



UNEP GUIDANCE

ON THE DEVELOPMENT OF LEGAL AND
INSTITUTIONAL INFRASTRUCTURES AND
MEASURES FOR RECOVERING COSTS OF
NATIONAL ADMINISTRATION FOR SOUND
MANAGEMENT OF CHEMICALS

UNITED NATIONS ENVIRONMENT PROGRAMME

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The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase international coordination in the field of chemical safety. The Participating Organizations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote coordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.



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The LIRA-Guidance was collaboratively developed by Mr. Armand Racine and Ms. Louise Gallagher (Ph.D.), and in cooperation with governments from developed and developing countries, IOMC and other organizations, industry sector and civil society and with contributions from and Mr. Kaj Madsen and Mr. Pierre Quiblier of the UNEP Chemicals Branch Mainstreaming team. A test version was used in some countries and then the LIRA-Guidance was reviewed and finalized by Mr. David Azoulay from the Center for International Environmental Law (CIEL). The development of the Guidance benefitted by inputs from an expert group comprised of governments, intergovernmental organizations, academia, civil society and private sector.

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ACRONYMS

BASA	Baseline Analysis and Solutions Assessment	NGO	Non-Governmental Organization
CBA	Cost Benefit Analysis	ODSs	Ozone Depleting Substances
CEiTs	Countries with Economy in Transition	OECD	Organization for Economic Co-operation and Development
COI	Costs of Inaction Initiative	PI	Partnership Initiative for the Integration of Sound Management of Chemicals into National Development Planning Processes
DCs	Developing Countries	PIC	Prior Informed Consent
CIp	Chemicals in Products	POPs	Persistent Organic Pollutants
DTIE	Division of Technology, Industry and Economics	SAICM	Strategic Approach to International Chemicals Management
DNA	Designated National Authority	(M)SDS	(Material) Safety Data Sheet
FAO	Food and Agriculture Organization of the United Nations	Sida	Swedish International Development Cooperation Agency
GATT	General Agreement on Tariffs and Trade	SMC	Sound Management of Chemicals
GC	Governing Council	SMEs	Small and Medium Enterprises
GHS	Globally Harmonized System for Classification and Labelling of Chemicals	SPS	Sanitary and Phytosanitary Agreement
GCO	Global Chemicals Outlook	TBT	Technical Barriers to Trade
GEF	Global Environmental Facility	TEEB	The Economics of Ecosystems and Biodiversity
HELI	Health and Environment Linkages Initiative	TRIPs	Trade Related Aspects of Intellectual Property Rights
HESA	Health and Environment Strategic Alliance	UNCED	United Nations Conference on Environment and Development
ICCM	International Conference on Chemicals Management	UNDP	United Nations Development Programme
ICM	Inter-Agency Coordination Mechanism	UNEP	United Nations Environment Programme
IISD	International Institute for Sustainable Development	UNITAR	United Nations Institute for Training and Research
ILO	International Labour Organization	WCO	World Customs Organization
IOMC	Inter-Organization Programme for the Sound Management of Chemicals	WHO	World Health Organization
IPCS	International Programme on Chemical Safety	WSSD	World Summit on Sustainable Development
ISO	International Standardization Organization	WTO	World Trade Organization
KemI	Swedish Chemicals Agency		
MEAs	Multilateral Environmental Agreements		
MSW	Multi-Stakeholder Workshop		

PREFACE

The design and implementation of comprehensive and coherent legal frameworks and related institutional arrangements for management of chemicals, including sustainable financing options is a cornerstone in achieving the goals from the World Summit on Sustainable Development in 2002 and reaffirmed at the Rio+20 Summit in Brazil in 2012, that by 2020 the use and production of chemicals should be done in ways that do not lead to significant adverse effects on human health and the environment.

One of the cornerstones for achieving the above 2020 goal will be the establishment of comprehensive and coherent legal frameworks and related institutional infrastructure including sustainable financing options.

To assist countries in his process, UNEP, with financial support from the Swedish government, has developed a Guidance document for the development of Legal and Institutional Infrastructures for the Sound Management of Chemicals and Measures for Cost Recovery of National Administrations (LIRA-Guidance).

The Guidance aims at providing practical, step-by-step support to policy makers for strengthening national legislation and institutional set-ups for achieving sound management of chemicals, including proposals for measures for financing necessary related administration activities.

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INTRODUCTION

1.1 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 can play an important role in our global economy, they can also cause significant damage if mismanaged. A growing body of research is documenting the various 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 levels¹.

There are very clear links between a precautionary approach to chemicals management and economic development. A knowledge-based, preventive approach to chemicals 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.

1.2 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 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 consumption². 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.

CHAPTER

1

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. Chemicals management is a concern for a row of ministerial departments. Legislations may have complementary scopes, and may differ in the way the issue is addressed and in the definition of “chemicals” (transport of dangerous goods, workers health and safety; major chemical accidents etc.).

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.

1.3 About this Guidance

1.3.1 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 to build capacity for improved integration of chemicals management into development agendas, and ultimately to mobilize sustainable financing for SMC⁴.

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 of comprehensive proposals, including realistic budgeting considerations, is required to be able to actually mobilize financial resources within the budget allocation process for the mainstreamed priorities. As part of this

approach, the LIRA-Guidance addresses the development of such proposals with regard to legal and institutional infrastructures⁵ 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 a 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.

1.3.2 Managing the Placement of Chemicals on the Market for SMC

Comprehensive chemicals management frameworks include measures for managing chemicals at every stage 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 so far been unable to establish complete support 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. Chemicals legislation provides knowledge on hazards and the general way to manage risks before chemicals are disseminated and used. Furthermore, by restricting the access to substances considered hazardous, chemicals legislation serve the other areas of chemicals management. Once the chemicals are dispersed and during use, it is generally much more difficult to prevent damages.

Several guidance documents have been developed on comprehensive national policies

and programmes for the sound management of chemicals⁷.

Tackling gaps and inconsistencies in the whole chemicals management legal framework at the same time would certainly prove demanding, especially in the context of scarce capacity and resources characterizing most DCs. There is therefore a pressing need for prioritization.

Classification and labeling is among the most important instruments for ensuring efficient and cost-effective lifecycle chemicals management as it ensures the generation and dissemination of information throughout the supply chain and assists in building awareness and capacity for chemicals management.

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. Placing a chemical on the market means making it available to a third party and for use in the supply chain. Such legislation will serve other areas of legislation where chemicals are of concern, but is not designed to replace them.

The responsible entity for placing chemicals on the market is the national producer as well as importer. All provisions for classification, labeling, Safety Data Sheets and restrictions to the placing of chemicals on the market should therefore be made effective as early as the import stage. Furthermore, importers of chemicals for their own use should be made to comply with these rules and provide, for example by providing safety data sheet at their work place.

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 chemical life-cycles;

- 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;
- Classification and labelling is one of the most important measures for the management of the marketing of chemicals.

1.3.3 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 capacity⁸ for lifecycle chemicals management.
- Strong inter-sectoral and multi-stakeholder 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, including a description of

the allocation of roles and responsibilities for the tasks involved.

1.3.4 Objectives

The LIRA-Guidance aims to provide practical, step-by-step support to policymakers in strengthening national legislation and institutional set-ups for achieving sound management of chemicals, including measures for financing necessary national administrative support.

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 the LIRA-Guidance are to:

- Support countries in reviewing their legal and institutional infrastructures and establishing a sustainable legal and institutional framework for the sound management of chemicals.
- 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, including a template for a framework law.
- 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.
- Provide tools for ensuring sustainable financing, including cost-recovery measures and access to national budget allocation processes.

REVIEWING LEGAL AND INSTITUTIONAL INFRASTRUCTURES



The Guidance aims at supporting the development of an action plan for strengthening legal and institutional infrastructures governing the placement of chemicals on the market as part of a life-cycle 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 fields of expertise involved (health, 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 and 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.

2.1 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.

CHAPTER

2

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. 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.

2.2 Main Phases of a Review Process

The review process proposed in these guidelines involves five main phases. In order to focus the LIRA- Guidance on the legal and institutional aspects, these phases are described in detail in Annex X. 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.

2.2.1 Mobilization Phase

2.2.1.1 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.

2.2.1.2 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?
- How is the coordination between ministries of environment and health?

2.2.2 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

2.2.2.1 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 and waste, 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 resources, 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 including waste. 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 the infrastructures, including existing cost-recovery measures. This will allow for the development of a resource 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 resource mobilization
- Revenue collection and allocation mechanisms

2.2.2.2 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, some economic analysis can be very useful for development of a strong justification for convincing finance policymakers to invest in the proposed developments.

2.2.3 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:

- a) Legislative proposals
- b) Proposals for institutional arrangements
- c) Cost-recovery measures, where appropriate

2.2.3.1 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

2.2.3.2 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

2.2.3.3 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

2.2.4 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 resource mobilization strategy

Analysis of the costs of the proposed developments and of the funding sources is critical for ensuring sustainable financing of infrastructure. 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 should be considered.

2.2.5 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 policymakers 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 policymakers being key for ensuring approval and financing of the plan, the development of targeted information material should be considered.

2.3 Elements for Strengthening Legal and Institutional Infrastructures Governing the Placement of Chemicals on the Market

Managing the placement of chemicals on the market has four main objectives⁹:

- 1) To generate/obtain knowledge on chemical properties, hazards and risks; Such knowledge is generally developed and agreed upon in international co-operation and national legislation normally refers to these agreements.
- 2) To disseminate information on hazardous properties of chemicals, and on safe handling procedures.

This goal is guided by regulations on hazard labelling and other types of hazard and risk information such as safety data sheets.

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

In most cases, enterprises would have to make appropriate choices when placing chemicals on the market. For pesticides and other

chemicals of special concern the choice would be made as part of registration regimes, and for chemicals of high concern as bans and restrictions.

4) To organize the safe use of chemicals.

Achieving these four objectives involves five phases including various activities presented in Table 1 below.

Table 1. Main Phases and activities in Managing Placement of Chemicals on the Market

Main Phases	Key activities
Identification and assessment of chemicals' hazardous properties and risks	<ul style="list-style-type: none"> • Collection of information on chemicals produced/used in the country • Establishment of requirements 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
Dissemination of hazard, risk and safety information	<ul style="list-style-type: none"> • 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
Making informed choices about chemicals to be placed on the market	<ul style="list-style-type: none"> • Organization and development of capacity for safe supply • Decisions on chemicals to market for low-concern substances • Enactment of bans and restrictions • Substances registration for chemicals of high concern • Licensing primary suppliers (for chemicals of high concern) • Consideration of conditions of use
Organization of workers and public safety	<ul style="list-style-type: none"> • Establishment of requirements/criteria for safe use (<i>especially for chemicals of high concern</i>) • Decisions on chemicals to use for low-concern substances • Development of measures and procedures for workers and public safety • Organization and development of capacity for safety
Compliance monitoring	<ul style="list-style-type: none"> • Inspections • Testing verification • Labeling verification • Testing of residues in products • Food monitoring • Monitoring of human health and environment

General roles and responsibilities for these activities by the national administration and industry in the management of the placement of chemicals on the market should be stated in a law. Roles and responsibilities related to certain

measures that are defined in specific regulations can be specified in these regulations. For guidance on how to define responsibility for these activities please see Section 4.2.

THE ORGANIZATION OF LEGAL AND INSTITUTIONAL INFRASTRUCTURES GOVERNING THE PLACEMENT OF CHEMICALS ON THE MARKET

3.1 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 into 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. The legislation should both present the framework for and lay the foundation for horizontal regulation when it comes to the detailed application rules.

Considering this is a fairly new area to most countries, it is recommended that the management of chemicals placed on the market be governed by horizontal law, making it possible for

one ministry to be the lead regulator, in charge of issuing secondary legislation such as regulations.

3.1.1 Laws

For the purpose of this Guidance, law is defined as parliamentary-level legislation – a 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.

CHAPTER

3

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, indicates a multi-sectoral and multi-stakeholder approach, and establishes the authority and ability to control chemicals and coordinates related management efforts
- **A knowledge base** to collect, interpret and disseminate information used to support decisions about which chemicals are acceptable for import and use, under what conditions, and how end of life issues should be managed
- **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.

3.1.2 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 repealed¹⁰.

3.2 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.

3.2.1 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.

- 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.

3.2.2 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/agency, which may need to build up sufficient capacity 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 temporarily increased workloads 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 objectives¹¹.

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 lifecycle, 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 should be publicly available and 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 entities¹².

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.

3.3 Organization of National Administration

3.3.1 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
- 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

All these activities represent administrative costs that could be considered for cost-recovery measures (see Section 7 of this Guidance). 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 and resources 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 hazards 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 could be needed for coordination efforts. The first requirement is that mandates to bodies are clearly given and combined with powers. If mandates are not clear the ministerial co-ordination cannot work efficiently. 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	<ul style="list-style-type: none"> • Avoiding overlaps/gaps in mandates and activities • Clarity and transparency • Cost-efficient 	<ul style="list-style-type: none"> • Might be difficult to establish due to required reorganization of political mandates • Might need to build the required capacity to perform the tasks
Coordinated	<ul style="list-style-type: none"> • Might be easier to reach consensus • Sharing of existing expertise • Specific responsibility allocated to the agency which has the capacity 	<ul style="list-style-type: none"> • Requires more coordination and cooperation to avoid gaps/overlaps • Might be more costly • Might be less transparent and clear • Might need to build more capacity to perform the tasks

3.3.2 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.

3.3.3 Information Needs and Exchange

The use of information is key for the development and sustaining of knowledge-based chemicals management systems. The lack of functional information from producers and importers of chemicals can be seen as the main cause for problems arising from chemicals. 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, for effective implementation and enforcement of the legislation, and for raising governmental and public awareness.

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 should be used as a basis for national chemicals management. A second step may include the consideration of specific conditions of use in the country. 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. In establishing information collection and management system, countries should also refer to UNEP Governing Council Guidelines for the Development of National Legislation on Access to Information, Public Participation and Access to Justice in Environmental Matters of 2010 (SS.XI/5 A).

3.3.3.1 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 and waste). 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. 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 may be sufficient for decision making, the practical risks of chemicals which include conditions of use and exposure should also be taken into account. Control measures such as registration generally rely on localized risk assessments

3.3.3.2 The use of international sources

A significant amount of information can be collected from international sources. This especially concerns information on scientific assessments of chemicals properties, and hazards 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 should be used as much 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 conditions of use with international guidelines, standards, limits and control options¹³.

Only validated sources should be assessed, as information uploaded on the internet is not always reliable. The evaluation of chemicals risks depends both on the intrinsic hazards of the chemical and on the specific local conditions (i.e. use patterns, types of ecosystems, etc.).

Countries where such localized information on conditions of use 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 for industry, this can allow the development of a broader experience base.

In most cases national evaluation of chemicals is therefore not necessary on a country basis as for most chemicals there is objective international information available. 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 significantly reduce national costs.

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

3.3.3.3 Information exchange

Better use of existing information can prove 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 (including from safety data sheets or past experience of the country) 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 used or set up in this regard, including¹⁴:

- Meetings and forums
- Designation of chemicals focal points
- Central repositories of chemicals information/chemicals information center

- Shared databases (e.g. ECHA, EFSA...)
- Chemicals information website/inventory
- Newsletters, bulletins, etc. (both hardcopy and electronic)

3.3.3.4 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.

3.4 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.

3.4.1 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 design of enforceable legislation in order to prevent and control international illegal traffic of these substances¹⁶.

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.

Prevention and control of illegal traffic is also an important component of the national implementation of chemicals-related Multilateral Environmental Agreements (MEAs) (see Section 3.4.5 below). If countries are parties to these MEAs, illegal traffic should therefore be addressed as part of the coordinated national implementation of these MEAs, in line with international requirements.

3.4.2 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 the same treatment. Article III establishes the national treatment rule 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 – allows parties to adopt measures necessary to protect “human, animal or plant life or health”, and exhaustible natural resources, subject to certain conditions¹⁸ 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 borders 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.

3.4.3 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 allow for international harmonization of national requirements, and facilitate international trade. They also provide useful guidelines for the development of national measures.

Classification, labelling and the use of Safety Data Sheets are the most important legal measures for the safe management of chemicals, and should be one of the first measures to be developed as part of legislation governing the placement of chemicals on the market. The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is supported internationally and it is encouraged to be introduced in all countries,

GHS ensures the generation and dissemination of information throughout the supply chain and assists in building awareness and capacity for chemicals management. It serves the needs for information on hazards and risks from chemicals in all areas where chemicals safety is a concern.

Examination of their applicability and introduction in national legislation should therefore be performed as a key 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.

3.4.4 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.

3.4.5 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 and mutual recognition of registration 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 national legislation governing 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.



MAIN CONSIDERATIONS FOR LEGISLATION GOVERNING THE PLACEMENT OF CHEMICALS ON THE MARKET

4.1 General

4.1.1 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 protection of human health and the environment and the fulfillment of the country's international commitments, and key principles such as precaution can form the foundation of the law. 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.

4.1.2 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.

4.1.2.1 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 possible²³.

The management of pesticides is typically regulated separately from other chemicals. This is justified by the intended highly hazardous nature

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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 4.3 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 pesticides (i.e. registration) used in agriculture and those intended for other uses (i.e. industrial, household, health protection, etc.). It is recommended to align legislation on industrial chemicals to the FAO 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 regard²⁴, and this area is likely to become more prominent in the near future. Legislation should therefore at least indicate if the hazards from chemicals in products are covered and in what way.

4.1.2.2 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 provides a legal basis for the management of chemicals after their placement on the market.

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

4.1.2.3 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 restrictions. These measures especially target the primary supply of chemicals (manufacture and import), and can include uses to a limited extent (i.e. general measures for safe handling).

4.1.2.4 Links with other chemicals management legislation

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 regarding 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 their marketing, 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).

However, it is important to take into consideration 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 cases 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 cases 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 manufacturing and importation*)
- 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.

4.1.3 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:** Citizens 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 their health and the environment.
- **Knowledge-based management:** Chemicals management decisions should be based on the most up-to-date available scientific understanding of the 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.

4.1.4 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 upon 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 as a result. 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 and flexible to allow for future inclusion of new terms (e.g. *nanomaterials*)
- 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 (*laws, regulations*)

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

4.2 Public Sector and Industry Responsibilities

Managing the placement of chemicals on the market is a shared responsibility between the various stakeholders involved – in particular between public authorities and industry. The allocation of roles and responsibilities for the tasks involved by such legislation helps 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 shared between national administration and industry sectors²⁵.

The legislation mainly regulates the responsibility of those manufacturing, importing and placing the chemicals on the market, not the substances/chemicals. At the stage of placement of chemicals on the market, it is the manufacturers and importers that need to acquire a certain necessary capacity and knowledge regarding chemicals risk management. Assigning the main responsibilities for risk management to the industry 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.

In addition, attention should be paid to the respective capacity of national administration

and industry to effectively conduct the tasks they are responsible for, as this will be a 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 cannot perform.

General roles and responsibilities of the national administration and industry 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 industry 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 does not 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.
- Cost internalization by industry
- Requiring that risk assessments are performed by industry is also generally considered to encourage the industry 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 industry 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.

4.2.1 Responsibilities of Manufacturers and Importers

Whatever allocation of tasks between national administration and industry is chosen according to the country situation, the responsibilities of entities that place chemicals on the market have to be clearly defined in the law.

The transfer of obligations to the industry advocated by many developed countries involves the requirement that industry carry out most of the main tasks involved in the management of the placement of chemicals on the market (See Box 3 above). Most importantly, the generation and diffusion of information on chemicals' properties, hazards, risks and handling procedures is the priority obligation²⁶.

This can also mean taking responsibility to make informed choices in marketing chemicals for which registration processes, bans or restrictions in use are nonexistent or not relevant (i.e. precautionary principle). Going further, the industry is obligated to organize the 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 industry actors, they should in this approach bear the main responsibilities²⁷.

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

- Pre-marketing testing and classification
- Labeling and developing safety data sheets
- Updating the information base when required

Distributors are generally at least responsible for:

- Conveying information provided by producers/manufacturers and importers to downstream actors
- Informing downstream actors in case they have identified new information regarding chemicals' hazards and risk.

Users have the minimum responsibility to obtain data and to take into account the hazards and safety measures for the decision of which chemicals to use and how.

Other tasks that industry stakeholders could be encouraged to perform (but not made compulsory by law) 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 (but not be made compulsory by law) 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 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 industry 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.

4.2.2 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 not only it is imperative the industry 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 for²⁸:

- 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

4.3 Administration

4.3.1 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 regarding the 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 it 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 4.3.2.1 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 environment²⁹. 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 authorities other than the primary authority, or can 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 mechanisms³⁰.

4.3.2 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 the highest level of government (i.e. prime minister's office) can also help avoid or at least circumvent ministerial conflicts over mandates.

4.3.2.1 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 additionally provides a good opportunity to establish coordination mechanisms for lifecycle chemicals management, or can formalize the existing ones. Therefore, as part of the approach underpinning this Guidance (see Section 1.3, 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 regarding 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.

4.3.2.2 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 as a result participation of non-governmental stakeholders should be limited to a consultative role.

4.3.3 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.

4.4 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.

Policy instruments can have a regulatory, economic or information component, or more often, a mix of these three components, depending on the type, as well as their design, including enforcement mechanisms and sanctions in cases of non-compliance.;

Bans and restrictions, classification and labeling registration 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.

4.4.1 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 information³¹. For other chemicals the establishment of a simple inventory of primary suppliers (including importers and producers/manufacturers) could be considered as a first step to serve 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 procedures should be developed and resources allocated. 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 registration

or licensing, depending on the capacity of public authorities and of the industry to handle the tasks involved by the system. Providing inventory information can be made a requirement to gain access to the market. 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:

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

Adapted from Bucht (2008); p. 17.

4.4.1.1 Notification schemes

Many countries with advanced chemicals management systems have introduced general notification schemes 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 decisions 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 4.2.1). 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 new chemicals produced or imported in the country and that are not already registered/authorized in a country with a reliable system in place.

4.4.2 Classification and Labelling

Classification and labelling is one of the most important measures for the management of the marketing of chemicals. Classification, labelling and Safety Data Sheets (SDS) provides one of the main tools for risk communication. 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.

National measures should at this point be harmonized to international standards and norms, especially the Globally Harmonized System for Classification and Labelling of Chemicals (GHS) as far as possible. By introducing obligations on classification, labelling and Safety Data Sheets according to GHS on chemicals manufacturers and importers, the system will be run by industry regarding the management of the majority of chemicals on the market, which is what GHS is designed to be.

Therefore, administration will be able to concentrate on regulatory actions regarding substances of high concern and enforcing bodies can concentrate on enforcement of obligations under GHS.

4.4.2.1 Assessment and classification

Legislation should indicate which standard has to be used for hazard assessment and classification. Use of the Global Harmonized System for Classification and Labelling of Chemicals (GHS) is highly recommended in this respect. 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 and licensing systems. Therefore, attention should be paid that requirements and criteria for making decisions on registration of chemicals and licensing of suppliers are consistent with assessment and classification criteria.

4.4.2.2 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.

4.4.2.3 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)³². 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.³³

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 producers/importers/users/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)³⁴. 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 right away 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-in approach, starting with the requirement to classify substances as a necessary first step before making the classification of mixtures mandatory. The same steps could be chosen for making SDS mandatory.

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 compatible with GHS 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 user

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

4.4.3 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 health 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 industry. However, bans and restrictions on the supply of chemicals can be decided by the

legislator on substances that are judged to cause an unacceptable risk for populations' health, the environment and/or property³⁵. Bans and restriction decisions are generally based on a localized assessment of the substance's risks as well as on the country needs. Bans and restrictions in neighboring countries or those in similar situations may help inform policy decisions.

The power of the primary authority to impose a ban or to 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 3.4.4).

The Stockholm Convention includes lists of Persistent Organic Pollutants (POPs) of 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 imposes 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 writing 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 ensured³⁶. 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.

4.4.4 Registration

A third category of policy instruments that can be used in the management of the placement of chemicals on the market is registration including national authority approval. Detailed guidance on the development of registration systems related to pesticides – including legislation – is provided in the implementing guidelines of the FAO Code of Conduct³⁷. Therefore, only the main elements are addressed in this section.

4.4.4.1 Registration/ authorization process

Registration/authorization is essentially the assessment by public authorities of information on chemicals that companies wish to place on the market³⁸. It is here advised to be used only in relation to pesticides. FAO defined registration “as the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment”.

Companies or individuals wishing to place a pesticide 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 taking local conditions of use into account), 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.

Approval after registration 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 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 4.3 above for more information on bans and restrictions).

Registration/decisions can typically be reviewed in case of availability of new information on the chemical risks from the pesticide. 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 4.4.1 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 ensuring that health and safety information cannot be considered confidential under any circumstances (i.e. see section H below).

Box 9. Key legal requirements for registration for pesticides

Elements to be included in legislation 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.

4.4.4.2 The use of registration

Registration can be an instrument for the authorities in 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 a number of legal elements (see Box 9), and the set-up of an extensive and costly process of development, review and verification of data on chemicals properties, hazards and specific risks in local conditions.

Therefore, registration is generally not recommended for chemicals management of industrial 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. For the majority of chemicals, industry is responsible for making the appropriate choices of placing chemicals on the market or not. For chemicals presenting a particularly high level of risk, such as pesticides, however the decision of placing such chemicals on the market choice can be made as part of authorization regimes.

Other chemicals are sometimes also included in such registration systems based on their impacts on health and the environment, such as carcinogenic, mutagenic, persistent, bioaccumulative substances, and chemicals with reproductive impacts. As registration systems are demanding and when limited implementation and enforcement capacity is available for ensuring effective control of the chemical considered, a ban or restrictions should rather be considered (see Section 4.4.3 above).

Most countries have a system in place 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 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 two types of provisions can be included in this regard³⁹:

- De-registration of pesticides for which a safer alternative exists
- Establishing shorter time limit for high-risk chemicals registered, therefore requiring more frequent renewal

4.4.5 Licensing

Licensing is a policy instrument that applies to a company/individual before allowing certain activities.

4.4.5.1 Characteristics of licensing schemes

In the context of these guidelines, licensing applies specifically to companies or individuals intending to place chemicals on the market (the primary suppliers-importers and manufacturers).

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 importing, manufacturing, packaging, re-packaging, labelling, selling, storing, or distributing – can be undertaken⁴⁰. Licensing systems can be tailored to various circumstances and needs.

Given the stakeholder orientation of licensing, the review focuses on the location, activity, expertise and capacity of the importers or manufacturer to safeguard against known risks. For this type of licensing system to be efficient, conditions for license attribution therefore, have to emphasize the need for companies to have appropriate qualifications for handling specified classes of chemicals in an appropriate way. Training requirements for obtaining a license are also important to consider.

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. The main difference is the criteria for evaluation and the information to be provided in an application.

Additionally, 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 bans and restrictions of the Chemicals Conventions. In addition to the provisions presented in Section 4.4 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.

4.4.5.2 Licensing scheme of suppliers

The relevance of a licensing instrument for suppliers of chemicals in a country situation has to be carefully assessed on national 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. How much administration would be needed? Small suppliers (i.e. SMEs) might be confronted with a significant challenge in getting the required level of qualifications, and this requirement might in some cases lead them to stop this activity. Also, such a licensing system is likely to be less relevant and more difficult to maintain in cases of occasional supply and/or handling.

Establishing a licensing system for suppliers of certain well-defined categories of chemicals (i.e. chemicals of high acute toxicity, high corrosiveness, high flammability, explosive chemicals, carcinogens, mutagens etc.) will 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.



Such a system presents several advantages for building the information base needed for informed decision-making on chemicals management:

- 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 of substances is much 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 can/will 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 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” (Article 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. This is very demanding in terms of expertise and resources, therefore such superposed systems are to be developed only for chemicals of very high concern.

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
- Make it possible to combine licensing with certain conditions (eg. on education and reporting)
- 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 denial
- 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.

4.4.6 Import and Export

Many developing countries have limited chemicals manufacturing capacity and mostly import the chemicals being used into the country. Imported goods continue to stay imported through its whole cycle after passing the border. The importer is therefore a key stakeholder in chemicals management that could be seated anywhere in the country.

A country can inspect an importer for effective action but this cannot be done only by customs. The national capacity to inspect importers therefore needs to be strengthened as part of

chemicals management. The role played by customs controls of chemicals should therefore be limited to border controls, 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 imported chemical can be conducted by customs officials. As customs inspections require specialized expertise that might not be available, they can be limited to ensuring that chemicals imported into the country are conveyed with relevant information and are adequately packaged and labelled. Customs 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, particularly 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 4.4.5. 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 schemes 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 customs 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).

Import 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 as well as imports and exports⁴¹. This would avoid conflicts with regard to WTO rules, and prevent dumping of unsuitable chemicals in other countries.

4.4.7 Assistance, Incentives and Disincentives

Assistance, incentives and disincentives can have a similar effect than sanctions. Sanctions⁴² 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.

4.4.7.1 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 objectives, 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.). In this case, a review of existing legal requirements could be recommended.

In the cases where offending companies are SMEs with limited capacity and scarce resources, an alternative consists of assisting offending entities with information about how to comply with the legal requirements, thus reducing the costs associated with the change in behavior.

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 sector and the industry. In the case where responsibilities for managing the placement of chemicals on the market are mainly allocated to the industry, attention should be paid for public authorities not to take over industry's 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.

4.4.7.2 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.

4.5 Inspections

Inspection activities are a crucial component of any legislation as, coupled with dissuasive sanctions, they are one of the main tools to make sure that legislation is complied with by the regulated entities (compliance monitoring). Inspections are intended to ensure that producers and importers have the skills and processes required to meet their responsibilities under the chemical management law. Inspections and supervision should therefore

focus, not only on product labeling and SDS, but also on companies' skills.

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
- Issue orders and/or apply sanctions in cases 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 the same entity being 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 situations of limited resources. Another way to save scarce resources is to target inspection activities to the high-risk chemicals/activities.

4.5.1 The Accreditation and Use of Laboratories

A component of enforcement and inspection activities is the access to and use of qualified laboratories. Such access is important in conducting inspections where monitoring and other tests are necessary for ensuring compliance. The national authorities should establish a system for identification and access to suitable laboratories.

The acceptance and use of international information or 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 significantly reduce the need for complex laboratory systems for risk assessments. Countries should have a national reference laboratory capable of performing

qualitative analysis for the chemicals of major concern for verification and monitoring purposes.

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 3.4.5).

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 where to find the qualifications required of inspectors
- Ensure comprehensive coverage of the inspection system (sectors/intervention points)

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

4.6 Record-keeping and Reporting

In addition 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.

4.6.1 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 format 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 chemicals⁴³.

4.6.2 Reporting

Reporting requirements can be tied in with registration 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 chemical 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. In addition 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 risks. Cases when the government is justified to request 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 situations 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.

4.7 Enforcement

A key aspect of enforcement is a clear legislative allocation of responsibilities within the administration as well as a clear distribution of enforcement powers to adequate enforcing authorities. 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 cases 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. Furthermore, proper enforcement of chemical regulation will generate valuable information for importers and producers of chemicals, with positive repercussions across the whole society.



4.7.1 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 situation, such separation might already be established in the country's constitution. In addition, the separation might also be guided by the country's international commitments⁴⁴.

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.

4.7.2 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 unlikely to attain their objective, even more if continuous non-compliance does not lead to tougher penalties or when enforcement is weak.⁴⁵

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 on the damaging entity restoration of 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. In this respect, one should refer to the 2010 Guidelines for the development of domestic legislation on liability response action and compensation for damages caused by activities dangerous to the environment of UNEP Governing Council.

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.

4.8 Confidentiality

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

This need for confidentiality must be balanced by the rights of the population to be informed about the identity of the substance and 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 and confined to prevent abuses. 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). 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.

4.9 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 decisions, licensing decisions, sanctions imposed, etc. Depending on the country's 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 should be 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. This helps advance the chemical safety missions of relevant administrative authorities.

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.

5.1 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 steps 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. However, authorities should not be made responsible for informing entities about what is required in existing legislation.

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 2.2.2.1 and 4.3.2) 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.

5.2 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

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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 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 programmes can therefore be developed. For example, a licensing process for primary suppliers of chemicals might require that the applicant demonstrate an adequate level of capacity to safely handle the chemicals they intend to place on the market, which would mean 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 industry 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 industry 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 process⁴⁶.
- 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, firms' internal training programmes for workers, programmes of mentoring from larger 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 be another useful means of organizing education and training programmes.

5.3 General Awareness Raising

In addition, raising awareness of the broader public on chemicals risks and safety measures is also important for the sound management of chemicals. The development and maintaining of labeling and Safety Data Sheets plays an important role for raising awareness of chemicals' hazards and safety measures in the society. 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 adequate information and level of detail, and should be in an appropriate language for the target audience. In addition, coordination of the communication from different groups (industry,



NGOs, public authorities) should be sought out as much as possible in order to avoid the target group being presented 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 improve understanding. 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 the lessons learned to emerge, effective monitoring and evaluation of the communication programmes is required.

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

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 cost⁴⁷ 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, licensing and permitting systems that are the central components of efforts to manage the placement of chemicals on the market at the national level, 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. Consideration should be given to the fact that low-cost measures may save resources in the short-term but impose higher costs in the long term.

The requirement of industry to carry out most of the main tasks involved in the management of the placement of chemicals on the market, in effect, transfers some costs from government to

industry. 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.

Therefore, 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:

- Generating knowledge and 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.
- The dissemination of information, through establishing and maintaining systems for classification and labeling (C&L; SDSs)
- Administrative charges related to registration/authorization applications, including repeat and fast-track applications

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- Annual registration/authorization maintenance fees
- Administrative fees related to licensing and permitting applications
- Laboratory analysis work required, particularly in relation to supervision and appeals procedures
- Fines related to noncompliance with the chemical regulation as well as 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, government costs are considered here and not industry's costs per se. Depending on the needs at the 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/licensing processes
- Length of validity of a registration, permit, license, (i.e. how often the administration process has to be completed to maintain registration/licensing)
- Schedules for revision of registers and permit/license 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.

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.⁴⁸

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. Therefore, 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.⁴⁹

Within national budget cycles, in theory, chemicals-related line ministries (LMs) 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 for the whole society through reducing or avoiding typical health, environmental and economic ‘costs of inaction’ from chemicals mismanagement. The existing medical evidence is well advanced in linking exposures to chemicals with illness, disease, loss of cognitive functions and death. However, the link between sound management of chemicals and sustainable economic development

is generally not sufficiently established in the minds of key finance decision-makers, to the detriment of national funding support for chemicals management activities. Translating the arguments in support of the sound management of chemicals (SMC) into economic arguments is therefore pivotal to ensure the success of establishing a sustainable legal and institutional infrastructure for SMC and securing predictable and adequate funding from national budgets to support implementation 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 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 3. Cost categories for all stakeholders of development or reform of legal and institutional infrastructure governing the marketing of chemicals

<p>Producers and Importers Commercial entities producing or importing chemicals that they intend to sell or use</p>	<p>Public Sector Government entities providing services that contribute to governing the placement of chemicals on the market</p>	<p>Society</p>
<ul style="list-style-type: none"> • Provision of information required as part of registration/authorization/licensing procedures, including credible hazard and risk information and labeling • Transfer of safety information in the supply chain • Length of waiting times for registration authorization/licenses/permits • Length of validity of a registration, permit, license, etc. determining how often businesses must undergo registration/authorization/licensing procedures • Reporting obligations • Control programmes for monitoring the environment • Changes in productions processes due to restrictions 	<ul style="list-style-type: none"> • Investment in registration/authorization/licensing systems for managing market access for chemicals • 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 	<ul style="list-style-type: none"> • Distortionary impacts on economy from increased costs to business • Health and environmental benefits, including increased work force productivity.

SUSTAINABLE FINANCING THROUGH COST RECOVERY CHARGE SYSTEMS

This section will look at options for the sustainable financing of SMC activities, and in particular to mechanisms for cost recovery – charges and fees⁵⁰ attached to particular public services with the intention of recovering costs to government ministries and agencies of providing those services.

This question of cost-recovery mechanism is central to the objective of the LIRA-Guidance to support countries in establishing sustainable legal and institutional framework for the sound management of chemicals. In effect, only through sustainable and integrated financing of SMC activities will countries be able to establish a durable and functioning legal and institutional infrastructure for SMC.

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. They enable a better cost burden-sharing between the public authorities and industry for chemicals management services.

Furthermore, when the authorities provide specific services, it is a fair and widely accepted principle that cost recovery for such service should be proportionate to its effective cost.

The exact cost of said service should however be evaluated in detail so as to integrate overhead costs for administration of the service, such as costs of the use of office space, direction costs, IT costs etc. These overhead costs can be integrated in the cost of services on top of wage costs and non-salary wage costs of staff delivering the service.

The particular nature and structure of these mechanisms will, to a large extent, depend on the national conditions, including the type of institutional structure put in place (centralized vs. coordinated). Similarly, the collection of revenues as well as the form of allocation of these revenues, will largely depend on the national budget cycles and rules.

In any case, setting up these cost-recovery mechanisms requires a preliminary effort to educate all sectors of government of the benefits of SMC. In this respect, articulating economic arguments in relation to the Cost of Inaction in relation to SMC is critical to demonstrate the importance and value of establishing a sustainable legal and institutional framework for SMC for the country's development. Similarly, explaining the value and benefits of SMC to economic operators is a key preliminary activity to ensure general support for the initiative.

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7.1 Benefits to Industry of Better Regulation of Chemicals Being Placed on the Market

Better regulation of chemicals benefits the industry. 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.

7.1.1 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 into 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 products⁵¹, chemicals residue testing for aquaculture products⁵², and textile, toy and food safety standards, etc. being currently implemented or anticipated in the near future in other markets.⁵³

Not meeting product and food safety standards because of poor chemicals management policies has very real impacts for national balance of payments.⁵⁴

Furthermore, surging consumer demand in industrialized markets is growing for products and services that are certified and labelled as being sustainably produced.

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.

7.1.2 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 eliminated.

7.1.3 Increased Well-Being and Productivity

Even where international export markets are not the primary focus for the industries using chemicals and products containing chemicals of concern, there are significant benefits in terms of workers' health, well-being and productivity from better management of chemicals being placed on the market.

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 due to underreporting.⁵⁵ Similarly, the economic costs of these nonfatal poisonings are thought to be considerable. In Sri Lanka, the estimated productivity costs of farmers' exposure to pesticides are, on average, equal to about a month's income for these farmers.⁵⁶ Similar links to productivity losses have been identified for lead⁵⁷ and mercury⁵⁸.

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 expo-

asures 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.

7.1.4 Benefits for Ecosystem Services and Associated Economic Sectors

Ecosystem services are the benefits that people obtain from ecosystems.⁵⁹ 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 performance⁶⁰, 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 pollinators⁶¹
- 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)⁶²
- Reduced cost of drinking water treatment in New York City through reducing the impacts of pesticides and other agrochemicals in management of the Catskills watershed⁶³

7.1.5 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 minimize 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.

7.1.6 Improved National Reputation as a Place to 'Do Business'

AccountAbility's⁶⁴ 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.

7.1.7 Cost Recovery Practicalities

Setting up cost-recovery mechanisms requires good coordination among several sectors of government as well as wide stakeholder engagement. In particular, 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.

The design of the regime and the activities required under every aspect of its operation will influence greatly the cost, implementation and

enforcement capacities of the system, including 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 SMC.

Progressing from a localized pilot (either in geographic or sectoral terms) to broader implementation can offer a ‘grace period’ to policymakers 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.⁶⁵

7.2 Legal basis

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 industry 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 substances⁶⁶ 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
- 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 the minister to enact regulations required for better implementation of the cost-recovery system
- Date of commencement and length of validity of the cost-recovery system

7.3 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

7.4 Targets for 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.⁶⁷ 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.

7.5 Monitoring and Enforcing Compliance

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.

7.6 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.

7.6.1 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.

7.6.2 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 aim 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.

7.6.3 Fees for Inspection Activities

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

7.6.4 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 access to 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 laboratory testing, 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 4. 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	<i>The responsibility for the tasks falling under this step is allocated to the industry. See p. 32.</i>	
2. Dissemination of hazard, risk and safety information	<i>The responsibility for the tasks falling under this step is allocated to the industry. See p. 32.</i> • Training and outreach activities for suppliers	• Fee for training activities
3. Bans, restrictions and 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

7.7 Allocating Revenues earned through Cost Recovery

A cost-recovery mechanism, as the name indicates, should not be viewed as a new source of revenue for the government, but rather as a way to cover the costs of a particular service (in this case, cost of sound chemical management). This should be kept in mind in both the design of the system, and the allocation of revenue it generates.

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
- Direct appropriation by the ministry implementing the cost-recovery charges

Available options will often depend on the specific country situation and internal procedural rules.

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, minimizing 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?

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 (LM). 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

LM. 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 for not earmarking – should preferably be made at the stage of law development and included in the law. Therefore providing the possibility to consider and do a balanced assessment of the various revenue raised in relation to SMC; cost-recovery mechanisms, noncompliance penalties, and environmental taxation 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.

CONCLUSIONS AND RECOMMENDATIONS

8.1 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 to information, stakeholders' participation, publicity and communities' 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 administrative authorities and the industry, taking into account respective capacity and

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resources. Many countries have transferred the main responsibilities for safe management of chemicals to companies. At a minimum, 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 and education and training can be considered – especially for SMEs.

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, regulation 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 of effective implementation and enforcement.

Inspections systems should be designed to ensure adequate power and capacity for inspectors. Coherent and efficient coordination of inspection activities should occur at the three intervention points (customs, primary supply, use). Access to basic laboratory capacity should be ensured. Reporting requirements can be useful for monitoring compliance and collecting information, but should only be developed to the extent needed, as these are demanding for public authorities and companies. Offences and sanctions in cases of non-compliance should be carefully designed to ensure effective deterrence of unlawful practices.

8. Regional and international 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 acceptance of regional or internationally available information and/or decisions as part of registration/authorization systems should always be considered. 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.



8.2 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 of strengthening legal and institutional infrastructures governing the placement of chemicals on the market for all government ministries, industry and society as well as the costs of inaction.

Showing that clear net benefits from legal and institutional infrastructures exist, and the benefits are to be shared across all sectors of society and government. Showing the benefits for all sectors is a precondition to effective cost sharing.

3. Ensure efficient legal and institutional infrastructures.

The costs of new legal and institutional infrastructures will depend on the adequate sharing of responsibilities between public authorities and industry more than on the design of registration, licensing and permitting systems. The principle of a level playing field is to be upheld by equal requirement on all industry actors. However, the public administration has a responsibility to ensure that costs are minimized from the outset through sensible cost effective system design and to precisely assess the costs with a view to recover the full costs of the system.

4. Build credibility with the industry.

In paying at least part of the cost for managing the placement of chemicals on the market to reduce risks across the chemicals lifecycle, industry has the 'right' to expect an adequate service in return. That is to say, that inventories will be adequately maintained and that bans and restrictions and when relevant registration/authorization and



licensing regimes are enforced such that any firm found to be noncompliant will face costly consequences. 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 mechanisms to service delivery (including testing costs, inspections costs etc.), resistance within industry or society to cost-recovery systems may be overcome.

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.

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 policymakers and invested stakeholders without taking on an unacceptable degree of political risk.

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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 FAO 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:
- Certified laboratory:
- Importer:
- Exporter:
- Waste:

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 and waste

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 and multi-stakeholder 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 chemical 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 or 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 denial. 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 making sure that health and safety information cannot be considered confidential.

5.1. Obligations to register chemicals

The subsection must clearly define who is obligated to register the chemicals (ie. Identify what stage of the supply chain, types/categories of chemicals that need to be 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 hazard and 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 should 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 license or 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 granting of a license, list the types of licenses, define the term of validity of the license 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

In most cases national evaluation of chemicals is not necessary on a country basis as for most chemicals there is objective international information available. Information generated in other countries can significantly reduce national costs for evaluation.

To ensure quality when in uncommon cases national evaluations are needed, legislation should define what the expected outcomes of an evaluation are.

7.2. Responsibility of evaluation

Defines who would be responsible to evaluate the risk of the chemical, when for national reasons such evaluation is considered needed. Available evaluations should be used to the extent possible, see Section 3.3.3.2.

7.3. Method of evaluation

To minimize resources required, allow for the use of evaluations done in other jurisdictions so long as they comply with certain standards (i.e. OECD Guidelines or GHS). Very broadly, the legislation

could accept all evaluations done under REACH or similar programmes.

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.

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 Safety Data Sheets (SDSs) publicly to the user by the supplier.

10.2. Storage/Transportation requirements

The legislation should clearly state the requirement for importers/producers/users/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 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

In addition 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. reporting 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 require that a system is established 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 requirements of a schedule for inspections to be developed by the authority related to certain highly hazardous 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 of any 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.

14. 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.

15. 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 4.7 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. However, it is appropriate for the law to state that health and safety information cannot be claimed as confidential.

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 or safety, 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.

ANNEX 2: SECTORAL PUBLIC BODIES GENERALLY ENGAGED IN SOME ASPECT OF CHEMICALS MANAGEMENT⁶⁸

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
- *Customs Authorities* are generally responsible for ensuring that chemicals and waste 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
- Ministries of *Transport* are generally concerned with the safe transportation and storage of chemicals during the distribution phase

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.* <http://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/Documents.multilingual/Default.asp?DocumentID=71&ArticleID=972&l=en>*UNEP Chemicals Information Exchange Network.* <http://jp1.estis.net/communities/cien/>
- *OECD eChemPortal* http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en

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 censuses, demographic data, health statistics, health/environmental monitoring results, etc.
- Publications and research papers from research institutions and universities and 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
- General and comprehensive information made available by ECHA, the European Chemical Agency in application of REACH

ENDNOTES

- 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 adapted from: Bucht (2010); p. 18.
- 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: <http://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 cannot 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 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.
- 26 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).
- 27 Bucht (2008); p. 27.
- 28 Adapted from Bucht (2008); p. 28.
- 29 For more information on the rationale for and value of this approach, see: www.who.int/heli/, and www.unep.org/roa/hesa/
- 30 See the chapter “Sustainable Financing through Cost Recovery Charge Systems” of this Guidance, and especially sections G and I.

- 31 See FAO (2007); p. 49.
- 32 For more information on the GHS, see: <http://www.unitar.org/cwm/ghs> and the related publications.
- 33 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.
- 34 See: http://www.who.int/ipcs/publications/pesticides_hazard/en/
- 35 It is to be noted that Parties to the WTO need to notify the secretariat of their bans and restriction decisions.
- 36 FAO (2002); Article 7.5, p. 18.
- 37 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.
- 38 For definitions of "registration", see: IPCS-IOMC (August 1998); Annex 2, p. 75, as well as FAO (November 2002); p. 7.
- 39 See for example: FAO (2007); p. 43.
- 40 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
- 41 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.
- 42 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.
- 43 UNEP (1995); p. 40.
- 44 The Basel Convention for example requires that Parties consider illegal traffic of hazardous waste as a criminal activity (article 9).
- 45 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
- 46 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).
- 47 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.
- 48 SAICM/ICCM.2/12: 7-9 and para. 28,31.
- 49 SAICM/ICCM.2/12, para. 29.
- 50 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.
- 51 FAO(2004): 56-57.
- 52 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.
- 53 See for example, Australia and New Zealand: <http://www.daff.gov.au/aqis/import/food>, accessed 15 June 2010.
- 54 WHO/UNEP (2008): 58-60.
- 55 FAO/UNEP (2004).
- 56 Wilson and Tiddsell (2001), Wilson (2002).
- 57 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.
- 58 See Hylander and Goodsite (2006); Trasande et al. (2005, 2010).
- 59 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.
- 60 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=14Y2nqqlICg%3d&tabid=1021&language=en-US>, accessed 16 June 2010.
- 61 TEEB (2010:8).
- 62 See Perrot-Maitre (2006), <http://www.ibcperu.org/doc/isis/8085.pdf> last accessed 30 March 2011.
- 63 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.
- 64 AccountAbility (2007) <http://www.accountability21.net/default2.aspx?id=982>, last accessed 14 June 2008.
- 65 O'Connor (1998):107.
- 66 An orphan substance is a substance found on the market, which cannot be traced back to a specific producer or importer.
- 67 See above discussion on compliance with international trade rules on pg 25.
- 68 Adapted from: UNITAR (January 2004), *Developing and Sustaining an Integrated National Programme for Sound Chemicals Management*, pp. 30-31.



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The Guidance aims at providing practical, step-by-step support to policy makers for strengthening national legislation and institutional set-ups for achieving sound management of chemicals including proposals for measures for financing necessary administration activities in this regard.