposed chemicals management policies.

Another approach is to identify areas of responsibility where duplication, gaps or lack of clarity are observed in existing public bodies mandates and to explore opportunities for improved synergies. Solutions for improving allocation of public bodies' mandates can include, depending on the situation:

- Reallocation of mandates towards more qualified bodies
- Undertaking of joint activities (i.e. joint inspections)
- Sharing of resources (finance, technological means, information, expertise)
- Harmonization of methods and procedures

However, it is to be noted that the more dispersed mandates are between public bodies, the more resources will be needed for coordination efforts. A careful assessment of the advantages and drawbacks of different approaches (including costs and benefits) should be performed in the country situation.

Table 2. An Overview of Pros and Cons for Concentrated and Coordinated Administrative Structures

Administrative Structure	Pros	Cons
Concentrated	• Avoiding overlaps/gaps in mandates and activities • Clarity and transparency • Cost-efficient	• Might be difficult to establish due to required reorganization of political mandates • Might need to get new expertise (by hiring or from outside) • Might not have the required capacity to perform the tasks
Coordinated	• Might be easier to reach consensus • Sharing of existing expertise • Specific responsibility allocated to the agency which has the capacity	• Requires more coordination and cooperation to avoid gaps/overlaps • Might be more costly • Might be less transparent and clear

2. Organization for Resources Mobilization

A key –though often neglected– element for ensuring the availability of the required resources is the establishment of institutional mechanisms enabling access of national chemicals management administration to national budget allocation process.

The development and mainstreaming of an integrated, cross-sectoral chemicals management policy, the demonstration of the benefits of investing in preventive measures, and the design of cost recovery measures with appropriate revenue collection and allocation procedures all facilitate the mobilization of finance for the regime. But these arguments ultimately need to be fed into the national budget process in the right form and in a timely manner in order to convince the budget allocation decision-makers to effectively allocate the required amount of finance for the proposed developments.

It is therefore critical to dedicate administrative resources and efforts towards effective participation of the national budget, based on a clear understanding of the functioning of the budget planning and allocation processes.

3. Information Needs and Exchange

The use of information is key for the development and sustaining of knowledge-based chemicals management systems. Information is the basis for designing a realistic chemicals management policy, for classifying chemicals and prioritizing regulatory actions, for making informed decision on which chemicals can be supplied and under which conditions, and for effective implementation and enforcement of the legislation.

Given the number of chemicals in circulation, the extent and diversity of data needed and the resources and capacity required for analysis and interpretation, the availability of information is often seen as an important issue for developing countries where such information is sorely lacking.

As a first step, validated information from other countries or international bodies can be used as a basis for national chemicals management. In addition, setting up mechanisms for cross-sectoral information exchange can also help uncover a significant amount of information. Such mechanisms can then provide the foundations for the establishment of integrated information management systems required for informed decision-making.

i Main Types of Information

Various types of information are required throughout decision-making, management and enforcement of the legislation. The key types of information include:

- **Flows of chemicals in the country** (including imports, exports, sales, manufacturing). Such information provides knowledge of the country situation with regard to primary supply of chemicals (imports, manufacture). Such knowledge is critical to make informed decisions on which chemicals to regulate, as well as on the type and design of the control measures.
- **Properties and hazards of the chemicals** placed on the market. Knowledge of the inherent properties of the chemicals placed on the market is required for classification of chemicals, as a basis for prioritization of regulatory action. As well, product labeling is often based on chemicals hazards.
- **Chemicals risks for human health and the environment** (including exposure monitoring, problem reporting, etc.). While inherent properties and hazards of chemicals provide useful information on their potential effects, the practical risks of chemicals also depend on the mode of use and exposure. Control measures such as registration/ authorization generally rely on localized risk assessments.

ii The Use of International Sources

A significant amount of information can be collected from international sources. This especially regards information on scientific assessments of chemicals properties, hazards and risks made in developed

countries or by international organizations, but also information on existing systems for and experience in regulating the flow of chemicals, international guidelines and methodologies, etc.

Such existing information can to a certain extent be useful for other countries, and use should be made of it as far as possible as it will avoid duplication of work and save costs. In addition to the support it provides for national activities, internationally collected information provides a good basis for comparing local exposures with international guidelines, standards, limits and control options[13].

Internationally available information should however be used with caution. First, only validated sources should be assessed, as information uploaded on the internet is not always reliable. In addition, risk assessments made in countries should be carefully assessed before being applied in the national context. In effect, the evaluation of chemicals risks depends on the specific local conditions (i.e. use patterns, types of ecosystems, etc.), meaning that risks assessment might not be relevant in different conditions.

Countries where such localized information is lacking can make use of information generated in countries with relatively similar conditions. In particular, opportunities of using information produced in the region should be explored, especially in cases of shared conditions and/or ecosystems. Regional or sub-regional cooperation for information sharing can also be valuable (see section D.5 below). In addition to reducing the costs of data generation and analysis, this can allow the development of a broader experience base.

A list of international, regional, national and local sources of information is provided in annex 3.

iii Information Exchange

Better use of existing information can also prove to be very useful. Various agencies and stakeholders collect information related to chemicals supply, use, characteristics and impacts. However, as chemicals management is generally fragmented between various public bodies and non-government stakeholders, information tends to be fragmented too; hampering sound analysis of what is happening in the country and how to effectively take action.

A careful cross-sectoral assessment and analysis of existing chemicals-related information often helps uncover precious information for chemicals management. Therefore, a key need for efficient knowledge-based and integrated chemicals management is the development and ongoing use of mechanisms for information exchange. Several mechanisms can be set up in this regard, including[14]:

- ⇨ *Meetings and Forums*
- ⇨ *Designation of Chemicals Focal Points*
- ⇨ *Central Repositories of Chemicals Information/ Chemicals Information Center*
- ⇨ *Shared databases*
- ⇨ *Chemicals Information Website/ Inventory*
- ⇨ *Newsletters, bulletins, etc.* (both hardcopy and electronic)

iv Health and Environment Surveillance

Protecting human health and the environment are two major inter-related goals of a sound management of chemicals policy. In this respect, localized information on chemicals' impacts on ecosystems and human health is critical for informed chemicals management decision-making, implementation and evaluation. However, the lack of such information is often seen as a major issue for DCs with very limited budgets and capacity.

Recent experience as part of the UNEP-WHO Health and Environment Strategic Alliance (HESA)[15] has shown that a significant amount of information on environmental degradations and on health issues is already regularly collected in countries. But improved inter-sectoral coordination for information collection and management could significantly improve strategic analysis of the environmental determinants to health diseases, allowing the design of integrated actions on health and environment.

Health and environment monitoring activities are not strictly part of legal and institutional infrastructures governing the placement of chemicals on the market. However, the review of these infrastructures provides an opportunity to improve health and environment surveillance systems as a basis for chemicals

management decision making by strengthening inter-sectoral collaboration, and information collection and management systems.

D. The International Dimension of the Placement of Chemicals on the Market

The trade-related approach underlying the focus on legislation governing the placement of chemicals on the market requires that special attention be paid to the links between these requirements and the international/ regional dimension of chemicals management.

1. Prevention and Control of International Illegal Traffic of Chemicals

One of the main areas of focus of legislation governing the placement of chemicals concerns bans and restrictions. Of critical importance in this regard is the prevention and control of international illegal traffic of these substances[16].

While this issue is addressed in many specific projects, and is therefore not the main focus of the Guidance, care should be taken to address the elements of illegal traffic related to legal and institutional infrastructures governing the placement of chemicals on the market. The first step is to include trade and customs stakeholders in the inter-sectoral discussions.

Illegal traffic is generally dealt with in specific legislation. However, given the crucial importance of this issue in a trade-oriented approach towards the sound management of chemicals, special attention should be paid to adequately link legislation governing the placement of chemicals with the national legislation for prevention and control of illegal traffic of chemicals (see section A.4 above).

Prevention and control of international illegal traffic is also an important component of the national implementation of chemicals-related Multilateral Environmental Agreements (MEAs) (see sub-section section 5 below). If countries are Parties to these MEAs, international illegal traffic should therefore be addressed as part of the coordinated implementation of these MEAs, in line with international requirements.

2. Compliance with Trade Agreements

Countries undertaking a review of their legislation governing the placement of chemicals on the market will generally be part of at least one supra-national trade agreement. Such agreements are numerous and include the World Trade Organization (WTO) and other international trade agreements, as well as regional/sub-regional trade agreements and integration processes (i.e. customs unions, political integration processes within a region, etc.).

Using the international trade regime as an example, the General Agreement on Tariffs and Trade (GATT) establishes the core legal principles of the WTO with which all Parties must endeavor to comply. Article I sets out the 'most-favored nation' rule whereby tariff and technical barriers to trade exist, all nations are subject to same treatment. Article III establishes the national treatment rue whereby 'like'[17] goods and services of other countries are required to be treated the same under tariff and non-tariff regimes as domestic goods and services. Article XI specifically prohibits the use of import or export bans or quotas, though to date there have been no disputes raised with the Multilateral Environmental Agreements. The environmental exceptions – Article XX – allow parties to adopt measures necessary to protect "human, animal or plant life or health", and exhaustible natural resources, subject to certain conditions[18] and the requirement that measures do not constitute arbitrary or unjustifiable discrimination between countries or a disguised restriction on international trade.[19]

Other particularly relevant agreements include the Agreement on Technical Barriers to Trade (TBT), the Sanitary and Phytosanitary Agreement (SPS) and the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs). International chemicals management links include labeling requirements, human health and environmental standards (particularly under the SPS which deals with "necessary" standards to protect human, animal and plant life and health from hazards associated with international trade of plants,

animals and foodstuffs), and measures to protect intellectual property rights in registration processes for chemical substances.[20]

The review of legislation governing the placement of chemicals on the market – and any associated cost recovery charges that if only apply at national boarders could be viewed as discriminatory measures – should be performed with due attention paid to the links of these requirements with international/regional/sub-regional trade agreements. This is especially important at the stage of selecting and designing the policy measures that will be enforced; so that these measures are in accordance with the trade agreements the country is Party of.

3. Harmonization with International Standards and Norms

Various standards and norms related to chemicals management have been adopted at the international level. These include the FAO Code of Conduct on the Distribution and Use of Pesticides and implementing guidelines, standards on classification and labeling such as the Globalized System for Classification and Labelling of Chemicals (GHS), on the transport of hazardous materials, norms on maximum residue limits of agricultural products, etc.[21] These standards and norms allows for international harmonization of national requirements, and facilitate international trade. They also provide useful guidelines for the development of national measures.

However, they might not always be relevant or suitable in the country's situation. Examination of their applicability in the country should be performed as part of the review of legal and institutional infrastructures governing the placement of chemicals on the market.

In general, it is advised not to significantly adapt international standards to national conditions, as this would diminish their usefulness in terms of international harmonization and facilitation of trade. However, a certain level of adaptation to national circumstances might be more relevant than simply rejecting the standard.

4. Coordinated Domestication of Chemicals-related Multilateral Environmental Agreements

Various Multilateral Environmental Agreements (MEAs) are dealing with components of the sound management of chemicals. While many aspects of these agreements require relatively similar interventions, national implementation is often managed by different authorities, and has therefore suffered from fragmentation.

Several important aspects of the chemicals-related MEAs (i.e. Rotterdam and Stockholm Conventions, Montreal Protocol, International Labour Organization (ILO) Convention 170 concerning Safety in the use of Chemicals at Work) are related to chemicals trade and placement on the national market, and involve similar requirements such as labelling and classification, provisions for marketing, bans and use restrictions, import/ export control requirements, prevention and control of international illegal traffic, etc.

When examining options for harmonizing/ consolidating legal requirements governing the placement of chemicals on the market, incorporating the requirements of chemicals-related MEAs into this legislation should be considered. [22] Furthermore, it is critical to include the MEAs' Focal Points or Designated National Authorities (DNAs) in inter-sectoral mechanisms. This will ensure coordination of national chemicals management activities including chemicals-conventions implementation, and consistency with international chemicals management requirements.

5. Regional Harmonization and Cooperation

Regional/sub-regional harmonization can be beneficial for trade relationships with regional/sub-regional trade partners. Furthermore, engaging in a process of cooperation with neighboring countries can provide opportunities for sharing of knowledge and resources (i.e. by grouping activities at the regional level, sharing expertise, human resources, etc.).

Opportunities for regional/sub-regional harmonization and cooperation should be assessed throughout the process of reviewing national legal and institutional infrastructures governing the placement of chemicals

on the market. Regional cooperation can be initiated through an existing regional agreement where such agreement exists. In addition, such cooperation can be established in a phased approach; starting from cooperation on specific issues (i.e. common criteria for registration/ authorization and mutual recognition of registration/ authorization decisions, sharing of information on chemicals risks and flows, establishment of a shared laboratory network, etc.).

Box 2. International elements to consider in the review of national legislation governing the placement of chemicals on the market

When strengthening their legislation governing the placement of chemicals on the market, countries should:

- ⇨ Take into account the prevention and control of international illegal traffic of chemicals, especially by building appropriate links with legislation on illegal traffic, including international commitments.
- ⇨ Pay attention that the measures adopted for the management of the placement of chemicals on the market do not conflict with the country's obligations with regard to international trade agreements.
- ⇨ Consider harmonizing national measures to international standards and norms, especially the Globally Harmonized System for Classification and Labelling of Chemicals (GHS).
- ⇨ Consistently integrate the trade-related requirements of chemicals MEAs into the legislation governing the placement of chemicals on the market for more coordinated national domestication of these MEAs.
- ⇨ Consider the opportunities for regional/sub-regional harmonization and cooperation.

IV. Main Considerations for Legislation Governing the Placement of Chemicals on the Market

A. General

1. Purpose and Objectives

Legislation governing the placement of chemicals on the market must demonstrate a high level of transparency if it is to be a key driver in providing policy coherency. As such, the purpose and objectives of the legislation must be clearly stated.

The purpose of legislation is generally stated as an introduction to a law (either in a non-legally binding preamble or in the first article). In case harmonization is preferred to consolidation, and no specific law is developed to govern the placement of chemicals on the market, the objectives and scope should at least be stated in an underpinning strategic document. Special attention should be paid that the proposed measures consistently address the same objectives.

Typical objectives include the fulfillment of the country's international commitments, and the protection of human health and the environment. However, objectives more directly related to the country's development objectives should be considered: such as the promotion of safer alternatives, achievement of the Millennium Development Goals, etc. The ultimate goal of Sound Management of Chemicals is to minimize chemicals negative effects on health and the environment to fully benefit from their positive impacts in terms of development. Therefore, the integration of chemicals management policy into national development policy is key for improved efficiency of national activities.

2. Scope

As legislation gives formal reality to a policy, its scope needs to be accurately defined. Accurate definition of the scope of legislation includes the clarification of its coverage in terms of substances, risks and activities. This is to be done in light of the purpose and objective of the policy, and taking into account the links with other existing legislation on chemicals management, which are to be clarified.

i Coverage of Substances

The value-added of legislation governing the placement of chemicals on the market mainly lie in its broad coverage in terms of substances and mixtures, so as to provide a harmonized framework for dealing with trade-related aspects of chemicals management. In that sense, the scope of legislation governing the placement of chemicals on the market should preferably include as many substances as reasonably possible[23].

The management of pesticides is typically regulated separately from other chemicals. This is justified by the intended highly hazardous nature of these substances, and by the high probability of exposure. However, given the similarities between general principles and processes regulating the marketing of these and other chemical substances (industrial, consumer chemicals), it seems appropriate to include these requirements into the scope of legislation governing the placement of chemicals on the market.

The choice of whether or not to include pesticides into the scope of legislation governing the placement of chemicals on the market is to be made in line with the national context. If it is decided to include the management of the placement of pesticides on the market, adequate provisions should be included clearly indicating that the requirements governing these substances will be the responsibility of the competent authorities (i.e. ministry in charge of agriculture) (see section C.3 below).

If the choice is to keep pesticides management separated, attention should be paid to avoid duplication and overlaps in tasks and responsibilities – such as the development of dual systems for managing (i.e. registration/ authorization) pesticides used in agriculture and those intended to other uses (i.e. industrial, household, health protection, etc.). It is recommended to align legislation on industrial chemicals to the

Code of Conduct and its accompanying technical guidelines and to ensure consistency in the implementation of both areas.

Chemicals largely flow into national markets through products and articles, and environment and health risks are in this case due to leakages of chemical substances from these articles. As such, risk management policies and measures should address the risks resulting from chemicals in products. Attention to this issue has only recently been growing internationally. However, several efforts are under way in this regard[24], and this area is likely to become more prominent in the near future. Legislation should therefore at least indicate if the risks from chemicals in products are covered and in what way.

ii Coverage of Hazards and Risks

The scope of legislation governing the placement of chemicals on the market should cover hazards and risks, regarding environment, health and property.

This broad coverage of hazards and risks is important as measures and requirements governing the first preventive step of chemicals risks management will influence management at other points of the supply chain. Mismanagement practices at later phases of the lifecycle can be damaging to human health, the environment as well as to property, and it is therefore crucial that legislation on managing the placement of chemicals on the market recognizes these harms and provide a legal basis for the management of chemicals after their placement on the market.

With regards to the protection of human health, chemicals' risks for workers, consumers and the general public should be included, as these groups are all vulnerable to chemicals' negative impacts.

iii Coverage of Activities

The focus of legislation on the placement of chemicals on the market in terms of activities covered must also be clarified.

Legislation discussed in these guidelines focuses specifically on requirements for generation, collection and dissemination of information on chemicals properties, hazards and risks as well as bans and restriction. These measures especially target primary supply of chemicals (manufacture and import), and can include uses to a limited extend (i.e. general measures for safe handling).

iv Links with other Chemicals Management Legislations

Sound management of chemicals is about managing all chemicals at every step of their lifecycle – from production to disposal. Legislation governing the placement of chemicals on the market will therefore always complement other chemicals management legislation (occupational health and safety, environment protection, food quality and safety, illegal traffic, pesticides, pharmaceuticals, etc.).

Consideration of pre-existing legislation is critical for the definition of the scope of legislation governing the placement of chemicals on the market. Careful delimitation of the scope of legislation governing the placement of chemicals on the market with regards to other existing chemicals-related legislation will allow avoiding gaps, overlaps and duplication in the overall lifecycle chemicals management legal framework.

Where specific chemical substances are governed by specific laws (radioactive substances, pharmaceuticals, etc.) including the management of marketing of these, the extent to which they are exempted (or not) from the legislation governing the placement of chemicals on the market must be clearly indicated in setting out the scope (with reference made to alternative legislation, where required).

It is important to take into consideration however that the scope of these laws is often limited and might not encompass all issues of importance for managing the marketing of the substances covered (i.e. raw material and/or environmental impacts are often excluded). Such gaps should be filled either by revising the specific laws, or by including the omitted aspects into legislation governing the placement of chemicals on the market.

In addition, legislation governing the placement of chemicals on the market will in any case operate in parallel with legislation on specific issues (i.e. general environmental protection, workers safety, transport of chemicals, etc.). The relationship between legal requirements governing the placement of chemicals on

the market and other chemicals-related legislation should be made clear – in particular which one takes precedence in case of conflicting requirements.

Box 3. Key considerations on the scope of legislation governing the placement of chemicals on the market

The scope of legislation governing the placement of chemicals should:

- ⇨ Define the coverage in terms of substances, and in case of split responsibilities specify which authority will be responsible for which group of chemicals
- ⇨ Address chemicals' hazards and risks to human health (including workers, consumers and the public), the environment, and property
- ⇨ Indicate the activities covered (i.e. placement on the market, especially targeting manufacture, and import)
- ⇨ Clarify the links with other legislation on chemicals management, including exemptions, with particular attention to the consistency of the requirements governing the placement of chemicals on the market.

3. Key Legal Principles

Enacted in legislation –often incorporated into a law– key underpinning legal principles can provide a useful basis for interpretation of the legal requirements in specific cases brought to the court, and for formulation of jurisprudence. Among the main legal principles encapsulated in SAICM are:

- ⇨ **Prevention:** chemicals should be managed before their negative impacts on health and the environment are observed for more efficiency and cost-effectiveness.
- ⇨ **Precaution:** Where there are threats of serious or irreversible health and/or environmental damage, cost-effective measures should be used even if some cause-and-effect relationships are not fully established scientifically.
- ⇨ **Polluter-pays:** The polluter should bear the costs of pollution prevention and control measures.
- ⇨ **Right-to-know:** Citizen and workers should have the right to know the chemicals to which they may be exposed during their daily life and the related risks for health and the environment.
- ⇨ **Knowledge-based management:** chemicals management decisions should be based on the most up-to-date available scientific understanding of chemicals properties, hazards and risks, communicated effectively through appropriate media, i.e. labels, safety data sheets, etc.
- ⇨ **Transparency:** Public authorities should make rules and measures publicly available.

Enactment of these and other legal principles in the new or revised legislation governing the placement of chemicals on the market should be considered carefully. An assessment of the applicability of these principles in the country situation, and in line with the objectives of the changes proposed, should provide the basis for the decision on which legal principles are incorporated into legislation governing the placement of chemicals on the market.

4. Definitions

Particular attention should be paid to the development of clear, accurate and up-to-date definitions of the terms and expressions used. Ensuring that ambiguity in interpretation of definitions is minimized will allow the legislation to be effectively enforced.

Only technical terms used in legislation (law, regulation) and potentially subject to interpretation should be defined from the start. Several international agreements provide definitions for the most common terms and expressions used in chemicals management. Using these internationally-agreed definitions would ease the definition of the main terms, allow for increased international harmonization and sharing of information, and therefore be beneficial for trade relationships. In order to avoid confusion and distortions

of markets due to unclear definitions, the clarifications elaborated in the GHS are recommended as the starting point for establishing these definitions.

Furthermore, flexibility should be provided to modify definitions if need be, as it is possible that new issues are identified, that new terms and expressions are introduced, and that definitions have to be modified consequently. For the same reason, flexibility should be given to governing bodies to define substances as "toxic" or "hazardous" even despite their categorization under the current definitions.

Special attention should be paid that all terms are coherently defined, so that the list of definitions is internally consistent. In addition, it is critical that all legal documents (laws, regulations, ordinances, etc.) governing the placement of chemicals on the market use the same definition when referring to the same terms. Using internationally agreed definitions would also facilitate such harmonization.

Box 4. Key considerations for the definition of key terms

Definitions of key terms related to the management of the placement of chemicals on the market should:

- ⇨ Be clear, accurate and specific
- ⇨ Encompass all relevant terms in applicable international instruments
- ⇨ Be up-to-date
- ⇨ Be broad enough to include all substances and uses covered under the scope
- ⇨ Be internally consistent
- ⇨ Only include the terms that appear in the legislation (law, regulation)

Adapted from: FAO (2007), *Designing National Pesticide Legislation*, p. 34.

B. Public and Private Sectors Responsibilities

Managing the placement of chemicals on the market has four main objectives[25]:

1. To generate/ obtain knowledge on chemicals properties, hazards and risks;
2. To disseminate information on hazardous properties of chemicals, and on safe handling procedures;
3. To make informed choices of chemicals in order to avoid hazards;
4. To organize the safe use of chemicals.

Achieving these objectives involves five phases including various activities presented in table 3 below.

Table 3. Main Phases in Managing Placement of Chemicals on the Market

Main Phases	Examples of activities
1. Identification and assessment of chemicals' hazardous properties and risks	• Collection of information on chemicals produced/used in the country • Establishment of requirement for testing and classification • Development of criteria and protocols for testing and classification • Organization and development of capacity for testing, assessment and classification • Pre-marketing testing • Classification of toxicity
2. Dissemination of hazard, risk and safety information	• Development of inventories • Establishment of requirements for labeling • Organization and development of capacity for labeling, and SDSs • Labeling, conveying of Safety Data Sheets • Training and outreach activities for suppliers
3. Making informed choice of chemicals to be placed on the market	• Organization and development of capacity for safe supply • Decision on chemicals to market for low-concern substances • Enactment of bans and restrictions

	• Substances authorization/registration for chemicals of high concern • Licensing primary suppliers (for chemicals of high concern)
4. Organization of safe use	• Establishment of requirements/criteria for safe use (especially for chemicals of high concern) • Decision on chemicals to use for low-concern substances • Development of measures and procedures for safe use • Organization and development of capacity for safe use
5. Compliance monitoring	• License/authorization inspections • Testing verification • Labeling verification • Testing of residues in products • Food monitoring • Monitoring of human health and environment

Managing the placement of chemicals on the market is a shared responsibility between the various stakeholders involved – in particular between public authorities and private companies. The allocation of roles and responsibilities for the tasks involved by such legislation defines the distribution of the costs incurred by these tasks. A fair allocation of roles and responsibilities is therefore critical, so that the costs of managing the placement of chemicals on the market are equitably shared between the public and private sectors[26].

In addition, attention should be paid to the respective capacity of public and private sector stakeholders to effectively conduct the tasks they are responsible for, as this will be determinant for successful implementation of and compliance with the requirements. In particular public authorities with very tight capacities and resources should not take responsibility for activities they can't perform.

General roles and responsibilities of the public and private sectors in the management of the placement of chemicals on the market should preferably be stated in a law. Roles and responsibilities related to certain measures that are defined in specific regulations can be specified in these regulations.

The current structure of the global chemicals market – in which private actors generally produce, handle and use chemicals – provides several arguments for allocating the main responsibility for ensuring safe use of chemicals to these actors for the following reasons:

- Given complexity of chemicals processes and uses, the State often doesn't have the capacity to control all the flows of chemicals in the national market;
- On the contrary, producers, importers, handlers and users, private actors and especially chemicals industries are in the best position to manage the chemicals they produce/ use. In particular, producers have the required expertise for assessing the properties, hazards, and possibly risks of the chemicals they manufacture;
- In addition, assigning the main responsibilities for risk management to the private sector is also a way to have private companies internalize the costs of their activities, the costs of some negative impacts (remediation activities, health care costs, etc.) being otherwise taken by the public authorities; and
- Requiring that risk assessments are performed by industry is also generally considered to encourage the private sector to seek less-hazardous alternatives.

In line with this stance, many developed countries have generally transferred significant portion of the tasks involved by sound management of chemicals to the private sector and away from governmental institutions. This approach requires State capacity for ensuring enforcement and compliance with the law. Private companies have the responsibility of performing the main tasks required by chemicals risk management and public authorities have the responsibility to ensure these tasks are performed correctly.

1. Responsibilities of Private Stakeholders

Whatever allocation of tasks between public and private sectors is chosen country situation, the responsibilities of entities which place chemicals on the market have to be clearly defined in the law.

The transfer of obligations to the private sector advocated by many developed countries involves the requirement on the private sector to carry out most of the main tasks involved in the management of the placement of chemicals on the market (See table 3 above). Most importantly, the generation and diffusion of information on chemicals properties, hazards, risks and handling procedures is the priority obligation[27].

This can also mean taking responsibility to make informed choices in marketing chemicals for which authorization/registration processes, bans or restrictions in use are nonexistent or not relevant, i.e. precautionary principle. Going further, the private sector is obligated to organize safe use of chemicals when legislation only requires that precautionary measures are taken while leaving the choice of the concrete action to the industries.

Primary suppliers (including producers/manufacturers and importers/distributors) being the main targeted private actors, they should in this approach bear the main responsibilities[28].

Typically, producers/ manufacturers are at least made responsible for:

- ⇨ Pre-marketing testing and classification;
- ⇨ Labeling and developing Safety Data Sheets;
- ⇨ Updating the information base when required.

Importers/ distributors are generally at least responsible for:

- ⇨ Conveying information provided by producers/ manufacturers to downstream actors;
- ⇨ Informing downstream actors in case they have identified new information with regards to chemicals hazards and risks.

Users have the minimum responsibility to obtain data and to take into account the risks and safety measures in the decision on which chemicals to use and how.

Other tasks that private sector stakeholders could be encouraged to perform with regard to the marketing of chemicals are presented in Box 5 below.

Box 5. Other possible tasks that companies could be encouraged to perform with regard to the marketing of chemicals

- ⇨ In the countries where they operate, support the efforts of the government authorities to secure a safe use of chemicals throughout the life-cycle;
- ⇨ Develop community right-to-know programmes based on international guidelines;
- ⇨ Fulfill the commitments made at UNCED, and incorporated in Responsible Care™ and product stewardship initiatives, to take responsibility for chemicals which they produce over their entire life cycle;
- ⇨ Implement the UNEP Code of Ethics on the International Trade of Chemicals and the provisions related to industry in the FAO International Code of Conduct on the Distribution and Use of Pesticides;
- ⇨ In the case of trans-national corporations, demonstrate their commitment to adopt standards of operation that are at least as stringent as those existing in their country of origin, wherever they may operate;
- ⇨ Work with industry in developing countries to encourage and support the development and adoption of relevant procedures for risk reduction.

Adapted from IPCS-IOMC (August 1998); p. 65.

When assigning responsibilities to private sector stakeholders, attention should be paid to the capacity of the targeted groups to fulfill the tasks they are responsible for. Small and Medium Enterprises (SMEs) – which in some countries represent a significant portion of the primary suppliers and are key drivers of employment and economic development– might not have the capacity to perform highly technical

assessments. Furthermore, as they often operate on the financial margins, they might not be able to bear the costs of complying.

To assist these, compliance promotion and training programmes can be developed (See Chapter V). Such programmes should however be designed in light of the allocation of responsibilities between the public and private sectors. In effect, when the main responsibilities for chemicals management are allocated to the private sector stakeholders, these should in principle take the necessary phases to comply with the legal requirements without help from the public authorities.

2. Responsibilities of Public Authorities

As well, the responsibilities and obligations imposed on governing bodies also have to be clearly stated in the legislation. For the proper function of legislation it is imperative that not only the private sector is obligated to carry out specific activities, but the governing bodies are also to be held accountable to perform their job.

In the approach adopted by most developed countries, the government bodies involved strive to maintain an oversight role – supervising the risk and management activities being carried out, by issuing legislation, providing general information on chemicals risks and enterprises' responsibilities, and by enforcing and monitoring compliance.

More precisely, public authorities have the responsibility for[29]:

- ⇨ Enforcing legal requirements and take the required measures to ensure compliance;
- ⇨ Ensuring they rely on up-to-date information about risks caused by chemical substances;
- ⇨ Participating in international co-operation;
- ⇨ Monitoring and report on compliance with the legislation.

C. Administration

1. Designation of the Primary Authority

Laws typically identify a Primary Authority responsible for supervision and management of the legislation. This facilitates the coordination of activities and avoids overlaps and duplication in the work of the various public bodies involved.

Generally, the Primary authority is a ministry (i.e. agriculture, environment, health, etc.) or a separate agency (i.e. Environmental Protection Agency). However, given the highly cross-sectoral dimension of chemicals management, this can create problems with regard to capacity to undertake the wide variety of tasks involved in holding broad responsibility for legal requirements governing the placement of chemicals on the market. Therefore, countries might judge more relevant to give shared authority for decision-making to several ministries/agencies. This can be done through the establishment of an executive inter-ministerial body as the Primary authority for the legislation (see section 2.*i* below).

A relatively new approach promoted by WHO and UNEP seeks the establishment of a strategic alliance between the Ministry of Health and the Ministry of Environment[30]. The strategic alliance then acts as a chair for an inter-ministerial mechanism gathering representatives from the other ministries having a stake in health and environment linkages. Particularly relevant in the case of chemicals management given the strong health and environment linkages associated with chemical substances, this approach has proven to be very useful and effective, as many complementarities between the health and environment sectors can be exploited for improved coordination and greater impact on decision-making and especially budget allocation.

In some situations, it might be relevant to have specific groups of chemicals managed by different authorities. In particular, in most countries management systems for agricultural chemicals are already in place under the authority of the ministry in charge of agriculture; while this ministry might not be the most appropriate to supervise the management of industrial chemicals.

If responsibilities for different aspects of the legislation are allocated to different public bodies, it should be clearly indicated. The law can simply indicate that some parts of the legislation can be delegated to other authorities than the Primary Authority, or specify which public body has the authority for which group of chemicals (i.e. Ministry of Agriculture for the management of pesticides' marketing).

In any case, adequate powers should be provided to the Primary Authority to carry out its mandate. Key powers include:

- ⇨ Issuing subordinate enactments (regulations, rules, guidelines);
- ⇨ Collecting and maintaining information on the chemicals regulated in the law, including the power to require information from the regulated entities;
- ⇨ Restricting and controlling chemicals production, import, uses and other activities;
- ⇨ Carrying out and ensure compliance with the law (i.e. conducting inspections);
- ⇨ Calling on other public authorities (including provincial/ local authorities) for assistance in the implementation and enforcement of the law;
- ⇨ Ensuring international communication and cooperation;
- ⇨ Charging fees for services provided.

In general, the power to issue subordinate enactments is not limited in the law, and the Primary Authority is authorized to issue all regulations required to achieve the objectives of the law. In some cases, a list of areas for possible regulations is included in an annex to the law.

It is also possible to give power to the primary authority to retain fees collected. However, this possibility depends on the national fiscal/budget legislation, which might set the procedure for collection and allocation of revenues collected. In addition, it might not be desirable for transparency and accountability reasons that the primary authority directly retains the fees outside of the national budget process. Several systems for revenue collection and allocation can be considered, depending on the country situation and on existing mechanisms[31].

2. Coordination Mechanisms

Various types of inter-sectoral mechanisms can be created to avoid conflicts over the allocation of powers and mandates, and promote cooperation. A clear legal basis for these bodies should preferably be established in law, including their mandate, functions and powers. Raising the function of Primary Authority to highest level of government (i.e. Prime Minister Office) can also help avoid or at least circumvent ministerial conflicts over mandates.

i Inter-Sectoral

Given the cross-cutting dimension of the placement of chemicals on the market, the primary authority will anyway have to collaborate with other government bodies to ensure effective and efficient management. These include other sectoral authorities, ministries in charge of finance and development planning, police authorities, provincial/ local authorities, focal points or Designated National Authorities (DNAs) for chemicals related conventions, etc.

Therefore, coordination mechanisms for chemicals management are often established by countries wishing to improve inter-sectoral collaboration for chemicals management. However, such mechanisms have not always been very effective, due to factors such as lack of commitment from involved ministries, lack of clarity in the mandate and powers, lack of resources, etc.

In this regard, setting forth a clear legal basis for such mechanisms can help. The development/ strengthening of legal and institutional infrastructures governing the placement of chemicals on the market in addition provides a good opportunity to establish coordination mechanisms for lifecycle chemicals management, or formalize the existing ones. Therefore, as part of the approach underpinning this guidance (see section I.C), the setting up of an advisory inter-ministerial coordination mechanism for SMC in general is recommended at minimum.

Various types of coordination bodies can be established; depending on their powers, mandate and functions. Essentially, inter-sectoral coordination mechanisms can be either advisory or have executive powers. They can have broad policy mandates, or take the form of technical committees, task forces or working groups can be set up to deal with specific technical issues.

Box 6. Legal basis for inter-sectoral coordination mechanisms

Key provisions to be included in legislation regarding the establishment of coordination mechanisms include:

- ⇨ Clarification of the powers, mandate and functions of the mechanism;
- ⇨ Designation of the authority to appoint members;
- ⇨ Definition of the membership, especially with regard to the qualifications of the members;
- ⇨ Definition of conditions for appointment and removal;
- ⇨ Delineation of rules of procedure;
- ⇨ Authority and provisions for setting detailed procedures;
- ⇨ Permission to establish working groups/ task forces/ sub-committees.

Adapted from FAO (2007); p. 39.

ii Multi-Stakeholders

As well, participation of non-governmental stakeholders in decision-making can provide valuable inputs into the process, and facilitate understanding of and compliance with the requirements. Therefore, mechanisms should be set up to allow participation of these stakeholders. On the other hand, public authorities should ensure their independence in decision-making, and participation of non-governmental stakeholders should as a result be limited to a consultative role.

3. Delegation

The nature of legal and institutional infrastructures governing the placement of chemicals on the market provides a strong rationale for allowing delegation of powers. First, the highly scientific and technical characteristic of preventive and knowledge-based management requires the availability of adequate capacity and resources generally spread between the various public bodies in charge of chemicals management. Second, the frequent need for updating of technical requirements implies that rapid amendments may be required, without having to legislate. Therefore, the legislation should include a provision allowing the Primary Authority to delegate powers to subordinated bodies.

In addition, if the authority for supervision and management of the some aspects of the legislation is allocated to different public bodies (i.e. ministry in charge of agriculture for pesticides management), adequate provisions should be included clearly indicating that the management of these aspects will be delegated to the competent authorities.

Furthermore, in federal countries or countries engaged in a decentralization process, delegation to provincial/ local authorities should be included. In general, national authorities are responsible for matters of policy, standardization and harmonization while provincial/ local authorities are made responsible for some aspects of practical implementation, monitoring and enforcement activities. However, such provisions will likely depend on the allocation of powers included in the source law (i.e. the constitution) or in a national decentralization policy.

D. Policy Instruments governing the Placement of Chemicals on the Market

Legislators can use a wide spectrum of policy instruments to implement effective legislation governing the placement of chemicals on the market. The most commonly used instruments in environmental policy are regulatory (also called 'command and control'), but many other instruments are used, including economic ones.

Depending on the type, as well as on their design, including enforcement mechanisms and sanctions in case of non compliance, policy instruments can have a regulatory, economic or information component, or – more often – a mix of these three components.

Bans and restrictions, classification and labeling registration/ authorization and licensing systems are the standard regulatory policy instruments applied through legislation governing chemicals marketing and for this reason are the primary focus for this guidance.

1. Development of Inventories

The development of inventories (lists or registers) allows public authorities to keep track of the chemicals flow (chemical substances that are imported, produced and/ or used) in the country. Such information is key for decision-making, as well as for the implementation of the Prior Informed Consent (PIC) procedure of the Rotterdam Convention that requires that governments know which chemicals are in use in the country.

Various types of inventories can be developed; from the simplest ones only including names of the substances or companies with their addresses and the chemical substances they handle, to the most complex computerized ones including a variety of data. However, maintaining an inventory is a relatively costly activity for public authorities, and the more complex the system is the more costly it is likely to be. Therefore, the development of complex inventories for all chemicals might not be the best option to prioritize for countries with very scarce resources to invest in chemicals management, and simpler designs might have better results.

Registration systems for pesticides typically include record-keeping requirements for the responsible authority, and therefore the development of an inventory with relatively detailed information[32]. For other, lower-concern chemicals, as a first step the establishment of a simple inventory of primary suppliers (including importers and producers/manufacturers) could be considered, as a basis for planning and inspection work. Depending on the availability of resources, the inventory can be further developed by adding information on the types, uses and contents of the chemicals placed on the market by the inventoried primary suppliers. This would allow generating a general overview of the flows of chemicals in the national market and provide useful information for decision-making and implementation.

It should be noted that an inventory is only useful if properly maintained and updated. Therefore, adequate procedure should be developed and resources allocated in this regard. In addition, several public bodies might need to access information collected in inventories for implementation and enforcement purposes. For this reason, adequate mechanisms for shared access to the inventories should be set up, including for example the establishment of shared databases.

An inventory can be developed on its own, but it is often used in complement to authorization/registration or licensing, depending on the capacity of public authorities and of the private sector to handle the tasks involved by the system. Countries having developed inventories of pesticides should take advantage of these existing structures and of the data available.

Box 7. A stepwise approach for building up an inventory in a context of scarce resources:

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

Adapted from Bucht (2008); p. 17.

i Notification Schemes

Many countries with advanced chemicals management systems have introduced general notification scheme for all "new" chemicals –chemicals that were not in use in the country before a specified date. Very demanding in terms of resources and expertise, such systems are used to generate information, and facilitate regulatory decision on chemicals not produced and used elsewhere.

In most DCs, the chemicals used were primarily formulated in other countries. Information on the properties and hazards of these chemicals should already have been generated in the producing country, and can be used as a basis for decision making (see section I.B.3). For these reasons, the development of notification scheme is only recommended in countries where chemicals are formulated. As they are very resources intensive, such schemes can be restricted to the categories of chemicals produced in the country and that are not already registered/authorized in a country with a reliable system in place.

2. Classification and Labelling

Classification and labelling is one of the most important measures for the management of the marketing of chemicals. It allows information on chemicals properties, hazards, risks and safe use procedures to be generated and disseminated throughout the supply chain, and thereby ensures a possibility for informed chemicals management decisions. In addition, design and enforcement of classification and labelling systems have proven to provide valuable domestic experience on several aspects of chemicals management. Therefore, classification and labelling should be one of the first measures to be developed as part of legislation governing the placement of chemicals on the market.

i Assessment and Classification

Legislation should indicate which standard has to be used for hazard assessment and classification. The list of criteria to be assessed and detailed protocols can be included in specific regulations. Assessment and classification criteria are the basis for establishing and implementing registration/ authorization and licensing systems. Therefore, attention should be paid that requirements and criteria for making decisions on registration/ authorization of chemicals and licensing of suppliers are consistent with assessment and classification criteria.

ii Labelling

Labelling of chemicals ensures that information on the chemicals hazardous properties is conveyed throughout the supply chain to the end users. It is critical that information included in labels is understandable to all the users. Labelling requirements therefore have to be tailored to the targeted audience, while using internationally recognized pictograms.

iii Classification and Labelling Schemes

Hazard assessments, classification, and labelling shall ideally be done in accordance with the Global Harmonized System for Classification and Labelling of Chemicals (GHS) and related safety Data Sheets (SDS)[33]. This is because:

- GHS is the most internationally recognized and used standard, and its use ensures international harmonization of classification and labelling of all types of chemicals;
- It facilitates international trade of chemical substances and products containing chemicals, including facilitating access to developed countries' markets for DCs' products (i.e. food, textiles, etc.) in complying with importer requirements;
- GHS gives access to the knowledge on chemicals hazards already generated in other countries, and therefore reducing the costs of assessing all chemical substances entering the country;
- GHS is a way for improved national implementation of trade-related chemicals MEAs.[34]

If GHS with SDS are selected as the instruments to be used in the country for classification and labelling of chemicals, it is suggested that as few modifications as possible are made so that its benefits in terms of international harmonization of classification and labelling are maintained. The legislation should in that case clearly state the requirement for users/producers/distributors to follow standard protocols in SDSs and GHS for storage and transportation. This would include requirements for proper signage on transport vehicles and storage vessels, records of transport, and use of specific safety equipment and vehicles.

In case other instruments for classification and labelling are selected, coherent protocols should be required to be followed, and clearly described. GHS and SDSs and related guiding documents can still be used as sources of information and inspiration for designing new systems.

Classification and labeling requirements should in principle be similar for all types of chemicals, imported and manufactured. In this regard, it should be noted that assessment and classification of pesticides is generally done on the basis of the WHO hazard classification as recommended in the FAO Code of Conduct (Article 7.2)[35]. The WHO classification is not entirely compatible with GHS, especially as it does not take into account chronic effect of pesticides. However, efforts are underway to harmonize both systems and WHO Hazard Classes have recently been aligned to the GHS Acute Toxicity Hazard Categories.

While implementation of GHS should be considered, it might currently be difficult to implement in some countries with limited resources and capacity as information on chronic effects of chemicals might not be easily available. Therefore, countries may wish to adopt a phased approach to classification by adopting the easiest standard to implement (WHO Hazard Classification) in a first step, and moving to the GHS once the capacity and resources are available.

Box 8. Key elements of the legal basis for classification and labelling

With regard to classification, legislation should:

- ⇨ Indicate the standard to be used for hazard assessment and classification;
- ⇨ List the criteria to be assessed and protocols for assessment;
- ⇨ Ensure that requirements and criteria for making decisions on registration/ authorization of chemicals and licensing of suppliers are consistent with assessment and classification criteria.

With regard to labeling, legislation should:

- ⇨ Be in accordance with international guidelines;
- ⇨ Specify the language(s) and pictorial representations to be used in line with the country situation;
- ⇨ Clarify which information should be included in labels, including appropriate custom code from the World Customs Organization to comply with the Rotterdam Convention;
- ⇨ Characterize how the information is to be communicated (i.e. the size of the label, the measurement system to be used, translation into local languages, rules for affixing labels on the package, etc.).

With regard to Safety Data Sheets (SDSs), legislation should:

- ⇨ Indicate the information to be contained in SDSs
- ⇨ Specify the form and language to be used
- ⇨ Require that an SDS be sent to each importer

Adapted from FAO (2007); pp. 64-68.

3. Bans and Restrictions

Bans and restrictions are the most stringent type of regulatory instruments for chemicals management. They set forth a schedule or list, of specific compounds which are considered to cause unacceptable risk to human heath and/or the environment. While bans strictly prohibit the production, sale and/or use of the substance, restrictions limit the availability of the chemicals to specific uses/ conditions.

In the approach adopted by most developed countries, the choice of chemicals to place on the market is in general the responsibility of the private sector. However, bans and restrictions on the supply of chemicals can be imposed by public authorities on substances that are judged to cause an unacceptable risk for populations' health, the environment and/or property[36]. Bans and restriction decisions are generally based on a localized assessment of the substance's risks as well as on the country needs. Therefore, replication of bans and restrictions in place in other countries should in general be avoided, unless such decision is part of a regional cooperation scheme or if evidence shows that similar risks are anticipated in the national conditions.

The power of the Primary Authority to ban or restrict the supply or use of chemical substances should preferably be enacted in a law. However, specifics (i.e. the list of substances banned or restricted, the schedule for banning/restricting the supply, etc.) can be included in regulations.

Several chemicals-related MEAs, which also provide a good basis for establishing the legal foundations for national chemicals management systems, include bans and restrictions of certain chemicals. National domestication of these requirements should preferably be done within legislation governing the placement of chemicals on the market (see section III.D.4).

The Stockholm Convention includes lists of Persistent Organic Pollutants (POPs) which production and use are to be banned (Annex A) or restricted (Annex B). The Montreal Protocol requires Parties to eliminate the

production and consumption of substances that deplete the ozone layer (ODSs). As well, the Rotterdam Convention on Prior Informed Consent impose that Parties who don't consent to import a chemical substance listed in Annex III also prohibit national production of this substance. If the Party consents to the import with conditions, the same conditions have to be imposed on production. In addition, Parties that ban or restrict import/production of a chemical have to notify the Convention Secretariat in written within 90 days.

Furthermore, the FAO Code of Conduct on the Distribution and Use of Pesticide recommends that countries ban the placement of very hazardous pesticides (i.e. WHO classes Ia and Ib) on the market when sufficient control measures or good marketing practices for the product to be used safely can't be ensured[37]. This precautionary approach is particularly relevant to the situation of countries with very limited enforcement capacity, and adopting a similar one for industrial chemicals should be considered.

4. Registration/ Authorization

A third category of policy instruments that can be used in the management of the placement of chemicals on the market is registration/ authorization. Detailed guidance on the development of registration systems – including legislation – is provided in the implementing guidelines of the FAO Code of Conduct[38]. Therefore, only the main elements are addressed in this section.

i Registration/ authorization process

Registration/ authorization is essentially the assessment by public authorities of information on chemicals that companies wish to place on the market, in order to determine that the substance is efficient for the intended use while not causing unacceptable risks to human health, the environment and property.[39]

Companies or individuals wishing to place a chemical on the market submit an application dossier containing information on the chemical to the responsible authority, according to the conditions and format specified. The responsible authority reviews the dossier based on defined criteria (preferably based on internationally recognized guidelines), and decides to a) approve, b) approve with conditions, or c) deny the registration. In case a decision can't be made based on the data provided, the responsible authority can generally ask the applicant for additional information.

Registration/ authorization approval enables the applicant to conduct a specific activity (import, manufacture, packaging, labeling, storing, sale, and/ or distribution) with a particular substance, mixture or product for a limited period of time. Denial of registration/ authorization forbids the applicant from carrying out the foreseen activity, but – contrary to a ban – does not prevent a new application to be submitted for the same product. Decisions to deny the registration of a chemical can however lead the authorities to ban or restrict its production and use (see section D.3 above for more information on bans and restrictions).

Registration/ authorization decisions can typically be reviewed in case of availability of new information on the chemical risks. Based on this, the responsible authority can impose new conditions or revoke the registration/ authorization.

Registration/ authorization systems for pre-market approval of products, discrete substances or mixtures are generally combined with the development of inventories (see section D.1 above). This allows keeping track of registered chemicals, and contributes to the building of an information base on chemicals risks. Special attention has to be paid to ensuring the confidentiality of information provided (i.e. see section H below).

Box 9. Key legal requirements for registration/ authorization

Elements to be included in legislation with regard to registration include:

- ⇨ Identification of the responsible body and clarification of its powers and function
- ⇨ Indication of substances/ activities included in authorization/ registration
- ⇨ Application procedure, including:
  - Indication of who should apply
  - Procedure in case of chemical already registered/ under conditional approval
  - List of information to be included and application form to be used
  - Exemption of small quantities imports for scientific purposes, including criteria
- ⇨ Decision-making procedure, including:
  - Clarification of the decision-making criteria
  - Time for authorities to deliver a decision
  - Procedure for denial of registration and appeal
  - Indication of the validity of the registration/ authorization
- ⇨ Conditions for review, re-registration, revocation
  - Provisions for review and change in conditions in view of new information
  - Possible provisions for periodic re-registration
  - Power of the responsible authority to revoke authorization/ registration
- ⇨ Responsibility for and content of record-keeping
- ⇨ Provision for confidentiality of information

Adapted from: FAO (2007); pp. 42-49.

ii The Use of Registration/ authorization

Registration/ authorization can be a powerful instrument for making informed decisions on chemicals to be used in the country, as well as for generating comprehensive knowledge on chemicals properties, hazards and risks. However, it is also demanding in terms of expertise, finance and time for public authorities and companies. Registration/ authorization requires an extensive and costly process of development, review and verification of data on chemicals properties, hazards and specific risks in local conditions.

Therefore, this instrument is not recommended for all chemicals, especially in the context of very scarce resources often characterizing DCs' public authorities. It is more often used for chemicals presenting a particularly high level of risk in use, such as pesticides and biocides. Chemicals are sometimes also included in such systems based on their impacts on health and the environment, such as carcinogenic, mutagenic, persistent, bioaccumulative substances, and chemicals with reproductive impacts. When very limited implementation and enforcement capacity is available for ensuring effective control of the chemical considered, a ban should be considered (see section D.3 above).

Most countries have in place a system for the registration of pesticides, as recommended in the FAO Code of Conduct. Such systems for industrial/ household chemicals are generally less developed. If the choice is made to also require registration of some high concern industrial/ household chemicals, existing registration systems should as far as possible be used as a basis in order to avoid the creation of two parallel systems. This allows making best use of the limited human and financial resources available, promotes collaboration and the use of combined expertise, reduces the costs of the system, and avoids inconsistent decisions for chemicals used in agriculture and other sectors.

In addition, registration/ authorization requirements can be tiered according to probable risks, as well as extent of use and/or production of the substances, in order to promote the use of safer alternatives. In particular, at least four types of provisions can be included in this regard[40]:

- ⇨ Setting up less demanding requirements for application for lower-risks chemicals
- ⇨ Designing hybrid charges rates with lower charges for lower-risk chemicals
- ⇨ De-registration of pesticides for which safer alternative exists
- ⇨ Establishing shorter time limit for high-risk chemicals registered, therefore requiring more frequent renewal

5. Licensing

Licensing is a policy instrument in many aspects very similar to registration/ authorization, except that it applies to a company/ individual to assess whether its activities with a chemical do not result in unacceptable risks to human health, the environment and property.

i Characteristics of Licensing Schemes

Licensing is generally defined as the process by which public authorities provide a time limited permission (a license) to private stakeholders before certain activities – including manufacture, pack, re-pack, label, sell, store, or distribute – can be undertaken[41]. Licensing systems can therefore be tailored to various circumstances and needs. In the context of these guidelines, licensing applies specifically to companies/ individuals intending to place chemicals on the market (the primary suppliers).

Given the stakeholder orientation of licensing, the review focuses on the location, activity, expertise and ability/ capacity to safeguard against known risks of the applicant. For this type of licensing system to be efficient, conditions for license attribution have therefore to emphasize the need for companies to have appropriate qualifications to handle the specified classes of chemicals in an appropriate way. Different criteria for licenses can be established for manufacturers and importers, with manufacturing licenses generally more focused on the product's quality and safety measures in the manufacturing plant. However, as most DCs mainly import the chemicals used in the country, manufacturing provisions can generally be more basic than in countries producing chemicals.

General requirements to be included in legislation for licensing systems are very similar to those for registration/ authorization. The main difference is the criteria for evaluation and the information to be provided in application. As well, development of legal requirements for the establishment of licensing systems for primary suppliers of chemicals is likely to require attention to legislation on commercial licensing. Moreover, attention should be paid to include bans and restrictions of the Chemicals Conventions into manufacture licensing requirements. In additions to the provisions presented in section D.4 above, the ILO Convention applying to workers safety might have to be reflected in criteria for manufacture licensing if the country is a Party to it.

ii Licensing Scheme in the National Context

The relevance of such instrument in the country situation has to be assessed on a case by case basis. In particular, the type of primary suppliers and the frequency of supply are key factors for the design and success of the licensing system. Small suppliers (i.e. SMEs) might be confronted to a significant challenge in getting the required level of qualifications, and this requirement might in some cases lead them to stop this activity. As well, such licensing system is likely to be less relevant and more difficult to maintain in cases of occasional supply and/ or handling, in which case simple, short-time licenses might be used.

Establishing a licensing system for suppliers of well defined categories of chemicals (i.e. chemicals of high acute toxicity, high corrosiveness, highly flammable, explosive chemicals, carcinogens, mutagens etc.) will also reduce the costs and expertise needed for the administration to maintain the system. It can be combined with a licensing system for users of the same categories of chemicals for greater control of the chemicals' flows. This latter system is not really part of legislation governing the placement of chemicals on the market, and should preferably be regulated as part of other laws (i.e. workers safety, environmental protection, etc.).

Coupled with the development of an inventory, licensing systems for primary suppliers can serve an important information collection function (see section D.1 above). Such a system presents several advantages for building the information base needed for informed decision-making on chemicals management compared to general authorization/ registration systems:

- As importers or primary suppliers are very likely to be far less numerous than the chemical substances they market, licensing them instead of a general registration/ authorization scheme is less demanding in terms of expertise and resources;
- Moreover, the collection of basic information on the primary suppliers and the chemicals they supply through licensing allows authorities to ensure reasonable knowledge of the flows of chemicals in the country and in a certain measure to control users for which running a licensing systems is more complex and resource-intensive;
- Licensing primary suppliers finally leaves the responsibility of deciding which chemicals to be marketed to the companies (within the limits of the conditions for license attribution), which is more in line with the approach adopted by many countries with advanced chemicals management legislation.

As they serve different functions, licensing and registration/ authorization systems can also be superposed. For example, the FAO Code of Conduct recommends that governments "develop regulations and implement licensing procedures relating to the sale of pesticides" (art 8.1.1.), in addition to the development of a registration system for pesticides. The practical link between the two systems is that chemicals have to be registered before the entity supplying them can apply for a license. Very demanding in terms of expertise and resources, such superposed systems are to be developed only for chemicals of very high concerns and only if the required capacity is available in the country.

Box 10. Legal requirements for licensing systems

In case of establishment of a licensing system, legislation should:

- ⇨ Require licenses for all persons importing/manufacturing the targeted group of chemicals
- ⇨ Charge the competent authority with receiving, evaluating, approving or denying applications
- ⇨ Establish a system of evaluation of applications
- ⇨ Set out clear criteria for the grant or denial of licenses, as well as conditions for imposition of conditions, suspension and revocations
- ⇨ Charge the authority with providing notice of the reasons for denying
- ⇨ Establish the term of validity and procedure for renewal
- ⇨ Back up the licensing scheme with inspections
- ⇨ Enable the authority to charge fees for services associated with licensing
- ⇨ Set out an appeal procedure

Adapted from: FAO (2007)*;* pp. 55-56.

6. Import and Export

Many developing countries have limited chemicals manufacturing capacity and mostly import the chemicals in use in the country. Therefore, custom controls of chemicals can play an important role in the implementation of legislation governing the placement of chemicals on the market, especially with regard to the prevention of illegal traffic of chemical substances and the implementation of the PIC procedure of the Rotterdam Convention.

Such controls are generally done through the establishment of an import permit system. As for registration/ authorization and licensing systems, an application procedure is provided and criteria are specified for the review by the competent authority, to ensure that only desired chemicals are imported.

In addition, inspections of the chemical imported can be conducted by custom officials. As customs inspections require specialized expertise that might not be available, they can be limited to ensuring that chemicals imported in the country are conveyed with relevant information and are adequately packaged and labelled. As well, custom control for different groups of chemicals might require different sets of expertise. Countries with limited financial and technical capacity can have difficulties in mobilizing such expertise at each port of entry. A way to overcome this constraint is to assign specific ports of entry for various groups of chemicals requiring similar expertise and/ or verification procedures.

Import permit systems are often operated in conjunction with registration/ authorization systems, as in particular for pesticides. In that case, the chemicals for which an import permit is requested should already have been registered/ authorized. In addition, it is possible to link the import permit scheme with a licensing system for importers (see section D.5 above). Licensed importers would still have to apply for an import permit, but the process for obtaining it would be faster as they are already recognized as primary suppliers.

Import permits scheme should also reflect the country's international obligations. In particular, under the Rotterdam Convention, imports of Annex III chemicals should be prohibited, unless written consent has been sent to the Secretariat of the Convention by the Responsible Authority. Harmonized System custom codes developed by the World Customs Organization (WCO) should be used on shipping documents. Similarly, the Stockholm Convention requires Parties to restrict the import of Annex A and B chemicals to two cases: a) environmentally sound disposal, and b) for permitted use (the country has obtained an exemption).

Imports requirements should be linked to export requirements. In particular, under the Stockholm Convention, the same conditions apply for export and import of annex A and B chemicals. The Rotterdam Convention requires that Parties ensure that exporters comply with decisions of importing countries no more than six months after being informed by the secretariat. Furthermore, as a general principle the same conditions should be imposed to domestic production than imports and exports[42]. This would avoid conflicts with regard to WTO rules, and prevent dumping of unsuitable chemicals in other countries.

7. Assistance, Incentives and Disincentives

Assistance, incentives and disincentives can have a similar effect than sanctions. Sanctions[43] penalize entities in case of non-compliance, or impose complying measures. On the other hand, assistance aims to decrease the cost of compliance by assisting the non-complying entity to take the necessary phases for complying. Similarly, incentives promote compliance by rewarding "good" behavior, while disincentives are intended to discourage "bad" or "less good" behaviors.

i Assistance

The ultimate objective of a sanction is the improvement of the behavior of regulated entities as compared to the goal of the policy and for the benefit of the whole society. In that sense, sanctions have in some situations failed to achieve their objective, in that they have resulted in the end of the underlying productive activity, and generated other issues (loss of jobs and livelihood, end of some activity important for economic development, generation of behavior that are more damaging for human health and/ or the environment, etc.).

An alternative therefore consists of assisting offending entities to comply with the legal requirements, which would reduce the costs associated with the change in behavior. Such an approach is particularly suited in the case where offending companies are SMEs with few capacity and scarce resources.

However, the adoption of such measures should be considered on a case by case basis, and examined in line with the allocation of responsibilities between the public and the private sector. In the case where responsibilities for managing the placement of chemicals on the market are mainly allocated to the private sector, attention should be paid for public authorities not to take over private sector responsibilities. This would tend to generate disincentives for the regulated entities to change behavior by themselves as the costs of such measures can be at least partly transferred to the public authorities.

ii Incentives and Disincentives

Another means for ensuring that a policy goal is achieved is to reward "good" behaviors through incentives, and/ or discourage "bad" or "less good" behavior through disincentives. Incentives and disincentives can take many different forms, depending on their type (i.e. economic, symbolic, etc.). The most well-known rewards however are economic incentives such as tax rebate, subsidy, etc. which constitute a specific category of economic instruments.

In addition, other types of market incentives/ disincentives can be used, for example a company's public image and the reputation impacts associated with a change in the public perception of the company's environmental performance. These instruments can be used as a means to complement the regulation, encouraging entities to comply with standards, or go beyond regulatory requirements, and foster a culture of innovation. They are also sometimes set up as voluntary, self-reported measures. However, experience has shown that the most efficient incentives/ disincentives are backed by regulatory measures.

E. Inspections

Inspection activities are a crucial component of any legislation as, coupled with dissuasive sanctions, they are one of the main tool to make sure that legislation is complied with by the regulated entities (compliance monitoring). In addition, inspection systems can provide valuable information to the responsible authority (i.e. for evaluation of the applications for licenses). Therefore, legislation governing the placement of chemicals on the market should establish a comprehensive inspection system.

Depending on the countries, responsibility for appointing inspection officers can be attributed to the authority responsible for the administration of the legislation, or to a central government agency in charge of appointing public servants and officials.

In their duties, inspectors should be allowed to:

- ⇨ Enter and inspect premises or storage facilities;
- ⇨ Search vehicles, persons and containers;
- ⇨ Take samples and seize equipment;
- ⇨ Take photographs;
- ⇨ Ask for information and evidence; and
- ⇨ Issue orders and/or apply sanctions in case of non-compliance.

In addition, they can often request assistance from the police when needed. These rights should be clearly stated in law.

Because inspectors' powers are broad, they should be clearly defined. Such definitions should be done in line with the national legal framework defining the powers of public officials, and include limitations and obligations. Inspectors must be held accountable for their responsibilities. Rights and duties of inspectors can be outlined in a law, and detailed in subsidiary enactments (i.e. outline of procedures for carrying out inspections, taking and marking samples and submitting them for analysis).

The effectiveness of inspections crucially depends on the capacity of inspectors to perform their duties. Therefore, legislation should clarify required qualifications of inspectors. Inspection responsibilities should be allocated on the basis of the three main intervention points: the point of primary supply (targeting producers and importers), the point of retail sales, and the point of uses. In addition, the inspection scheme should be designed to allow coverage of large, medium and small companies.

As inspections at the three intervention points and in different sectors might require specialized sets of skills, it can be advantageous to house the inspection groups for certain sectors/ intervention points in government bodies already familiar with the operations to facilitate enforcement actions, or to use their existing capacity. Therefore, the law can include provisions for the responsible authority to use employees of various authorities (i.e. custom officers, agriculture inspectors, local authorities) for enforcement activities.

If different public bodies are responsible for specific inspection activities, good coordination of these activities is to be ensured. This will avoid that the same entity is inspected by more than one inspectorate on the same issue.

Inspections can be conducted on a scheduled or surprise basis, spot checks generally being the most effective for ensuring compliance. Inspections can also be conducted as a response to problems reported by public authorities, private companies, individuals or civil society organizations. This constitutes a cost-effective solution for designing an inspection scheme in situation of limited resources. Another way to save scarce resources is to target inspection activities to the high-risk chemicals/ activities.

1. The Accreditation and Use of Laboratories

A key component of enforcement and inspection activities is the use of laboratories. These are critical for conducting monitoring and other tests needed for ensuring compliance. Legislation governing the placement of chemicals on the market should establish a system for identification and certification of analysts and laboratories. This power is generally attributed to the Primary Authority. While such system is generally outlined in a law, the rules and procedures can be detailed in subsidiary enactments.

The development and maintaining of a comprehensive network of national laboratories may constitute a significant financial burden for countries with very limited budget for chemicals management. Therefore, countries should not seek to replicate the laboratory infrastructure of countries with advanced systems for chemicals management.

The acceptation and use of information generated in other countries (i.e. hazards assessments from countries with advanced chemicals management systems, risks assessment from countries with relatively similar conditions) can reduce the need for complex laboratory systems. In this case, countries should ideally at least have a national reference laboratory capable of performing qualitative analysis for the chemicals of major concern for verification and monitoring purpose.

Another option for reducing the costs of laboratory infrastructure is to engage in regional/ sub-regional cooperation. The establishment of a joint laboratory infrastructure with countries sharing similar chemicals issues and/ or ecosystems can be a cost-effective and efficient way to build analytical capacity in a region (see section III.D.5).

Box 11. Legal Basis for Inspections Systems

In establishing an inspection system, legislation should:

- ⇨ Provide the authority to appoint inspectors
- ⇨ Clarify the powers and obligations of inspectors, as well as work procedures
- ⇨ Ensure consistency with legislation on powers of public officials
- ⇨ Specify the qualifications required of inspectors
- ⇨ Ensure comprehensive coverage of the inspection system (sectors/ intervention points)
- ⇨ Establish a scheme for certification laboratories and appointment of analysts

Adapted from: FAO (2007); pp. 39-41.

F. Record-keeping and Reporting

In complement to inspections, record-keeping and reporting can facilitate compliance monitoring of regulated entities. They can also allow regulating bodies to collect data consistently over time, which can be a great asset to further develop chemicals management legislation.

1. Record-keeping

Review of records kept by regulated entities can greatly assist inspectors in their work. Record-keeping requirements generally specify the type of information to be recorded, the form of the record, and the duration of record-keeping. Such requirements can include the obligation for regulated entities to keep records of (1) chemical assessments; (2) samples; (3) types/amounts of chemicals handled; (4) chemicals problems uncovered or reported; and (5) communications regarding the handling of chemicals[44].

2. Reporting

Reporting requirements can be tied in with registration/ authorization, and licensing systems when such instruments are selected. This provides the basis for ensuring that decisions to authorize/ register a chemical substance or license a company for supplying a type of chemicals are updated based on the most recent available scientific knowledge.

Reporting requirements provides a useful way of ensuring that there is good communication between government and industry and that government is in-tune with chemical activities within the country. Further to collecting data on parameters related to chemical use, production, or distribution, reporting can include requirements to report emergency management and safety plans. This would encourage and implement a culture of assessing chemical release risk and provides a protocol to be followed in case of emergency.

To ensure that the governing bodies are informed about the latest information on chemical risks, reporting upon request can be included. For example, the party responsible for risks assessments and other parties can be obligated to report any new information they discover related to the risk of chemicals.

In addition, the responsible authority(ies) should be allowed to ask for any information about chemicals related to health and environmental risk. Cases when the government is justified to request for information should be clearly defined (e.g. when new evidence points to altering the risk associated with a chemical).

For the information collected under reporting to be easier to analyze, consolidate, and process, it is important to ensure that it is provided to the government in a consistent format. Therefore, it is important that templates are provided for forms. This also allows the governing bodies to clearly define the information that they wish to collect from the regulated entities. The structure of such templates can be outlined in the law and/or clarified in the subsidiary instruments.

While useful for monitoring compliance, reporting schemes can also be very demanding as they require the review of reports by qualified public officials. Their effectiveness in addition depends on the capacity to assess and use information reported for decision making and implementation. The development of such schemes should therefore be considered based on the available capacity and resources. In situation of scarce resources and capacity, reporting upon request should therefore be considered rather than regular or annual reporting.

In addition, reporting can only be efficient if backed up with credible sanctions in case of non-compliance, including incomplete or misleading reporting.

G. Enforcement

Several enforcement tools are available for governments to ensure compliance with the legislation. These tools are complementary and are generally used together. However, effective enforcement always critically relies on the availability of credible sanctions in case of non compliance. Effective inspection systems and reporting requirements are needed to ensure that regulated entities fulfill their responsibilities, while health and environment monitoring allows keeping track of the impacts of chemicals.

1. Offences

Sanctions (or penalties) are generally defined based on a list of specified offences to the law. The list should include offences from the regulated entities as well as from public authorities' officials. The offences then have to be separated between criminal and administrative ones. Depending on the situations, such separation might already be established in the country's constitution. In addition, the separation might also be guided by the country's international commitments[45].

In other cases, a choice can be made. As they are not imposed within the judicial process (not applying criminal court procedures and requiring lower evidentiary standards), administrative sanctions can be more cost-efficient and practical than criminal ones to implement. They can also be more efficient in situations where the judicial system is weak.

2. Sanctions

Sanctions (or penalties) are generally applied in cases of non-compliance with the legal requirements (intentional or not). Sanctions can include a) monetary punishments, b) imposing the execution of corrective action, c) limitations/ cessation of the activities of the entity (through cancellation of the permit, or through temporary/permanent closure of the facility), or even, for serious offences, d) incarceration.

To efficiently change behavior of the regulated entities in the desired direction, sanctions need to be carefully designed. In effect, low penalties (especially financial ones) that are perceived as less costly than changing behavior are likely to fail to attain their objective, even more if continuous non-compliance does not lead to tougher penalties or when enforcement is weak.[46]

Sanctions for non-compliance with environmental law generally depend upon the penal system of the country, and are sometimes included in the main criminal law. In other cases, they can directly be mentioned in the environmental law, or, in the case of penalties related to the legal requirements governing the placement of chemicals on the market, in the related law. The general principle is however that sanctions are to be based on high-level legislation (i.e. law).

In addition, sanctions can also include liability measures that allow the victims of environmental damage to be compensated for the effects of this damage, or impose to the damaging entity to restore the damaged place/ ecosystem. Such systems have sometimes proven difficult to implement due to the challenges in demonstrating the causal relationship between an activity and damages.

The possibility of applying sanctions depends on the clarity of the requirements contained in the law. These requirements therefore have to be made extremely clear for sanctions to be applicable in real cases.

H. Confidentiality

Some of the information provided by companies to the public authorities for authorization, licensing, or other purposes may be confidential. Businesses and other entities which are required to provide information should therefore be entitled to request that some information is not distributed to the public.

This need for confidentiality is balanced by the right of the population to be informed about the chemicals hazards and risks for health and the environment. Such information should therefore be kept outside of the scope of confidentiality requirements, and the type of information that can be made confidential should be clearly delineated. In addition, public authorities should be allowed full access to information.

Confidentiality rules and requirements are typically defined in a specific legislation, often in accordance with the rules established by the World trade Organization (WTO). The prevailing rules should therefore be applied with regards to confidentiality of information provided for the management of chemicals. In general, it is important to clarify which information is to be kept confidential and which is of public interest, how confidential records have to be maintained and stored, and who should have access to the records.

I. Appeals

In order to ensure transparency and the right to due process, legislation should enable appeals against decisions of the responsible authority(ies).

Appeals should be authorized for various types of decisions, including registration/ authorization decisions, licensing decisions, sanctions imposed, etc. Depending on the country legal tradition, special appeal procedure can be defined for chemicals management legislation or appeals can be channeled through the normal legal process.

Only specific groups are generally entitled to appeal to courts for an observed case of non-compliance. These typically include the persons directly affected by the decision. However, this is not sufficient in the

case of environmental protection, and right to appeal is most frequently extended to groups that are deemed to represent the public interest (i.e. NGOs, class action, citizen's suits, etc).

Adequately defining who is entitled to appeal to courts is crucial for the effectiveness of the legislation, as it is also through bringing cases to tribunals (or through the threat of it) that the legal requirements will be complied with. Public authorities, groups of users, and NGOs dealing with chemicals issues could be entitled, depending on the country situation.

V. Tools for Compliance Promotion

Enforcement activities are traditionally only considered in their negative dimension – punishing non-compliance. While required, this approach is very demanding in terms of resources, and sometimes even inefficient in changing the behavior of regulated entities in the desired way.

Compliance promotion activities can provide a cost-effective way of ensuring compliance compared to regulatory enforcement. However, effective compliance promotion activities are based on a credible system for enforcement of legislation, including sanctions. Therefore, compliance promotion activities should not be developed as a substitute to clear and effective regulatory enforcement systems but rather as a complement to such systems.

A. Transparency and Communication

To be able to comply with legal requirements, regulated entities first need to be aware of the goal of the policy and of their responsibilities and obligations. Regulated entities are even more likely to make the necessary phases towards compliance if they understand and agree with the requirements. Ensuring transparency and communication throughout the process therefore provides a cheap means of promoting compliance.

The first – and probably most efficient – option for ensuring regulated entities' awareness and understanding of the legal requirements is to involve them in the decision-making process through the establishment of multi-stakeholders consultative mechanisms (see sections II.B.1.*i*, and IV.C.2.*ii*) or other means (i.e. request for comments on draft papers, etc.). The development of websites, guidelines, and other types of information material can also facilitate access of the regulated entities to the requirements, and therefore promote compliance.

B. Education and Training

Several requirements governing the placement of chemicals on the market are likely to require training of various stakeholders.

For industry these include, among others:

- Assessing properties, hazards and risks of chemicals
- Classification and labeling of chemicals
- Adequate handling and use of chemicals

For authorities these include, among others:

- Establishment of technical criteria and standards
- Verification and approval of submitted dossiers
- Conducting inspections

Personnel from public authorities at different levels (e.g. parliament, ministries, agencies, inspectorates, etc.) need to be adequately skilled for developing and implementing the policy, including monitoring and inspection activities. In addition, personnel from private companies (primary suppliers) have to have expertise for proper management, including appropriate labeling, safe handling, and making proper decisions on chemicals to market, etc. Similarly, users of chemicals should be able to understand labels and Material Safety Data Sheets provided by suppliers in order to choose chemicals to use and to use them safely. Basic education on chemicals risks and appropriate – preventive and curative – measures can also contribute to effective enforcement of the policy.

Education and training programme can therefore be developed. For example, a licensing process for primary supplier of chemicals might require that the applicant demonstrate an adequate level of capacity

to handle safely the chemicals they intend to place on the market, which would involve that companies that do not have this expertise have to develop it through education and training.

These education and training components can either be included in the form of requirements that the regulated entities have to fulfill by themselves or of programmes that the authorities establish to build capacity of the regulated entities, or both. Where the private sector is made responsible for the main tasks involved by managing the placement of chemicals on the market, public authorities would normally not provide education and training programmes for companies, which would have to develop strategies for building the required capacity (internally, or through consulting companies).

In other cases where the targeted private sector group is comprised of small companies, it might be more effective for public authorities to provide education and training programmes to assist with capacity building in these small to medium sized enterprises (SMEs).

Depending on the targeted audience, on the expertise needed and on the national context, different approaches can be used for education and training programmes:

- Involving stakeholders in the policy making process can be an effective tool for building capacity of stakeholders, in addition to the other benefits of involving stakeholders in the decision making process[47].
- Development and diffusion of guidelines explaining procedures and options for selected activities (Access to international schemes on assessing risks of chemicals, laboratory practice for testing and evaluation, safe handling, etc.) can also help the regulated community build its capacity.
- Development of specialized curriculums in relevant universities and schools can also, though on a longer term, build capacity in the country for activities requiring highly specialized skills such as scientific assessments. It should be noted that the development of curriculums might not be sufficient to ensure that the capacity developed is effectively used, and so that such programmes could include activities to use this capacity.
- Organizing targeted workshops and training courses for selected stakeholders is another way for the public authorities to assist stakeholders in building their capacity.
- Establishing partnerships with civil society organizations and NGOs can also prove an efficient and cost-effective way for public authorities to build capacity of stakeholders, as some of these organizations have such activities as part of their mandates anyway and can have direct access to the local communities.
- Company training (through federations, firm's internal training programmes for workers, programmes of mentoring from big companies, promotion of consulting markets) can also be promoted through various means. Effective sanctions in case of non-compliance can already act as an incitation to build the required capacity, provided that the targeted companies have the resources to do so.
- Working with specialized international organizations that provide such assistance can finally be another useful means of organizing education and training programmes.

C. General Awareness Raising

In addition, raising awareness of the broader public on chemicals risks and safety measures can also contribute to the sound management of chemicals. The development of labeling and safety data sheets plays an important role for raising awareness of chemicals hazards and safety measures. In addition, awareness raising campaigns can be undertaken.

Attention should be paid to the selection of the target group for the awareness raising activity, as this is key for the success of the campaign. Special care should also be taken to communicate the adequate information, level of detail, and in an adequate language to the targeted audience. In addition, coordination of the communications from different groups (industry, NGOs, public authorities) should be sought as far as possible in order to avoid that the target group is faced with contradictory information.

Options for awareness raising activities include:

- Involving stakeholders in the policy making process
- Information workshops
- Public awareness campaigns (through the media, NGOs)
- Organizing training for journalists
- Making information publicly available
- Organizing site visits (of industries, laboratories) and other events
- Organizing information sessions in schools

The choice of one or several of these options will generally depend on the targeted audience, the type of information to be communicated, the context of the country, etc. The choice of the best communication strategy should be assessed on a case-by-case basis. See Box 12. below for a discussion on effective communication strategies.

Box 12. Five Guiding Principles for Effective Communication

- ⇨ ***Careful selection of the target audience*:** Special attention should be paid to the selection and identification of the target group. Characteristics of this group (type of impacts on/ from the policy, culture, perception of the issue, geographic location, access to media, etc.) are crucial inputs for the development of the communication programme.
- ⇨ ***Meeting the needs of the target audience*:** The communication programme should be tailored to the needs, perceptions and concerns of the target audience. A two-way communication process from the beginning of the process can greatly help understand these. The format and style of the information presented should be adapted to the needs, perceptions and concerns of the target group as well as to the situation.
- ⇨ ***Providing comprehensive, balanced and easily understood information*:** The language in which the information is communicated should be adapted to the audience. This includes the level of technicality, the use of appropriate dialects, expressions, pictograms and symbols, etc.
- ⇨ ***Ensuring that the provider of information is reliable, credible and accountable*:** Special care should be taken in choosing the provider of information. The choice will typically depend on the target audience, as well as on the situation.
- ⇨ ***Evaluate the effectiveness of the communication programme*:** Communication efforts should be based on the lessons learned and feedback from preceding programmes. For these lessons learned to emerge, effective monitoring and evaluation of the communication programmes is required.

Adapted from IPCS-IOMC (August 1998); p. 53.

VI. Costing the Development or Reform of Legal and Institutional Infrastructure Governing the Marketing of Chemicals

The resources available to address chemicals management issues at national, regional and global levels are widely recognized as inadequate. As such, the cost of legal and institutional infrastructures is seen as a key obstacle preventing countries with very limited budgets from developing and sustaining adequate frameworks for managing chemicals.

The cost[48] to all stakeholders – business, government and society as a whole – of better governance of chemicals introduced to domestic markets will depend in part on the information, monitoring and enforcement 'ambitions' for legal instruments. The number of chemicals subject to registration, authorization, licensing and permitting systems that are the central components of efforts to manage the placement of chemicals on the market at the national level: design elements like these determine the complexity of legal and institutional infrastructure, and therefore the cost of implementing them. A balance must be found between simplicity, or low resource requirements, and effectiveness of the various systems to reach the objective of managing the placement of chemicals on the market.

The requirement of industry to carry out most of the main tasks involved in the management of the placement of chemicals on the market (see table 3., p. 28) in effects transfers some costs from government to the private sector. Registration or licensing systems can be designed to either register discrete chemicals, chemical mixtures, products containing chemicals or individual firms involved in the import or production of such substances or products. As such, the higher the number of chemicals requiring registration and authorization, or the more complex the chemical and difficult to detect in products or mixtures, the more costly the procedures for firms to generate complete applications for registration, authorization, licenses and the application assessment, checking, monitoring and enforcement activities for government officials. Depending on the roles and responsibilities established under new legislation, or refined under existing legislation, industry can be held accountable for costs of:

- The preparation of a complete dossier for application to registration, authorization, licensing or permitting procedures including description of product, conduct of independent risk assessments, drafting of labels to be included on the product …etc.;
- Administrative charges related to registration/authorization applications, including repeat and fast-track applications;
- Annual registration/authorization maintenance fees;
- Administrative fees related to licensing and permitting applications;
- Further laboratory analysis work required, particularly in relation to appeals procedures;
- Fines related to noncompliance with registration, authorization, licensing or permitting regulations or the reporting and inspection procedures coupled with these;
- Clean-up and remediation resulting from disasters associated with chemical(s) being placed on the market, where the firm has been proven to be negligent;
- Compensation payments to victims, at least to cover the cost of medical treatment, lost earnings, destruction to property …etc.

Given that the primary focus of this guidance is cost recovery for public services delivered by all levels of government to the private sector for better managing chemicals being traded on markets, government costs are considered here and not private sector costs per se. Depending on the needs at national level, public costs related to the establishment of new legal and institutional infrastructures, or strengthening of existing structures, for managing the placement of chemicals on the market can include capital investment and operational costs in activities enabling the four main steps to be implemented.

For the purpose of this guidance, it is assumed that national governments have their individual cost estimation methods established within standard policy making procedures. However the following key elements set out what factors determine the magnitude of the costs of strengthening legal and institutional infrastructures for managing placement of chemicals on the market that may assist costing processes:

- The number of firms/commercial entities likely to be subject to registration/authorization/licensing processes;
- Length of validity of a registration, permit, license, i.e. how often the administration process has to be completed to maintain registration/authorization/licensing;
- Schedules for revision of registers and permits/licenses databases and the duration of this activity for government officials;
- Administrative burden of reporting assessments determined by schedules for firm (importers and producers) reporting requirements;
- Frequency of inspections, dictating the number of inspectors required.

As in all policy-making, the costs of these legislative and institutional efforts to govern the placement of chemicals on the market but be weighed against the benefits for society from that policy to determine how best to invest scarce public resources. Choosing the solutions should be based on the net costs for all stakeholders balanced with the positive impacts of improved sound management of chemicals resulting from development or reform of systems governing the placement of chemicals on the market.

The effectiveness of coordination between government ministries for existing and new functions is an important consideration in the cost-effectiveness of the legal instruments and institutional infrastructures is how existing resources can be better organized to deliver results before new resources – human and financial – are marshaled, including identifying opportunities for joint service delivery.

The costs of new legislation and institutions are likely to be considerable where no resources previously exist. However, given the expertise and capacity already developed in similar governance issues (i.e. drug enforcement, customs, tax collection), it is often the case that the real question is how to coordinate numerous government ministries and agencies effectively to establish a cost-efficient infrastructure that allows chemicals policy makers to know what chemicals are entering their national markets (through importation or production). The guiding rule of thumb should be that where expertise (i.e. other types of registration systems, inspections, and information management), human resources, office requirements (i.e. computers, desks) …etc. already exists, it should be factored into the design of the regime to minimize costs.

New resources required for the various activities required under the different roles and responsibilities set out in legislation and structure of the regime means either investing in training of existing or new personnel, or hiring new personnel with the capacities required.

Many developing countries currently rely heavily on external funding coming from the Quick Start Programme Trust Fund and the Global Environmental Facility (GEF), as well as other bilateral and multilateral mechanisms to finance national public chemicals management activities taking place across various national Ministries.[49] However, Quick Start funds are limited to two years and typically seek to spread funding across a number of countries; and GEF windows are limited to specific themes and issues that do not cover the full range of chemicals management concerns potentially facing developing and 'in transition' countries. As such, it is suggested that if funding for chemicals management activities is to be sustainable, it is imperative that options for national-level funding are fully explored.[50]

Within national budget cycles, in theory, chemicals-related line ministries (LM) must simply ask for support for their activities. For many reasons, however, predictable, reliable and sufficient funding is not always forthcoming. In the context of evolving aid modality – from project to General Budget Support (GBS), following the principle of country ownership – partnership funding for development is potentially one of the largest sources of financial and technical capacity for national chemicals management only if links are made between chemicals management and central decision making processes.

In making their case for further investment in public chemicals management activities, chemicals policymakers need to demonstrate to parliamentarians how investment in more stringent governance of chemicals being traded in national markets reaps benefits for other line ministries (e.g. health, economic development) industrial development, as well as societal health and well-being, through reducing or avoiding typical health, environmental and economic 'costs of inaction' from chemicals mismanagement. Yet these arguments are all too rarely 'translated' into the economic arguments pivotal to securing predictable and adequate funding from national budgets to support implementation activities. Moreover, the link between sound management of chemicals and sustainable economic development is not firmly established in the minds of key finance decision-makers, to the detriment of national funding support for chemicals management activities.

In addition to national budget and international funding, bolstering private sector financial and technical participation in meeting the costs of development/strengthening of legislation for Sound Management of Chemicals (SMC) at the national level, and the full implementation and enforcement of chemicals-related laws through adequately resourced institutions is thought to be a key feature of generating sustainable finance – defined here as sources of finance that are dependable, secure, predictable.

Table 4. Cost Categories for all Stakeholders of Development or Reform of Legal and Institutional Infrastructure Governing the Marketing of Chemicals

Private Sector Commercial entity producing or importing chemicals that they intend to sell or use	**Public Sector** Government entities providing services that contribute to governing the placement of chemicals on the market	**Society**
• Provision of information required as part of registration/authorization/licensing procedures, including credible hazard and risk information • Length of waiting times for authorization/licenses/permits • Length of validity of a registration, permit, license …etc. determining how often business must undergo registration/authorization/licensing procedures; • Reporting obligations	• Investment in registration/authorization/licensing systems for managing market access for chemicals • Training and outreach activities for importers and other primary suppliers • Testing verification • Labeling verification • Testing of residues in products • Food monitoring • Monitoring of human health and environment	• Opportunity cost of investment in chemicals management • Distortionary impacts on economy from increased costs to business

VII. Sustainable Financing through Cost Recovery Charge Systems

Economic instruments are increasingly recognized as one set of policy mechanisms that are ripe for further exploration in chemicals management financing. One subset of economic instruments of particular interest is that of cost recovery – charges and fees[51] attached to particular public services with the intention of recovering costs to government ministries and agencies of providing those services. In the context of managing placement of chemicals on the market, cost recovery measures essentially shift the hidden public costs of managing marketing of chemicals – administrative, capital and operational costs of programmatic activities, such as providing and maintaining chemical registration/authorization/licensing systems - from government budgets to private sources. Cost recovery mechanisms do not necessarily need to cover the full costs of such systems; what is important is that they enable a more appropriate cost burden-sharing between public and private sectors for chemicals management services.

A. Benefits to Private Sector of Better Regulation of Chemicals being Placed on the Market

Better regulation of chemicals benefits the private sector. There are very clear links between a precautionary approach to managing chemicals' placement on the market and economic growth; in particular the reduction of costs and creation of opportunities for business both directly and indirectly linked to chemicals production and use. Trade is a particularly important aspect.

1. Securing and Boosting Exports through Meeting International Product Standards

New legal and institutional infrastructures for the placement of chemicals on the market can play a role in preparing chemicals importers, producers and users for competing in international markets for their particular products and services.

Government regulations enforcing product and food safety standards represent an ever-strengthening safeguard blocking entry to the market of chemicals or products containing unsafe levels of chemicals or chemical residues worldwide. Perhaps the most commonly referred to example currently is the EU REACH Directive, but there are many other examples of pesticide residue testing for agricultural products[52], chemicals residue testing for aquaculture products[53], and textile, toy and food safety standards…etc. either being currently implemented or anticipated in the near future in other markets.[54]

Not meeting product and food safety standards because of poor chemicals management policies has very real impacts for national balance of payments. For example, in Thailand, it is estimated by the Department of Agriculture's Office of Agricultural Economics that the value of returned agricultural exports rose from US$11million in 1992 to US$27.8million in 2001 after 20 years of growth in intensive pesticide usage.[55]

Furthermore, surging consumer demand in industrialized markets is growing for products and services that are certified and labelled as being sustainably produced. This demand is perhaps most effectively signaled to smaller-scale producers, exporters and importers through large-scale corporations such as international food producers, clothes manufacturers and supermarkets. Current examples include sustainability efforts by Nestlé[56], H&M, Cargill[57], Walmart[58]and Carrefour[59].

With the government providing systems for managing chemicals placement on the market, support is being provided to businesses aiming to develop higher value-added organic food production or simply to ensure acceptance of agricultural exports. Higher standards do not necessarily mean a threat to the viability of industries – conversely it can help improve potential for business expansion in foreign markets.

2. Harmonized Standards and Costs for Compliance

The costs of meeting standards demanded by end users in foreign markets can be high, particularly at the top end of the market. By establishing a system that requires all national players in that industry to 'step up

their game', a level-playing field is created whereby unfair advantages from placing unregulated chemicals on the market are to be eliminated.

3. Improved National Reputation as a Place to 'Do Business'

AccountAbility's[60] 2007 report on Responsible Competitiveness, which covers 108 countries and 96% of global economic activity, suggests that nations who do not address Corporate Responsibility issues, including those related to environmental performance, expose industries located within the State to risks in international economic competitiveness and prospects for growth across the board. Continued 'bad press' reduces the attractiveness of poorly performing nations as places to live and work, and as destinations of investment capital belonging to responsible investors. This infers positive knock-on effects from managing chemicals risks for other industries indirectly connected to chemicals production or use in secondary and service business activities.

4. Increased Well-Being and Productivity

Even where international export markets are not the primary focus for the industries engaged in using chemicals and products containing chemicals of concern in a country, there are significant benefits to be had in terms of health, well-being and productivity from governance of chemicals being placed on the market.

The negative health impacts of chemicals mismanagement typically fall on chemicals workers, chemicals users and local community where chemicals are produced, stored, used or disposed of (with the attendant risks of chemicals accidents and environmental releases). The existing medical evidence is generally well advanced in terms of linking exposures to illness, disease, loss of cognitive functions and death. Without trivializing the human suffering in this story, the 'value' of health, well-being or avoidance of loss of life is typically integrated into policy decision-making through using surrogate monetary values based on measures like costs of medical treatment, compensation for loss of life and loss of future earnings, amongst others.

The work to translate the health impacts from chemicals mismanagement into economic costs is not very well advanced outside of industrialized economies. Nonetheless, the link between chemicals exposure and ability to work, or labor productivity is observed worldwide.

As just one example, FAO/UNEP estimates that from 1 million to five million deaths occur each year due to pesticide poisoning, though official figures on both acute poisonings and deaths are likely to be significantly underestimated because of the problem of underreporting.[61] To continue with this example, the economic costs of these nonfatal poisonings are thought to be considerable. In Sri Lanka, the estimated the productivity costs of farmers' exposure to pesticides are, on average, equal to about a month's income for these farmers.[62] Similar links to productivity losses have been identified for lead[63] and mercury[64].

What is more, because children are uniquely vulnerable to the subclinical and developmental neurotoxic effects of pesticide, mercury and lead exposures, the associated costs to productivity across the economy are not confined to a single economic group or generation. Childhood exposures can undermine educational achievement and lifetime economic productivity, in turn affecting the economic opportunities for future generations.

As such, preventing exposures through managing the placement of chemicals on the market (and risks at other points on the chemicals life cycle), has the potential to secure increased well-being in a nation's population and with it, national productivity.

5. Benefits for Ecosystem Services and Associated Economic Sectors

Ecosystem services are the benefits that people obtain from ecosystems.[65] Most services provided by the natural environment are not captured by conventional macro-economic indicators because they are not traded in markets. However, given their vital contribution to long-term economic performance[66], to omit them in an assessment of benefits of managing chemicals placement on the market is to render that assessment incomplete. Further work is required in linking chemicals management to ecosystem services,

but some benefits from improved management of chemicals have been observed in the following examples:

- Reduced pesticide and nitrate use in agricultural production improves crop pollination services from honey bees and other insect pollinators[67];
- Improved water quality from reducing intensive use of pesticides and other agrochemicals reducing treatment costs and securing the Vittel brand (now a brand of Nestlé Waters)[68];
- Reduced cost of drinking water treatment in New York City through reducing the impacts of pesticides and other agrochemicals in management of the Catskills watershed[69].

6. Positive Feedback for Reduced Costs from Risk across the Chemicals Life Cycle

Instituting a new consideration of chemical risks at the point where the product is being placed on the market is likely to encourage greater early or upstream risk management. Incentives to minimise risks from chemicals are weak because they do not fall wholly on the stakeholders who benefit from their exchange on the market. Without counting human health and environment costs, net benefits perceived from the sale and use of chemicals may be artificially high and not fairly shared between those taking risks with their health and the health of their communities and ecosystems and those who do not take these risks but benefit nonetheless. Re-balancing the costs burden of investment in sound management of chemicals upstream sends a strong signal to importers and producers to take a greater consideration of lifecycle chemicals risks and their management when choosing which chemicals to bring to the market.

B. Service Provision in Governing the Marketing of Chemicals: Options for Cost Recovery Systems

Cost recovery charging systems are usually linked to regulatory systems which provide legal and institutional framework for their implementation and enforcement. It is important to note, that while environmental fines and sanctions do generate financial support for many public agencies engaged in chemicals management at the national level, sustainable cost recovery is not associated with such measures. Rather, cost recovery closes the loop between the delivery of a publically run service enabling better regulation of chemicals being placed on the market and the beneficiaries of such services.

The following is a list of the specific public services for managing the placement of chemicals on the market to which cost recovery fees can be attached. This is not to say that each and every service should have fees attached to it – one charge system is in many cases more efficient, both for administrators and firms.

1. Fees for Administration of registration, authorization and licensing systems

Cost recovery fees can be established to fund the administrative process of providing and maintaining systems for governing the placement of chemicals on the market, including the personnel, technical equipment and computer systems required for this activity.

Fees and charges for cost recovery can be linked to the sequence, schedule and duration of the tasks or activities for managing the placement of chemicals on the market. Once-off fees may be payable for the initial registration of a new substance, as well as ongoing, annual maintenance charges or fees for periodic renewal of the registration. Authorizations and licenses will also have a set length of validity after which they must be renewed – with an administrative charge payable for that renewal process.

2. Fees for training activities for regulations on placing chemicals onto the market

The introduction of new requirements for pre-market risk analysis and approval procedures in an national market will require outreach activities for importers, producers and dealers to inform them of what the regulations want to achieve and what compliance will require of various stakeholders. Charges can be implemented for training courses (with or without certification) that will cover the cost of preparing and delivering workshops to the private sector.

3. Fees for inspection activities

Under compliance monitoring, fees can be mandated for inspection activities and related follow-up verification procedures.

4. Fees for verification activities

While current approaches to chemicals management require private enterprises producing or bringing chemical substances and products containing chemicals to market to conduct the pre-marketing hazard testing, the work of public institutions may require chemical, analytical, biochemical, biological and forensic testing capabilities to verify applications for registration/authorization and/or licenses in some cases. In order to provide financing for the provision of necessary laboratory infrastructure, one option is to implement charges for verification testing procedures for applicant appeals to decisions to reject inclusion in inventories, registration/authorization and licenses due to concern over downstream risks the substance or product presents.

Where few options exist nationally for conducting the original risk analysis on a substance or product for an application for registration, authorization and/or licenses, applicants could feasibly contract a public laboratory to conduct this work. It is worth noting that where national laboratories are directly dependent on verification testing fees for funding, these facilities should not conduct both the original analytical work and the appeal or verification testing for the same application for moral hazard/conflict of interest reasons.

Table 5. Cost Recovery Measures in Managing Placement of Chemicals on the Market

Main Phases in Managing Placement of Chemicals on the Market	Example Public Services	Possible Cost Recovery Measures
1. Identification and assessment of chemicals' hazardous properties and risks	*The responsibility for the tasks falling under this step is allocated to the private sector.* See p. 32.	
2. Dissemination of hazard, risk and safety information	*The responsibility for the tasks falling under this step is allocated to the private sector.* See p. 32. Training and outreach activities for suppliers	• Fee for training activities
3. Limitation of sales and use of certain chemicals	Mandated registration/provision and maintenance of an inventory Supply controls, including imports Substances authorization Licensing dealers	• Registration fees • Authorization fees • License fees
4. Compliance monitoring	License/authorization inspections Testing verification Labeling verification Testing of residues in products Food monitoring Monitoring of human health and environment	• Inspection fees • Charges for verification procedures

C. The Legal Basis for Cost Recovery Charges

Cost recovery charging systems for services enabling management of chemicals introduced to markets are linked to the related regulatory systems providing the legal and institutional framework for implementation and enforcement described discussed earlier in this guidance. Cost recovery measures require a legal basis to provide the authoritative basis for these instruments and an institutional organization that oversees effective implementation.

As part of the overarching legislation, necessary elements underpinning cost recovery instruments include the following:

- Empowerment of the Minister, acting in consultation with relevant stakeholders, to enact fees or charges under the respective legislation for activities on managing the placement of chemicals on the market – i.e. requirements for registration, authorization and licensing;
- The allocation of responsibilities for hazard and risk analysis verification activities, stipulating essentially if the private sector must pay for verification analyses to be undertaken, or if the government takes on this responsibility –with the attendant costs;
- The actual fee amount to be paid for a first-time registration, authorization and licensing services, including fast-track applications;
- Annual registration/authorization maintenance fees;
- The interval at which renewals/repeat applications need to be made for the above, and the fees to be paid in respect of this service, including fast-track applications;
- The interval at which inspections and monitoring for compliance with terms of registration/ authorization/licenses may be made and the fees to be paid with respect to inspection, monitoring or verification conducted by the public authority,
- Provisions to be made for payment of fees in the case of "orphan" chemical substances or products containing chemical substances that require licenses for importation, production and handling or must be included in national inventories;

- Waiver of fees payable for such services listed above; and
- Fees for further laboratory analysis work required, particularly in relation to appeals procedures;
- Use of revenues generated by the fees should be clearly stated;
- Empowerment of Minister to enact regulations required for better implementation of the cost recovery system; and
- Date of commencement and length of validity of the cost recovery system.

D. Who is Subject to Cost Recovery Systems?

The beneficiaries of public services for managing the placement of chemicals on the market are subject to cost recovery charges or fees, be they domestic producers, foreign-owned firms or importers.[70] Cost recovery charges should be non-discriminatory, with international firms being treated similarly to national firms, and state-owned firms being subject to the same fees as non-state enterprises. Box 13. lists some questions for identifying firms and individuals likely to be beneficiaries.

Box 13. Questions for identifying entities subject to administrative charges and fees

⇒ What entities produce or import chemical substances or products containing chemicals substances that require importation, production and/or handling licenses?

⇒ What entities produce or import chemical substances or products containing chemicals substances that are required to be registered on national inventories?

⇒ What entities produce or import chemical substances or products containing chemicals substances that require licenses before they can be placed on domestic markets?

⇒ What entities benefit from public training activities vis-à-vis regulations for placement of chemicals on the market?

⇒ What entities are subject to inspections to ascertain compliance with registration/authorization/licensing requirements?

⇒ What entities have initiated appeal procedures which require verification procedures to be conducted by public services?

E. Cost Recovery Charge/Fee Structures

Cost recovery charging typically uses flat rate fees per unit (i.e., per chemical, per volume, per firm) that do not differentiate environment or health impacts of chemical substances or products being registered/authorized, but simply provide a predictable, steady source of funding that covers the cost of providing and maintaining the registration/authorization and licensing system. However, there is scope with these instruments to levy fees by chemical substance, toxicity class, by quantity (per unit), by emissions level, or a combination of these, if desired. Moreover, fee structures do not have to remain fixed over time. As national requirements change, so can the design of cost recovery measures.

1. Flat rate fees

Flat-rate fees per unit (per chemical, per volume, per firm) do not differentiate between chemical substance properties but is instead raised on service provision, product sales, importation or production (with no differentiation between different products within this category based on environmental or health impacts) or volume of emissions above a certain threshold level. Flat rate charging may not create incentives for environmental improvement but it can generate a guaranteed level of revenue at lower information and monitoring costs (though enforcement will still be important) with which public environmental agencies can support other chemicals management activities.

2. Differentiated fees

Environmentally-motivated fees and charges can be graduated with respect to toxic or hazardous properties of a product or a substance to be placed on the market. This system is likely to be fairer and more environmentally-effective than flat-rate versions but is also more difficult to implement as the knowledge to classify all chemicals with respect to the risk they represent is not complete, even in developed countries. As such, the classification would have to be based on a political judgment which could be then open to appeals and challenges.

It is also worth noting that setting significant charges for processing documentation on small number of the most hazardous pollutants, products or perhaps a single sector to reduce information, monitoring and enforcement requirements may not raise adequate financing. Where substitutes that present a lower risk to health and environment are not obliged to be registered/ authorized being traded in markets, differentiated charges can have the effect of reducing the import or production of a more risky product or substance, but little revenue for the government. As such, policy-makers who have revenue-raising as a secondary goal for charge measures must take account of the scope and environmental impact of substitutes available when designing differentiated fee structures.

3. Hybrid fees

The third option is a hybrid between flat and variable rate levies combining flat-rate charges to recover administrative costs and differentiated taxes or fees corresponding to chemical risk. This option, though more complicated than simple flat-rate fees, is a compromise that can generate stable income flows while also providing environmental incentives.

F. What Level should Cost Recovery Charges be set at?

Typically expenditure on public service provision funded through cost recovery mechanisms is driven by the revenues received. An inverse funding process, known as valorization, sees desirable activities identified and finance raised to implement them. In this case, charge and fee levies are set in accordance to the cost of providing a particular service such as administering Pollutant Release and Transfer Registers (PRTRs), Integrated Pollution Control licenses or permits, chemical risk assessments, inspection services and training. There may also be national preferences for how taxes and charges are levied in this regard that will be important to consider, but the following guidelines are relevant to most cases.

1. The advantage of low initial charge levels

Low charges, even below the cost of providing the services and systems that manage the placement of chemicals in the market, can be one way to initially secure the cooperation of the private sector in paying new cost recovery-oriented charges.[1] This is particularly important the context of illegal trade and use. The more time-consuming and costly it is for private sector firms to engage in the systems established to manage the placement of chemicals on the market, the more likely they are to risk operating outside of these structures, resulting in increases in illegal movements of products and substances. One further concern to be aware of includes the potential for hoarding of products which polluters know in advance will be required to register (as has happened in pesticides or fertilizers taxation).

2. Administrative feasibility

The design of the regime and the activities required under every aspect of its operation will influence greatly the cost of the systems, their implementation and enforcement – and therefore either the cost-effectiveness of the regime and the amount of financing that must be raised to support implementation. Overall, a balance must be found between simplicity, or low resource requirements, in system design and effectiveness of the various systems to reach the objective of managing the placement of chemicals on the market. Otherwise, administrative procedures become prohibitively expensive for all stakeholders. Box 14. summarizes important considerations for the simplicity of systems that aim to manage the placement of chemicals on the market.

3. Stakeholder engagement

The inclusion of industry stakeholders – including producers, importers and dealers – in setting charge levels for cost recovery instruments is likely to be pivotal to their acceptability and therefore their success.

A good rule of thumb is that charges be kept as low as possible and the services to which they are attached demonstrate clear good 'value-for-money'. Box 14 lists some important considerations for simplicity of systems design to achieve lowest running costs for regulatory systems governing placement of chemicals on the market.

Box 14. Considerations for systems design to achieve lowest running costs for regulatory systems governing placement of chemicals on the market

- ⇒ Are licenses or authorization given to firms or substances?
- ⇒ How many firms are envisaged as being subject to the register/permits/license systems?
- ⇒ What case for firms with many substances/products containing chemical substances?
- ⇒ What length of validity should be given to registration, permit, license …etc.?
- ⇒ How often should inspections take place?
- ⇒ How well are the sequence of all activities are organized and planned, including length of waiting times?
- ⇒ How often should registers and permits/licenses databases be revised?
- ⇒ What is a reasonable schedule for firm (importers and producers) reporting/application requirements, and their assessment by government officials?

G. How are Charges to be Implemented?

Successful implementation of cost recovery is conditional on private sector cooperation, effective institutional arrangements for charge implementation and efficient revenue collection systems.

1. Value-for-Money Services and Closed Loop Charges

The degree of industry opposition to new cost recovery measures is likely to depend on the costs involved, the size of the company[71] and the extent to which they can pass on the additional cost to consumers. Linking cost recovery clearly to the service being charged for may help overcome resistance within an industry or in society. Where there is an overlap between payers and beneficiaries, a 'closed-loop' of paying charges and receiving benefits of service within a particular sector, locality or in the context of a particular pollution control issue is more positively perceived than money disappearing into the labyrinthine "pot" of general government revenues.[72]

Incentive compatibility issues are also important to consider. Is there a moral hazard or conflict of interest created in the design of the system, i.e. if institutions are directly dependent on fees and charges for services rendered, are they likely to 'oversupply' their service and therefore reduce value-for-money?

Some partnership models exist that represent an opportunity for closed-loop charge systems, whereby academic institutions, public agencies and private firms work together on implementing governance measures aimed at improving chemicals control (*See* Box 15).

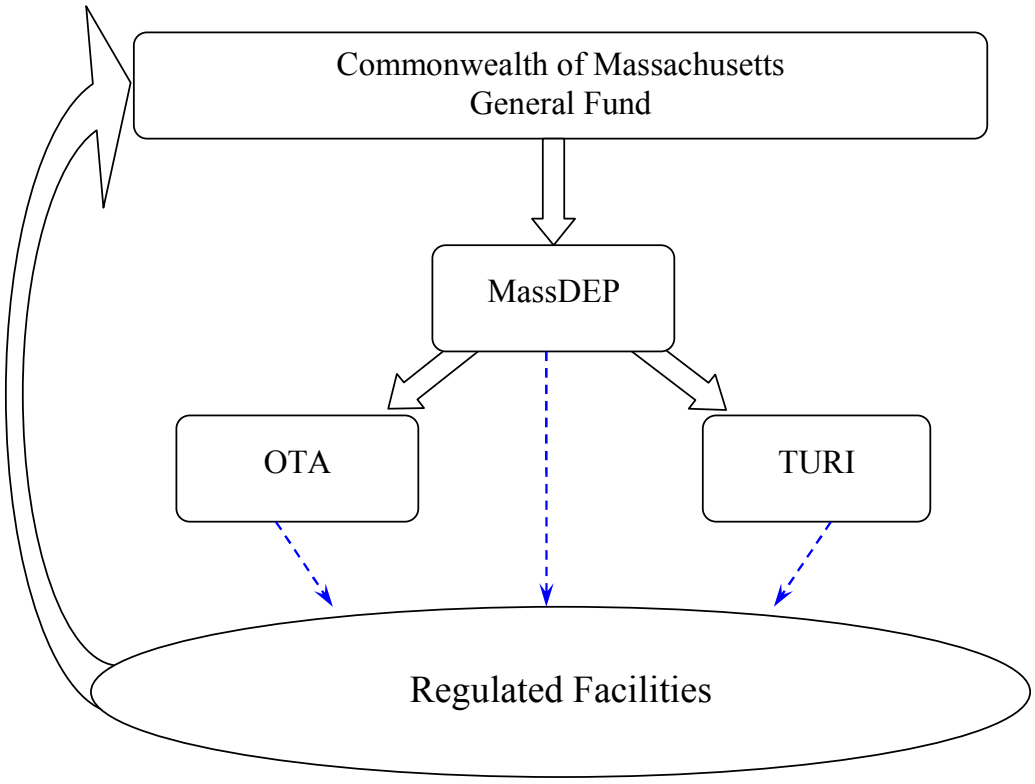
Box 15. The Massachusetts Toxic Use Reduction Act (TURA) program funding model

The Massachusetts Toxics Use Reduction Act (TURA) programme provides an example of a successful closed-loop charge system.

Under TURA – adopted in 1989 to protect public health and the environment while enhancing the competitiveness of Massachusetts businesses – facilities that use large amounts of toxic chemicals are required to report on their chemical use, conduct toxics use reduction planning every two years, and pay an annual fee. The fees vary by size of facility and by the number of regulated chemicals reported. These fees support the work of the three TURA implementing agencies, including the Massachusetts Department of Environmental Protection (MassDEP), the Office of Technical Assistance & Technology (OTA), and the Toxic Use Reduction Institute (TURI) of the University of Massachusetts, Lowell.

Prior to 2003, all TURA fees went into a dedicated Toxics Use Reduction Fund (TURF). The fund was eliminated in 2003 and the fees now go into the state's general fund. In order to ensure that the fees paid by facilities subject to TURA program requirements are spent for TURA enforcement activities, funds are allocated to a retained revenue account at MassDEP. They are then distributed accordingly to the implementing agencies. In particular, the funding collected is used to provide a wide variety of services, including training, research, grant programs and technical assistance that promote and assist compliance of the regulated facilities. The allocation of collected revenue for compliance promotion services was an instrumental compromise to make industry accept the law.

TURA funding flows:



⇨ : Cash flows
- - →: Compliance promotion services

Sources: - http://www.mass.gov
- http://www.turi.org
- Ellenbecker and Geiser (2011)
- Informal consultation with Dr. Kenneth Geiser, TURI

2. Phased Implementation

Progressing from a localized pilot (either in geographic or sectoral terms) to broader implementation can offer a 'grace period' to policy-makers and other stakeholders without taking on an unacceptable degree of political risk. Moreover, given uncertainties surrounding actual performance small-scale piloting can give a less costly indication of likely outcomes before moving to a larger scale implementation. [73]

3. Institutional Organization for Cost Recovery Systems

In terms of institutional arrangements, clarification of responsibilities in implementation is fundamental and must be mapped thoroughly to assign roles in cost recovery operations as efficiently as possible, and set out in the legislation underpinning the charge systems which details the designation of authorities.

The level to which the fiscal system is centrally or de-centrally organized for implementing charges will have implications for cost recovery mechanisms. Specifically, designers of cost recovery charge systems must identify which ministry or agency is best suited to:

- Designing necessary legislation that underpins the charge system
- Collecting revenue from maintaining registries of domestically-produced or imported chemical substances or products, issuing licenses or authorizations, conducting testing and conducting training (either inter-agency or for private enterprise)
- Engaging in stakeholder consultations on the charge systems
- Monitoring compliance with charge systems
- Enforcing compliance with charge systems

4. Systems for Revenue Collection

A transparent, pragmatic approach must be followed in revenue collection activities. Identifying mechanisms that already exist for collecting charges is not only important in determining pre-existing fiscal burdens for charge payers, but also might serve to identify appropriate payment vehicles on which new charges may build on existing charges or fees to avoid unnecessary additional administrative costs. Box 16. lists some questions to be considered in thinking about how fees are to be collected. In the interest of transparency, it is recommended that fees are not collected directly by inspectors due to corruption risks.

Box 16. Important considerations in establishing revenue collection procedures

⇒ Which ministry or agency typically engages in revenue collection?

⇒ Can this system facilitate or be reasonably adapted to suit the needs of the proposed cost recovery charge system?

⇒ How can transparency and accountability be ensured?

H. Monitoring and Enforcing Compliance with Cost Recovery Charges

Inspection services must be in a position to detect firms that have either not completed mandated registration/authorization procedures and/or have not paid the administrative fees attached to these types of systems for managing the placement of chemicals on the market with some degree of regularity.

What is more, even if 'fee-avoiders' have a reasonable chance of detection but it is unlikely that they will be prosecuted, the effectiveness of cost recovery measures will be poor. Weak laws, corruption or a lack of capacity to initiate and persevere with legal action can present problems. In the case of revenue-generating instruments, enforcement mechanisms can capitalize on existing tax laws and their enforcement; and if environmental-related fees, charges and taxes are covered by the same branch of law, performance with other public finance-raising structures will indicate the likelihood of success of these instruments.

The use of sanctions and penalties for late or non-payment of fees can also be considered to encourage compliance with the cost recovery system.

I. Allocating Revenues earned through Cost Recovery

Five generalized options for managing revenues are:

- Direct contribution to general government revenue with no earmarking of the costs recovered;
- Earmarking tied to national budget approval procedures whereby revenues are allocated to supporting chemicals management activities across all ministries in accordance with national prioritization of chemicals management in development planning processes;
- Earmarking tied to national budget approval procedures, whereby funds are returned to the ministry implementing the cost recovery charges via the national budget allocation process;
- Earmarking through environmental funds external to national and line ministry budgets; and
- Direct appropriation by the ministry implementing the cost recovery charges.

At first glance, it seems obvious that revenue raised through cost recovery instruments is generally captured for the provision of services by the agency responsible for chemicals management to fund their own sector or subsector programmes and activities. Yet, revenue raised through chemicals management cost recovery and other financing mechanisms are not always routed back into providing public chemicals management services.

Often, the rules of procedure governing the management of public revenues stipulate that funds raised go to the general returns for the government. From a governance standpoint, earmarking or hypothecation can be viewed as placing costly limitations on how taxes and expenditures are managed. The argument is that effective budgetary control is not possible when government revenue is managed in opaque funds outside the national budget; that earmarking has potential to generate a misallocation of resources, with too much funding been given to earmarked activities and not enough to other social priorities. Furthermore, setting aside revenue infringes on the discretionary powers of the legislative and executive branches of government to decide how government expenditure best matches national interests.

The criticisms of earmarking rest largely on the assumption that central government 'knows best' however. That it is a single entity with a single will that reflects the preferences and wishes of the population, holding the correct understanding of priorities for the nation and operates with close to zero inefficiency. Yet central government inefficiencies certainly do exist. Furthermore, in the case of chemicals management, minimising chemicals risks it is not a priority in many of the countries where it perhaps should be, for many reasons. How then can it be assured that chemicals management receives appropriate funding levels from central government while also maintaining efficiency in governance of national budgets?

From this point of view, cost recovery fees and charges on systems governing placement of chemicals on the market should be routed back into providing financial support for chemicals management activities across ministries. This support can take many forms however. For example, it may be desirable that at least some portion of these funds be returned to industry to support compliance promotion activities, particularly small-to-medium sized enterprises training. Schemes such as these may also have the knock-on effect of reducing public monitoring and enforcement costs.

Similarly, allocating some revenue to a separate national fund (or other instrument) for responses to chemicals-related accidents and incidents may be appropriate, so long as the fund is transparently managed and included in national budget accounting.

Given the cross sectoral nature of chemicals management, it is typically the case that chemicals management activities take place under the programme and project work of various Line Ministries. For governing the placement of chemicals in the market, it may be however, that the Ministry of Environment (MoE) is responsible for chemicals registration and permitting systems that manage chemicals upstream and thereby reduce downstream costs for other Ministries, e.g. Health, Agriculture. Where benefits from managing chemicals that are traded on the market in line with the 'sound management' principle are observed across LM budgets, there is a strong argument for somehow ensuring that the cost of investment in the legislation and institutions required to do this does not fall solely on one already underfunded Line Ministry. Essentially, this can mean allowing for situations whereby funds raised through tax or cost

recovery measures in one institution is earmarked to support chemicals implementation activities in another.

The case for earmarking – or no earmarking – should preferably be made at the stage of law development and included in the law. Therefore, some balanced assessment of the various options for allocating revenue raised through cost recovery, noncompliance penalties and environmental taxation instruments related to the placement of chemicals on the market. The choice between options is a choice to be taken at the national level, depending on what the policy goals and legal/institutional strengths and limitations are in the national context.

VIII. Conclusions and Recommendations

A. Legal and Institutional Infrastructures

1. Legislation should be adapted to the national legal framework and be in accordance with the international commitments of the country.

The choice of the elements to include at the level of law or subsidiary instruments is to be made in accordance with the legal tradition. In general, the law should be kept simple and the technical requirements included in regulations. The law should also provide adequate powers for public bodies to succeed in their mandates. Given the trade related dimension of the placement on the market, particular attention should be paid to international/regional agreements, standards and norms, as well as addressing illegal international traffic. International/ regional harmonization also provides trade opportunities.

2. Improved inter-sectoral information exchange is critical for efficient use of existing information.

Understanding chemical flows, hazards and risks is an integral aspect of proper chemicals management. Proactive and informed decisions to protect human and environmental health can be made in concert with the expanding body of chemicals' risk knowledge. The establishment of cross-sectoral information management systems can help uncover precious existing information, strengthen strategic planning, and facilitate the development of integrated solutions. Careful use of information generated internationally and in countries with similar conditions can also prove to be valuable when localized data are lacking.

3. Legislation governing the placement of chemicals on the market should be comprehensive, coherent, and transparent.

In order to provide an enabling framework for SMC, the scope of legislation governing the placement of chemicals on the market should be broad enough in terms of substances and risks covered. It should clarify the links with other chemicals management legislation (management of chemicals production, use, transport, pesticides, etc.) and to national environment and development policies in a life-cycle perspective. Legislation should address the principle of transparency in decision making, right of information, stakeholders' participation, publicity and community right to know about the presence and emissions of toxic chemicals.

4. There must be a very clear delineation of obligations and responsibilities of key stakeholders affected by chemicals management.

Clear responsibilities should be allocated to public and private sectors stakeholders, taking into account respective capacity and resources. Many countries have transferred the main responsibilities for safe management of chemicals to companies. At least, producers and importers should have the responsibility to generate and provide information on chemicals properties, hazards, risks and safety measures throughout the supply chain. The need for all stakeholders to build the required capacities for sound management of chemicals should be addressed. Education and training can be considered – especially for SMEs, but taking into account the allocation of responsibilities between the public and private sectors.

5. Best use of resources and strong coordination are key for efficient organization of national administration.

Mandates of public authorities should be clear and specific at the three levels (decision-making, implementation and enforcement), and inter-sectoral coordination should be strengthened and formalized. Rules on the conflict of mandates can help improve coordination and resolve potential conflicts. Coherence in public authorities' activities should be sought, by concentration and/or sharing of expertise and resources. Arrangements for resources mobilization should be ensured.

6. Selection and design of policy instruments and measures can be tailored to national circumstances, implementation and enforcement capacity.

Classification and labelling is among the most important instruments for ensuring efficient and cost-effective lifecycle chemicals management. It ensures generation and dissemination of information

throughout the supply chain and assists in building awareness and capacity for chemicals management. Information inventoried through licensing systems for primary suppliers and registration of high-concern chemicals also contribute to building the knowledge-base critical for lifecycle chemicals management. Furthermore, bans and restrictions, and import and export permits are critical instruments for preventing negative impacts of chemicals.

7. Comprehensive and credible compliance systems are the basis effective implementation and enforcement.

Inspections systems should be designed to ensure adequate powers and capacity for inspectors. Coherent and efficient coordination of inspection activities should occur at the three intervention points (customs, primary supply, use). Basic laboratory capacity should be ensured. Reporting requirements can be useful for monitoring compliance and collecting information, but should only be developed to the needed extent as these are demanding for public authorities and companies. Offences and sanctions in case of non-compliance should be carefully designed to ensure effective deterrence of unlawful practices; Compliance promotion activities provide a cheap means for ensuring enforcement of the legislation in complement to effective inspections and sanctions.

8. Regional cooperation can provide an effective and cost-efficient means for strengthening chemicals management.

Cooperation with countries of the same region can provide opportunities for sharing of knowledge and resources. Mutual acceptation of information and/ or decisions as part of registration/ authorization systems should be considered when localized data and capacity are lacking. As well, the development of shared laboratory infrastructures can assist in making the best use of limited resources. Sharing of experience in chemicals management can also be valuable.

B. Sustainable Financing

1. Policy conditions do not need to be perfect for achieving sustainable financing

What matters for effective implementation of these measures is not that policy conditions are ideal but that chemical policy goals are coherent with related economic, environmental and social goals, that an appropriate legal and institutional context has been created and that the design of cost recovery charge systems are consistent with the strengths and limitations of the institutional framework in which they operate.

2. Demonstrate net benefits to all government Ministries, industry and society of strengthening legal and institutional infrastructures governing the placement of chemicals on the market (COI)

Showing that clear net benefits from legal and institutional infrastructures exist, and the benefits are to be shared across both the public and private sectors, the task of arguing for sharing the cost of investment to obtain these benefits between the public sector and private industry is not as impossible.

3. Minimise costs of legal and institutional infrastructures upfront

Since the costs of new legal and institutional infrastructures will depend on the design of registration, licensing and permitting systems and the effectiveness of coordination between government ministries in implementing the new legislation, amongst other cost factors, the public sector has a responsibility to ensure that costs are minimized from the outset through sensible cost effective system design. Charges should be kept as low as possible.

4. Build credibility with the private sector

In paying at least part of the cost for managing the placement of chemicals on the market to reduce risks across the chemicals lifecycle, the private sector has the 'right' to expect an adequate service in return. That is to say, that inventories will be adequately maintained and registration/authorization and licensing laws enforced such that any firm found to be noncompliant *will* have costly consequences to face. In this way, the principle of a level-playing field is upheld with those who do not play by the rules of the game not benefiting from an *unfair* competitive advantage.

5. Make it clear what is being paid for

By closely linking cost recovery charging with spending – or service delivery – resistance within industry or society to cost recovery systems may be overcome. A 'closed-loop' of paying charges and receiving benefits of service within a particular sector, locality or in the context of a particular issue, is more positively perceived than money disappearing into the labyrinthine "pot" of general tax returns. The services to which they are attached demonstrate clear good 'value-for-money'

6. Seek out windows of opportunity

Identifying 'windows of opportunity' or opportune moments in broader policy-making or legislative changes will increase the chances of successfully funding programmes for managing placement of chemicals on the market.

7. A broad range of stakeholder consultation means a more considered legal and cost recovery system design (general point)

Identifying and engaging with a broad range of stakeholders is one way of ensuring that important design issues are covered and political acceptability for the measures achieved.

8. Phased Implementation

Progressing from a localized pilot (either in geographic or sectoral terms) to broader implementation can offer a 'grace period' to policy-makers and invested stakeholders without taking on an unacceptable degree of political risk. Moreover, given uncertainties surrounding actual performance small-scale piloting can give a less costly indication of likely outcomes before moving to a larger scale implementation. Low charges to higher

IX. References

Bucht B. (2008), *Legislation for risk management at marketing of chemicals – the first step of the supply chain*, Swedish Chemicals Agency, KemI PM 4/08.

Bucht B. (2010), *Capacity Building for Sound Management of Chemicals. Organisation, responsibilities and tasks of governmental and institutions and enterprises*, Swedish Chemicals Agency, KemI PM 1/10.

Ellenbecker M., Geiser K. (2011), "At the source: the origins of the Massachusetts toxics use reduction program and an overview of this special issue", *Journal of Cleaner Production*, n° 19, pp. 389-396.

FAO (2007), *Designing National Pesticide Legislation*, Development Law Service, FAO Legal Office, Rome.

FAO (2002), *International Code of Conduct on the Distribution and Use of Pesticides*, Food and Agriculture Organization of the United Nations, Rome.

FAO (April 2010) *International Code of Conduct on the Distribution and Use of Pesticides. Guidelines for the Registration of Pesticides*, Food and Agriculture Organization of the United Nations, Rome.

FAO (January 1989) *International Code of Conduct on the Distribution and Use of Pesticides. Guidelines for Legislation on the Control of Pesticides*, Food and Agriculture Organization of the United Nations, Rome.

Griffith B. (January 2011), "Elements of Inspiration", *Chemistry World*, Royal Society of Chemistry, United Kingdom.

Grosse S.D., Matte T.D., Schwartz J., Jackson R.J. (2002), "Economic gains resulting from the reduction in children's exposure to lead in the United States", *Environ Health Perspect*, 110:563-569.

Hylander, L.D. and Goodsite, M.E. (2006) "Environmental costs of mercury pollution", *Science of the Total Environment* 368 (2006): 352-370.

IISD/UNEP (2005), *Environment and Trade: A Handbook* (2nd Edition), International Institute for Sustainable Development, Manitoba.

IPCS-IOMC (August 1998), *Key elements of a national programme for chemicals management and safety*, United nations Institute for Training and Research, Geneva.

Landrigan P.J., Schecter C.B., Lipton J.M., Fahs M.C., Schwartz J. (2002), "Environmental pollutants and diseases in American children: estimates of morbidity, mortality, and costs for lead poisoning, asthma, cancer, and developmental disabilities", *Environ Health Perspect*, 110:721-728.

O'Connor D. (1998), "Applying Economic Instruments in Developing Countries: From Theory to Implementation", *Environment and Development Economics 4*, 91-110.

OECD (2005), *Environmental Fiscal Reform for Poverty Reduction, DAC Guidelines and Reference Series*, Organisation of Economic Cooperation and Development, Paris.

OECD (2001), *Environmental Outlook for the Chemicals Industry*, Environmental Directorate, Paris.

OECD (2008), *Environmental Outlook to 2030*, Environmental Directorate, Paris.

SAICM (March 2009), *Long-term financing for implementation of the Strategic Approach to International Chemicals Management* (SAICM/ICCM.2/12).

Salkever D.S. 1995. "Updated estimates of earnings benefits from reduced exposure of children to environmental lead", *Environ Res*, 70(1):1-6.

Schwarz J. (1994), "Societal benefits of reducing lead exposure", *Environ Res,* 66:105-124.

Sterner (2002), *Policy Instruments for Environmental and Natural Resource Management,* Resources For the Future (RFF), Washington DC.

TEEB (2009), *The Economics of Ecosystems and Biodiversity for National and International Policy Makers – Summary: Responding to the Value of Nature*,

http://www.teebweb.org/LinkClick.aspx?fileticket=I4Y2nqqIiCg%3d&tabid=1021&language=en-US, last accessed 30 March 2011.

TEEB (2010), *The Economics of Ecosystems and Biodiversity: Mainstreaming the Economics of Nature: A synthesis of the approach, conclusions and recommendations of TEEB*, http://www.teebweb.org/LinkClick.aspx?fileticket=bYhDohL_TuM%3d&tabid=1278&mid=2357, last accessed 30 March 2011.

Trasande L., Cortes J.E., Landrigan P.J., Abercrombie MI, Bopp RF, and Cifuentes E. (2010) "Methylmercury exposure in a subsistence fishing community in Lake Chapala, Mexico: an ecological approach." *Environmental Health.* 2010 Jan 11 9:1.

Trasande L., Landrigan P.J., Schechter C. (May 2005), "Public health and economic consequences of methylmercury toxicity to the developing brain", *Environmental Health Perspectives*; 113(5): 590-596. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1257552.

UNDP (2010), *Technical Guide for the Integration of the Sound Management of Chemicals into MDG-based Development Planning*, Environment and Energy Group, New York.

UNEP (1995), *Guidance on Chemicals Legislation: Overview*, International Register of Potentially Toxic Chemicals.

UNEP (2004), *The Use of Economic Instruments in Environmental Policy: Opportunities and Challenges*, United Nations Environmental Programme, Geneva.

UNEP (Nov2009), *Global Chemicals Outlook: Scoping Paper and Research Proposal*, Chemicals Branch, Geneva.

UNEP-CIEL (2007), *Elements of Good Practice in Legal Frameworks for the Implementation of the Stockholm Convention on Persistant Organic Pollutants (POPs) in Latin America. A Toolkit for Decision-Makers and Interested Stakeholders*, Center for International Environmental Law.

UNEP-WHO (2007), *Strategic Approach to International Chemicals Management*, United Nations Environment Programme, Nairobi.

UNITAR (August 2001), *Information Exchange for Sound Chemicals Management. A Guidance Note*, United nations Institute for Training and Research, Geneva.

UNITAR (June 2010), *Understanding the Globally Harmonized System for Classification and Labelling of Chemicals (GHS). A Companion Guide to the GHS Purple Book*, United nations Institute for Training and Research, Geneva.

UNITAR-IOMC (January 2004) *Developing and Sustaining an Integrated National Programme for Sound Chemicals Management. Guidance Document*, United nations Institute for Training and Research, Geneva.

UNITAR-IOMC (August 1998), *Developing & Strengthening National Legislation and Policies for the Sound Management of Chemicals. Observations and Conclusions of an International Expert Meeting. Final Report*, United nations Institute for Training and Research, Geneva.

UNITAR/UNDP/GEF Action Plan Project review (April 2005) *Guidance on Action Plan Development for Sound Chemicals Management. Guidance Document*, United nations Institute for Training and Research, Geneva.

Wallsten TS, Whitfield RG. (1986), *Assessing the risks to young children of three effects associated with elevated blood-lead levels*, ANL/AA-32, Argonne, IL:Argonne National Laboratory.

Wilson, C. and Tisdell, C. (2001), "Why farmers continue to use pesticides despite environmental, health and Sustainability costs", *Ecological Economics*, v. 39, pp. 449-462.

Wilson, C. (2002), "Private costs and the relation between pesticide exposure and ill-health: evidence from Sri Lanka", *Environmental Economics and Policy Studies*, Vol. 5, pp. 213-227.

Perrot-Maître, D. (2006) *The Vittel payments for ecosystem services: a "perfect" PES case?* International Institute for Environment and Development, London, UK. http://www.ibcperu.org/doc/isis/8085.pdf, last accessed 30 March 2011.

WHO-UNEP (2008) *Health and Environment: Managing Linkages for Sustainable Development – A Toolkit for Decision-Makers,* WHO UNEP Health and Environment Linkages Initiative (HELI), http://whqlibdoc.who.int/publications/2008/9789241563727_eng.pdf , retrieved 12 July 2009.

X. Annexes

A. Annex 1: Template for a Framework Law Governing the Placement of Chemicals on the Market

1. General

1.1. Purpose of the legislation, scope and general application

This section clearly defines the purpose of the legislation.

1.2. Scope

The scope should clarify the coverage of substances/ uses, hazards and risks, and activities. The scope should also identify the existence of other pre-existing, specialized chemicals management legislation and state the exemptions.

1.3. Definitions

This section provides a list of the definitions used in the legislation. In drafting the definitions, internationally agreed sources such as the Code of Conduct should be used, along with other national legislation on related subjects, if any.

Possible terms to define include:

- Chemical:
- Substance:
- Mixture:
- Toxic chemical:
- Use:
- Import/export:
- Supplier:
- User:
- Distributor:
- Qualified user/distributor/supplier (eg. what qualifications are needed to handle the chemical):
- Pictogram:
- Symbol:
- Label:
- Hazard:
- Package:
- Storage label:
- Risk:
- Active substance:
- Official laboratory:
- Importer:
- Exporter:

1.4. Discretion in definitions

This subsection provides flexibility to altering definitions as issues are identified or more stringent policies are set in place. Included in this section can also be provisions to allow the governing body(ies) to define substances as 'toxic' or 'hazardous' despite their categorization under the current definitions.

2. General Responsibilities

2.1. Governing bodies

This subsection should present, in detail, the responsibilities and obligations imposed on governing bodies. This includes activities such as licensing, enforcement, risk assessment review, preparation of annual summary reports for public disclosure, etc.

2.2. Enterprises and others handling chemicals

This subsection should present, in detail, the responsibilities of entities which handle chemicals in some form. Obligations might include the reporting of hazard and risk information to users and the obligation to ensure that all held and distributed chemicals conform to GHS standards.

3. Administration

This sub-section allows for clearly stating the powers and mandates of public authorities. Inter-sectoral coordination mechanisms can also be formalized in this section.

3.1 Powers of the Primary Responsible Authority

This section describes the powers of the Primary Responsible Authority. Adequate powers should be provided to the Primary Authority to carry out its mandate.

3.2 Power to issue detailed provisions

This section adds flexibility to the legislation, by allowing for the issuance of more detailed regulations at a later date.

In general, the power to issue subordinate enactments is not limited in the law, and the Primary Authority is authorized to issue all regulations required to achieve the objectives of the law. In some cases, a list of areas for possible regulations is included in an annex to the law.

3.3 Coordination mechanisms

This section outlines the mandate, functions and powers of the coordination mechanisms. The section should designate the authority to appoint members and the conditions for appointment and renewal, define the membership (especially with regard to qualifications), and delineate rules of procedure.

3.4 Delegation

Further flexibility is added to the legislation in this section, with provisions allowing for the government to delegate and assign authorities on specific subjects. This could include external sources of risk assessment information such as GHS.

4. Bans and Restrictions

This section provides authority to the Government to ban or restrict import, marketing, use, export, or other handling of a dangerous chemical, including its use in articles, in the country. The list of banned of restricted substances can possibly be presented as regulation.

5. Registration/ Authorization

This section should identify the authority responsible for registration/ authorization, and clarify its power and functions. The powers of the responsible authority will typically include the right to ask for further information at any time, to amend, suspend or cancel the registration if new information justifies it, and to charge fees.

An application procedure should be established, including the procedure to follow when applying for already approved chemicals or chemicals conditionally approved.

Legislation should also define transparent criteria to be used by the responsible authority for decision making. These criteria should preferably be based on internationally recognized guidelines. Generally, a bounded period is given to authorities to make and communicate a decision to the applicant. In addition to risk factors, the label is generally also reviewed as part of the registration/ authorization process. In case the decision is to deny registration/ authorization, authorities are commonly required to provide a written explanation of the reasons for the denial. A procedure should also be established for applicants to appeal against the decision.

Possible decisions by the responsible authority should also be indicated. Three types of decisions are generally included: approval, conditional/provisional approval, and deny. Registration/ authorization

should be time limited because of the need to take into account evolution of scientific knowledge on chemicals risks.

Provisions allowing the responsible authority to review registration/authorization in light of new knowledge should also be included, as well as powers to impose new conditions, or revoke the registration/ authorization if a) the use of the chemical is not judged desirable, and b) as a penalty for non-compliance. To facilitate enforcement, third parties presenting new relevant information can also be entitled to call for a re-evaluation the application by the responsible authority.

The authority responsible for record-keeping is to be assigned, and the content of the records defined. Special attention should be paid to the confidentiality of information provided by companies.

5.1. Obligations to register chemicals

The subsection must clearly define who is obligated to register the chemicals (ie. What stage of the supply chain), what types/categories of chemicals need to registered, as well as what information is required.

5.1.1. Valid External Sources

To alleviate some resource concerns, the legislation can identify external sources which serve as "valid" sources of information for risk data or any other information presented in the registration form.

5.2. Exemptions, special cases

To add flexibility to the legislation, exemption of specific substances can be given. This could be in the form of a "pre-authorization" or inherent registration. This would only apply for low risk chemicals or chemicals that are low risk when used in small quantities.

6. Licensing

Similar detail to registration would be required, such as when licensing is required, what enterprises or chemicals require licensing, renewal period for licensing, information required to apply for a/licensing, etc.

The law on chemicals should charge the competent authority with receiving, evaluating, approving or denying applications for licenses, specify the application form and procedure, indicate the requirements for the grant of a license, list the types of licenses, define the term of validity of the licence and the procedures for its renewal. The law should require products to conform to relevant standards. It should also set out an appeal process linked to the licensing scheme.

7. Evaluation

7.1. Purpose of Evaluation

To ensure quality of evaluations, legislation must clearly define what the expected outcomes of an evaluation are. Possibly there could be several types of evaluations for different categories of chemicals, quantities, uses, inherent toxicity, and other such defining characteristics.

7.2. Responsibility of Evaluation

Defines who is responsible to evaluate the risk of the chemical.

7.3. Method of Evaluation

To facilitate the risk assessment process and to ensure comprehensive studies, a standard protocol and/or guidelines to evaluate the risk of a substance can be provided in this subsection. Several unique protocols would likely be needed depending on the category of chemical. The protocol and classification scheme can be adopted from another program (i.e. GHS). It is suggested that detailed protocols be included as regulation or schedules to the legislation.

7.3.1. Valid External Evaluations

To minimize resources required, allow for the use of evaluations done in other jurisdictions so long as they comply with certain standards (ie. OECD Guidelines or GHS). Very broadly, the legislation could accept all evaluations done under REACH or similar programs.

8. Import and export

Specifies the authority for import and export permit systems. The application procedure for import and export permits should be outlined, as well as the procedure and criteria for decisions.

Donations or imports by public entities for identified specific purposes can be exempted.

9. Packaging and repackaging

The law should contain provisions on packaging and repackaging of chemicals, taking into account the Rotterdam Convention.

10. Classification, Labelling, Storage/Transportation requirements

10.1. Classification and Labelling

Explicit statement that hazard assessments, classification, and labelling shall be done in accordance with the selected classification and labeling scheme (i.e. GHS). It should be clear what chemicals, substances, mixtures, and intermediate products this applies to.

When the GHS is applied, this section should also make clear the obligation to provide Material Safety Data Sheets (MSDS) to the user by the supplier.

10.2. Storage/Transportation requirements

The legislation should clearly state the requirement for users/producers/distributors to follow standard protocols of the classification and labeling scheme applied (i.e. in GHS and MSDS sheets) for storage and transportation. This would include requirements for proper signage on transport vehicles and storage vessels, records of transport, and use of specific safety equipment and vehicles.

11. Reporting Requirements

11.1. Authority to request for information

The subsection is to provide provisions which allow for the governing bodies to ask for any information about chemicals related to health and environmental risk. Clearly define when the government is justified to request for information (eg. when new evidence points to altering the risk associated with a chemical). It is also possible to tie in reporting requirements with registration, authorization, and licensing.

11.2. Obligation to report new information

To ensure that the governing bodies are always kept informed about the latest information on chemical risk, a provision should be included which obligates industry (and other parties) to report any new information they discover related to the risk assessment of chemicals.

11.3. Obligation to give information about activities with registered chemicals

Further to collecting data on parameters related to chemical use, production, or distribution, reporting requirements can include requirements to give access to information upon request i.e. on report emergency management and safety plans. This would encourage and implement a culture of assessing chemical release risk and provides a protocol to be followed in case of emergency.

11.3.1. Form of reports

This subsection indicates the form of reports to be submitted as part of the reporting requirements. Templates can be provided as part of this subsection, so as to maximize standardization of information reported.

12. Inspections

12.1. Inspection Authority

Delineates the authority/authorities that are given the responsibility of inspections. Inspectors can be appointed by a governing body to carry out these activities.

The law should permit this authority to use not only its employees but also employees of other ministries or agencies or even private contractors for carrying out the inspection measures. This possibility can be allowed for by including in the law that inspectors are those officers appointed "or designated" as such.

The law should establish a system for identifying and certifying the official analysts and laboratories that will carry out the required analysis of samples taken under the law.

12.1.1. Obligations of enforcement authority

States the obligations and activities that must be carried out by the enforcement authority. This could include a schedule for inspections related to certain high risk chemicals or a general statement about inspections when it is deemed necessary (by the authority).

12.1.2. Power of enforcement authority

Makes clear statements about the power of the enforcement authority to request for information, inspect premises or storage, and to ask for evidence within the scope of enforcing this legislation. This section can likely be adapted from existing legislation with inspection and enforcement provisions.

12.2. Orders

This section allows for an order to be imposed by an enforcement agent to an entity under this legislation. The order provides a record of non-compliance and should provide a timeline for the entity to come into compliance. This allows for further escalation of enforcement activities and penalties to be issued. This subsection must clearly delineate what can be asked for in an order (eg. cease and desist)

12.2.1. Appeal of orders and enforcement actions

Allows for the appeal of order and enforcement actions. Clearly delineates what group or body would be in charge of overseeing the appeal and given the responsibility to pass final judgment.

13. Advertising

Provisions for the control of advertising should be included in the law. The authority for enforcement of advertising requirements should be designated.

Advertising ofany unregistered or illegal chemical; advertising any chemical in a false or misleading manner or in a manner intended to deceive; and advertising in a way that is contrary to the conditions of the registration of the chemical or contrary to its approved label should be prohibited.

15. Offences

Offences must be defined in the law, as a basis for determining the penalties that may be imposed. The offences should also include actions by persons acting officially on behalf of the competent authority. They should be categorized as criminal or administrative observing the country's international commitments such as the *Basel Convention on the Transboundary Movement of Hazardous Wastes and Their Disposal*.

16. Penalties, sanctions

16.1. Penalties

Delineates that penalties (typically fiscal) can be applied for non-conformance with any part of the legislation (and regulations) as well as any order made by the enforcement authority under 0. The schedule of fees for various types of violations would typically be delineated in regulations

16.2. Sanctions

In cases of continual non-conformance with orders, allows for the governing body/bodies, in their judgment, to apply sanctions and restrict the operations of the non-conforming entities.

16.3. Procedure

After determining the applicable penalties, the law should next set out the procedures applicable once an offence has been committed (unless this is governed by a criminal or administrative procedure code). These

procedural rules are important as they protect an individual's basic rights by defining, *inter alia,* the notice obligation, the right to a hearing and the right to appeal a negative decision.

17. Confidentiality

The confidentiality of the information provided by the companies in the course of the registration process is a sensitive topic for the production industry and requires detailed provisions. Therefore, it is recommended not to include provisions governing the confidentiality into the law on chemicals or pesticides but to refer to the provisions and guidelines specifically concerning the confidentiality of intellectual property on formulations.

17.1. Request for confidentiality

This section states the conditions under which information submitted to public authorities by businesses and other entities required to provide information can remain confidential and not distributed to the public.

17.2.1. Confidential Business Information

Delineates what types of information can be made confidential and the acceptable types of justification.

17.2.2. Form of application

Clearly states what must be provided by the business in a request for confidentiality.

17.2.3. Exemption from confidentiality

Allows for the governing body to distribute any information to the public, if it is in the interest of public health, regardless of confidentiality claims or requests.

18. Appeal

Sets out procedures for appeals against negative administrative decisions. Appeals should be allowed for registration, licensing and permit decisions, as well as with regard to penalties and sanctions.

Clearly delineates what group or body would be in charge of overseeing the appeal and hear the appeal. In some countries the appeals can or have to be channeled through the normal legal system.

19. Miscellaneous provisions

Under this section, the law may contain other issues that do not fit into the categories already addressed but a country may wish to address in the law. These include provisions on the liability of inspectors or officials, legal presumptions, appeals against negative administrative decisions under the chemicals law and the many subject matters that the minister or other competent person may address through regulations in order to carry out the purposes of the law.

20. Entry into force and application. Transitional

20.1. Schedule of Entry into Force

Clearly states when the legislation (or pieces of it) come into force and must be complied with. If periodic reporting is required, ensures that it is clear when the schedule for reporting starts and the deadline for submission of the first report.

20.2. Transitional

Clearly defines how previous activities with now regulated substances will be handled. If other regulations are being phased out when this legislation comes into force, ensure that the transition between legislation is clearly defined. This can be done through regulation.

It is important to explicitly refer to any existing law or legal provisions that are superseded by the new law. If an earlier pesticide law is being replaced, then the new law will either state that the old law is repealed in its entirety, or it may list specific provisions that have been repealed.

B. Annex 2: Sectoral Public Bodies Generally Engaged in Some Aspect of Chemicals Management[74]

The titles of ministries are generic and countries may use different ones for their authorities:

- ⇨ Ministries of *Agriculture* are generally concerned with the use of agricultural chemicals for the benefit of securing food supplies;
- ⇨ *Customs Authorities* are generally responsible for ensuring that chemicals do not enter or leave the country contrary to government regulations, and tariffs and duties;
- ⇨ Ministries of *Environment* are generally concerned with the direct and indirect effects of releasing chemicals into the environment as emissions and wastes to air, water and land;
- ⇨ Ministries of *Finance* have a central role in financial resource allocations for chemicals related activities;
- ⇨ Ministries of *Foreign Affairs* usually co-ordinate all international aspects of chemicals management, such as participation in relevant international agreements and conventions;
- ⇨ *Government printing/publications offices* are generally concerned with the publication and distribution of laws, regulations and other government documents, and can play a role in raising public awareness;
- ⇨ Ministries of *Health* are mainly concerned with the short- and long-term health impacts of chemicals (including emergencies and poisonings) on the general public or specific population groups;
- ⇨ Ministries of *Industry* are often concerned with the production of chemicals and chemical products and the introduction of cleaner production technologies;
- ⇨ Ministries of *Justice* or *Legal Affairs* are generally concerned with the development and enforcement of laws and regulations, and often deal with issues concerning public access to information, the protection of confidential business information, criminal and forensic issues and accidents/incidents/terrorism;
- ⇨ Ministries of *Labour* are generally concerned with occupational health and safety issues related to the use and handling of chemicals at the workplace;
- ⇨ Ministries of *Planning* primarily deal with economic planning (and land use/regional development). This ministry can also often deal with the donation or receipt of development assistance, which could include chemicals for agricultural use, technical or financial assistance for the development of chemical industries, or technical assistance for the management of chemicals;
- ⇨ Ministries of *Science and Technology* play an important role in deciding the future direction and resource allocations for research and, at least indirectly, action on chemicals;
- ⇨ Ministries of *Trade* are generally responsible for regulating the import and export of chemical substances and often have the authority to issue relevant trade permits; and
- ⇨ Ministries of *Transport* are generally concerned with the safe transportation and storage of chemicals during the distribution phase.

C. Annex 3: Sources of Information for Chemicals Management

International sources of information include:

- *IOMC Global Information Network for Chemicals (GINC).*
- *WHO Global Health and Environment Library Network (GELNET).*
- *UNEP-WHO Health and Environment Linkages Initiative (HELI) website*. www.who.int/heli
- *IPCS INCHEM*. http://www.inchem.org/
- *WHO International Agency for Research on Cancer (IARC).* http://monographs.iarc.fr/
- *UNEP-INFOTERRA*. http://www.unep.org/infoterra/
- *UNEP Chemicals Chemicals Information Exchange Network.* http://jp1.estis.net/communities/cien/
- *OECD eChemPortal*. http://webnet3.oecd.org/echemportal/Home.aspx
- International Council of Chemicals Associations (ICCA) Global Product Strategy (GPS) Chemicals Information Search Portal. http://www.icca-chem.org/en/Home/ICCA-initiatives/global-product-strategy/chemical-information-search/
- Different types of publications:
    - *Environmental Health Criteria* documents;
    - *Concise International Chemical Assessment Documents*;
    - *Health and Safety Guides*;
    - *International Chemical Safety Cards*;
    - *Poisons Information Monographs;*
    - JECFA and JMPR Monographs;
    - OECD *Screening Information Data Sets (SIDS) Information Assessment Reports*;
    - UNEP and European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) *inventory of critical reviews on chemicals*.
    - OECD *Guidelines for the Testing of Chemicals and Principles of Good Laboratory Practice*;

Regional, national and local sources of information include:

- Public bodies involved in one aspect or the other of chemicals management (transport, industry, agriculture, mines, health, environment, etc.). Cross-sectoral and multi-level sharing of available information can be beneficial for all as it allow the development of new knowledge on and solutions for addressing the country's needs, and considerably reduces the costs of information.
- General national assessments such as census, demographic data, health statistics, health/ environmental monitoring results, etc.
- Publications and research papers from research institutions and universities, professional bodies;
- Data and publication from private sector import organizations;
- Data and publication from trade unions;
- Data and publication from "grass roots" organizations;
- Information maintained by rescue service agencies (e.g., police and fire departments), hospitals and local planning/zoning boards;
- Information on toxic exposures to chemicals and on chemical incidents collected by poison centers

[1] For a preliminary overview of existing information on environment and health impacts of chemicals, see UNEP (Nov2009).
[2] OECD (2001):35, OECD (2008): 381
[3] SAICM/ICCM.2/12, para. 29
[4] SMC is defined as: the application of "*managerial best practices to chemicals throughout their life cycle to prevent, and, where this is not possible, to reduce or minimize the potential for exposure of people and the environment to toxic and hazardous chemicals*." UNDP (2010); p. 5.
[5] For the purpose of these guidelines, the expression "legal and institutional infrastructures" includes legislation and institutional arrangements. Legislation includes the collection of legislative statutes and subordinate enactments regulating a specific issue (i.e. the placement of chemicals on the market). Institutional arrangements are the organization of human, financial and technical resources of national administration for decision-making, implementation and enforcement of a national chemicals management policy.
[6] Note: "SAICM does not cover products to the extent that the health and environmental aspects of the safety of the chemicals and products are regulated by a domestic food or pharmaceutical authority or arrangement.", Overarching Policy Strategy, Section II Scope, p. 11.
[7] See for example: UNEP (1995), IPCS-IOMC (August 1998), UNITAR/UNDP/GEF Action Plan Project review (April 2005), and UNITAR-IOMC (January 2004).
[8] As: "the basic governance framework – such as legal, technical, administrative, institutional, civic, and policy capabilities – which a country must have to support effective management of chemicals throughout their life cycles." See: UNEP-CIEL (2007); p. 6.
[9] These categories are taken from UNEP (1995).
[10] FAO (2007); pp. 86-88.
[11] See UNITAR-IOMC (August 1998); p. 19.
[12] Some Small and Medium Enterprises (SMEs) might not have access to Internet.
[13] UNITAR-IOMC, 1998, p. 33.
[14] For more information on information exchange mechanisms and on the use of electronically available information, see: UNITAR (August 2001); and IPCS-IOMC (August 1998).
[15] For more information, see: www.unep.org/roa/hesa/
[16] This issue has been recognized as crucial in SAICM and is one of the five main categories of needs for SAICM implementation. See *SAICM Overarching Policy Strategy*, para. 11, p. 14.
[17] Under the WTO rules, "like" is defined not by the physical or chemical properties of a product; if two products have the same end-use, perform to the same standard, are considered substitutes, and require no different treatment for use, handling or disposal, they are considered to be "like" products. *See* IISD/UNEP (2005: 34-38) for further discussion on interpretations of "like" products. Far beyond the scope of this guidance, but interesting nonetheless, would be some further analysis on how the principle of substitution in sound management of chemicals relates to this concept.
[18] The justification must be scientifically based and the need for trade measure clearly demonstrated. Furthermore, the Chapeau of Article XX states that countries can not require another State to adopt a certain technology; differences in conditions prevailing in other countries must be shown to have been taken into account; negotiations must precede unilateral measures; foreign countries must be given time to adjust; and, due process must be followed.
[19] *See* http://www.wto.org/english/tratop_e/gatt_e/gatt_e.htm, last accessed 30 March 2011.
[20] *See* http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm1_e.htm, last accessed 30 March 2011.
[21] Information on a significant amount of standards can be found on the website of the International Standardization Organization (ISO), at: www.iso.org
[22] Bucht (2008); p. 6.
[23] In this Guidance, broad coverage of chemical substances is defined in line with SAICM's scope. See section I.C.1.
[24] See for example the UNEP Chemicals in Products (CiP) project: http://www.chem.unep.ch/unepsaicm/cip/default.htm
[25] These categories are adapted from: Bucht (2010); p. 18.
[26] Such cost-sharing allocation should be done in light of a) the hidden public costs of managing the marketing of chemicals, and b) of the private benefits of better regulation. See chapter VII, Sustainable Financing through Cost Recovery Charge Systems.
[27] As included in the Dubai Declaration on International Chemicals Management of SAICM, 2006, paragraph 20: "We stress the responsibility of industry to make available to stakeholders such data and information on health and environmental effects of chemicals as are needed safely to use chemicals and the products made from them" (p. 8)
[28] Bucht (2008); p. 27.
[29] Adapted from Bucht (2008); p. 28.
[30] For more information on the rationale for and value of this approach, see: www.who.int/heli, and www.unep.org/roa/hesa/
[31] See the chapter "Sustainable Financing through Cost Recovery Charge Systems" of this Guidance, and especially sections G and I.
[32] See FAO (2007); p. 49.
[33] For more information on the GHS, see: http://www.unitar.org/cwm/ghs and the related publications.
[34] Several chemicals conventions have either included reference to GHS or have use GHS criteria in their requirements. For more information, see: UNITAR (June 2010); p. 9.
[35] See: http://www.who.int/ipcs/publications/pesticides_hazard/en/
[36] It is to be noted that Parties to the WTO need to notify the secretariat of their bans and restriction decisions.
[37] FAO (2002); Article 7.5, p. 18.
[38] See in particular: FAO (April 2010), FAO (January 1989). For other related guidelines, see: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/code/list-guide/en/, and FAO (2007); pp. 42-49.
[39] For definitions of "registration", see: IPCS-IOMC (August 1998); Annex 2, p. 75, as well as FAO (November 2002); p. 7.

[40] See for example: FAO (2007); p.43.
[41] See for example: ILO, *Encyclopaedia of Occupational Health and Safety*, Part VII. "The Environment", art. Laws and Regulations, http://www.ilo.org/safework/info/databases/lang--en/WCMS_113329/index.htm
[42] The article 8.2 of the FAO Code of Conduct specifically recommends that manufacturers ensure that exported pesticides meet the same quality standards than comparable domestic products.
[43] Sanction is generally defined as "the detriment, loss of reward, or coercive intervention annexed to a violation of a law as a means of enforcing the law". Adapted from the Merriam Webster online dictionary, at: http://www.merriam-webster.com/dictionary/sanction. In this approach, "penalty" is defined as a negative sanction.
[44] UNEP (1995); p. 40.
[45] The Basel Convention for example requires that Parties consider illegal traffic of hazardous waste as a criminal activity (article 9)
[46] See, for example: International Labour Organisation (ILO), *Encyclopaedia of Occupational Health and Safety*, "Part VII. The Environment, art. Laws and Regulations", available at: http://www.ilo.org/safework/info/databases/lang--en/WCMS_113329/index.htm
[47] For more information of the benefits of involving stakeholders in the policy making process, see for example: IPCS-IOMC (August 1998), UNITAR/UNDP/GEF Action Plan Project review (April 2005), and UNITAR-IOMC (January 2004).
[48] The following discussion does not detail all potential costs for individual national cases, nor are all the cost categories and factors relevant for each and every circumstance. Rather, the purpose is to outline the different cost categories generally anticipated in designing, establishing and implementing new chemicals legislation and the factors influencing the magnitude of these costs.
[49] SAICM/ICCM.2/12: 7-9 and para. 28,31.
[50] SAICM/ICCM.2/12, para. 29
[51] Charges refer to prices typically levied on a pollution source to finance the service provision, administration and enforcement of legislation concerning that particular pollution. Fees are paid as remuneration for administrative services.
[52] FAO(2004): 56-57
[53] *See* SEAFDEC (2000) *Use of Chemicals in Aquaculture in Asia,* http://www.seafdec.org.ph/pdf/Use_of_Chemicals_in_Aquaculture_in_Asia.PDF, accessed 16 June 2010
[54] *See* for example, Australia and New Zealand: http://www.daff.gov.au/aqis/import/food, accessed 15 June 2010;
[55] WHO/UNEP (2008): 58-60
[56] *See* http://www.nestle.com/MediaCenter/NewsandFeatures/AllNewsFeatures/TheCocoaPlan.htm, accessed 15 June 2010
[57] *See* http://www.cargillcocoachocolate.com/News%20Centre/2010_article06.shtml, accessed 15 June 2010
[58] *See* http://walmartstores.com/Sustainability/9292.aspx, accessed 15 June 2010
[59] *See* http://www.carrefour.com/cdc/responsible-commerce/product-safety-and-quality/, accessed 15 June 2010
[60] AccountAbility (2007) http://www.accountability21.net/default2.aspx?id=982, last accessed 14 June 2008.
[61] FAO/UNEP (2004)
[62] Wilson and Tiddsell (2001), Wilson (2002)
[63] *See* Wallsten and Whitfield (1986); Schwarz (1994); Salkever (1995) ; Grosse et al. (2002), Landrigan et al.(2002); Tsai and Hatfield (2010), http://www.csun.edu/~vchsc006/lead.pdf, last accessed 30 March 2011.
[64] *See* Hylander and Goodsite (2006); Trasande et al. (2005, 2010)
[65] UNEP (2009) *Ecosystem Management Programme: A New Approach to Sustainability,* http://www.unep.org/ecosystemmanagement/LinkClick.aspx?fileticket=gbPVsoUCp-E%3D&tabid=293&language=en-US, accessed 16 June 2010
[66] TEEB (2009) The Economics of Ecosystems and Biodiversity for National and International Policy Makers – Summary: Responding to the Value of Nature, http://www.teebweb.org/LinkClick.aspx?fileticket=I4Y2nqqIiCg%3d&tabid=1021&language=en-US, accessed 16 June 2010
[67] TEEB (2010:8)
[68] *See* Perrot-Maître (2006), http://www.ibcperu.org/doc/isis/8085.pdf last accessed 30 March 2011.
[69] *See* New York City Watershed Programme, Department of Environmental Conservation, New York State, http://www.dec.ny.gov/lands/25599.html, accessed 16 June 2010
[70] *See* above discussion on compliance with international trade rules on pg 25.
[71] OECD (2005):100
[72] Sterner (2002):98
[73] O'Connor (1998):107
[74] Adapted from: UNITAR (January 2004), *Developing and Sustaining an Integrated National Programme for Sound Chemicals Management*, pp. 30-31.