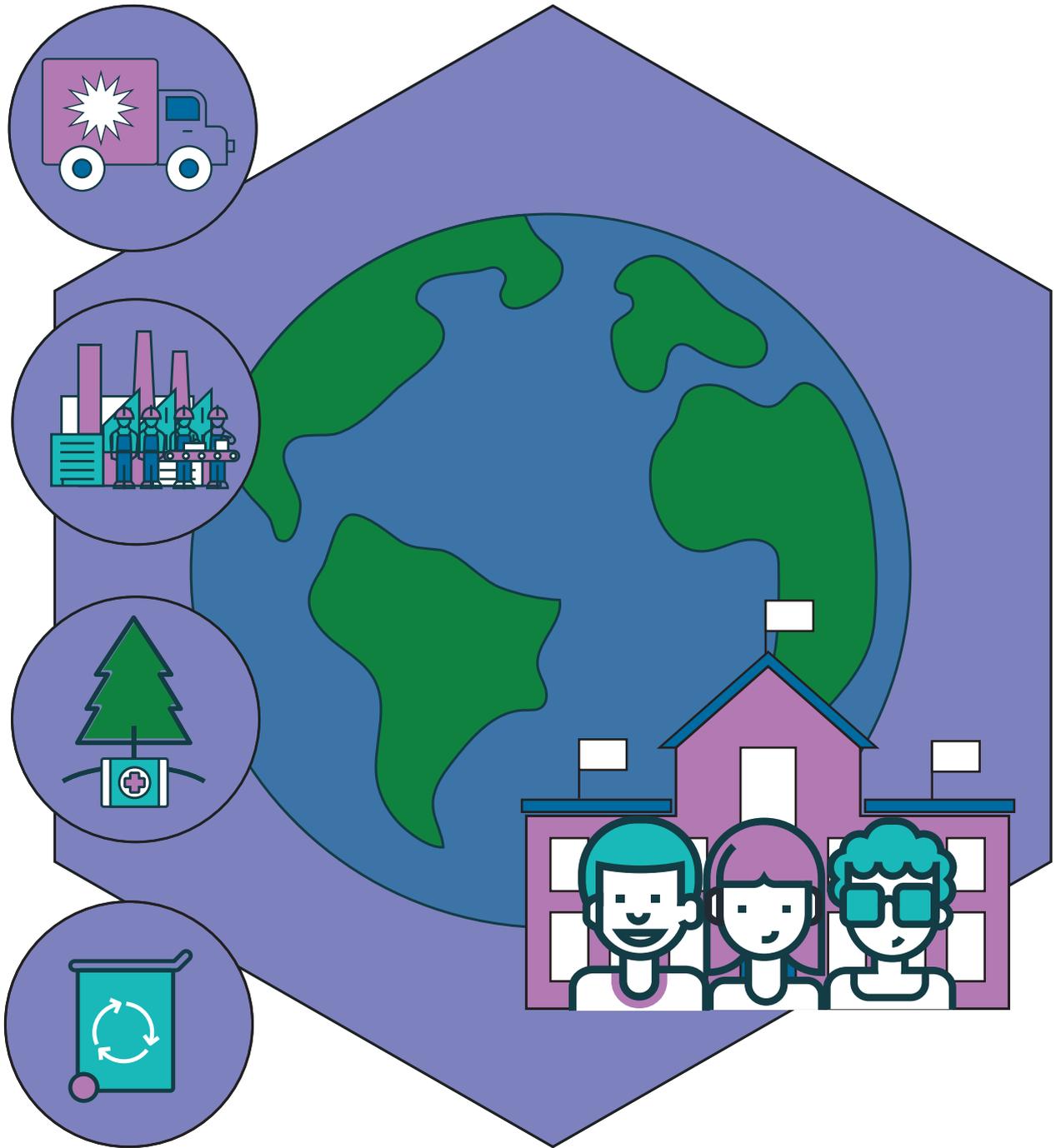


UNEP GUIDANCE

National Authority for Chemicals Control: Structure and Funding



UNEP GUIDANCE

National Authority for Chemicals Control: Structure and Funding

EXECUTIVE SUMMARY

The establishment and implementation of legal frameworks for industrial and consumer chemicals is an aspect of sound chemicals management still lacking in many countries, especially in developing countries. The term “chemicals control” is used to refer to the regulation of industrial and consumer chemicals before or at the point when they are placed on the market. In most countries, pesticides are covered in separate legislation and are often subject to stringent requirements.

In parallel to establishing the legal requirements, the related institutional capacity for chemical safety needs to be established or improved. Adopting these measures at an early stage provides many benefits and is a cost-effective way of strengthening national chemicals management systems.

This document builds on an earlier United Nations Environment Programme (UNEP) publication, *Guidance on the Development of Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration for Sound Management of Chemicals (LIRA Guidance)*; and provides additional information on how to establish and maintain a national authority structure for chemicals control.

Consistent with the LIRA Guidance, this document emphasizes that creating clear legal responsibilities for manufacturers and importers is a key element of successful chemicals control.

Key concepts of chemicals control include:

- **Clear division of roles and responsibilities.** The top priority in designing a chemicals control system is to clearly define, in legislation, the roles and responsibilities of both industry and government, especially with regards to information generation, dissemination and management. Conditions for placing chemicals on the market and the institutional arrangements for decision-making, implementation, fees and enforcement should be defined in legislation. These clear definitions make it possible to manage chemicals successfully throughout their life cycle. Defining government functions clearly and narrowly, while creating clear obligations for industry, also helps to keep government costs manageable.

- **Basic government functions.** Government is responsible for developing legislation and regulations, and enforcing legal requirements. There are also a number of other tasks that governments carry out as they support these two main tasks. These include keeping registries of manufacturers and importers for compliance monitoring purposes and for levying fees; dialogue/consultation with industry; managing information; coordinating among agencies; and cost recovery.
- **Prevention.** This concept is embodied in the Precautionary Principle (from the 1992 Rio Declaration), which states, in part, that “[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”.
- **Classification and labelling.** Classification and labelling is the most important measure for chemicals control as it provides information on hazards and on precaution for daily chemicals management. Implementing the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), including Safety Data Sheets, should be a legal obligation of doing business in a country.
- **Chemical bans or restrictions.** An essential component of chemicals control is to adopt and maintain a system for enacting chemical bans or restrictions.
- **Cost recovery.** Chemicals control activities should be funded in large part through fees paid by the regulated industries.

Basic functions of a national chemicals control authority

Chemicals control legislation requires a clear scope, and it should be able to interface with specific legislation for other categories of chemicals such as pesticides and pharmaceuticals, as well as with legislation on worker protection, waste management and other topics. It may be designed to give a specific official or government body the general authority to

implement its provisions. It should also ensure inter-agency coordination by requiring consultation and involvement. If more than one agency is assigned responsibility for implementing a law, a lead agency may be designated in order to ensure efficient coordination. Basic functions of a national chemicals control authority focus on legislation, coordination, information and enforcement.

Activities related to the development of regulations include the adoption of classification and labelling requirements; the adoption of chemical bans or restrictions; and fulfilling obligations under global conventions. It is important to link enforcement to specific regulations in order to monitor compliance and to ensure an effective system for sanctions in the event of violations.

Designating the responsibilities of manufacturers, importers and downstream users is key to a successful chemicals control system:

- Manufacturers and importers must follow regulations on banned and restricted products, or products subject to authorization; classify and label all hazardous chemicals; keep and share records with the government as necessary; and generate Safety Data Sheets to distribute downstream.
- Downstream users and retailers must follow regulations on banned and restricted products; check for adequate labelling; handle chemicals appropriately; package and store chemicals correctly; and keep and share records with the government as necessary.

The chemicals control authority may create and maintain registries (also known as registers or inventories) of manufacturers and importers, chemicals, and/or products in order to track the flow of chemicals in the country.

Governments in a number of countries have implemented, or are developing elements of, chemicals control. This document provides several examples.

Staffing options

Staff functions include building, maintaining and enforcing a functional legal framework for chemicals control. Staff may be dedicated to chemicals control only or may serve multiple functions.

Personnel with administrative, technical and legal skills are needed to implement the chemicals control system. Depending on the types of chemicals under its jurisdiction (among other factors), initial staffing of a chemicals control authority can be relatively small. The staff can be expanded over time as needed. The expertise needed includes knowledge of relevant legislation, compliance and environmental issues, as well as administrative skills. Most staff members do not need to have a detailed knowledge of chemicals and their effects on health and the environment. However, it is important for them to have access to objective scientific expertise for consultation. Staff should also have the skills to be able to do spot checks of chemical labelling and classification carried out by manufacturers and importers.

It is important to provide relevant training and education for staff members. Training of personnel in the public sector is the responsibility of governments, while training of personnel in private enterprises is primarily the responsibility of the private sector. In addition to initial training, it is important to build a system for long-term education in order to keep workers up-to-date and maintain continuity when there is staff turnover.

Setting up a government-run verification laboratory is generally not recommended, as maintaining a laboratory that is directly dependent on fees can be burdensome in terms of maintaining equipment and trained personnel. Instead, national authorities can contract certified private sector chemical testing and reference laboratories. Laboratories must meet the Good Laboratory Practices standards and be neutral in relation to the government and the company.

Funding options

Chemical management costs are relatively small compared to the social, environmental and economic costs of inaction. Clearly defined responsibilities for industry can significantly reduce government administrative costs.

To establish institutional capacity for managing chemical risks, it is necessary for governments to set up sustainable domestic funding mechanisms and to reflect the funding mandate in legal provisions.

Legislation that provides for adequate and stable funding of government activities is a prerequisite for successful implementation of chemicals control. It is important to include chemicals control in national budgets. In preparing the budget estimate,

government functions should be defined clearly and narrowly, while also creating clear obligations for industry. Regional cooperation with other countries can also help to reduce government costs.

The costs to government of chemicals control result from the activities of businesses that manufacture, import and use chemicals, so it is logical to consider legislation that applies special fees or taxes on enterprises or on their products, or that charges fees for specific services. Factors to consider when assessing funding options include the degree of secure financing; administrative feasibility and simplicity; and fairness.

Cost recovery fees can provide a predictable source of funding that covers the cost of inspections and registries, as well as licensing and authorization systems, when relevant. Taxes or fees should be kept as low as possible, while still covering the costs of the services performed. They should simply cover the costs of chemicals control activities and should not be used to generate additional revenue.

PREFACE

This document is part of a series of guidance documents that are designed to complement the information provided in UN Environment Programme's (UNEP) 2015 publication, *Guidance on the Development of Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration (LIRA Guidance)*.¹ Specifically, this document provides further information on government functions for chemicals control, staffing and financing options.

The approach suggested in the LIRA Guidance is referred to in this series as "chemicals control" and primarily addresses industrial and consumer chemicals before or at the point when they are placed on the market.

The series is composed of four documents, one on the benefits of chemicals control and three guidance documents:

- Benefits of Chemicals Control
- National Authority for Chemicals Control: Structure and Funding
- Risk Reduction Tools for Chemicals Control
- Enforcement of Chemicals Control Legislation

By supporting the development of chemicals management frameworks at the national level, the LIRA Guidance and these complementary documents contribute to the priorities developed in the context of the Strategic Approach to International Chemicals Management (SAICM) and the Overall Orientation and Guidance (OOG) document, as well as the implementation of the Basel, Rotterdam, Stockholm and Minamata Conventions, and the Sustainable Development Goals under Agenda 2030.

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CONTENTS

Executive Summary	2
Preface	5
Acknowledgements	7
1. Introduction	9
1.1 Background.....	11
1.2 Scope and aim.....	11
1.3 Key concepts of chemicals control.....	11
2. Basic Functions of the Authority	13
2.1 Coordination.....	13
2.2 Legislative functions.....	15
2.3 Enforcement capacity.....	16
2.4 Gather and manage information.....	17
3. Staffing for Chemicals Control	21
3.1 Approaches to staffing.....	21
3.1.1 Examples of different staffing structures.....	22
3.2 Staffing expertise and capacity.....	25
3.3 Education and training for government personnel.....	26
3.4 Access to laboratory capacity.....	27
4. Financing National Administrations	29
4.1 Overview and general considerations.....	29
4.2 Legal basis for funding.....	29
4.3 Financing options.....	30
4.4 National budget allocation.....	31
4.4.1 Estimating a budget.....	31
4.5 Cost recovery fees.....	32
4.6 Fee collection system.....	33
4.7 Setting fee levels.....	33
4.8 External funding.....	34
References and further reading	35
Annex 1: SAICM Overall Orientation and Guidance (OOG) document, 2015	37
Annex 2: Resources for information on chemicals	38
Annex 3: National approaches to authority structure for chemicals management	40
Endnotes	44

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A young girl with brown hair in a ponytail, wearing a blue polka-dot vest over a pink long-sleeved shirt, is blowing bubbles. She is holding a yellow bubble wand. The background is a blurred green park setting. A purple rectangular box with the word 'INTRODUCTION' in white capital letters is overlaid on the left side of the image.

INTRODUCTION

Chemicals are integral to modern life, and their sound management is a key aspect of sustainable development. Adoption and implementation of chemicals control legislation is an aspect of sound chemicals management that many countries often lack. A focus on prevention in this context is consistent with broadly accepted international principles.ⁱⁱ

In this document, the term “chemicals control” is used to refer to the regulation of industrial and consumer chemicals before or at the point when they are placed on the market. This includes chemicals used in industrial processes; chemicals used in everyday life, such as cleaning products and paints; and chemicals in articles, such as clothing, furniture and electrical appliances (not including pesticides, pharmaceuticals, cosmetic products or food additives). Placing on the market means supplying or making available chemicals, whether in return for payment or free of charge. This includes imports.

Most countries have adopted environmental and worker protection, waste management and transportation requirements that relate to the reduction of possible risks from chemicals. Moreover, most countries have legislation in place that regulates the marketing of pesticides, pharmaceuticals and, in some cases, cosmetic products. The establishment and implementation of legal frameworks for industrial and consumer

chemicals is an aspect of sound chemicals management still lacking in many countries, especially in developing countries.

Roles and responsibilities of both industry and government need to be clearly defined. Chemicals control can be addressed in free-standing law or can be built into a broader chemicals management law or other framework legislation related to the protection of health and the environment. Framework legislation identifies basic principles and obligations, while leaving details to further legislation or other government activities. The conditions for placing chemicals on the market and the institutional arrangements for decision-making, implementation, fees and enforcement need to be defined in legislation.

In parallel to establishing new legal requirements for industrial and consumer chemicals, the related basic administration and authority needs to be established or improved.

The complementary relationship to existing regulations must be clarified. In most countries, pesticides are covered in separate legislation and are often subject to more stringent requirements than industrial or consumer chemicals. Guidance on pesticide regulation is available from the Food and Agriculture Organization of the United Nations (FAO). Although guidance

CHAPTER

1

on pesticides, pharmaceuticals, cosmetic products and food additives is not directly provided in this document, there is some overlap with elements of control regulations for all chemical categories – for example, in basing labelling provisions on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Establishing chemicals control legislation with adequate institutional capacity has prevention-related benefits throughout the chemical life cycle. It can reduce costs, and complement and contribute to other aspects of chemicals risk management, such as the regulation of chemicals in the workplace, waste disposal, clean-ups and other downstream risk management activities. See further details in the Benefits of Chemicals Control document.

1.1 Background

Adopting chemicals control legislation and the related institutional frameworks is consistent with Agenda 21 (adopted in 1992), the 2020 goal of the Strategic Approach to International Chemicals Management (SAICM), and the Sustainable Development Goals stated under Agenda 2030. Within SAICM, a set of 11 basic elements for sound management of chemicals has been identified in the SAICM Overall Orientation and Guidance (OOG) document, completed in 2015. These are critical to the attainment of sound chemicals and waste management, at both national and regional levels.ⁱⁱⁱ These basic elements include legal frameworks; enforcement and compliance mechanisms; strong institutional frameworks and coordination mechanisms; and defined responsibilities for industry across the chemical life cycle. For additional details, see Annex 1. Within SAICM there is a “Beyond 2020” process under way. The outcome of this process “will form the basis for formal decision-making and adoption of a future policy framework for sound management of chemicals and waste beyond 2020”.^{iv}

To assist countries in the process of establishing chemicals control legislation and related institutional frameworks, in 2015 UNEP published Guidance on the

Development of Legal and Institutional Infrastructures for Recovering Costs of National Administration (LIRA Guidance). The LIRA Guidance provides options for organizing the legal and institutional infrastructures governing the placement of chemicals on the market, including a template for a framework law. It also provides suggestions for ensuring sustainable financing, including cost recovery measures.

In 1995, UNEP published *Legislating Chemicals: An Overview*.^v This resource also provides guidance on organizational structure, areas of required staff expertise, preventive measures and compliance. Much of the information provided remains relevant today.

The Guidelines for the Exchange of Information on Chemicals in International Trade, published by UNEP in 1989, contains proposals for governments on how to establish chemicals legislation;^{vi} and the Code of Ethics on the International Trade in Chemicals, published by UNEP in 1994, provides industry and other private sector parties with standards of conduct “for the promotion of environmentally sound management of chemicals in international trade”.^{vii}

A report from the Rotterdam Convention Secretariat of UNEP, *Guide on the Development of National Laws to Implement the Rotterdam Convention*, identifies elements that should be included in chemicals legislation. It notes basic elements of successful legal and policy frameworks for protecting health and the environment developed over the past 30 years. These include notions of sustainable development; linkages between environmental protection, human health and poverty; public participation and the “right to know”; pollution prevention; common but differentiated responsibilities; and science and precaution.

An additional resource document is *Developing National Legal Frameworks to Implement the Stockholm Convention – A Guide*.^{viii}

1.2 Scope and aim

This document complements the information provided in UNEP's 2015 LIRA Guidance. More specifically, it supplements LIRA by providing further suggestions to governments for establishing and maintaining a national authority structure for the administration of chemicals control regulation.

This document, as well as the UNEP LIRA Guidance, focuses on chemicals control legislation as one element of the broader concept of sound management of chemicals (SMC).

Aims of this document include:

- Provide suggestions on the basic authority functions that should be present during implementation of chemicals control
- Provide guidance on the staff expertise that is needed for implementation of chemicals legislation
- Assist countries to establish budget estimates of the administrative framework for chemicals control
- Describe options for funding the necessary institutional capacity

This document is intended to be used by countries that are currently working to establish, amend, update or implement chemicals control legislation for industrial and consumer chemicals, and the associated institutional capacity. Specifically, it is directed at technical government officials who are actively working to build government capacity for chemicals control.

It provides information on which basic cost-efficient functions the government authority should provide, and how to estimate and fund the costs of providing these functions. Ideally, this document will also help government officials to prepare for discussions about national budget planning. It is meant to provide options, without being exhaustive.

This document aims to complement

the available resources identified in the Internet-based Organisation for Economic Co-operation and Development (OECD) *IOMC [Inter-Organisation Programme for the Sound Management of Chemicals] Online Toolbox for Implementing Chemicals Safety'* (IOMC Toolbox).^{ix}

1.3 Key concepts of chemicals control

The following are key concepts of chemicals control that are relevant for establishing and maintaining the related national institutional capacity. These concepts are described in the LIRA Guidance,¹ and inform this document.

Clear division of roles and responsibilities.

As described in the LIRA Guidance, the top priority in designing a chemicals control system is to provide a clear legal definition of the roles and responsibilities of both industry and government. Chemicals control legislation should include the obligation for manufacturers and importers to collect or generate and disseminate data on the health and environmental properties of chemicals. A basic requirement in the legislation should be that companies are responsible for ensuring that their products do not harm people or the environment. The legislation should give clear authority to the government to require the generation, dissemination and management of information about chemicals; and, when relevant, ban or restrict hazardous chemicals or conduct enforcement activities. Clear roles and responsibilities provide the basis for establishing a basic, cost-efficient national authority that can focus on monitoring compliance. For more information on the importance of enforcement see UNEP's *Enforcement of Chemicals Control Legislation Guidance Document*.

Basic requirements for industry should include:

- Gather knowledge and, if necessary, generate new knowledge on chemical properties, hazards and risks
- Classify and label their chemicals in accordance with the GHS

¹ LIRA Guidance, section 1.3.2.

- Disseminate information on hazardous properties of chemicals and on safe handling procedures, including providing Safety Data Sheets (SDSs) to professional users
- Supply additional information about the products, when necessary, in order to enable and facilitate the best choice of products for downstream users and to ensure the safe handling of the products
- Ensure that no banned substances are produced, imported or placed on the market
- Make informed choices about chemicals in order to avoid hazards and risks
- Substitute for safer chemicals or processes whenever possible, in accordance with the substitution principle
- Organize and ensure the safe use of chemicals and their storage, transport and appropriate disposal
- For downstream/professional users of chemicals, comply with risk management measures, choose the safest chemical, and handle the chemicals they use or dispose of in a safe way

Classification and labelling. Classification and labelling is an essential element, as it provides information on hazards and on precautions for daily chemicals management. Using the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) should be a legal obligation of doing business with chemicals. For more information on the importance of adopting requirements based on GHS, see the guidance document, Risk Reduction Tools for Chemicals Control.

Chemical bans or restrictions. An essential component of chemicals control is to adopt and maintain a system for enacting chemical bans or restrictions. Bans and restrictions, and enforcement to ensure compliance are discussed further in Risk Reduction Tools for Chemicals Control and in Enforcement of Chemicals Control Legislation.

Cost recovery. Chemicals control activities should be funded, to a large extent, through fees paid by the regulated industries. Defining industry roles and responsibilities clearly helps to keep overall costs for the administration low. The financial and technical participation of chemical producers and importers is central in chemicals control. Financing options are discussed further in Section 5.





BASIC FUNCTIONS OF THE AUTHORITY

The development of the various functions of the institutional capacity for chemicals control requires legal frameworks. As described in UNEP's 1995 overview of chemicals legislation and in the LIRA Guidance, laws related to chemicals generally have five major components: organizational structure, the establishment of preventive and corrective measures, a compliance scheme, the creation of a knowledge base, and provisions for funding over the long term.^x

Depending on the country, the chemicals control authority may exist within a larger government entity, where administrative functions are already provided. The authority may also be partially or entirely separate from other entities, in which case these functions need to be included in planning and budgeting. The guidance presented here presupposes that there are authorities addressing chemicals safety in other areas of legislation, such as pesticides control, environmental protection, workers' health and safety, major accidents prevention, transport of dangerous goods, consumer protection, and related topics.

The two main government functions for chemicals control are enforcing legal requirements and further developing the legislation and regulations. Coordination and cooperation among different parts of the government (among ministries and/

or authorities, including coordination with those responsible for pesticide regulation) is also an important function. There are a number of other tasks that administrations carry out as they support these main tasks. These include keeping registries of manufacturers and importers for compliance monitoring purposes and for levying fees; dialogue/consultation with industry; providing information to stakeholders, including the general public; and cost recovery.

Adequate general administrative functions, either housed within a larger agency or ministry or as a separate agency, are a prerequisite for successful implementation of the basic functions. These include basic requirements such as ensuring that relevant record keeping is maintained, fees are received and recorded, and staff are paid.

2.1 Coordination

Chemicals control legislation is often a new, additional or complementary regulatory area that countries, when establishing administrative capacity, need to align with existing legislation. It is often the case that several different laws relate to chemicals and that authority is distributed among multiple government agencies.

In some cases, the capacity for chemicals control will be established within a national

CHAPTER

2

authority with the responsibility for managing the entire life cycle of chemicals, from chemicals control through to disposal. In other cases, there may be one authority that is responsible for industrial and consumer chemicals control, while other authorities deal with different aspects of chemicals management (such as workplace standards or disposal, or with specific chemicals, such as pesticide legislation).

Regardless of the set-up, an important function of the national authority will include coordination with other government authorities, both domestically and internationally. Coordination with regional authorities is also necessary.

Inter-agency coordination. Every new piece of legislation addressing chemicals control must explain its relationship to existing laws. One important function is the administrative capacity to coordinate with other authorities, including for enforcement and supervision purposes. Coordinating with other governmental institutions can also help to ensure that efforts are more cost-effective.

Chemicals control legislation for industrial and consumer chemicals should be clear in its scope and interface with legislation for specific categories, such as pesticides or pharmaceuticals, waste management and worker protection. It may be designed to give a specific official or government body the general authority to implement its provisions. It should also ensure inter-agency coordination by requiring consultation and involvement. If more than one agency is assigned responsibility for implementing a law, a lead agency may be designated to ensure efficient coordination. It is important for there to be a clear enforcement mandate in the legislation, with a clear definition of which authority or authorities will carry out enforcement. For more information on coordination mechanisms, see LIRA Section 4.3.2, as well as section II in UNEP's 1995 document.^{xi}

International coordination and cooperation capacity.^{xii} The transboundary effects of inadequate management of chemicals have prompted the need for cooperation

between countries. This cooperation has resulted in several international conventions to eliminate or reduce the use of certain hazardous chemicals, such as persistent organic pollutants and mercury. A central aspect of successful chemicals control is international cooperation, such as participation in international conventions and agreements. International coordination "facilitates national legislative work, gathering of information on the properties of chemicals, tracking flows and uses of chemicals and monitoring of compliance with regulations". This increases efficiency and helps to conserve both government and private sector resources.^{xiii} International coordination allows countries to solve problems, share information, learn from others and harmonize approaches.

Box 1. Example of coordination: Costa Rica

When different aspects of the life cycle of chemicals are coordinated by different government entities, it is helpful to establish an official coordination mechanism. This ensures a commitment at the political level by the authorities involved to cooperate, collaborate and coordinate. In Costa Rica, a voluntary coordination agreement (common in many developing countries) was considered insufficient. Instead, a legally established coordination mechanism was considered necessary to ensure a commitment to the coordination of chemicals management.

The Technical Coordination Secretariat for Chemicals Management was established in Costa Rica in 2006 through Executive Decree no. 33104.^{xiv} It was signed by the Ministries of Foreign Affairs, Agriculture, Environment and Health. The Executive Decree mandates that the Secretariat is composed of two representatives from the Ministry of Agriculture and Livestock; two from the Ministry of Health; two from the Ministry of Environment and Energy; one from the Ministry of Foreign Affairs; two from

Customs Services from the Treasury; one from the Occupational Health Council; two from NGOs related to the chemicals management agenda; two from the Associations and Chambers of Industry; and two representatives from the National Council of Rectors.

The Executive Decree states that the Secretariat has the mandate to monitor and support, among others:

- the policies, strategies, programmes and actions for the management of chemicals at the national level; and
- the coordination and integration of any action or measure taken on chemicals management.

This is considered the legal basis for establishing coordinated and effective protocols for different situations involving chemicals management. Strengthening this coordination mechanism with high-level decision makers from each member authority facilitates and expedites decision-making on chemicals management.

Governments may cooperate on activities including policy development, adoption and development of standards, and testing protocols, among other activities.^{xv} Other forms of coordination can include participation in webinars, conferences or international training sessions, as well as use of internationally maintained databases and other information resources.

A database of experts involved in the work of the Basel, Rotterdam and Stockholm (BRS) Conventions enables users to identify an expert in their region or country that specializes in specific areas of expertise in chemicals and waste issues.^{xvi} For disposal and end-of-life considerations, numerous tools and resources are available to help reduce the harmful impacts of chemicals on health and the environment – as addressed in the Basel Convention.

Examples of *regional and international coordination* related to chemicals safety include:

- the South African Development Community (SADC)
- the Economic Community of West African States (ECOWAS)
- the Bamako Convention on the Ban on the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa
- the Waigani Convention to Ban the Importation into Forum Island Countries of Hazardous and Radioactive Wastes and to Control the Transboundary Movement and Management of Hazardous Wastes within the South Pacific Region²

In 2007, the health departments of the Governments of Canada and Australia signed a Statement of Intent to collaborate on risk assessment and management of existing chemicals.^{xvii} A Cooperative Arrangement between the two countries focuses on sharing information on new industrial chemicals; Australia has formally

recognized Canada's risk assessment protocol for new chemicals as a competent authority under the National Industrial Chemicals Notification and Assessment Scheme.^{xviii}

The Common Electronic Submission Gateway is a potentially relevant example of regional cooperation from the pharmaceuticals sector. Canada and the United States developed the Gateway to enable companies to submit information about pharmaceuticals to both countries simultaneously, thus reducing administrative costs for both government and industry.

2.2 Legislative functions

A variety of functions relate to legislation and regulations or rules. These include developing new legislation and regulations, as well as continuously updating existing requirements, according to the legislative procedures in the country. Activities related to the development of regulations include the adoption and maintenance of classification and labelling requirements, including requirements for Safety Data Sheets. They also include adoption and maintenance of a system for enacting chemical bans or restrictions, and fulfilling the obligations of being a party to global conventions such as the Stockholm, Rotterdam and Minamata Conventions.^{xix}

Framework legislation – also known as primary legislation – is usually adopted by the highest legislative body in a country. It should not include technical details that will need to be amended in the future due to technical developments. Instead, it should include an explicit mandate for the authority to develop more detailed regulations – also known as secondary legislation. These regulations may include the detailed requirements related to classification and labelling, and Safety Data Sheets; a system for enacting bans and restrictions for specific substances; and the authorization of specific chemicals based on clear criteria.

Maintaining an ongoing dialogue with

² Information on these and other regional agreements can be found on the Basel Convention Article 11 website, <http://archive.basel.int/article11/multi.html>

industry and other stakeholders should be included in the legislative function. Industry-sector dialogue can be useful in providing the participating authorities with a better understanding of the conditions faced by different industries. In determining the need to regulate a chemical, it is advisable to assess its marketing and use in the informal as well as in the formal sector; this is discussed further in the following section.

2.3 Enforcement capacity

Enforcement capacity is an essential component of chemicals control. Enforcement tasks include inspection and monitoring activities to promote compliance among companies. A country should consider covering the costs associated with enforcement activities through fees. All decisions related to enforcement should treat the inspected companies in a consistent manner and should not be influenced by the approach of individual staff members at the enforcement authority.

Enforcement involves monitoring to promote compliance, and to detect problems and violations. Enforcement activities and sanctions can include warnings, citations and orders; investigations of possible violations; penalties; and prosecutions. Record keeping, reporting and inspections are all part of monitoring compliance. Inspections can include both routine and spot checks to determine whether practices meet with legal requirements.

Principles of enforcement include a focus on full and continuous compliance; developing a broad culture of compliance; creating clear and comprehensible requirements; and providing for a fair and predictable government response to violations. It is important to link enforcement to chemicals control regulations that define the responsibilities of manufacturers and importers, as well as retailers. In order to provide for adequate means to monitor compliance, fees for providing enforcement should be considered (see Section 4 for more on this). For additional information, see UNEP Guidance: Enforcement of Chemicals Control Legislation.

Compliance with chemical control laws

is fundamentally the responsibility of manufacturers and importers. Industry responsibilities include the following:

Manufacturers and importers of chemicals have a responsibility to refrain from selling banned products; to comply with all requirements related to restricted products; to classify all chemicals and to label the hazardous chemicals correctly; to generate Safety Data Sheets and distribute them to downstream customers; and to keep all relevant records and share them with the government as prescribed. If an authorization system is in place, manufacturers and importers are responsible for placing only authorized chemicals on the market.

Downstream users and retailers also have certain legal responsibilities. The responsibilities of retailers include refraining from selling banned products; selling restricted products only in permissible cases, and with appropriate safeguards; ensuring that products are sold only if they have the required labelling and/or Safety Data Sheets; packaging and storing products correctly; and keeping all applicable records and sharing them with government as prescribed. If an authorization system is in place, downstream users and retailers are also responsible for not using a chemical if it has not been authorized.

Separate from enforcement-related activities, it would be useful for governments to support industry to comply with the requirements by providing guidelines and information resources. This may involve allocating staff time for providing guidance or general information to industry. This function is referred to in some countries as a "help desk". Since this is a different function from enforcement, inspectors should not be responsible for providing this guidance and general information, although they can act in a supporting role.

Many countries have a large informal sector that uses and sells chemicals. It should not be assumed that workers in the informal sector will be using appropriate personal protective equipment. The informal sector should be considered when establishing national enforcement capacity. The informal

economic sector comprises more than half of the global labour force, according to the International Labour Organization.^{xx} Workers in the informal sector do not have permanent employment status and are typically not covered by government employment or social programmes, including occupational safety and health protection.

Box 2. Examples of technical assistance and compliance assistance

The purpose of the US Government's Federal Service Desk "is to help visitors get the information and assistance they need for the systems (websites)" that the desk supports in regard to government grants and contract systems. There is no charge for these services.^{xxi}

In the US State of Massachusetts, the Office of Technical Assistance provides on-site, confidential technical assistance to encourage businesses to reduce the use of toxic chemicals and help them ensure they are in compliance. Such functions are separate from enforcement-related activities.

At the Swedish Chemicals Agency (KemI), there is a clear differentiation between staff members who assist companies in achieving compliance and those who work in enforcement.

In Serbia, advisory missions provide input on compliance.

2.4 Gather and manage information

The chemicals control authority may create and maintain registries to help with identification of priorities and assessment of hazards and exposures. The development of registries (also referred to as registers, inventories or lists) enables governments to track the flow of chemicals that are imported,

produced and/or used in the country. To be effective, a registry must be consistently updated over time.

According to the LIRA Guidance, the simplest registries include the names of the substances or companies, their addresses and the chemical substances they handle. The most complex registries include a variety of data. However, maintaining an inventory is a relatively costly activity for a government agency. The authority should make sure it designs an inventory that is relatively simple to develop so that, realistically, it can be maintained over time. The first step could be to create an inventory of manufacturers and

importers in an Excel file. This can then be expanded as needed.

Box 3. A stepwise approach for building up registry functions

- Inventory of primary suppliers of chemicals in the country (manufacturers and importers)
- Inventory of data on import and manufacture of pure substances
- Inventory of import and manufacture of mixtures in certain groups of chemicals (e.g. lubricants, paints, glues)
- Inventory of hazardous components in mixtures

Source: LIRA Guidance

A registry of chemical manufacturers and importers can be compiled from national profiles or a national company register created for other regulatory or record-keeping purposes. Information on selected importers can also be derived from data received through the Rotterdam Convention on Prior Informed Consent (PIC). It may also be helpful to coordinate and exchange data with registries set up by pesticide authorities.

Before deciding on the content, format and availability of a registry, it is important to carefully define its purpose. What information about manufacturers and importers is already in place, and can that information be used or adopted? What information should be available for whom, and in what format? A clear background description is useful to clarify the direction and scope of the work to all involved, including government employees and other stakeholders. Such considerations can also help to keep the costs as low as possible.

The most useful tool for identifying and selecting subjects for enforcement activities is a register of manufactures and importers (see the discussion on identifying subjects of enforcement in Guidance Document on Enforcement of Chemicals Control Legislation). Such a registry could facilitate other activities, including the financing of the national administration for chemicals control (see Section 4).

The Australian Government, as part of its Department of Health National Industrial

Chemicals Notification and Assessment Scheme, requires businesses to register if they import and/or manufacture relevant industrial chemicals, or certain products that contain such chemicals, for commercial purposes.^{xxii} The agency provides a questionnaire to help businesses determine whether they need to register. Registration is online, on the agency's Business Services website, and requires payment of a registration fee.

Register of chemicals

A decision to develop a registry for all existing industrial and consumer chemicals in a country, including information on the ways in which these are being used, should not be made lightly as such an inventory would require a great deal of time and effort, both to develop and to maintain. If resources allow, countries with substantial industrial or consumer chemical production and/or imports could consider developing such a registry. Developing an online system can facilitate these efforts. Companies importing or producing particular substances and mixtures – those that are designated by certain selected codes in accordance with the Harmonized Commodity Description and Coding System (the Harmonized System, or HS) – could be required to report to the registry.^{xxiii}

Chemicals in such a register should be identified by internationally used names. Standardized chemicals identification allows data to be shared effectively. The Chemical Abstracts Service (CAS) registry number permits access to available information worldwide.

Under the European Union's REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) regulation, manufacturers and importers are required to provide information to the European Chemicals Agency (ECHA) through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. The focus of the registration process is on the chemical

itself, but it also provides the authority with company information.^{xxiv}

The Swedish Chemicals Agency uses its Products Register "to store information on chemical products and biotechnical organisms that are manufactured in or transferred or imported into Sweden and information on the ways in which these are being used. Anyone manufacturing or importing products that have to be reported must provide this information to the Agency" and update it annually.^{xxv} At a certain volume, additional details, including amounts, must be reported. This requirement applies to certain chemical products that have customs tariff numbers that are listed in the country's chemical products law.^{xxvi}

Denmark has a Product Registry that includes information about chemical products that are manufactured in or imported into Denmark. If a company manufactures or imports a product that falls under the country's obligation to report, these products must be reported to the registry.^{xxvii}

An alternative option for setting up a chemicals products registry is to request information from companies via structured inquiries and surveys. Information from other countries' registries can also be used as a resource, and is often sufficient.

Several countries have established or are establishing Pollutant Release and Transfer Registers (PRTRs). According to OECD, a PRTR "is a publicly accessible database or inventory of chemicals or pollutants released to air, water and soil and transferred off-site for treatment. It brings together information about which chemicals are being released, where, how much and by whom."^{xxviii} The OECD recommends that member countries develop and implement PRTRs. "Although it is not a registry that has to do with the registration of industrial chemicals,^{xxix} it is likely that several of the entities audited under a PRTR will also be audited under a register of industrial chemicals." Use of such a register, where it exists, may help to avoid duplication and reduce costs for the authority, as well as reduce the burden for the audited entities.

In many countries, different authorities keep records of different phases of the life cycle of chemicals. In this case, “single registry and reporting windows” can be useful. These are online systems that collect information from different audited entities and about different chemical types. This information can therefore be accessed by any official of any authority that needs to make use of this information. Some examples of single-window systems include PRTRs as well as inventories. Examples include the PRTR single-window of Chile,^{xxx} Canada’s Environment and Climate Change single window,^{xxxi} and the PRTR system in Israel.^{xxxii}

Annex 3 includes examples of various national approaches to authority structure for chemicals management, including the development of registries and inventories.

Box 4. Online register in Costa Rica

The registration system for “products of sanitary interest” in Costa Rica, led by the Ministry of Health, uses an online platform called REGISTRELO (www.registrelo.go.cr). The system enables the procedures related to the registration of these products to be carried out in a single online window. The objective is to significantly reduce the time needed to register a product and to streamline the entire process.

The online platform was established to promote the country’s competitiveness and improve the supply of products to consumers. Its implementation has significantly facilitated the registration tasks of the competent authority, as well as those of the regulated entity.

REGISTRELO uses simple forms to collect data and has the ability to obtain a digital signature for official documents. It provides comprehensive and useful statistics on registered products.

The platform can be consulted by anyone, national or foreign, who wishes to find out about or follow up on the registration procedures of a product of sanitary interest.

manufacturers and importers to collect or generate the data, they should be allowed the option of using information from other countries. This information can be augmented, when needed, with information on use and exposure domestically, if there are sources of exposure that pose a particular concern. In many cases, however, existing information is sufficient. Within the European Union (EU), the sharing of data and of testing costs among companies has been formalized and is a legal obligation.

Knowledge on hazards and necessary precautions is to be gathered and conveyed by both the chemicals manufacturers and the importers, as they are the primary actors in the production or supply of chemicals for use in supply chains. Importers will obtain this information primarily by requesting it from their suppliers in other countries. In all cases, it is essential to make use of existing data sources. Databases on chemical properties, ecotoxicological data and toxicological data are often available from other countries, regions or global actors. Testing and assessing chemicals for hazardous properties is labour-intensive and costly. Testing of the same chemicals in several countries should be avoided to reduce duplication and costs. The use of existing data for assessment purposes in chemicals management can substantially minimize costs for tests as well as reduce the need for animal testing. Risk evaluations that have been generated by other countries or regions are often useful as well. Industry and governments can substantively reduce costs by making use of existing data.

Using databases on chemical properties

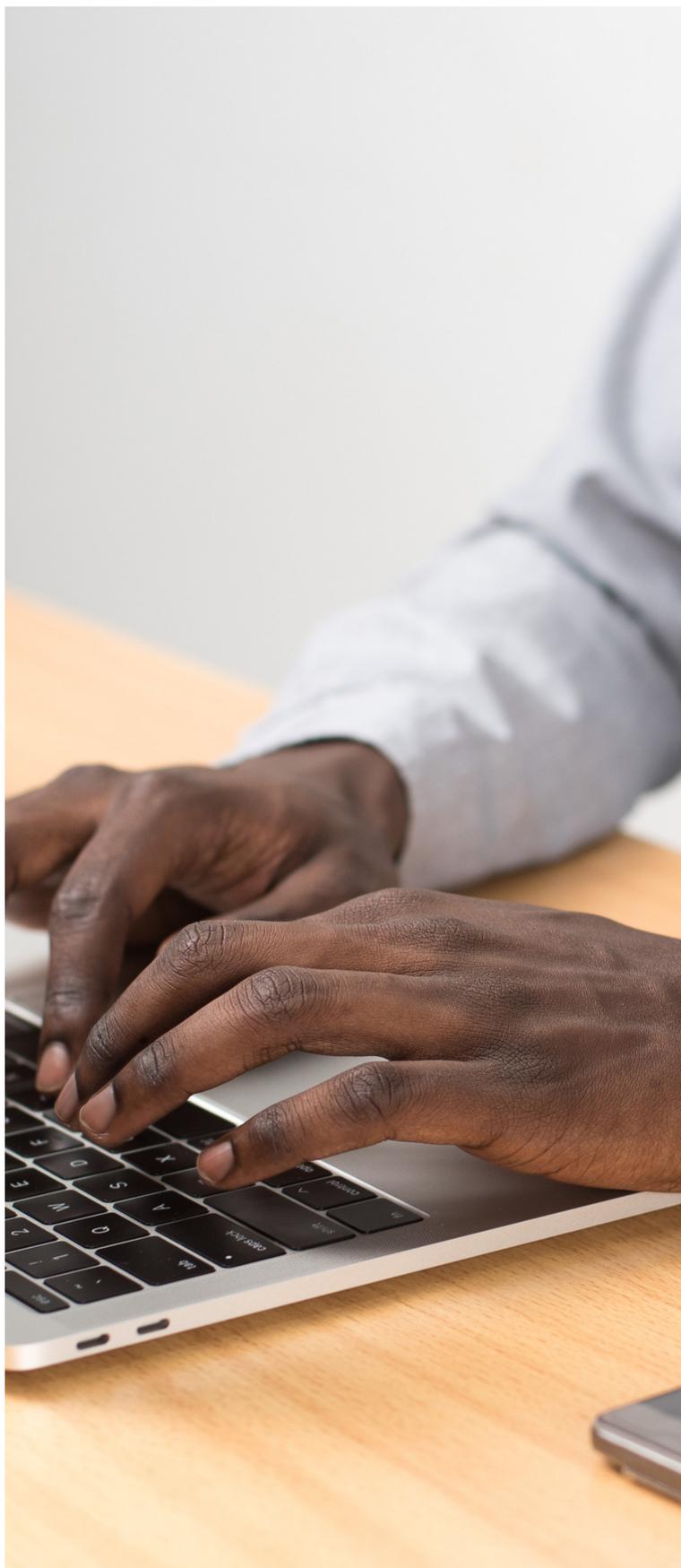
Countries can avoid redundancy by using existing databases that are available internationally. Annex 3 of LIRA and Annex 2 in this document provide examples of useful resources.

Countries should allow for the use of data and evaluations from other jurisdictions, as long as they comply with internationally recognized standards, such as guidelines from the OECD. As it is the responsibility of

Box 5. Mutual Acceptance of Data (MAD)

The OECD Council adopted a decision in 1981 on MAD. It states that “test data generated in any member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment”. Additional OECD Council Acts establish procedures for monitoring GLP compliance as well as a framework for a stepwise procedure that enables non-OECD countries to take part as full members and benefit from the data.^{xxxiii}

Data on chemical properties are openly shared through various platforms, such as the OECD eChemPortal and the ECHA databases. Hazard data should be adopted from existing sources, using the wide variety of database resources that are available internationally. These include databases of chemical hazard information, regulatory information and ingredients in consumer products.





STAFFING FOR CHEMICALS CONTROL

This section provides suggestions related to staffing size, capacity and expertise for the chemicals control activities of a national authority. These staff members may also have other responsibilities in the area of chemicals safety.

3.1 Approaches to staffing

Countries setting up a chemicals control system for the first time are likely to have only a small number of staff working on the issue initially. Over time, the staff may be expanded.

Staffing should reflect the fact that the role of the authority is to build up, maintain and enforce a functional legal framework for chemicals control. Industry should be required to conduct most of the technical/scientific work, with monitoring of compliance by the government authority.

Countries differ in the areas of responsibility assigned to different authorities. In some cases, staffing of the authority in charge of chemicals control will include staff that are responsible for the implementation of pesticide legislation, including the review and authorization of pesticides. In other cases, pesticides are covered by separate legislation and a separate authority. For example, in Serbia, the same authority is responsible for industrial chemicals and biocides, but not for pesticides; whereas in Sweden, the authority is responsible for the regulation of both industrial chemicals and pesticides.

Table 1 provides an overview of a possible basic staffing structure for a newly formed chemicals control authority in a medium-sized country - excluding work with pesticides.

Table 1: Suggestions for initial staffing and staff expertise

Activity	Staffing for chemicals control
Legislation & regulations development, including development of bans/restrictions	<ul style="list-style-type: none">• Legal professional or policy analyst.• Professional with knowledge of chemical bans and restrictions for industrial chemicals.

CHAPTER

3

<p>Legislation & regulations development – adoption of GHS for chemical classification & labelling</p>	<ul style="list-style-type: none"> • Professional (e.g. legal professional, policy analyst, chemist or toxicologist) with knowledge of classification and labelling. • Domestic legal professional with ability to draft domestic secondary legislation to incorporate GHS, analyse gaps in existing legislation, and related tasks. Tasks may vary over time, from the initial drafting of basic legislation to the ongoing updating of registers, evaluation of substances for bans, and other activities, depending on staff competencies.
<p>Information collection & management, or knowledge management platform – creation of company register</p>	<ul style="list-style-type: none"> • Policy analyst or other professional able to review existing government lists, ensure usability, and update as needed.
<p>Enforcement</p>	<ul style="list-style-type: none"> • Professionals with general expertise in chemicals control to develop and provide training for the regulated community during the phase-in period, as stipulated in the legislation, and to train/educate any existing inspectors in other programmes who may also be involved in enforcement of Chemicals control requirements. • When legal requirements are in force, a group of at least three inspectors is recommended, both for industrial and consumer chemicals.
<p>Administrative functions, including fee administration</p>	<ul style="list-style-type: none"> • This function may be carried out by existing staff from other programmes or may require one or two administrative staff members. • Head of the authority/unit.

3.1.1 Examples of different staffing structures

Chemicals management in Southeast Asia: Staffing for existing programmes. A recent report from the Stockholm Environment Institute examined the status of chemicals management in nine countries in South or Southeast Asia.^{xxxiv} The report examines institutional infrastructure for chemicals management in each country, notes gaps in the existing systems, and offers

recommendations. The report does not explicitly include chemicals control legislation as one of the criteria against which to measure the existing systems, but it does provide information on implementation of GHS, as well as other information on government structures that is relevant to the adoption or implementation of chemicals control legislation. The report provides detailed information on staffing at agencies currently working on various aspects of chemicals control.

In each country, a number of agencies are involved in chemicals management. Thailand has four agencies involved in this area of work; several other countries have between seven and ten agencies.

Thailand is highlighted as one of the countries that has been relatively successful in establishing institutional infrastructure for chemicals management. Specific staffing for two of the four relevant agencies are included in the report. As shown in Table 2, these two agencies have a total of 6 and 12 staff working on chemicals management, respectively. These figures do not include the staff at the country's eight poison control centres. Thailand has implemented GHS for industrial hazardous substances, household

hazardous substances and livestock (the staffing for this effort may not be included in the staffing figures shown here). Thailand has also developed a web-based chemicals inventory, among other resources.

In another example, Vietnam has 15 staff members working on pesticides management (pesticides and fertilizers) within its Plant Protection Department; 9 chemicals staff in a Pollution Control Department; and 38 chemicals staff in the Vietnam Chemical Agency (VINACHEMIA), as shown in Table 2. Vietnam has adopted GHS. VINACHEMIA reports to the Ministry of Industry and Trade.

Table 2: Examples of staffing for existing industrial/consumer chemicals management programmes: Thailand and Viet Nam

	Name of department and its functions	Number and type of staff
Thailand	Ministry of Public Health and its Food and Drug Administration (FDA): Chemical Safety Group within FDA develops policies and plans for chemicals management; carries out research; and other functions.	4 permanent staff with pharmacy degrees; 2 temporary staff with 'minimum first-level university degrees'.
	Pollution Control department within Ministry of Natural Resources and Environment: Develop and implement policies and plans; develop standards, measures and guidelines; and other activities.	9 permanent staff and 3 temporary staff with 'minimum first-level university degrees'.
Viet Nam	Pollution Control Department under Ministry of Natural Resources and the Environment: Chemical regulation, environmental protection, inventories, pollution control and other activities.	9 staff in the Division of control of chemical pollution, chemical incidents and environmental health. One holds a PhD; others hold master's degrees in chemistry and environmental studies.
	Viet Nam Chemical Agency (VINACHEMIA): Implements chemicals control and prevention of chemical accidents.	Total 38 staff. These include 10 addressing chemical management; 10 addressing development of national chemical industry; 12 addressing chemical incident response and chemical safety.

Source: Information drawn from Stockholm Environment Institute (SEI), 2017: Study on Chemicals Management in South-East Asia, October 2017. Updated information about staffing in Viet Nam provided by Nguyen Thi Ha, VINACHEMIA, personal communication, May 2018.

As shown in Table 3, the Serbian Department for Chemicals currently has 14 employees. In 2010, the then newly established Serbian Chemicals Agency had 35 staff members.^{xxxv}

The staffing structure at the Zambia Environmental Management Agency (EMA) provides another example. Zambia's EMA currently has just under 20 staff members, as shown in Table 4. Almost all of these have responsibilities other than chemicals management.^{xxxvi}

Table 3: Chemicals control staffing in Republic of Serbia (within the Ministry for Environmental Protection)^{xxxvii}

Job title/organizational unit title	Responsibilities	Area of training/expertise
Division for Chemicals (Head + 4 employees)	Bans and restriction of chemicals; List of Substances of Very High Concern; Detergents; PIC legislation/ Rotterdam Convention; parts of Stockholm Convention; national provisions on chemical advisers and national provisions on permits for placing on the market of particularly dangerous chemicals.	Chemists and Chemical Engineers, general expertise in chemicals management supported by basic training.
Group for Chemicals Classification, Hazard Assessment and Communication (Head + 2 employees)	Classification, packaging and labelling (CLP); Safety Data Sheets, test methods, provisions on Chemicals Safety Assessment and hazard criteria.	Chemists and one toxicologist; general expertise in chemicals management; CLP and REACH expertise; advanced hazard assessment and classification training.
Group for Integrated Chemicals Register (Head + 2 employees)	Record and database keeping on chemicals (e.g. trade name, composition, classification, quantities, etc.) placed on the market.	Chemists and chemical engineers, basic expertise in chemicals control.
Group for Biocidal Products (BP) Risk Management (Head + 2 employees)	Assessment of BP and issuing decisions/ authorization for placing of the BP on the market.	Chemical engineers, expertise in BP risk assessment and management, advanced training in BP.

Box 6. Example: Staffing for enforcement in the Republic of Serbia

In the Republic of Serbia, industrial chemicals control is currently managed by the Ministry for Environmental Protection and a Department for Chemicals within it.

An enforcement unit has been established within the Ministry of Environmental Protection, where all inspectors have a background in chemistry. In some cases, they are supported by colleagues who work in the unit for supervision and control of "Seveso" facilities (under the Industrial Accident Regulation) and who are also trained in the inspection of chemicals.

Enforcement is also provided through the Ministry of Health and Ministry of Trade. The Ministry of Health sanitary inspectors enforce provisions on bans and restrictions of chemicals in the chemical products intended for use by the general public.

Market inspectors within the Ministry of Trade enforce rules related to chemicals in the retail sector.

Sources: *Transposition and Implementation of Environmental and Climate Change Acquis - Chapter 27: Status and Plans*, Belgrade, September 2015. Section VII, Chemicals Enforcement, p. 184, viewed at http://www.pregovarackagrupa27.gov.rs/?wpfb_dl=71, January 23, 2018.

Bojana Djordjevic, Ministry of Environmental Protection, Republic of Serbia, personal communication, August 2017 and January 2018.

It is not necessary for all staff members to have a detailed knowledge of chemicals and their effects on health and the environment. Their principal role is to ensure that the legal framework is functioning and to promote compliance through enforcement. Manufacturers and importers have the principal responsibility for classification, labelling and development of SDSs and, if required, pre-market testing. There needs to be some capacity to conduct spot checks to ensure that classification and labelling is correct, using existing databases and other resources.

Staff members at the authority should be trained to use existing database resources and to avoid redundancy by creating unnecessarily duplicative database resources domestically. It is also important that core staff have access to scientific expertise for consultation (human toxicology and ecotoxicology, evaluation of chemicals). These scientific experts do not need to be employees of ministries or government executive bodies; in some cases, they may belong to scientific institutes that have arrangements that ensure access to their support. There are two main ways of achieving this: (a) by requisition (the government places an obligation on the academic institution in a piece of regulation or by an order), or (b) through contracts between the competent authority and either the academic institution or individual academics.

Legal knowledge and understanding is an essential area of capacity for a new authority or for an authority undertaking new activities. For institutions in the public sector, it is most important to have the relevant legislative and technical capacity and the resources needed for the development, implementation and management of the legislation.

Compliance monitoring capacity. The introduction of new chemicals control legislation creates new responsibilities related to compliance monitoring. Reliable and consistent capacity to enforce existing requirements is essential to building trust in any chemicals management system.

Table 4: Staffing at Zambia's Environmental Management Agency, 2018

Activity	Number of officers
Legal Department	2
Border Control	7
Licence Preparation	1
Assessment of applications	3
Ordinary Inspections	4
Register of Importers	1
Registration of chemicals	1

Source: Frederick Muyano, Zambia Environmental Management Agency, personal communication.

3.2 Staffing expertise and capacity

The types of expertise needed among the staff of a chemicals control authority include knowledge of legal, compliance and environmental topics, as well as administrative capacity.

A detailed discussion of enforcement and the capacity of inspectors is provided in the guidance document, Enforcement of Chemicals Control Legislation.

If a function to support industry to comply with the requirements is established, some capacity and staff time would need to be allocated to this.

Coordination and collaboration also requires staff with the relevant capacity within the authority. Development or amendment of legislation and implementation activities require coordination and cooperation with the private sector, stakeholders and other government authorities, as well as international collaboration.

Staffing expertise needed for international coordination includes training in technical or policy topics, and familiarity with international standards.

3.3 Education and training for government personnel

Important training needs for government employees include legal training and information retrieval. It is also important for government officials to have access to individuals trained in toxicology and ecotoxicology, evaluation of chemicals, classification and labelling, and evaluation of Safety Data Sheets. Since an individual staff member who receives training may subsequently leave the agency, it is important to focus on building institutional capacity to ensure maintenance of knowledge over time.

Training experiences in Serbia. Currently, the Serbian chemicals authority exists as the Department for Chemicals within the Ministry of Environmental Protection. Training was provided for at least ten Ministry staff on conducting the “competent authority tasks” for EU chemicals legislation. This included specific training on biocidal products used for mosquito control; evaluation of a technical dossier for a biocidal product; risk assessment; risk management; and mutual recognition procedures for biocides. In addition, training was provided for inspectors. The goal was to train at least

30 inspectors. Training was provided on topics including Classification, Labelling, and Packaging (CLP); compliance control for CLP; and compliance control for biocidal products. More recently, training workshops were provided on a range of topics.^{xxxviii}

Approach to training at the Swedish Chemicals Agency (KemI): Professional staff at KemI have university degrees in fields including law, economics, chemistry, public health, toxicology and ecotoxicology, biology, and other fields. In addition to their academic qualifications, the staff receive on-the-job training. Specifically, most inspectors are assigned a tutor/mentor to help them over the first six months to a year, before taking on all aspects of the work on their own. In addition, they receive legal training to help them understand their role as government representatives.^{xxxix}

Specialized postgraduate degrees in South Africa. Postgraduate degree programmes can be an important means of educating current or future government staff members, as well as others who will be working in the area of chemicals risk management, including in industry. For example, the University of Cape Town (UCT) has a postgraduate Diploma in Pesticide Risk Management structured around the FAO/WHO International Code of Conduct for Pesticide Management.^{xl}

UCT also offers an Environmental Health track within its Master’s programme in Public Health. This track covers the international conventions on chemicals, as well as the Sustainable Development Goals, human and child rights, and climate change. It includes an option to specialize in chemicals management.^{xli}

UCT is also working to provide training to the informal sector. Specifically, UCT has begun providing training to informal vendors of pesticides. The first step of the training involved meeting with vendors, providing initial information, and inviting them to begin selling and promoting safer alternatives, which the informal vendors expressed interest in doing.^{xlii}

International training opportunities. The United Nations Institute for Training and Research (UNITAR) offers a variety of training opportunities through its Chemicals and Waste Management (CWM) programme. This includes an e-learning course on GHS.^{xliii} Other UNITAR e-learning opportunities include modules on chemical conventions, the life cycle approach to chemicals, and inventories.^{xliv}

The Swedish Chemicals Agency manages an International Capacity Development Programme that is funded by the Swedish International Development Cooperation Agency (Sida). During the period 2018–2022, the Swedish Chemicals Agency will organize and run a programme entitled Developing Strategies for National Chemicals Management. The programme is primarily intended for ministries and authorities in cooperation countries, in order to provide the participants with the knowledge and skills to develop national preventive chemicals control strategies. This includes relevant legislation, institutional capacity and systems of enforcement.

3.4 Access to laboratory capacity

For verifying or testing chemicals or chemical content, access to laboratories is needed. Such access to analytical competence is important for conducting inspections where monitoring and other tests may be required for ensuring compliance.

National authorities should have access to a reference laboratory – typically a privately owned laboratory that conducts reference or measurement procedures – capable of performing analyses of the chemicals of major concern for verification and monitoring purposes. A reference laboratory may carry out tests to determine the composition of chemical formulations, or to determine the identity and concentration of a chemical. The responsible authority should establish agreements with laboratories of this kind to carry out these services as needed. All laboratories should meet the Good Laboratory Practices (GLP) standards. Training of inspectors at the authority could include GLP inspections.

The option of using the services of external laboratories at the national level can reduce unnecessary costs for the authority. Regional collaboration and the establishment of a laboratory infrastructure with other countries can also be a cost-effective and efficient way of building access to regional analytical capacity. Maintaining a state-operated national laboratory can be burdensome in terms of maintaining equipment and trained personnel. Therefore, in general, it is not recommended that governments establish their own laboratories as part of efforts to create institutional capacity. Many governments use certified private laboratories. These laboratories must be neutral in relation to the government and the regulated companies. Regional facilities may also be considered.





FINANCING NATIONAL ADMINISTRATIONS

This section builds on Chapters 6 and 7 of the LIRA Guidance, providing additional details about measures for recovering the costs of the national administration of chemical control laws.

4.1 Overview and general considerations

By establishing institutional capacity for managing chemical risks and by allocating appropriate resources, governments can secure sustainable, cost-effective risk management that benefits the whole of society. In order to build institutional capacity over the long term, it is necessary to set up sustainable domestic funding mechanisms, and to reflect the funding mandate in legal provisions. Each country has primary responsibility for its own economic, environmental and social development and thus for its chemicals control. Incorporation of chemicals management in national planning documents supports buy-in from the relevant ministries and secures resources for chemicals management. It also promotes national inter-institutional coordination.

The three components of an integrated approach to financing sound management of chemicals and waste (adopted by the UNEP Governing Council in its decision 27/12 in 2013)^{xlv} are:

- mainstreaming of sound management of chemicals in national budgets and development assistance plans

- industry involvement, including designating the responsibilities of industry and the wider business community.
- dedicated external finance.

These components are mutually reinforcing and are all crucial for financing (Annex 1 of Resolution 1/5 of UNEA1).

The Global Environmental Facility (GEF) and the UN Environment Assembly (UNEA) Special Programme on Chemicals both aim to provide dedicated external finance to support the mainstreaming of chemicals management in national budgets, and legal and institutional capacity to ensure defined industry involvement. These external financing elements are discussed further below.^{xlvi} As noted in United Nations Environment Assembly Resolution 1/5 on Chemicals and Waste, these elements are mutually reinforcing and are all important for the long-term financing of the sound management of chemicals and waste at all levels.^{xlvii}

4.2 Legal basis for funding

Legislation that provides for adequate and stable funding of government activities is a prerequisite for successful implementation of chemicals control. The costs to government of chemicals control result from the activities of businesses that manufacture, import and

CHAPTER

4

use chemicals. Therefore, it is logical to consider legislation that applies special fees or taxes on enterprises or on their products, or that charges fees for specific services.

Both taxes and cost recovery measures require a legal basis and an institutional structure for implementation and enforcement. The entities subject to fees or taxes are those that manufacture or import chemicals.

Laws establishing fees should include a provision empowering the Minister or other relevant authority to enact any regulations required for better implementation of the financing system. In addition to fees for services, some government activities related to chemicals control may be covered by state revenues. This occurs when the activity performed by the government is part of more general chemicals control activities rather than a service provided specifically to companies. Such activities include establishing, maintaining and further developing legal frameworks; carrying out national efforts related to chemicals in articles where the particular companies concerned cannot sufficiently be defined; and conducting regional or international collaboration.

4.3 Financing options

The main options for funding new institutional capacity for chemicals control are financing from fees and from an allocation in the state budget.

The difference between taxes and fees is that a tax is a required contribution to the state without direct service in return, while a fee is matched by a service performed by the state. This includes services related to enforcement.

Box 7. Distinction between fees and taxes

Fee: Fees are paid as compensation to cover the costs of general or specific public administrative services.

Tax: Taxes refer to a payment determined by law from persons, groups or companies in order to provide the state and municipalities with income. Examples include income tax, value added tax, real estate tax, and taxes on alcohol, tobacco, and energy and emissions.

Financing from the state budget can be used for all tasks carried out by the administration, while fees should only finance tasks that are provided as a service to those paying the fees. When the linkage between an activity and the service provided to the companies is considered too tenuous, the funding should come from the state budget. Such activities include establishing and maintaining legal frameworks, ensuring dialogue with stakeholders other than the regulated companies, and regional and international collaboration.

Some practical funding suggestions are:

- Identify available national resources and those that can be developed to include chemicals control.
- Aim to select a financing system that minimizes the administrative burden, while still ensuring sufficient funds.
- Set fee levels to match the cost of providing the relevant government services and activities.

It is generally advisable to ensure a national budget allocation that receives revenue from a simple flat rate fee (per company and per ton of each chemical) to finance the national administration's chemicals control activities. Based on the experience of many developed economies, an effective method is to use fees to support many of the national administration's chemicals control activities, while also covering some activities from general revenues. In general, a flat fee or tax is the most practical to administer.

Box 8. Comparing financial options

The following criteria can be used for comparing the different options for financing national administrations:

- **Degree of secure financing** – in other words, how stable the flow of funding is and how dependent it may be on influences such as political prioritization, which may vary over time.
- **Administrative feasibility and simplicity** – how practical it is to implement the system.
- **Fairness** – how close the payments of a company are to the real administrative costs of chemicals management needs generated by that company. It may also relate to ensuring that the taxes and fees are non-discriminatory, with international companies being treated similarly to national companies, and state-owned companies being subject to the same fees as private companies.

Source: Keml. 2018. Sustainable financing of institutional capacity for Chemicals control.

4.4 National budget allocation

The most secure way of financing the costs of a national administration for chemicals control is likely to be from the governmental budget. A national budget allocation typically takes place annually, and sufficient funding depends on political and financial decision makers' understanding of the importance of chemicals management to the sustainable development of the country. Actual implementation costs or the costs of activities related to chemicals management are small compared to the magnitude of the social, environmental and economic costs of inaction.^{xlviii} Such arguments need to be included in the budget allocation process at the right time and in the proper form.

It can be helpful to present decision makers with information on the economic benefits of reduced environmental and public health impacts, as well as the economic benefits of creating regulatory certainty and a level playing field for industry. For information about the benefits of chemicals control, see the companion information document to this guidance document, Benefits of Chemicals Control, as well as UNEP's Global Chemicals Outlook.^{xlix}

4.4.1 Estimating a budget

A key element for ensuring the resources for covering the costs of a national administration for chemicals control is to participate in the national budget allocation process.

In preparing for discussions related to national budget planning, it is important to be able to estimate the costs of basic and cost-efficient institutional capacity for chemicals control and to be clear about how the funds are to be spent. Defining government functions clearly and narrowly, while creating clear obligations for industry, helps to keep government costs manageable. These cost estimates should also be complemented with proposals for stable cost recovery over time and estimates of the amounts that the linked cost-recovery mechanisms would collect. Cost internalization, or cost recovery, can be an important source of funds for covering the costs of national administration for chemicals control.

Costs to support basic institutional capacity depend on national conditions including the size and population of the country, general salary levels, the complexity of the industry sector and existing institutional structures. However, some common elements presented herein may be useful to government officials in making the necessary estimates. It would also be useful to describe the allocation of responsibilities to both industry and the government administration.

Other considerations include ensuring that the national administration works cost-efficiently. Adequate staffing, both in terms of the numbers and qualifications of personnel, is likely to be the most costly component of establishing institutional capacity for chemicals control. The staff of a national chemicals control authority in most countries is initially likely to be a small unit within a larger ministry/authority, which could provide administrative support and office space. A large country with a substantial chemicals industry would need a larger number of staff than a country with a less active industrial sector. Keeping the number of staff low – mainly through clearly defined roles, with a focus on monitoring compliance – can support efforts to secure adequate funding. In principle, the legal and institutional infrastructure for chemicals control, as proposed in the LIRA Guidance, can be accomplished by a relatively small group of government employees. To reduce costs, specialist experts that are only needed occasionally can be contracted from other institutions. Regional cooperation with other countries is also an option, to share work and thereby reduce costs.

Initial three years. The estimated costs for the first three years – for establishing the chemicals control legislation – would cover the salaries of professional staff and general overhead costs. The authority is likely to be established as a unit within a larger ministry/authority that would provide administrative support and office space. These staff members would focus on raising awareness of responsibilities within the regulated industry and building up enforcement capacity for monitoring compliance.

Longer term. Assuming that national cost recovery mechanisms start functioning during this initial three-year period, and the activities of the authority generate sufficient funding, an estimate for the longer-term costs would cover the salaries and overheads of a larger number of professional staff.

4.5 Cost recovery fees

Cost recovery fees can provide a predictable, steady source of funding that covers the cost for inspections or providing and maintaining registration, licensing or authorization systems. Several types of cost recovery fees can be used to finance a chemicals control system.¹ Categories of cost recovery fees include annual fees and fees per service (e.g. fees for authorization, inspections and import licences). Fees can have the advantage of being earmarked for chemicals management and not directly dependent on political decisions.

When the authorities provide specific services, it is a widely accepted principle that fees are based on the costs of these service. These should include reasonable overhead costs for the administration of the service, such as the costs of office space and IT equipment.ⁱⁱ Fees can be calculated based on the average cost over time for handling a variety of cases.

Annual fees. One option is to levy an annual fee on all chemical producers or importers. This fee can be used to cover a range of the authority's core activities, such as creating and maintaining registries and carrying out inspections. The fee can be calculated based on a number of factors including the total cost of activities to be carried out and the number of companies that will be subject to the fee requirement.

A flat rate fee can be charged per unit (per firm, chemical or volume) for service provision, product sales, importation or production. Administratively, this is the most straightforward approach in most cases.

Alternatively, the fee can be differentiated based on, for example, a fee per chemical, per ton, per year. The differentiation of fees, however, requires additional effort and

greater capacity on the part of the authority. Factors that may be taken into account in differentiating fees include company size (using total turnover, number of employees or amount of product as a proxy for overall size) or amount of chemical produced or imported.

In principle, fees can also be differentiated with respect to the toxic or hazardous properties of a substance or product to be placed on the market. However, differentiating based on toxicity level should generally be avoided as it requires extensive knowledge resources.

Fees per service. Another option is to charge fees per service provided – for example, for inspections or assessments of applications. This requires the ability to quantify the cost of a specific service. Like annual fees, fees for services can include a degree of differentiation, either by company size or by the complexity of the service required. However, such differentiation should be as simple as possible.

There may be a need for a range of charges linked to different inspection activities; the cost of inspections varies depending on the type of inspection and size of the affected company. There are, however, some concerns in regards to funding through fees per service. All producers and importers benefit from law enforcement. If only a few companies are selected annually for inspection activities, these will have to cover the costs for the entire national enforcement capacity, which could be perceived as unfair.

A vital component of enforcement and inspection activities is verifying or testing. It is important that all the costs of verifying or testing are covered by fees.

Fees for chemical licensing or authorization. Authorization systems can be used for chemicals of high concern. Many countries have authorization systems for pesticides, and many of these have introduced some level of fees to cover the cost for authorization. Authorization systems for industrial and consumer chemicals of

high concern are less common but are used in some cases. The number of these applications may vary from year to year.

Import fees, permits or licences. A common approach is to charge a fee for the right to import and sell chemicals on the domestic market. In such a case, the fees for each delivery are paid at the border. Importers are either charged per ton or charged an administrative fee each time they import. Fees for import licences primarily cover the costs of processing the licensing, and tend to perform poorly in terms of securing financing for chemicals management. That these fees only apply to imports, not to the domestic production of chemicals could be perceived as unfair.

In countries with import permit or licensing systems, information on imports can be used to compile a basic register of chemical importers that could be useful in establishing an annual fee.

Import permit or licensing systems can be costly to administer, as they require a system in place for the clearance of permission for all products that pass through the national border at all times, and sufficient personnel to carry out random monitoring of compliance. These activities can be facilitated by the use of software such as the Automated System for Customs Data (Asycuda World), a system created by the United Nations Conference on Trade and Development (UNCTAD), to help modernize customs systems.^{lii}

4.6 Fee collection system

In general, it is advisable to minimize the operating costs of the fee collection system. Existing mechanisms for collecting charges may provide a cost-effective way of collecting new fees. For instance, if there is system for charging general taxes on producers and importers, the same administrative system can be used to levy taxes on producers and importers of chemicals. When designing a financing system, it is important to identify which ministry or agency is best suited to establishing the system, collecting revenue and enforcing compliance.

In order for a fee system to be effective, the government authority must be able to identify non-compliant businesses, ensure that they pay the fee, and apply a penalty if necessary. For more information on this topic, see Guidance Document: Enforcement of Chemical Controls Legislation.

4.7 Setting fee levels

Every country has its own approach for levying taxes and fees, but the following guidelines are relevant in most cases.

- Tax/fee levels should be set to match the cost of providing the relevant government services and activities. It is important to make clear that the purpose of the fees is to cover the costs of chemicals management, not to create revenue for government. Fees should be kept as low as possible while still covering the costs of the services performed. Fees should cover staff as well as overhead costs such as office space and general administration of the relevant government body.^{liii}
- Avoid conflicts of interest created in the design of the system – in other words, if institutions are directly dependent on fees for services rendered, they may be encouraged to ‘oversupply’ their service.
- In a number of countries, pesticide regulation is more developed than the regulation of industrial chemicals. For example, many countries have a pre-marketing registration system for pesticides. It is often more practical to finance pesticide registration through specific application fees, as well as an annual fee. Regional cooperation with other countries for pesticide management often helps to reduce the national workload and related costs.

The registration fee in Costa Rica for “products of sanitary interest” is an example of a cost recovery fee; it is calculated to recover the following institutional costs:^{liiv}

- Cost of designing and maintaining the registration online platform.

- Cost of keeping company files/registries on the platform's server.
- Institutional Internet costs for working on the registration platform.
- Institutional cost for computers and other equipment necessary to run the platform.
- Bank charges for receiving and administering payments by registering companies.

the financing of sound management of chemicals and wastes, taking into account national development strategies, plans and priorities. The goal is to "increase sustainable public institutional capacity for the sound management of chemicals and wastes throughout their life cycle".^{lvii} Activities funded through the programme include evaluation of institutional capacity, policy coordination, strengthening of progress reporting and performance evaluation, and fostering ratification of multilateral environmental agreements (MEAs), among others.

4.8 External funding

For some countries, international assistance can be an important supplement to domestic resources. Such assistance may be useful during the initial phase of creating a domestic regulatory infrastructure or for other short-term start-up activities. Funding may be available from intergovernmental initiatives such as the GEF or UNEP's Special Programme on Institutional Strengthening. As such funding generally only helps with the cost of initiating an activity, long-term chemicals management requires a domestic means of financing the national administration.

Bilateral aid is assistance given by a government directly to the government of another country. This can be in the form of support to the general budget of the country seeking assistance, or to a specific programme related to chemicals safety. In both cases, support is only likely if chemicals management is included in national development plans. More information can be found in the United Nations Development Programme (UNDP) Guide for Integration of Sound Management of Chemicals into Development Planning.^{lviii} The UNDP guide includes a template for chemicals-related text that can be included in national development plans.

Global Environmental Facility. GEF is an important source of financial support for chemicals management activities.^{lv} GEF has combined its work on persistent organic pollutants (POPs), ozone-depleting substances (ODS), mercury and SAICM into a single focal area, to maximize "cross-cutting global environmental benefits".^{lvi} However, GEF windows are limited to specific themes and issues that do not cover the full range of national chemicals management. Additional resource mobilization from national or private sources is required in projects covered by GEF.

UNEP's *Special Programme to Support Institutional Strengthening*, established in 2015, is designed to support country-driven institutional strengthening at the national level for implementation of the Basel, Rotterdam and Stockholm Conventions, the Minamata Convention and SAICM. It supports such strengthening in the context of an integrated approach to address

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ANNEX 1:**SAICM Overall Orientation and Guidance (OOG) document, 2015: 11 basic elements critical to sound chemicals and waste management (Excerpts - Section IV:19)^{lix}**

The following set of 11 basic elements has been recognized as critical at the national and regional levels to the attainment of sound chemicals and waste management:

- (a) Legal frameworks that address the life cycle of chemicals and waste
- (b) Relevant enforcement and compliance mechanisms
- (c) Implementation of chemicals and waste-related multilateral environmental agreements, as well as health, labour and other relevant conventions and voluntary mechanisms
- (d) Strong institutional frameworks and coordination mechanisms among relevant stakeholders
- (e) Collection and systems for the transparent sharing of relevant data and information among all relevant stakeholders using a life cycle approach, such as the implementation of the Globally Harmonized System of Classification and Labelling of Chemicals
- (f) Industry participation and defined responsibility across the life cycle, including cost recovery policies and systems as well as the incorporation of sound chemicals management into corporate policies and practices
- (g) Inclusion of the sound management of chemicals and waste in national health, labour, social, environment and economic budgeting processes and development plans
- (h) Chemicals risk assessment and risk reduction through the use of best practices
- (i) Strengthened capacity to deal with chemicals accidents, including institutional strengthening for poison centres
- (j) Monitoring and assessing the impacts of chemicals on health and the environment
- (k) Development and promotion of environmentally sound and safer alternatives

ANNEX 2:

Resources for information on chemicals

A range of resources are available for government and industry employees wishing to find information about chemicals. Many of these resources are publicly available; others are available for a small subscription fee. A few examples are shown below.

- **Chemical Hazard and Alternatives Toolbox (ChemHAT)**, <http://www.chemhat.org/en>. This resource is an online database that aims to provide easy-to-use information for workers, families and other interested parties, to help protect themselves from the harm that chemicals can cause. It provides answers to the question: “Is there a way to get this job done without using dangerous chemicals?” ChemHAT was initiated through a partnership between the Industrial Division of the Communications Workers of America and the BlueGreen Alliance, and has since incorporated the work of university and government experts, among others.
- **Decision Guidance Documents prepared for the chemicals listed in Annex III to the Rotterdam Convention**, <http://www.pic.int/TheConvention/Chemicals/DecisionGuidanceDocuments/tabid/2413/language/en-US/Default.aspx>. These contain basic information on each chemical included in Annex 3 to the Rotterdam Convention, including hazard classification, additional sources of information on the chemical, and information on possible alternatives.
- **ECHA Classification and Labelling Inventory**, <https://echa.europa.eu/regulations/clp/cl-inventory>. This resource provides classification and labelling information for all chemicals that have been notified or registered under REACH. It is also a good resource for reviewing the EU’s approach to harmonized classifications (<https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling>), and it includes an Excel file showing an up-to-date list of chemicals with their harmonized classifications (<https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp>).
- **European Chemicals Agency (ECHA) REACH Registration Database**, <https://echa.europa.eu/information-on-chemicals/registered-substances>. This website offers users a “Chemical Property Data Search”. As substances are registered under REACH, registrants are required to provide information on the substances they manufacture or import. ECHA then makes this information available to the public. Information provided on this website includes hazardous properties, classification and labelling of registered substances.^{lx}
- **GreenScreen List Translator through Pharos**, <https://www.pharosproject.net/>. Developed by the non-profit Healthy Building Network, this website provides health and environmental information about building products. It also includes the GreenScreen List Translator, which provides information on toxicological and regulatory classifications from around the world. This resource requires a subscription, for a relatively low fee.
- **Global Product Strategy, GPS Chemicals Portal** provides access to information on chemicals: <http://icca.cefic.org/> The GPS Safety Summaries provide product safety information from companies on the chemical products they manufacture.
- **Hazardous Substances Data Bank (HSDB)**, <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>. Part of the US National Library of Medicine, HSDB is, according to its website, “a toxicology database that focuses on the toxicology of potentially hazardous chemicals. It provides information on human exposure, industrial hygiene, emergency handling procedures, environmental fate, regulatory requirements, nanomaterials and related areas. The information in HSDB has been assessed by a Scientific Review Panel.”

- **OECD e-Chem Portal**, <https://www.echemportal.org>. This web resource provides information on physical chemical properties, ecotoxicity, environmental fate and behaviour, and toxicity.
- **University of Massachusetts Lowell Toxics Use Reduction Institute - Environmental, Health and Safety Data Resources**, <http://guides.turi.org/beyondmsds>. This website provides links to a variety of pages for finding general and/or detailed information on chemicals, including physical properties, health effects and environmental fate.

ANNEX 3:

National approaches to authority structure for chemicals management

Authority structure in Serbia. In the Republic of Serbia, chemicals control is managed by the Serbian Chemicals Agency, within the Ministry for Environmental Protection. In its initial phase, the Serbian Chemicals Agency was an independent government agency. The Agency addresses chemicals and biocidal product issues, including bans and restrictions, compliance with international agreements, classification and labelling, SDSs, decisions on placing of biocidal products on the market, record keeping, and other topics.

In addition to the Chemicals Agency personnel, an enforcement unit for chemicals and biocidal products has been established within the Ministry for Environmental Protection. Enforcement is also provided through the Ministry of Health and the Ministry of Trade. The Ministry of Health's sanitary inspectors enforce provisions on bans and restrictions of chemicals in chemical products intended for use by the general public, while the Ministry of Trade enforces rules related to chemicals in the retail sector.^{lxii}

Authority structure in Sweden. The Swedish Chemicals Agency (KemI) is an example of a separate agency under the Ministry of Environment. As a separate agency, KemI has its own secretariats for finance and accounts, human resources and communications. Many of these functions are not necessary for a chemicals authority that is housed within a larger agency or ministry.

Authority structure in Zambia. The Zambia Environmental Management Agency (ZEMA) administers the Zambia Environmental Management Act of 2011. ZEMA is a stand-alone agency, created by an act of Parliament. The act provides guidelines for accomplishing three primary goals: a) develop and enforce measures aimed at preventing and controlling pollution; b) develop standards and guidelines to protect air, water, land and other natural resources from pollution; and c) carry out research, surveys, training and investigations of environmental management.

The law provides structure through the creation of a Board, composed of specialized part-time members appointed by the Minister. Division 5 of the act specifically states that any person intending to manufacture, import, export, use or repurpose pesticides or toxic substances must apply for a licence through ZEMA; this enables the agency to monitor chemical users and intended uses. In return, ZEMA is responsible for a number of services including providing proper labelling, supporting efficacy testing, and collecting information from industries about substance production, use and effects on human and environmental health. The act also provides details of a plan for transparency by creating a public registry with a list of all policies, plans, guidelines, studies, reports, decisions, recommendations and other publications relating to the environment produced by the Agency.

Authority structure in Ghana. Ghana's Environmental Protection Agency was established in 1994 through Act 490. It was given the responsibility of regulating the environment and ensuring the implementation of government policies addressing the environment. A previous body, the Environmental Protection Council (EPC), was predominantly an advisory body to government. With the creation of a ministry responsible for the environment – the Ministry of Environment, Science and Technology – the role of the EPC was redefined and its policy role moved to the Ministry. Ghana's Environmental Protection Agency Act of 1994 (Act 490) incorporated the EPC into the current Agency, which now has regulatory and enforcement roles, among others. Management of daily operations is carried out by an executive director and three division heads.

Development of new chemicals control legislation in Brazil.^{lxiii} As of 2015, Brazil has the eighth largest chemicals industry in the world, and the largest in Latin America. Brazil is currently working to develop chemicals control legislation for industrial and consumer chemicals. There are separate laws for pesticides, pharmaceuticals and cosmetics, so the draft law excludes these categories from its scope. The draft law is close to completion.

Key aspects of the proposed legislation include registration of chemicals; chemical prioritization; adoption of the GHS for substances; use of available information; use of risk-based assessment and risk management; and penalties for non-compliance.

Under the proposed legislation, Brazil will create an inventory of all chemicals manufactured or used over a three-year period (“substances inventory”). Within this large inventory list, a smaller list will be created of priority chemicals for assessment (“priority list”). Risk assessments will be carried out for these priority chemicals. Based on the results of the risk assessments, a smaller number of chemicals will be included on the “toxic list”. These chemicals will be subject to special risk management measures.

At the registration phase, companies will be required to provide information including company identification, substance identification, volume range, uses and GHS hazard classification.

Authority structure and staffing in South Africa.^{lxiii} In South Africa, responsibility for chemicals regulation is currently shared among several government authorities, including the Departments of Agriculture, Fisheries and Forestry, the Department of Environmental Affairs, the Department of Health, the Department of Transport, the Department of Water Affairs and the Department of Labour. Each authority has a separate mandate.

For example, the Department of Labour is responsible for regulating chemicals manufactured, used or stored in work environments. Two laws govern this area of work: the Occupational Health and Safety (OHS) Act of 1995 and the Compensation for Occupational Injuries and Diseases Act of 1993. Under the OHS Act, specific regulations have been adopted on topics including hazardous chemical substances and explosives.

The national head office of the Department of Labour has three Deputy Directors who are responsible for national policy development, including updating and reviewing legislation and overseeing national legislation. In each of the country’s nine provinces, a Specialist is responsible for implementing national programmes developed at the National Office.

Initial steps for chemicals control in Colombia.^{lxiv} Colombia developed a National Action Plan for Management of Chemicals in 2013. Among other elements, this plan envisioned the development of a national policy on comprehensive management of chemicals. Building on this plan, Colombia adopted a Program for Management of Industrial Chemicals (PGSQUI). Colombia also adopted a Risk Management Policy for the Use of Chemicals in October 2016.

Under PGSQUI, a number of activities are envisioned. These include chemical classification; risk assessment for selected chemicals; data collection; development of risk management actions; use of an authorization system; and monitoring of health and environmental effects. However, a budget has not yet been established to cover the costs of these activities.

Under PGSQUI, government is responsible for activities including managing records, approving risk management actions, and monitoring the health and environmental effects of chemicals. Chemical manufacturers and importers are responsible for generating hazard information, managing risk reduction measures and extending risk reduction measures through the supply chain.

Difficulties faced by Colombia include the absence of systems for collecting information on chemical manufacture, import or use, including a lack of information about chemical transport and storage. Analysis of import data is complicated by the use of tariff heading numbers that group multiple chemicals under the same heading.

In parallel with PGSQUI, work will be conducted over the period 2017–2020 to create a national register of chemical manufacturers and importers: to create new tariff subheadings that will make it possible to disaggregate chemicals; and to implement GHS, among other activities.

The OECD has identified steps that Colombia needs to take in order achieve accession to the organization. Among these, it must convince the representatives of the OECD Member countries that it is able to implement all OECD legal instruments within the committee’s competences, and that Colombia’s policies and practices are in line with OECD best policies and practices in relevant areas. Key issues currently include the establishment of a comprehensive chemicals management programme, legislation for industrial chemicals, and the establishment of a chemical accident prevention, preparedness and response framework.^{lxv} The November 2017 issue of ChemicalWatch included a news item about Colombia’s plans to adopt GHS.^{lxvi}

Pesticides are regulated under a separate law (Ley de 1979 sobre uso y manejo de plaguicidas). This is consistent with the obligations of Colombia as a member of the Andean Community, which regulates chemical pesticides through two different regulations (pre- and post-registration).

Planning for chemicals controls in Peru.^{lvii} A recent report presents options and recommendations for Peru as it works towards a consolidated approach to chemicals management. Below are selected topics covered in the report.

Identifying companies. There are several options for identifying companies that will be subject to a chemicals control law. They can be identified through a registry, through business roundtables, through sector-specific organizations (industry associations), through the supply chain or with help from the customs authority, among other options. These options are not mutually exclusive; several can be employed simultaneously.

Diagnostic study. In 2013, a diagnostic study was conducted to create a preliminary inventory of chemicals on the market in Peru. As a source for this information, Peru was able to draw upon the harmonized system codes used for tariff and customs purposes. This was the only information source available in the country at the time. While this information was useful in creating a baseline, it also made clear the need for a registry of chemical manufacturers and importers in Peru.

Recommendations for a simple registry. Peru could begin by creating a simple registry of manufacturers and importers. Under this approach, it would be obligatory for any entity to report to the registry if it manufactures or imports more than a specified amount of a chemical. Harmonized system codes used for tariff and customs purposes can be used as a starting point to identify the categories of businesses that are subject to the requirement, since these codes are already familiar to the businesses. The registry should be updated every one, two or three years. Over the longer term, Peru can work towards the development of a more complex registry that would include information about the use of substances as ingredients in formulations.

Registries and Inventories

The **Australian** Government, as part of its Department of Health National Industrial Chemicals Notification and Assessment Scheme, requires businesses to register with them if they import and/or manufacture relevant industrial chemicals, or certain products that contain such chemicals, for commercial purposes.^{lviii} The agency provides a questionnaire to help businesses determine whether they need to register. Registration is online, on the agency's Business Services website, and requires payment of a registration fee.

Under the **EU's** REACH regulation, manufacturers and importers are required to provide information to ECHA through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. The focus of the registration process is on the chemical itself, but it also provides the authority with company information.^{lxix}

A review of chemical policies in Southeast Asia includes a number of data collection examples. For example, in **Lao PDR**, the Ministry of Industry and Commerce maintains a list of industrial chemicals used in the country. The **Philippines** maintains an Inventory of Chemicals and Chemical Substances. In **Bangladesh**, industries are colour-coded by impact and location (green, orange A, orange B, and red), with chemical industries generally categorized as "red".^{lxx}

Malaysia has several requirements pertaining to the creation and maintenance of a chemical inventory (registry). Under the Occupational Safety and Health (OSH) Classification, Labelling and Safety Data Sheet of Hazardous Chemicals (CLASS) Regulations of 2013, chemical manufacturers and importers must submit annual information to an inventory of chemicals placed on the market at more than 1 ton per year. Information to be submitted includes composition of the hazardous ingredients (in a mixture), product classification and volume. In addition, Malaysia has a voluntary Environmentally Hazardous Substance Notification and Registration (EHS N&R) scheme. If converted into a mandatory programme, this system will provide a means to create a more complete inventory of chemicals manufactured, imported or used in the country. The inventory applies to substances manufactured or imported at or above 1 ton per year, except for carcinogens, mutagens and reproductive toxicants (CMRs), which have no volume threshold.

Additionally, Malaysia has developed an inventory tool to comply with the GHS Software for Chemical Mixture – also known as “Classification Tool for Chemical Mixture (CATCH)”. The website includes a search function for chemicals that is available to the public. The website can also inform manufacturers and importers of whether a chemical is listed in an existing regulation. It is expected to address both the GHS Purple Book (6th revised edition) and the CLASS Regulations 2013. The website outlines the chemicals registered in the country and the act/regulation with which particular chemicals must comply.^{boxi}

ENDNOTES

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