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Organization



International Code of Conduct on Pesticide Management

Guidelines on Pesticide Legislation



September 2015

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase international coordination in the field of chemical safety. The participating organizations are the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Organisation for Economic Co-operation and Development (OECD), the United Nations Environment Programme (UNEP), the United Nations Industrial Development Organization (UNIDO), the United Nations Institute for Training and Research (UNITAR) and the World Health Organization (WHO). The World Bank and the United Nations Development Programme (UNDP) are observers. The purpose of the IOMC is to promote coordination of the policies and activities pursued by the participating organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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Table of Contents

ABBREVIATIONS	V
1. INTRODUCTION	1
2. REASONS FOR UPDATING PESTICIDE LEGISLATION	4
3. THE PROCESS OF DRAFTING PESTICIDE LEGISLATION	6
3.1 STEPS IN REVISING OR DRAFTING PESTICIDE LEGISLATION.....	6
3.2 THE PESTICIDE LIFE CYCLE AND ITS REGULATORY FRAMEWORK.....	7
3.3 CONSISTENCY WITH THE NATIONAL LEGAL FRAMEWORK.....	7
4. ELEMENTS OF A NATIONAL PESTICIDE LAW	8
4.1 INTRODUCTORY PROVISIONS	8
4.1.1 <i>Preamble and objectives</i>	8
4.1.2 <i>Scope</i>	8
4.1.3 <i>Definitions</i>	9
4.2 ADMINISTRATION.....	10
4.2.1 <i>General institutional structure</i>	10
4.2.2 <i>Pesticide Registration Board</i>	12
4.2.3 <i>Pesticide Registrar</i>	13
4.2.4 <i>Pesticide advisory bodies</i>	13
4.3 REGISTRATION.....	14
4.3.1 <i>Application procedure</i>	16
4.3.2 <i>Data requirements</i>	16
4.3.3 <i>Decision-making criteria</i>	17
4.3.4 <i>Registration decisions</i>	18
4.3.5 <i>Re-registration</i>	20
4.3.6 <i>Modification of the registration data</i>	20
4.3.7 <i>Review</i>	20
4.3.8 <i>Record-keeping and confidentiality</i>	21
4.4 IMPORT AND EXPORT	22
4.5 LICENSING	25
4.5.1 <i>General requirements for licenses</i>	26
4.5.2 <i>Licensing for manufacture and formulation of pesticides</i>	27
4.5.3 <i>Licensing for storage of pesticides</i>	27
4.5.4 <i>Licensing for sale of pesticides</i>	28
4.5.5 <i>Licensing of commercial operators</i>	29
4.5.6 <i>Specific uses</i>	29
4.5.7 <i>Other license schemes</i>	30
4.6 PACKAGING AND RE-PACKAGING.....	30
4.7 LABELLING	32
4.8 USE	34
4.9 ADVERTISING	35
4.10 STORAGE, TRANSPORT AND DISPOSAL.....	37
4.10.1 <i>Storage</i>	37
4.10.2 <i>Transport</i>	38
4.10.3 <i>Disposal</i>	39
4.11 INFORMATION COLLECTION AND MONITORING.....	41

4.12	INCIDENT REPORTING	42
4.13	INSPECTION.....	43
4.14	OFFENCES AND PENALTIES	45
4.14.1	<i>Offences</i>	45
4.14.2	<i>Penalties</i>	47
4.14.3	<i>Rights and appeals related to enforcement procedures</i>	47
4.15	MISCELLANEOUS AND FINAL PROVISIONS	48
4.15.1	<i>Presumptions</i>	48
4.15.2	<i>Repeals, savings and transitional clauses</i>	48
4.15.3	<i>Power to make regulations</i>	48
4.15.4	<i>Implementing legislation</i>	49
5.	CONSIDERATIONS IN DESIGNING NATIONAL LEGISLATION.....	50
5.1	INTERNATIONAL FRAMEWORK	50
5.1.1	<i>Binding international agreements</i>	50
5.1.2	<i>Non-binding international instruments</i>	54
5.1.3	<i>Meeting supra-national obligations</i>	55
5.2	REGIONAL INITIATIVES.....	56
5.3	NATIONAL CONTEXT	57
5.3.1	<i>Constitution</i>	58
5.3.2	<i>Other national legislation</i>	58
5.3.3	<i>Policies</i>	59
5.3.4	<i>Implementation</i>	60
6.	FINAL REMARKS	61

Abbreviations

CWC	Chemical Weapons Convention
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
DNA	Designated National Authority (Rotterdam Convention)
FAO	Food and Agriculture Organization of the United Nations
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HHP	Highly Hazardous Pesticide
ILO	International Labour Organization
IPM	Integrated Pest Management
IPR	Intellectual Property Rights
IVM	Integrated Vector Management
MRL	Maximum Residue Limit
OECD	Organization for Economic Co-operation and Development
PCO	Pest Control Operator
PIC	Prior Informed Consent
POP	Persistent Organic Pollutant
SDS	Safety Data Sheet
UNEP	United Nations Environment Programme
WHO	World Health Organization
WTO	World Trade Organization

Explanation of key legal terms used throughout this document

The regulatory framework for the control of pesticides encompasses the full set of different types of legislation governing the management of pesticides. Besides pesticide legislation (see below), this may for instance include legislation on environmental protection, public health, occupational health, water, food safety, wildlife, marine protection, plant protection and general chemicals management. The regulatory framework also includes obligations under international instruments.

Pesticide legislation refers to legal instruments specifically designed to control pesticides. The term, pesticide legislation, may refer to a primary instrument, often a Law, Act or Ordinance, as well as a number of secondary or subsidiary legal instruments, such as Regulations, Decrees, Rules or Notices.

The **Pesticide Law**, or similar primary instrument, provides the core part of the pesticide legislation. It establishes principles, mandates and responsibilities. Its adoption generally involves parliamentary approval.

Pesticide Regulations, or other secondary legislation (also referred to as subsidiary legislation or implementing legislation), further regulate specific areas of the Pesticide Law in greater detail. Generally, these can be issued at Ministerial level.

Further details are provided in paragraph 4.15.4.

1. Introduction

International and national legal frameworks governing pesticide management have undergone significant changes over the past 25 years. *The International Code of Conduct on the Distribution and Use of Pesticides* was adopted by FAO in 1985. It was subsequently amended in 1989 to include the prior informed consent (PIC) procedure and revised in 2002. In 2013, it was updated to include public health pesticides and its title was changed to *The International Code of Conduct on Pesticide Management* (Code of Conduct). In 2014, the WHO also adopted the Code of Conduct as its reference framework for international guidance on pesticide management.

Since the first adoption of the Code of Conduct in 1985, several other international instruments dealing directly or indirectly with pesticides or pesticide management have come into force. The most important of these are the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam Convention), the Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention), the Basel Convention on the Transboundary Movement of Hazardous Wastes and their Disposal (Basel Convention), the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) and the International Labour Organisation Convention No. 184 on Safety and Health in Agriculture (ILO Convention 184). Other relevant developments have included the launch of a Strategic Approach to International Chemicals Management (SAICM) and the adoption of a new Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which is intended to standardize and harmonize the classification and labelling of chemicals.

At the time the Code of Conduct was first published, most developing countries and countries with economies in transition did not have pesticide legislation in place. Awareness of the hazards of pesticides was limited, while the use of pesticides, including highly toxic products, was increasing. Significant progress has been made since then, and now almost every country has some type of legislation covering pesticides. However, many of the existing laws have weaknesses. For example, they may not sufficiently reflect the requirements of international agreements or regional initiatives to harmonize requirements, or they may not be adequately connected to new national legislation on environmental protection, chemicals management, or other relevant areas. Changes in the institutional framework and associated mandates may not have been addressed. Other common issues include outdated penalties and the absence of a clear assignment of authority to enforce the legislation.

Requirements of various binding international agreements as well as the numerous recommendations of non-binding instruments can place a heavy burden on small or resource-poor ministries or departments in charge of pesticide management and regulation. Little comprehensive advice is available to assist countries with understanding which rules are binding or non-binding and which should or could be reflected in national pesticides legislation.

The purpose of these Guidelines is to provide guidance to governments that seek to review, update or design national pesticide legislation.¹ It should be emphasized, however, that

¹ This guideline covers legislation directly regulating pesticides, not legislation covering the control of pesticide residues, which properly belongs in a country's food safety legislation.

legislation alone cannot ensure effective pesticide management and adequate protection of the environment and public health. Governments will need to have in place the necessary institutional infrastructure for registering pesticides and enforcing legislation. Further, it will require effective supporting policies and tools to promote sustainable pest and pesticide management.² This may include promotion of Integrated Pest Management (IPM) and Integrated Vector Management (IVM) through training programmes and incentive schemes, enhancement of the availability and use of low risk products, fostering scientific research, carrying out public education campaigns and providing training for inspectors, retailers and professional users. A solid legislative framework should underpin the set of necessary institutional framework, policies and tools.

This document supersedes the Guidelines for Legislation on the Control of Pesticides of 1989.

For details regarding specific technical elements of pesticide legislation, reference is made to the set of technical guidelines that FAO and WHO have published. Regularly updated lists with links to these documents can be found at:

FAO: <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/>

WHO: http://www.who.int/whopes/recommendations/who_fao_guidelines/en/

Finally, FAO maintains a repository of national legislation relevant to agriculture. This includes the pesticide legislation of a large number of FAO member countries that might serve as a reference. The repository, called FAO-LEX, can be found at <http://faolex.fao.org/>

² See the Guidance on pest and pesticide management policy development:
http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Policy_2010.pdf

Code of Conduct provisions on regulatory requirements (Selected paragraphs from Article 6)

6.1 Governments should:

6.1.1 introduce the necessary policy and legislation for the regulation of pesticides, their marketing and use throughout their life cycle, and make provisions for its effective coordination and enforcement, including the establishment of appropriate educational, advisory, extension and health-care services, using as a basis FAO and WHO guidelines and, where applicable, the provisions of relevant legally binding instruments. In so doing, governments should take full account of factors such as local needs, social and economic conditions, levels of literacy, climatic conditions, availability and affordability of appropriate pesticide application and personal protective equipment;

6.1.2 as recommended by the International Partnership for Cooperation on Child Labour in Agriculture, introduce legislation to prevent the use of pesticides by and sale of pesticides to children. The use of pesticides by children in a work situation should be included in National Hazardous Work Lists for children under ILO Convention No. 182 on the Worst Forms of Child Labour in countries which have ratified it;

6.1.3 establish regulatory schemes such as licenses or permits for pest control operators;

6.1.4 establish pesticide registration schemes and infrastructures under which each pesticide product is registered before it can be made available for use;

6.1.8 promote the advantages of, and cooperate with other governments in, the establishment of harmonized (regionally or by groups of countries) pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards, and where possible incorporate these standards into national or regional legislation;

6.1.9 Allow for re-evaluation and establish a re-registration procedure to ensure the regular review of pesticides, thus ensuring that prompt and effective measures can be taken if new information or data on the performance or risks indicate that regulatory action is needed;
export, manufacture, formulation, quality and quantity of pesticides;

6.1.10 improve regulations in relation to collecting and recording data on import, export, manufacture, formulation, quality and quantity of pesticides;

6.1.12 permit pesticide application equipment and personal protective equipment to be marketed only if they comply with established standards;

6.1.14 Regulate and monitor pesticide residues in food in accordance notably with the recommendations of the Codex Alimentarius. In the absence of Codex standards, national or regional standards should be used. This should be done in a manner that is consistent with WTO requirements and will not lead to technical barriers in trade.

2. Reasons for updating pesticide legislation

Governments regulate pesticides for many reasons. The main objective is to protect human health and the environment from risks associated with pesticide use. This includes protection of pesticide users, consumers, the public, crops, livestock, wildlife, water bodies, etc. Other important objectives include ensuring the effectiveness of pesticide products for their proposed use and ensuring a fair market for manufacturers, importers and distributors of pesticide products. Legislation is one of the tools that countries use to achieve these objectives, by regulating the manufacture, importation, transport, storage, sale, use and disposal of pesticides.

Pesticides can have a broad bearing on many aspects of life. Consequently, in addition to specific pesticide legislation, other legislation on human and occupational health, environmental protection, agricultural practices, international trade, etc. tends to address or affect pesticides in some respect. Together these form the overall regulatory framework for the control of pesticides. Any review of pesticide legislation should thus start with a review of this broader regulatory framework.

The Code of Conduct emphasizes that governments, when regulating pesticides, should take full account of factors such as local needs, social and economic conditions, levels of literacy, climatic conditions, and the availability and affordability of appropriate application equipment and personal protective equipment. Monitoring of pesticide use in the local context may provide reasons to further develop the regulatory framework for the control of pesticides.

Existing national pesticide legislation may have become outdated with respect to changes in the regulatory and institutional framework, or because of new needs and issues arising in the country, or with respect to applicable international or regional standards. Objectives, priorities and needs may change, institutional responsibilities may change, information about hazards and risks may change, regional collaboration and harmonization may be introduced or new trade requirements may become important, for instance when non-compliance would affect export of agricultural produce. Many countries have ratified international instruments but have yet to implement the new obligations and standards in their national legislation. Other countries may wish to harmonize their pesticide legislation with non-binding international guidelines such as the Code of Conduct.

Inconsistencies within the regulatory framework for the control of pesticides often include varying definitions of pesticides and related terms, overlapping mandates for different agencies with pesticide management responsibilities and conflicting provisions regarding allowed pesticide uses. Inconsistencies may have arisen because different laws or regulations may have been developed without the necessary coordination or on an ad hoc basis to deal with specific problems in specific contexts.

Of particular concern are contradictory provisions in different pieces of legislation that may grant the same or overlapping powers to different ministries, departments or agencies. This may result in either duplicative administration of some tasks (creating burdensome and overlapping inspection systems), or gaps in coverage. Such overlaps may have originated from different agencies having been created at different times, each with its own domain. For instance, regulatory power over pesticides may originally have been assigned to the ministry responsible for agriculture, but with the increasing use of pesticides as a means to prevent human diseases, the ministry responsible for health may have been granted some authority in

relation to some pesticides. Equally, if pesticides have become a growing environmental problem, environmental protection agencies may have been assigned control. In systems where some types of pesticides are governed by one administrative body and other pesticides by another (for example, the Ministry of Agriculture for agricultural pesticides and the Ministry of Health for public health pesticides), it may be unclear to the user or even governments themselves which system is responsible for regulation. Both FAO and WHO therefore encourage governments to optimize the integration of Ministerial responsibilities regarding regulatory control of pesticides, preferably through one pesticide law that applies to all pesticides.

Besides redesigning the pesticide legislation, there also may be a need to strengthen some provisions of other pieces of legislation by making them specifically applicable to pesticides. For instance, although a legal provision may provide that the contamination of land or water with substances dangerous to human health is subject to criminal penalties, it may not be clear to all interested parties that pesticides are included as part of the definition of “hazardous substances” and that the disposal of obsolete or leftover pesticide products in a manner that would result in contamination is prohibited. Another example is general laws prohibiting misleading advertising: although the provisions may also apply to pesticide advertising, users might not appreciate this, and therefore more specific standards for pesticide advertising may lead to better results. Reviewing and revising pesticide legislation should also advance an overall objective to develop unified legislation covering all aspects of pesticides.

Updating pesticide legislation

The main reasons for updating pesticide legislation are to:

- ensure consistency in the overall regulatory framework with effective connections between pesticide legislation and other relevant legislation with minimal contradiction or overlap;
- clarify any issues related to responsibilities, authority or mandate of the institutions involved;
- incorporate provisions to address new requirements stemming from recent developments or updated priorities;
- facilitate multidisciplinary approaches to pesticide management;
- comply with requirements of international agreements and recommendations; and
- harmonize requirements with countries within the region.

3. The process of drafting pesticide legislation

This section provides a brief overview of the steps in the process of drafting pesticide legislation.

3.1 Steps in revising or drafting pesticide legislation.

Before revising or drafting pesticide legislation, due consideration will typically need to be given to the following steps:

- 1) Analysis of the national legal and institutional frameworks directly or indirectly relevant for pesticide management;
- 2) Identification of technical needs and regulatory failures, based on (i) field realities and experiences, (ii) new pesticide policy objectives; (iii) existing legislation; and (iv) international recommendations;
- 3) Drafting, which usually involves a team composed of legal and technical experts; and
- 4) Review of drafts with the involvement of key stakeholders.

The analysis of national legislation should consider the national legal system and review all national legislation directly or indirectly affecting pesticides management in all areas of the pesticide life cycle. Section 5.3 below provides detailed guidance on the laws and regulatory instruments that should be considered. As part of this analysis, it is important to collect information from stakeholders, including farmers, extension staff and local government representatives, about existing problems with the management of pesticides and to determine why these issues exist and why legislation has not yet improved the situation, as this may point to gaps or weaknesses in the legislation or in the institutional infrastructure for implementation of the legislation. Further, the analysis should also include a review of government policies relevant to pesticide management, such as, for instance, agricultural policy or environmental policy.

Following the legal analysis and consultations described above, drafters should identify the regulatory failures of the existing legislation and the missing elements that should be incorporated into national pesticide legislation. The regulatory failures will reveal the gaps and overlaps of the existing legislation that require regulatory action, serving as guidance for the drafting of the new law. Dispersed or scattered legislation may also trigger regulatory reform.

Finally, it is important that all relevant stakeholders are involved in relevant stages of the law development process, notably at the analysis stage described above and the final review stage. Effective stakeholder participation will help to adapt the law to the national circumstances and local capacities. Furthermore, stakeholder participation facilitates awareness, ownership, dissemination and adherence.

3.2 The pesticide life cycle and its regulatory framework

Analysis of the national legislation should cover all stages of the pesticide life cycle which – according to the Code of Conduct – includes manufacturing, formulation, packaging, distribution, storage, use and final disposal of a pesticide product and/or its container. For many of these stages there is likely to be a range of other legislation that should be considered. The same applies to institutional responsibilities, which also may vary for each stage of the life cycle.

Pesticide production, for instance, could be regulated under chemicals legislation or general industrial production legislation, and may further be affected by environmental legislation and occupational health legislation. Post-registration activities such as licensing or inspection can be embedded into decentralized authorities' legislation, market surveillance, public and/or environmental health, or legislation on the control of noxious substances. Other relevant legislation may include legislation on: transportation, storage and use of chemicals; the import and export of general agricultural inputs; and environmental legislation implementing the Rotterdam Convention or the Montreal Protocol, etc. Legislation on the packaging of pesticides may need to take into consideration broader legislation on the packaging of goods. The same applies to legislation on advertising for pesticides. Finally, pesticide disposal, including containers and obsolete pesticides are frequently regulated in environmental protection and waste management legislation.

To avoid gaps and overlapping and to ensure a consistent approach to pesticide management in all stages of the pesticide life cycle, it is generally recommended that pesticides are regulated under specific pesticide legislation that covers as many aspects of the pesticide life cycle as possible.

3.3 Consistency with the national legal framework

The exact format and contents of the legislation in each country will depend on the country's legal system, Constitution, applicable international obligations, existing legislation, available institutional infrastructure and relevant policies as well as government priorities and resources. Legislation should also take into account the economic and social situation and any specific circumstances in the country, such as the crops grown, pest problems, vector-borne diseases present, dietary patterns, types of pesticides that will be needed, the level of literacy of the population, the climate and the environment. Properly weighing and considering these factors should help ensure the drafting and enactment of a well-designed legal framework for the control of pesticides that is tailored to national needs and appropriate to the national context. Ideally, countries will have developed a pesticide policy ahead of time, which can be reflected in the legislation being drafted.

The various elements of a law, including the title, scope, institutional framework, substantive provisions and enforcement measures, should be consistent with each other. Such internal consistency requires that, for example, the title of the law should adequately reflect its scope. The institution mandated to implement the law must be vested with the necessary powers to ensure effective implementation in all areas under the framework of the law. Enforcement provisions must be sufficient to facilitate the role of national authorities in achieving compliance. A law with a very broad scope and a limited mandate for the authorities would fail the test of consistency. Along the same lines, a very broad title (Pesticide Law) with a

limited scope (pesticides for agricultural purposes) would also raise problems with internal consistency.

Further information on how to facilitate compliance with international and the national regulatory frameworks, and on how to facilitate implementation, is provided later on in Section 5.

4. Elements of a national pesticide law

This section sets out the specific areas that should be addressed in national pesticide legislation. It identifies the key elements that are normally included in a pesticide law.

4.1 Introductory provisions

4.1.1 Preamble and objectives

A national pesticide law should clearly indicate its objectives. Depending on the legal tradition, this can be done in the law's preamble, the long title, or in a specific provision,

The preamble is not a legally binding provision, but serves as a statement setting out the purposes of the law and defining its relationship to other legislation. The preamble, long title or provisions that set forth the objectives of a law are specific to the purposes, legal context and legal system of the country. They might state that the law is designed to assist the country in meeting its international obligations and to protect human health and the environment from the potential risks of pesticides. They might refer to specific policy objectives, such as the importance of Integrated Pest Management (IPM) or Integrated Vector Management (IVM) strategies, the desire to foster international trade in agricultural products, the need to reduce risks associated with pesticide use, the desire to make properly labelled quality pesticides available to users or the desire to reduce dependency on pesticides. The substantive provisions of the pesticide law will have to be consistent with the objectives stated in the preamble.

4.1.2 Scope

The scope of a national pesticide law describes what the law covers. These provisions identify the products, substances and the targeted activities to which the law applies. It is important for the scope to be stated clearly so that both regulators and the public will know exactly what substances and what activities are covered by the law.

One important question with respect to scope is whether the law should cover all pesticides (agricultural, public health, household and industrial³ pesticides) or whether it should be restricted to agricultural pesticides. FAO and WHO recommend that countries enact a comprehensive pesticides law that applies to all pesticide use within a country, covering agricultural, public health and household pesticides. There are, however, countries that prefer to regulate pesticides as part of a broader agricultural area, such as plant protection or

³ Industrial pesticides for instance include wood preservatives, pesticides in paints, anti-fouling agents, etc.

agricultural inputs (that would also include fertilizers). The disadvantage of this latter approach is that it only addresses agricultural pesticides and thus requires separate legislation for other pesticides. Having one instrument that covers all pesticides also tends to facilitate closer collaboration between the ministries concerned. This for instance could take the form of pooling of expertise in a national pesticide registration board.

Another common question is which aspects of the pesticide life cycle should be regulated in which type of legislation. Although the answer to this question tends to be particularly dependant on the national context, FAO and WHO, as a general rule, advocate that as many issues as possible be addressed in the pesticide law itself, rather than as a part of more general legislation such as environmental law, transportation law, labour law, advertising law, general chemicals law or business law. Among other reasons, it is desirable from the standpoint of sensitizing the public to the many issues surrounding the use of pesticides if all pesticide-related provisions are collected in one law.

If a country wishes to be explicit about certain groups of products, the scope is the place to clearly establish whether or not these products would fall under the pesticide law. For example, a country may want to make it explicit that certain groups of substances, such as nutrients, soil conditioners, human and veterinary drugs, are not covered by its pesticide law, or it may want to make it explicit that certain insecticides, such as those used in shampoos, creams or lotions, will be regulated in drugs and cosmetics legislation.

The scope should also specify the activities targeted by the law. In general, these should cover the life-cycle of pesticides from registration, production, import/export, distribution, storage, and application to disposal. For instance, the scope could clearly specify that the import and export of pesticides will be regulated under the pesticide law.

4.1.3 Definitions

The definitions included in the pesticide law assist with its interpretation. In developing definitions for a pesticide law, countries are advised to consider those provided in the Code of Conduct on Pesticide Management, as these represents the international consensus on terminology for pesticide management. Most international agreements also contain definitions. For example, the Rotterdam and Stockholm Conventions each have their own definition sections to be used in interpreting the particular agreement. If there is no international reference source available for certain terms, then drafters may want to take into consideration the definitions included in other national legislation.

Updating definitions when legislation is being revised can eliminate confusion and gaps in enforcement and foster consistency in judicial interpretation. Existing definitions may be ambiguous or there may be divergences among definitions in different laws passed at different times. The definitions in existing law may have become outdated, since pesticide technologies and industry standards gradually evolve. This can lead to a situation where new technologies are inadvertently excluded from regulation.

A clear definition of the term “pesticide” is particularly important since it will contribute to setting the scope of the pesticide law. Countries may want to incorporate the internationally accepted definition as provided in the Code of Conduct on Pesticide Management: “*Pesticide means any substance, or mixture of substances of chemicals or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth.*” This

definition covers all forms of pesticides for all uses, thereby preventing loopholes or legislative gaps, and applies to chemical and biological pesticides for agricultural, household, public health, veterinary, forestry and industrial use, among others. Even in laws that are intended to be more limited in scope, the definition can remain as provided in the Code of Conduct, but then be followed by further clarification in the provision on the scope of the law (all pesticides or only some pesticides).

Definitions should be as clear as possible, without archaic constructions like “the said permit” and “thereat.” The list of definitions should only include those terms that actually appear in the law and that are likely to be a cause for confusion if not defined. For example, if the legislation criminalizes the sale and use of "banned pesticides", then it will have to include a definition of what “banned pesticide” is. However, there often is a temptation to include in the pesticide law a very large number of definitions, even for terms that do not appear in the body of the law or for terms that are generally well understood in the language of the legislation. This is not advisable: the list of definitions should be manageable and limited to those concepts which are specific to the area that is regulated, and that may be ambiguous or unclear.

Finally, definitions should not include regulatory elements. For example, the definition of an institution should not explain its functioning or designation and the definition of a procedure (such as “registration”) should not describe how the procedure is implemented. Definitions should be limited to clarifying the meaning of a term which could otherwise be ambiguous.

Key Elements: Scope and Definitions

The pesticide law should have:

- a well-defined **scope** that makes clear whether the legislation covers all categories of pesticides. If not, the law should explicitly identify the groups of pesticides covered;
- **definitions** that are consistent and not ambiguous. As much as possible, definitions should be aligned with those provided in the Code of Conduct on Pesticide Management or the applicable pesticides and chemical Conventions.

4.2 Administration

4.2.1 *General institutional structure*

The pesticide law should designate the authority in charge of coordinating pesticide management in the country (the “responsible authority”). Depending on the situation in the country, this could be the ministry of agriculture, health or environment, although it also may be a separate body such as an independent environmental protection agency or pesticide agency. It is important to assign responsibilities to the proper authority, taking into account the national circumstances and resources, to ensure a coherent and effective institutional framework. This coordinating authority will be responsible to facilitate coordination among all different national institutions with a role on pesticide management in all areas of the pesticide life cycle.

Note: When advancing regulatory systems for the control of pesticides, some countries decide to assign the primary responsibility to the Ministry of Environment or Health because it is considered inappropriate if the institution that advises farmers on use of agricultural pesticides would also be responsible for the approval and control of such pesticide as this would present a potential conflict of interest. However, in many developing countries, responsibility for control often remains with the Ministry of Agriculture simply because there often is insufficient specific knowledge about pesticides outside of that ministry. Countries should take into consideration the benefits of separating control from advice functions.

The law should provide the responsible authority with all powers necessary to carry out its duties. These include the power to issue regulations, rules and guidelines relating to pesticide management, and to set up and coordinate an inter-ministerial body to assume the role of pesticide registration board (see below at 4.2.2). It also includes the assignment of powers related to licensing and enforcement. In some instances, the authority will be directly responsible for issuing all licenses and permits related to pesticides management. In other cases, the authority will coordinate with other competent authorities for the issuance of specific licenses (i.e. licensing for pesticide transportation might remain under the mandate of the ministry in charge of transportation).

Many countries are not able to implement or enforce their pesticide legislation because of a lack of funds. Where possible, provisions should be included in the law to ensure adequate funding of the institutions responsible for implementation and enforcement. In this respect, it is important to include the ability to charge fees for services provided. Many variations are possible, such as allowing fees to be charged in connection with pesticide registration (e.g.: for filing an application), for the approval of exemplars of pesticide containers or for laboratory analysis at the point of registration or importation. In some countries, the responsible authority is permitted to retain the fees it collects, for instance in accordance with a regulated cost-recovery mechanism. Other countries may require that all government-acquired fees be collected in the consolidated fund administered by the ministry responsible for finance, which then allocates funding to the various ministries and agencies through the normal budgetary process. Nevertheless, the financial sustainability of pesticide regulation and enforcement is necessary and should be provided by law.

An important duty is to collect and maintain information about pesticide use (quantities imported/produced) and pesticide incidents in the country. Information collection allows the competent authority to understand usage trends and therefore assess pest and pesticide related risks, which in turn informs policy making. It also enables the development and delivery of public education activities to raise awareness of pesticides and pesticide use. The legislation may determine the responsible authority for information collection, awareness raising and public education.

Some international instruments, such as the Rotterdam Convention, require the identification of a national focal point or designated national authority (DNA) to monitor implementation of the particular international instrument. Institutional cooperation between these focal points/DNAs, the responsible pesticide authority and other key stakeholders is essential.

4.2.2 *Pesticide Registration Board*

Many pesticide laws establish a pesticide registration board to review and decide upon pesticide registration applications. Such a board usually integrates expertise from the national ministries and agencies dealing with various aspects of pesticide management to ensure broad representation of disciplines relevant for risk assessment. This not only pools expertise from different ministries, but also shares responsibility for decisions and, as such, reflects broad national consensus. Pesticide registration boards tend to include relevant staff from the ministries responsible for agriculture, health (expertise on vector control, pesticide residues in food and on occupational and bystander health) and environment (expertise on fate of pesticides in the environment and toxicity for fish, birds, bees etc.). Pesticide registration boards may further include representatives from the ministries of transport (transport of dangerous goods); labour (occupational health and safety); trade; and other relevant ministries or government academic or research institutions. The pesticide registration board follows established procedures and criteria to determine whether specific pesticides can be permitted onto the market (see 4.3).

The law will generally establish how the members of the pesticide registration board are appointed, which ministries and agencies will be represented, what its tasks and powers are, what procedures it will follow (or how the procedure will be established), and how decisions will be taken. Tasks of the pesticide registration board may include, but are not limited to, the evaluation of pesticide registration applications against criteria set in the law, decision making on applications, establishing the list of banned and severely restricted pesticides, adoption of evaluation methods (efficacy, risk assessment), etc.

Regarding powers and procedures, legislation should clearly stipulate how and by whom a registration decision is made. In some countries, the pesticide registration board will have the authority to take the final decision to register a pesticide, while in others its decisions may be considered first instance decisions to be confirmed or endorsed by the Minister who holds the ultimate authority. The law may establish that members are appointed for specified periods that can be renewed. It may establish that members of the pesticide registration board will not be held personally liable for any misjudgements of the board in registering certain pesticides. The detailed rules and procedures governing the functioning and decision-making of the pesticide registration board are usually included in implementing regulations.

Given the importance of international obligations, the membership of the pesticide registration board should include the DNA or focal points identified under the Stockholm and Rotterdam Conventions, when the country has signed those conventions. Regarding the membership of the pesticide registration board, it also is important to find a balance between having the necessary expertise represented and not having too many members, as this may complicate meetings and decision making; if the pesticide registration board includes a large number of representatives from different Ministries, the key interests represented by the Ministries of Health, Agriculture and Environment in decision making processes could become diluted. The size of the pesticide registration board should determine the decision-making process and quorum. For a larger board it may not be feasible to expect decisions based on consensus.

Considering the sensitivity of the decisions on registration, it is normally recommended that the pesticide registration board is made up of representatives from entities or bodies which do not have conflicting interests in registration decisions, such as public entities or academia.

The pesticide industry and other private stakeholders are generally excluded from membership to ensure that there are no conflicting interests that might influence decisions. The law should set some restrictions on membership of pesticide registration boards, for example requiring that members not have a financial or other interest in any matter under discussion. Members may generally be removed for misconduct, absence from meetings, incompetence or conviction of a crime. The law often also provides the possibility for members to resign by writing to the responsible authority.

The law may not go into greater detail, such as on the appointment of a chairperson, the requirements for a quorum, the procedures for the creation of technical and advisory subcommittees and so forth. In most countries, this type of detail is included in secondary legislation (such as implementing regulations). In some cases the board has been given the power to establish its own operating procedures, while in others such responsibility is assigned to the Minister.

4.2.3 Pesticide Registrar

Often, a Pesticide Registrar is established to serve as Secretary to the pesticide registration board. This might be a person or an administrative entity, usually the responsible authority or a person from the responsible authority. Legislation should specify the role of the Pesticide Registrar. It is common practice that the legal basis is included in primary legislation and the details of the tasks and duties are developed in implementing legislation. Tasks frequently assumed by registrars are to receive applications for registration, to determine whether these are complete, to prepare review by the pesticide registration board and to conduct the necessary administrative follow-up action after a registration decision has been taken by the board. The law often establishes who will appoint the Pesticide Registrar and outlines the tasks and responsibilities of the Pesticide Registrar. It may also contain provisions to prevent conflict of interest.

4.2.4 Pesticide advisory bodies

Legislation may also establish, or give the responsible authority or the pesticide registration board the power to establish, other bodies, groups or councils that are different from the pesticide registration board. Such bodies usually have an advisory role and, depending on mandate and purpose, could have a broad stakeholder participation to ensure that all aspects of pesticide management are brought to the table, including the private sector and the pesticide industry. Legislation then should also establish who has the authority to establish advisory groups, how such groups will be administered and the limitations of its powers (only advisory).

It is important to recognize the difference between a pesticide registration board (normally only comprising representatives of public institutions) and an advisory group (government plus a broad representation of stakeholders). Pesticide registration boards undertake governmental functions, particularly the decisions on registration. Consequently, their composition should be limited to be effective and free of conflicting interests. The procedure and criteria for decision making should be clearly regulated and board members should be given clear responsibilities. Advisory groups, on the other hand, may have broader representation, may not need tightly regulated internal procedures and should serve as forum for participation and discussion of all stakeholders. Consequently, it would be acceptable that

specific interests are represented, as long as it is clear which members represent which interests and the group does not have decision-taking power.

Key Elements: Administration and Governance

The pesticide law should ensure that:

- a competent authority is designated to coordinate the implementation of the law and is assigned the possibility to call on other government units for assistance in the implementation and enforcement of the law, including information sharing;
- the competent authority is given necessary powers, including the power to inspect, charge fees and elaborate regulations;
- a Pesticide Registration Board composed of different public institutions representing the key regulatory interests (health, agriculture production, environmental protection) has been established and its membership and procedures are outlined;
- safeguards are in place to prevent conflict of interest in members of the Pesticide Registration Board; and
- consultative or advisory groups composed of a wider range of stakeholders could also be created to present the broader range of stakeholder perspectives.

4.3 Registration

An essential component of pesticide laws is to establish a mandatory pesticide registration system. Registration means the process whereby the responsible national authority approves, or does not approve, the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment. Countries may design their schemes according to national needs, but the basic concept is that it is prohibited to manufacture for domestic use, import, pack, re-pack, store, sell, distribute, possess or use pesticides that are not registered as prescribed, unless otherwise provided under the law.

Developing countries may wish to design registration schemes suited to their own needs, rather than emulating in their entirety the detailed systems in place in countries with greater budgets and technical capacity for pesticide registration. Pooling of resources through regional collaboration in pesticide registration may provide an alternative that enables a more rigorous process compared to what each country would have been able to do on its own. The FAO/WHO Guidelines for the Registration of Pesticides (2010) are a useful source of information for establishing or revising a national pesticide registration system. These are supplemented by the FAO/WHO Guidelines on Data Requirements for the Registration of Pesticides (2013). Furthermore, the guidelines on enforcement and post-registration surveillance can also be useful in this respect.

Countries need to assess the prevailing circumstances of pesticide use and local capacity to manage risks associated with such use. Depending on the situation, the registration process can encourage the use of fewer pesticides, or products of lower hazard. The level of risk vis-à-vis the anticipated use needs to be determined in order to inform decision-making in the

registration process, which could result in a positive or negative decision to approve a pesticide registration application.

The pesticide law might put in place a special procedure for unforeseen cases where risk management proves insufficient to handle hazardous products. For example, the law might state that, pending review of the registration status, the national authority could temporarily suspend or restrict the importation, sale, distribution or use of a registered product in order to prevent harm. The pesticide law or its implementing regulations will set out the details for such a procedure, including the conditions and limitations that may be imposed by the authority responsible for registration.

Some examples of measures to encourage registration and use of low-risk pesticides and discourage registration of highly hazardous pesticides through the registration procedure include: (a) creating a more streamlined and simpler registration process for pesticides with low human and environmental toxicity; (b) establishing a sliding fee scale for registration depending of the hazard and risk level, i.e. lower registration fees for low risk pesticides; (c) applying use or user restrictions to more hazardous products; or (d) applying comparative risk assessment and the substitution principle. The latter excludes high risk products from being registered if effective low risk alternatives are registered for the same purpose, and opens a revision of registration for high risk products when low risk alternatives get registered.

In many countries, registration is undertaken by a pesticide registration board (see 4.2.2). Some countries appoint an independent national statutory body that coordinates registration. Whatever the case, the entity's powers and responsibilities should be set out in the pesticide law. These powers should include the ability to request further information at any time from an applicant or registrant, to re-evaluate registrations at any time, and to cancel, amend or suspend a registration as new information becomes available. This might occur if the registration was secured based on false information, if the pesticide has been withdrawn from the market, if registration conditions have been breached or if re-evaluation leads to the conclusion that the pesticide is no longer effective for its intended use or is undesirable on the grounds of harm to plant, human or animal health or the environment.

The law could establish exemptions to the prohibition to import, sell and use unregistered pesticides for specific cases where such exemptions could be justified. For instance, a specific procedure may be established to allow the import of unregistered pesticides in small quantities for experimental use or scientific research. This might for example apply to imports for pre-registration testing. Some countries also include a provision to authorize importing unregistered pesticides to address emergency situations, for instance if it concerns new pests for which pesticides have not yet been registered. Such exemptions should be obtained from, and be approved by, the registration authority. Exemptions should be time-bound and defined through precise criteria so as to prevent the exemption being improperly used. In some cases, the law may allow that unregistered pesticides are manufactured for export only, or pass in transit (see 4.4). Legislation should include clear procedures and criteria if importation, manufacture or use of unregistered pesticides can be authorized for specific reasons.

4.3.1 Application procedure

The legislation should provide a procedure to apply for registration or provisional registration of pesticides. This procedure should clearly specify who may apply. This usually is the person or company that wishes to import or manufacture a pesticide for use in the country. It can also be large volume users, such as large industrial plantations or a national cotton company.

The legislation must indicate which application form should be used and what information the applicant must include, specifying the minimum data set that is required to initiate the registration procedure. Registration requirements can make distinction between a new registration and an amendment to an existing registration. Amendment of an existing registration may be required when: (a) the data provided in connection with registration have changed; (b) the product is proposed for new purposes (e.g., a different crop); or (c) the applicant seeks to change the product's label or to upgrade the approval status from provisional to full approval.

The pesticide law should list the criteria for decision-making and the time frame for obtaining the approval so that applicants are aware of what is required and how long it may take.

4.3.2 Data requirements

The law should specify the required information that must be submitted with an application for registration, or indicate how this will be provided in secondary legislation. Depending on the legal system, the manner in which data requirements are included in primary or secondary legislation may differ.

Mandatory data may include: the applicant's company details; trade name; common name; formulation; proposed use (crop/pest combinations); the manner of its use (including mixing instructions, use instructions, application method and rates); withholding periods; co-formulants; chemical properties and toxicological data; reports of efficacy trials conducted in the country or under conditions similar to those in the country; reports of residue trials; reports on risk to human health and the environment; proposed warnings, hazard symbols and pictograms; type of packaging; information on how the pesticide will be stored and handled and how used containers and any surplus will be disposed of; first aid instructions; etc. The registration application usually also includes a sample label that should include much of the above information.

Countries may wish to require the registration authority to review data submitted in analogous registration processes in other countries and the decisions taken in reference countries. Fewer efficacy tests may be required where pesticides are already registered in another country for use in similar agricultural and ecological conditions (so long as the prior registration took place according to internationally recognized efficacy evaluations) or where pesticides are already registered for one purpose and registration is sought for additional similar crops or circumstances. The pesticide law may establish the possibility of registration by reference, which would have implications for the required data to be reviewed. Details would typically be provided in secondary legislation on registration.

Legislation may establish that less comprehensive data requirements may suffice for low-risk products (e.g. biopesticides) or for products that are considered equivalent to other products already registered.

For further guidance on data requirements, reference is made to the FAO\WHO Guidelines on data requirements for the registration of pesticides (2013).

4.3.3 Decision-making criteria

The law should establish which criteria will be taken into consideration when reviewing a registration application and what decisions can be taken. The purpose of establishing these criteria is to enhance transparency in decision making and to avoid disputes with the applicant.

The criteria to be taken into consideration typically relate to efficacy and risk to health and the environment, and often include:

- the intended use (crop/pest) and the efficacy of the product;
- occupational health hazards and risks to workers and users at different stages of the product cycle;
- hazards and risks to public health with special attention to vulnerable groups;
- hazards and risks to animal health;
- hazards and risks to the environment, including effects on non-target species;
- envisaged mode and conditions of use and associated risk factors;
- any history of not following of label recommendations, including gross misuse;
- existence of alternatives that present lower risk;
- quality of the product;
- persistence, half-life and other factors contributing to the presence of residues on the crop concerned;
- pest resistance to pesticides;
- the proposed packaging and label.

In addition to the above criteria, consideration may be given to international agreements, policies and trends regarding the phasing out of Highly Hazardous Pesticides (HHPs)⁴, particularly in cases where phasing out is required under international agreements that the country has ratified. The Stockholm Convention may be such an agreement. Drafters may consider including a specific provision on the phasing out of HHPs in the pesticide law.

Consideration may further be given to the requirements of key destination markets for export crops, which may not accept products that have been treated with certain pesticides. For example, if an importing country has not approved use of a certain pesticide on a specific

⁴ The Code of Conduct on Pesticide Management defines Highly Hazardous Pesticides as pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as WHO or GHS or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous.

crop, it then typically would put the tolerance for residues of that pesticide at the detection level. This means that import of the consignment will be blocked if any traces of that pesticide are found on the crop concerned.

The prevailing conditions of use and local capacity to manage risk should be key considerations in the risk assessment. This means that factors such as the availability of protective gear, conditions under which protective gear is to be used, farm level storage facilities, level of understanding among users, etc. should be taken into consideration.⁵

Regarding the quality of pesticide, reference can be made to the pesticide specifications that are being published by the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). These provide information on the appearance, active ingredients, relative impurities and physical properties of each pesticide.

Regarding approval of labels, the legislation should rely on the FAO/WHO Guidelines on Good Labelling Practice for Pesticides, and use the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), or the WHO Recommended Classifications of Pesticides by Hazard (with the GHS classification being recommended). Labels should have the recognized hazard symbols as provided by the chosen classification system.

4.3.4 *Registration decisions*

After setting out the criteria for the registration authority's decision-making process, the pesticide law should indicate the possible outcomes of a final decision, which the authority must deliver within a specified period of time. The possible outcomes include:

1. Positive decision
2. Suspension of the application procedure (deferred decision)
3. Negative decision

- 1) **Registration (positive decision)**, which approves the sale and use of a pesticide. Registration decisions generally specify the crops and/or pests for which the product is approved and may add additional conditions that can be used to make explicit which risk mitigation measures are required or that only authorized persons can use certain pesticides or apply according to certain methods.

Legislation may enable the pesticide registration board to authorize **provisional registration** when certain information is missing or not fully satisfactory, but such information is not deemed to have a significant bearing on the risk evaluation. Provisional

⁵ The following articles of the Code of Conduct provide important reference in this respect:

(art 7.5) "Prohibition of the importation, distribution, sale and purchase of highly hazardous pesticides may be considered if, based on risk assessment, risk mitigation measures or good marketing practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment."

(art 3.6) "Pesticides whose handling and application require the use of personal protective equipment that is uncomfortable, expensive or not readily available should be avoided, especially in the case of small-scale users and farm workers in hot climates".

registration might be granted for a limited period of time and be subject to specific conditions, including the timely delivery of the specified information. Legislation should be clear on when and how provisional registration can be granted.

Products can be registered as **severely restricted pesticides**. In this case, their use might be prohibited, as a general rule, with a very limited number of exemptions for certain uses for which there are no less hazardous alternative and for which the use can be restricted to certain users that have been specially trained and equipped. To ensure that such conditions are met, countries may require users to be certified or to obtain a special license. Countries may want to consider this option only if the restriction can actually be enforced. Some countries maintain a list of severely restricted pesticides.

- 2) **Suspension** of the registration procedure would occur when relevant information is missing that is deemed relevant for accurate risk evaluation or when other requirements are not yet fully met to enable a final decision. In these cases, registration does not take place, and the procedure is suspended until the appropriate information is provided by the applicant. The criteria for decisions on the suspension of the registration procedure should be clear to prevent abuses and corruptive practices from the authority.
- 3) **Denial of registration** (negative decision). In this case the pesticide registration board, based on the risk evaluation or other set criteria, decides not to register the product. Denial of registration effectively prohibits the manufacture for domestic use, importation, distribution, sale and use of the product concerned. Denial of registration does not preclude the applicant or others to later reapply for registration when there is new information, such as a change in the product or its intended use.

Furthermore, a country may want to have the possibility to **ban** certain pesticides. Banning may occur when the pesticide registration board considers that the pesticide (or its active substance) entails risks to human health or the environment that are unacceptable for all formulations and uses in the country. Banning a pesticide is a final regulatory action that prohibits all activity and use of a pesticide compound in the country, and precludes any subsequent application for registration. Countries frequently create a list of banned products and/or active substances.⁶ Banning can be the outcome of a registration process, but it could also be done on the basis of new information, such as the listing of a product under an international instrument such as the Stockholm Convention or the Montreal Protocol. The legislation should specify the procedure for banning and the responsible authority.

The legislation should state that when registration is granted, the product is assigned a registration number and the authority issues a certificate of registration, in the form set out in a regulation or schedule to the pesticide law. The certificate indicates how long the registration is valid and specifies any restrictions or conditions imposed.

Usually, the label, an exemplar of which was attached to the application for registration, is approved at the time of registration. The legislation should state that no change can be made to the label as approved except with the permission of the registration authority.

⁶ The Rotterdam Convention requires each party that bans or severely restricts a chemical to notify its Secretariat in writing within 90 days of such action, in order that information reflecting the reasons for the national decision can be shared with other parties to the Convention.

If the decision is to suspend the registration decision, or to not register the pesticide, the law will generally require the registration authority to communicate a written explanation of the reasons for the denial within a specified time-frame and to afford the applicant the chance for an appeal. The explanation typically would refer to the criteria mentioned in the Registration section of the legislation. The appeal could be channelled either through the normal legal process, or other provisions in the pesticide legislation may create a special appeal process.

The section on registration should address the legal effect of the registration on who can produce or import. There are countries where the registration holder is the only person entitled to produce or import the product, unless the applicant expressly authorizes a second operator to import the product. In other countries, once the pesticide is registered everybody can apply for an import/distribution permit for that product.

4.3.5 Re-registration

Pesticide legislation should establish that the registration of a pesticide is valid for a certain period of time, after which the registration automatically expires, unless the product is re-registered. Re-registration is to be requested by the registration holder if the registration holder wants to keep the product concerned on the market. Re-registration usually requires a new application and involves a re-assessment to determine whether the considerations that led to the earlier registration decision are still valid with special attention to new information regarding its efficacy and risks, and the availability of less hazardous alternatives. Expiration of the registration without renewal through re-registration means that the registration is cancelled and the product can no longer be distributed and used. Legislation should establish the procedure, requirements and timeframe for re-registration.

4.3.6 Modification of the registration data

Legislation should require a registration holder to notify the registration authority of any change in the data included with the initial application for registration. Legislation should also define what the implications are of different types of changes.

If the product itself, its composition, its active ingredient or its formulation is changed, the legislation should require a new application for registration, which would involve a new risk assessment. Changes in packaging, labelling or use generally would require some sort of new assessment based on risk, before the approval and amendment of the registration certificate. For minor changes such as the contact details of the applicant or other minor amendments, the registration authority may only require notification.

4.3.7 Review

The law should provide that the registration authority may decide at any time to review a registration or provisional registration in light of new information about any health or environmental effects linked to the use of the pesticide. Such information may come from a

listing of the product under a relevant Convention⁷ or from reports of additional testing, poisoning cases, damaging effects on the environment, resistance, phyto-toxicity or information about control actions in other countries.

The law should empower the registration body to impose additional conditions on the manufacture, handling and application of a pesticide, or to revoke (cancel) that registration or provisional registration, where it determines from its review that the continued use of the pesticide may involve an unacceptable risk. Registration should also be revoked if it is found that the information provided in the applications was fraudulent.

4.3.8 Record-keeping and confidentiality

The registration authority should be charged with keeping a register of pesticides containing basic information on all registered pesticides, including the pesticide's brand name, common name, concentration, formulation, uses and the name and address of the applicant. The list of registered pesticides, with basic information as mentioned above, should be publicly available and easy to consult. In addition, the registration authority should maintain a dossier for each registered pesticide with the label and detailed information regarding the composition, co-formulants, hazards, test reports, and any other data deemed necessary by the registration authority.

In some countries, certain elements of the above information might be protected by industrial property rights or confidentiality. Protected information may include details about the manufacturing process, inert additives and certain business information that is considered confidential.

The protection of confidential information should be balanced with the right of stakeholders to have access to the information that is relevant for transparency related to health and environmental considerations. For instance, information about co-formulants that may pose additional health or environmental risks should be publicly accessible.

Legislation should identify which information shall be made public and available and which information shall be considered confidential. One typical area of confidentiality concerns Intellectual Property Rights (IPRs) related to information provided in the registration application, as protected by specific national IPR legislation. It should also specify how confidential records are to be maintained and stored and who shall have access to those records. The penalties for breaches of confidentiality should be sufficiently high to act as an effective deterrent and to assure industry members that the registration process will not compromise their business interests.

⁷ For instance, under the Stockholm Convention, parties must eliminate, or take steps to eliminate, the production of all pesticides and other persistent organic pollutants listed in Annex A and to reduce the production of chemicals listed in Annex B.

Key Elements: Pesticide Registration

The pesticide law should:

- establish a mandatory registration system for pesticides;
- set out the key elements of an application procedure for pesticide registration;
- outline the information and data requirements to be included in the application;
- provide the main criteria for decision-making criteria on registration.
- require that registration decisions are communicated to the applicant and include a justification based on the decision criteria.
- establish validity periods for registrations and provide information concerning re-registration;
- clarify which changes require a new registration and which a modification of the existing registration;
- indicate that registration can be reviewed at any time when new information has become available and that a negative outcome of such a review can lead to cancellation of the registration;
- regulate appeal procedures for cases in which the applicant believes denial is not sufficiently justified;
- regulate how registration data will be stored and which part of it will be made publicly available and which part not;
- include provisions ensuring confidentiality and protection of Intellectual Property Rights (IPRs).

4.4 Import and export

In many countries, pesticides are not manufactured or formulated domestically. In this context, tight control on imports of pesticides can effectively eliminate the presence and use of non-registered pesticides. Therefore, most pesticide laws prohibit the import of pesticides that have not been registered. In those cases, the law should also indicate whether there can be exceptions for reasons described in 4.3.

In addition, the pesticide law should prohibit the importation and distribution of all pesticides which do not meet the requirements set forth in national regulations and/or in the decision on registration. This includes counterfeit, substandard or outdated pesticides, as well as pesticides that are not properly packaged or labelled. The law, or its secondary legislation, should make explicit that all products are required to conform to minimum quality standards in order to safeguard human health and the environment, as well as to establish a common standard for different companies producing the same product. The FAO\WHO Pesticide Specifications⁸ serve as primary guidance in standard setting for the quality of specific products.

⁸ <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/en/>

The law should also establish whether pesticides not registered for use in the country can be exported. Pesticide manufacturing countries sometimes wish to have the possibility to export products that are not registered for use within the country itself. Others have found that it is difficult to prevent domestic use when production for export is still permitted and therefore prohibit production and export of products that have not been registered.

Further, the law should establish whether pesticides not registered for use in the country can pass through the country in transit, and if so, on what conditions. This may involve a special license and/or a restriction to special transit zones in a port.

When designing a pesticide import/export scheme it is important to take into consideration the Rotterdam Convention, which introduces specific obligations related to the international trade of pesticides. Each State party must implement the prior informed consent (PIC) procedure for the pesticides listed in Annex III of the Convention.⁹

To establish government control over imports, the law should provide that importation of pesticides is not allowed without appropriate import permission from the responsible national authority. Systems for such permission vary from country to country. In some cases pesticide importers require a permit for each consignment, while in others importers require a license, which serves as a general permission to import pesticides. With a license, they then generally would not need further specific permits for each consignment to be imported.

Import licenses or permits serve to provide assurances that the applicant has adequate facilities and knowledge to handle, transport and store pesticides. The law and its subsidiary regulations should elaborate the procedures and requirements for entities or individuals wishing to apply for such a permit or license. The purpose of licenses and permits is to ensure that all facilities are in place to correctly manage the consignment when it arrives, and to have a degree of control prior to the shipment. The differences between licenses and permits may vary from country to country and might be subject to different pieces of legislation.

To avoid arbitrary decision-making, the law should set out criteria for the granting or denial of a permit or license, including the requirements that a company must fulfil, in terms of facilities, equipment, local representation and staff. Requirements may further include obligations to keep records and to provide information. The law indicates the validity of the license (what is permitted with the license and on which conditions) and the procedure and requirements for renewal. Further, the law may provide that the responsible authority may request the submission of further data or may carry out site visits at the applicant's plant, to check storage facilities and the qualifications of staff. Legislation may require the importer or producer to notify the quantities of a pesticide imported or produced. It may establish that requirements related to the release date and guaranteed shelf-life period of the pesticides in question can be applied to import permits of large consignments in order to avoid the risk of the pesticides becoming obsolete soon after they arrive in the country.

⁹ The PIC procedure is a mechanism for formally obtaining and disseminating the decisions of importing Parties as to whether they wish to receive future shipments of those chemicals listed in Annex III of the Convention according to Article 10 and for ensuring compliance with these import decisions by exporting Parties. Import decisions taken by Parties must be trade neutral. That is, if the Party decides not to accept imports of a specific chemical, it must also stop domestic production of the chemical for domestic use and refuse imports from any source, including from countries that are not Party to the Convention.

The law should provide that imported pesticides are subject to inspection at the port of entry to enable control of their quality, packaging and labelling. Because the customs department is usually the first contact point for imported commodities, it has an important role in preventing the importation of pesticides that have not been cleared for use through the registration process and pesticides that are not properly packaged or labelled.

The law should include instructions on what should be done in cases where import is blocked because of non-compliance with requirements. Returning the consignment to the sender could be an option. Care should be taken to avoid confiscation of illegally imported pesticides in countries where there are no provisions for the environmentally sound destruction of hazardous wastes. Where no suitable destruction facilities exist it is common to find accumulated stocks of obsolete, confiscated pesticides that the authorities cannot dispose of. The law may stipulate that in cases where return to sender of non-compliant products is not possible, the importer will be responsible for the storage and disposal costs.

With regard to exports, pesticide manufacturers must ensure that exported pesticides meet the standards required by the importing country. Under WTO agreements, equal standards should apply to imported products as to domestically manufactured products. Under the Rotterdam Convention, each party is responsible for ensuring that exporters comply with decisions of importing parties not later than six months after being informed of those decisions by the secretariat of the Convention. Moreover, parties that export a chemical that is banned or severely restricted in their own territory have to provide an export notification to the importing party.

Although the Rotterdam Convention is the most important legally binding international instrument relevant to the international trade of pesticides, the Stockholm Convention on Persistent Organic Pollutants also contains provisions affecting the import and export of pesticides listed under its Annexes A and B. Importation and exportation of Annex A and B pesticides are only permitted for environmentally sound disposal or for a permitted use as to which the importing country has obtained an exemption.

Under the Basel Convention, parties may generally prohibit the import or export of hazardous wastes, or may prohibit imports of specific types of hazardous wastes or specific shipments of hazardous wastes. Exporting states may only move hazardous wastes across borders after providing prior written notification to the importing state and all transit states and after having received written consent. This is relevant to pesticide legislation in the context of managing obsolete products.

Section 5.1.1 provides further information regarding these and other Conventions.

Key Elements: Import and Export Requirements

The pesticide law should:

- explicitly prohibit the import of pesticides that have not been registered;
- specify any exceptions to the above;
- specify whether export or transit of non-registered pesticides is permitted, and if so specify the conditions that apply;
- prohibit the importation of counterfeit, substandard or outdated pesticides, or otherwise not meeting the prescribed requirements;
- establish and regulate a licensing and/or permit system for importation of pesticides and prohibit the importation of pesticides without the prescribed license or permit;
- for Parties to the Rotterdam, the Stockholm and the Basel Conventions, ensure that specific requirements of these Conventions are adequately reflected in the law's section on import/export;
- establish equal standards for imported and domestically produced products as required under the WTO Agreements.

4.5 Licensing

A pesticide law usually requires that all persons or businesses that manufacture, import, formulate, pack, re-pack, distribute or sell a pesticide be in possession of a valid licence. Legislation generally also requires pest control operators, aerial applicators and other specialized applicators to have a licence. Countries that severely restrict the use of certain pesticides generally require a special license for the use of such pesticides. A licence is a formal written permission granted for a specific period and issued by the responsible authority. Licensing may add further requirements to the general requirements specified in the legislation that are applicable to all distribution and use of pesticides.

Licensing is a valid tool for the responsible authority to ensure regulatory control over specific activities or products. It enables governments to maintain oversight on where pesticides are being produced, imported, sold and facilitates communication with the points of sale and other license holders. Through licenses, the responsible authority can (periodically) verify that licensed operators still meet the legal requirements and have the appropriate training, resources and capacity to deal with pesticides. Licensing, however, has a function that is significantly different from registration. Registration is a review process over the product and the risks that the product poses. Licensing is a review of the person, business or other entity to see if it is suitable to deal with already registered pesticides. The review is therefore focused on the location, the proposed activity, the competence of the applicant and the evidence of the applicant's ability to safeguard against known risks and the applicants compliance with legal requirements.

The number of licensing schemes and their requirements may differ from country to country and will usually adapt to the regulatory control needs. National inspection and enforcement capacities will also need to be taken into consideration before a licensing scheme is set up.

It should be noted that licensing may be an area of intersection with other national legislation governing commercial or importation licensing in general. But because of the risk involved, and the specialized technical knowledge required to evaluate the risks of commercial enterprises dealing in pesticides, legislation should establish a pesticide-specific licensing scheme that is administered by an entity with specific knowledge of pesticides.

In some countries, field responsibilities, including inspections, market surveillance and licensing systems are implemented by decentralized authorities, such as provincial or local authorities. These authorities will implement the central-level legislation as well as their own implementing provisions, within the framework of their regulatory and executive capacity. Decentralized countries should additionally implement notification and information sharing procedures to ensure an appropriate information flow.

The pesticide law should charge the responsible authority with receiving, evaluating, approving or denying applications for pesticide licenses. In some countries, some of these licenses might be directly executed by a different authority (this could be the cases for transportation licenses). In these cases, the responsible authority will coordinate with the competent authority the requirements, issuance of the licenses and record keeping. Requirements that need to be met in order to obtain a license should be specified in the law or in secondary legislation. Such requirements may include appropriate storage facilities, adequate record keeping and basic knowledge about pesticides. Applications should be submitted in the form specified by the law, and are approved or denied according to specified procedures and for specified reasons. The law should establish the term of validity of licenses and the procedures for renewal, and it may also empower the authority to charge a fee for licenses granted under the law. Further it should have provisions with criteria for the revoking of licenses and the transfer of licenses. Where the application for a license is denied or revoked, the authority should communicate in writing the reasons for the denial and give the applicant the possibility to appeal.

4.5.1 General requirements for licenses

The requirements for licenses for manufacture, formulation, distribution and sale of pesticides and for pest control operators differ greatly. Depending on the activity in question, the law may impose specific requirements or conditions that need to be met before a license can be issued. For example, licenses may be granted only upon successful completion of mandatory training in handling and safety or require the availability of special equipment. Licensing systems may also be designed to encourage selection of lower risk pesticides through differentiation in requirements or lower application fee. In this case the law may establish more rigorous requirements and/or a higher application fee for sale of higher risk pesticides.

The responsible authority should have the power to suspend or revoke a license if inspections reveal that requirements are not met, if there is a violation of any conditions on which the license was granted or if new facts come to light which would have led to the denial of the application in the first instance. To protect importers and retailers from mistakes or abuse, there should be an appeal procedure available for when the affected do not agree with the denial, suspension or revocation of a license.

Some of the activities for which a license may be required are set out in the next sections.

4.5.2 Licensing for manufacture and formulation of pesticides

Licensing of persons and companies that manufacture or formulate pesticides provides the government with assurance that the applicants are aware of the hazardous nature of the product they are dealing with and that they are technically competent to formulate or manufacture it.

The type and quality of products manufactured or formulated is often regulated by the pesticide legislation, while site selection, environmental safety of the plant and occupational health of its workers are frequently regulated by different instruments. The licensing system follows the actual distribution of responsibilities. As such, in most countries a license to operate a plant may not fall under the responsibility of the authority responsible for pesticide management, while licenses for the production of specific products would.

The licensing of the manufacturing or formulation of specific products will also have to reflect international obligations. For example, under the Rotterdam Convention, an importing party that does not consent to the import of a listed chemical must also prohibit the chemical's production for domestic use through national legislation (for example by including it as a banned chemical under the pesticide law). The same holds for any importing party that consents to the importation of a chemical with conditions: the same conditions must apply to domestic production. An efficient recordkeeping and communication system is therefore imperative to ensure that chemicals rejected under the PIC procedure of the Rotterdam Convention are not later approved for domestic production (or use).

The ILO conventions that apply to worker safety during manufacture will also have to be reflected in the pesticide legislation, the national legislation on occupational health, or other relevant national legislation. Furthermore, the Chemical Weapons Convention may have implications for what can be produced and which production processes can be used. Each country will have to evaluate which international obligations it is required to follow, in light of which international conventions it has signed or intends to sign, and how this should be addressed in the pesticide legislation or the broader legal framework for the control of pesticides.

4.5.3 Licensing for storage of pesticides

The pesticide legislation should provide the necessary provisions to ensure that the storage of pesticides is safe and conforms to relevant FAO technical guidance.¹⁰

The national legislation will establish general requirements for the storage of pesticides as listed in paragraph 4.10. These apply to all stored pesticides regardless of whether or not a license is required. In addition, it can be established that a specific license is required for pesticide storage above certain quantities or for a specific category of stores or products. Such a provision may require further safety measures and pose restrictions on the location of stores as described in paragraph 4.10. Licensing schemes for pesticide distributors and retailers may

¹⁰ FAO Pesticide storage and stock control manual <http://www.fao.org/docrep/v8966e/v8966e00.htm>

include storage requirements, which then do not need to be covered by separate licensing for storage. The legislation should impose record-keeping and reporting requirements on licensed storage facilities.

4.5.4 Licensing for sale of pesticides

Legislation usually requires a specific license for the sale of pesticides by retailers. This is often made explicit by prohibiting the sale of pesticides without being in the possession of a valid licence to sell pesticides. Licenses for the sale of pesticides help to ensure that proper products are provided to users and that stores do not pose risk to their surroundings. The Code of Conduct refers to the establishment of a licensing scheme where only sellers with competency and training are permitted to sell pesticides, to ensure that buyers receive sound information regarding selection and use of pesticides and the associated risks.

Licensing of retail pesticide shops helps to ensure that only registered and properly packaged and labelled pesticides are sold and that the facilities are appropriate for the safe storage of pesticides. Requirements for such licenses may include:

- the information in the application is complete and accurate;
- the applicant is technically competent to operate the business as proposed;
- the applicant has basic knowledge about pesticides, their uses and the risks involved in using or handling them and standard risk reduction measures;
- the applicant has knowledge of applicable pesticide legislation and the list of permitted, severely restricted or banned products;
- the applicant abides by the relevant pesticides legislation. Only registered pesticides are sold that are properly packaged and labelled.
- the applicant offers for sale the protective gear that is required for the proper use of pesticides being sold;
- sufficient occupational safety measures are in place to ensure the proper handling of the products (training, use of protective gear, equipment and materials to handle pesticides and to deal with emergencies and to provide first aid treatment);
- the location, land and facilities are appropriate for the proposed use without risk to human or animal health or the environment;
- the storage facilities of the applicant meet the necessary requirements and pesticides are properly displayed and adequately segregated from other products; and
- facilities and procedures are adequate to deal with leakage from pesticide containers and with the management of empty containers and waste products.

Depending on the legal system, such requirements might be detailed in secondary legislation.

The responsible authority should inspect the premises before issuing a license to assess compliance with the requirements specified in the law or relevant regulation. Follow-up inspections would serve to ensure that requirements continue to be met (see 4.13).

Some countries require shop-keepers to participate in training for which they then receive a certificate. Being in the possession of such a certificate is then made a condition for obtaining or continuing a license for the sale of pesticides.

Countries may also require a specific license for the sale of severely restricted pesticides. These licenses might be conditioned to specific training or storage requirements and include special obligations to only sell to licensed users.

Further guidance on licensing of pesticide retailers is provided in the Guidelines on Licensing and Inspection of Pesticide Retailers.¹¹

4.5.5 Licensing of commercial operators

Some countries include in their legislation a licensing scheme for persons applying pesticides for pay, such as pest control operators or aerial application services. This type of licensing scheme is designed to guarantee the responsible and proper use of the pesticides by these commercial operators. Licensing contributes to protecting the health and safety of those doing the ground or aerial application of pesticides and to reducing the risks to human and animal life and health and the environment due to the uncontrolled or incorrect application of the pesticides.

Pest control operators provide specialist services in pesticide application, which may involve handling more toxic formulations and therefore using specialist application equipment and protective gear. Some operators may specialise in agricultural applications, while others specialise in vector control and pest control on premises.

Some of the conditions that legislation may impose in order to obtain a license include: (1) the operator must take a prescribed training course and receive the necessary accreditation; (2) the accredited person must be the one who supervises and trains others working in the same company; (3) all pest control contracts must specify the use of the pesticides to be applied; (4) the business must be equipped with the required safety equipment and protective clothing for those doing the pesticide applications; (5) the company must have an occupational health programme for workers exposed to pesticides; (6) the company must put in place a maintenance programme for the spray equipment; and (7) the company must keep records of all pesticide-related operations.

4.5.6 Specific uses

Licensing requirements may also be established for special applications conducted by agricultural producers themselves, who are not contracting commercial operators for pesticide application. This could be the case for aerial applications, for instance for large plantations. Another example could be large fumigation operations.

Use of severely restricted pesticides is generally conditioned upon holding a specific license to use such products. Requirements to obtain such a license minimally include proof of knowledge about pesticides (including their proper handling, risk reduction and dealing with emergencies), use of the appropriate protective gear and application equipment, health monitoring of employees.

Other areas for which specific licenses or permits may be required include use of non-registered pesticides for research purposes or emergency applications. Such licenses should

¹¹ Expected to be published in 2015

put restrictions on the extent to which such pesticides can be used in terms of purpose, location and duration.

4.5.7 Other license schemes

Countries may also decide to set up other licensing schemes to strengthen the regulatory control over different activities, such as, for instance, pesticide transportation, disposal or waste management or pesticide training services.

Key Elements: Licensing

The pesticide law should:

- identify which pesticide-related activities (manufacture, sale, transportation, import, special applications) are permitted only to operators that hold a valid license;
- establish the necessary licensing schemes and designate the responsible authorities for their implementation.
- establish procedures and requirements for obtaining a license. The requirements should serve to ensure proper storage, handling, packaging and use.
- impose specific and more restrictive requirements for severely restricted pesticides;
- establish the term of validity of licenses and the procedures and criteria for renewal, suspension or revocation of licenses;
- clearly stipulate the obligations of license-holders and the consequences of non-compliance;
- ensure that Licensing schemes are backed up with inspections;
- enable the authority to impose fees for services associated with licensing; and
- set out an appeal process for cases where the license holder disagrees with denial or revocation of a license.

4.6 Packaging and re-packaging

The Code of Conduct defines packaging as “*the container together with the protective wrapping used to carry pesticide products via wholesale or retail distribution to users*” whereas re-packaging refers to “*the transfer of a pesticide from any authorized commercial package into any other, usually smaller, container for subsequent sale.*”

Proper packaging can reduce confusion about the contents of packages and also lower the risk that products might deteriorate faster than average. Poorly or inappropriately packaged pesticide products may pose significant dangers to human health and the environment. For these reasons, legislation must regulate the packaging and re-packaging of pesticides.

The pesticide law (or more likely, the subsidiary regulations) will specify the technical requirements for safe and effective packaging and re-packaging of pesticides. As noted earlier, the packaging for a pesticide is generally approved under the registration scheme, with the applicant supplying an exemplar along with the application for registration. In addition, the law or its regulations should also specify some basic packaging requirements. For example, the law should forbid any person to pack, re-pack, sell, import, transport or distribute any pesticide unless it is in packaging that:

- is safe for storage, handling and use and does not present unnecessary danger to human health or the environment;
- will not degrade under normal conditions of storage in the country and normal conditions of use for a specified time period;
- does not resemble common packaging for consumable goods;
- prominently displays the approved label with clear directions for use and risk reduction measures; and
- preferably, has a safety mechanism that prevents children from inadvertently opening the container;
- preferably, is designed to make it difficult to be re-used.

According to the Code of Conduct, packaging and re-packaging may be carried out “only on licensed premises where the responsible authority is satisfied that staff are adequately protected against toxic hazards” (art. 10.3.2). The Code of Conduct also calls on governments to prohibit the re-packaging of any pesticide into food or drink containers. Repackaging of pesticides should thus be prohibited, unless it is done in accordance with established rules. Such rules may include that only the person or company holding the registration may carry out the repackaging, to avoid problems of accountability if there is contravention of registration regulations. Another rule might be that a permit is required to conduct re-packing. Exceptions may be made for repackaging of damaged containers that needs to be done to prevent contamination, provided that the new containers are labelled the same manner as the original containers. If effective controls are not feasible in a particular country, it may be better to prohibit re-packaging altogether with the exception of emergency repackaging in case of leakage or high risk of leakage due to damaged packaging. To discourage pesticides repacking into smaller containers, legislation may specify that pesticides should be imported and marketed in containers that are of appropriate size for the local market (e.g. small scale farmers, small pest control operators and domestic use).

Specific UN recommendations have been issued for the packaging of pesticides that are to be transported internationally. These are provided in the UN Recommendations on the Transport of Dangerous Goods.¹² The legislation may refer to these recommendations or more broadly to international reference standards.

Key Elements: Packaging

The pesticide law should:

- prohibit the packaging or repackaging of pesticides without an appropriate license;
- prohibit the import, packaging, repackaging, transportation, distribution or sale of a pesticide unless it is packaged in accordance with criteria provided in the law.

¹² UN Recommendations on the Transport of Dangerous Goods, UNECE,
<http://www.unece.org/trans/danger/danger.html>
http://www.unece.org/trans/danger/publi/unrec/12_e.html

4.7 Labelling

The pesticide label conveys to the end user the information needed to make decisions on how, when and how much of the product to use. It is therefore essential that end users understand the messages on the label sufficiently to motivate them to use the pesticide properly and to take the necessary precautions. Country conditions should be carefully considered in determining the requirements for labels. In developing countries or in countries with economies in transition, end users may be illiterate or literate only in a local language or dialect. Accordingly, the legislation should require that the label is in the national language or languages and make use of GHS symbols, internationally recognized pictograms, and colour codes when appropriate. The legislation should also ensure that labelling requirements apply equally to imported and locally manufactured products.

The pesticide legislation should specify what information needs to be conveyed on a label. A common approach is to specify the main requirements in the law and then to refer to secondary legislation for the detailed requirements. The main requirements include:

- Product content information, including product name; product category; active ingredient name; active ingredient concentration; type of formulation; net contents.
- Hazard and safety information, including: hazard symbols and statements; signal words; precautionary statements, warnings and pictograms; hazard colour bands; first aid and medical advice, including, where available, the phone number of a poison control centre.
- Directions for use, including field of use (target crops/pests); dosage; mode of application; personal protection; pre-harvest intervals; storage and disposal; etc.
- Supplier identification and contact number.

The FAO/WHO Guidelines on Good Labelling Practice for Pesticides (2015)¹³ provide detailed guidance on labelling requirements. These guidelines serve as voluntary international standards for labelling. Following these guidelines thus contributes to the international harmonization of label requirements.

To avoid that labels are on outside packaging that contains a number of smaller sachets or bottles, the legislation should indicate that the label must be affixed to the smallest unit available for sale. The regulations may also state that in the event that all of the information cannot fit on the label directly affixed to the packaging, it is permitted to include an accompanying leaflet, but only where the affixed label clearly indicates the need to read the leaflet and still includes the most crucial information.

The pesticide legislation should establish the required format for the effective communication of label information. Depending on the national context, this may include the size of the label, the system of weights and measures to be used, the language(s) to be used, use of additional information leaflets, pictorial representations and/or requirements that vendors read labels to customers at the time of purchase. The legislation should also require that labels be resistant to normal wear and tear encountered in transport, storage and use over the course of the reasonably anticipated period that it may take for the product to reach the end user and be

¹³ *Add link once approved and posted*

used. Labels should also be printed in non-fading ink colours and be firmly affixed to the packaging.

The law will generally prohibit the sale of a pesticide unless it bears a label that meets the requirements as specified in the legislation and that has been approved by the responsible authority as part of registration. The label should also comply with general requirements established in any other general labelling legislation that might be in force.

Legislation may also establish requirements for the elaboration of a Safety Data Sheet (SDS) for each pesticide or pesticide product.¹⁴ The SDS is a specific form containing information on the hazard potential of the pesticide product, usually provided by the supplier (e.g. manufacturer or importer). Usually only medium and high risk pesticides must have SDS. In contrast to labels, which are attached to the pesticide product or its package, a SDS is a separate document including similar but more comprehensive information. A SDS usually includes more specific data regarding ingredients of the pesticide (active and inert), toxicology, first aid measures, handling, storage, personal protection, emergency measure in case of leakage or fire, disposal and transport. As it did for labels, the pesticide legislation will establish requirements for the form and language of a SDS in the national context. Countries implementing the GHS will need to have GHS-compliant SDSs.

The Rotterdam Convention obliges exporting parties to require that a SDS be sent to each importer of pesticides included in Annex III and of pesticides banned or severely restricted in the exporting country. The SDS must set out the most up-to-date information available and be in one of the official languages of the importing party (if practicable). The Stockholm Convention also encourages parties to use SDS to provide information on POPs.

Key Elements: Labelling

The pesticide law should:

- require that labels be subject to approval by the registration authority during the registration process;
- prohibit the sale of pesticides that are not properly labelled;
- outline what information must be provided on the label and, where relevant, indicate how this will be further specified. It should also provide the label language and format, and acceptable alternatives if labels do not fit on the package.
- refer to the relevant international standards and recommendations on pesticide labelling, including the FAO\WHO Guidelines on Good Labelling Practice for Pesticides.

¹⁴ GHS recommends use of the term Safety Data Sheet (SDS), which replaces the previously commonly used term Material Safety Data Sheet (MSDS).

4.8 Use

While the registration system identifies which pesticides are permitted in the country, use provisions dictate how the registered pesticides may be used. These are essential because even approved pesticides, when used improperly, can pose serious threats to human health and the environment. The Code of Conduct (art 7.1) therefore stipulates that “*Responsible authorities should give special attention to drafting legislation on the availability and use of pesticides. These should be compatible with existing levels of user training and expertise. The parameters on which decisions on the availability and use of pesticides are based vary widely and should be left to the discretion of each government.*”

To reduce environmental risks, pesticide legislation should include specific provisions to this effect. These may need to be aligned with existing provisions in the country’s environmental legislation. To reduce the risks to the environment and to human health, the pesticide law should:

- require the use of prescribed protective gear;
- prohibit the use of a pesticide for a purpose, or in a manner, other than that prescribed on the label or contrary to any conditions attached to the product’s registration;
- require that application equipment is cleaned in an appropriate manner that does not pose health or environmental risks;
- require that empty containers and left-over product are disposed of, or where relevant recycled, in a manner prescribed by the legislation;
- prohibit employers from recruiting children, pregnant women or other vulnerable persons to apply pesticides which may pose an unacceptable risk to their health;
- prohibit employers from requiring employees to use a pesticide for any purpose, or in any manner, that is not approved under the legislation;
- require employers to provide the necessary training and appropriate personal protective equipment to employees who handle pesticides; and
- require employers to provide periodic health evaluations of employees involved in the handling and use of pesticides in order to identify, assess and treat any pesticide-related illness or injury.

Pesticide legislation may also provide use restrictions related to environmental risk reduction, such as the use of buffer-zones, restrictions to aerial application, specific use instructions or restrictions for certain groups of pesticides (e.g.: fumigants, seed dressings), etc.

Pesticide legislation could also establish that pesticides should be used as much as possible within a context of Integrated Pest Management (IPM) and appoint the authority tasked with provision of farmer advice and education to enhance the uptake of IPM. Another concern is the prevention of the development of pesticide resistance.

Specific use requirements for Pest Control Operators (PCOs) may be detailed in secondary legislation related to the licensing and/or authorization of PCOs (see 4.5.5).

The Code of Conduct provides that governments should also regulate the types of pesticide application equipment and personal protective equipment sold on the market to ensure that

these conform to established standards.¹⁵ Guidance on regulating application equipment is provided by a specific set of FAO guidelines related to testing, certification and minimum requirements for agricultural pesticide application equipment.¹⁶

In general, governments should closely monitor protection for workers exposed to pesticide products. Legislation should establish a hierarchy of controls to monitor and reduce risks for workers, particularly in developing countries where appropriate personal protective equipment may not be sufficiently available to protect workers from exposure to health hazards. Such a hierarchy of control may specify responsibilities of employers, local government and national government in protecting workers. Workers involved in daily application of pesticides (e.g. for vector control under public health programmes; application teams on plantations; employees of commercial pest control operators) should be required by legislation to undergo routine risk assessments/health surveillance. Often only those employed under full contracts of employment are entitled to full protection, while family members, informal labourers, temporary and seasonal workers and self-employed workers are not. In this regard, the pesticide law should have a special provision to prevent the use of pesticides by and sale of pesticide to children. The ILO Convention No. 182 on the Worst Forms of Child Labour and No. 184 on Safety and Health in Agriculture may be used as guidance on these matters (see 5.1.1).

Key Elements: Pesticide Use

The pesticide law should:

- prohibit the use of pesticides for a purpose, or in a manner, other than that prescribed on the label;
- prescribe the use of personal protective equipment, proper application equipment, responsible cleaning of application equipment and safe disposal of empty containers with the objective of protecting health of users and the public, and the environment;
- require employers to take the necessary measures to protect the health of workers (provision of training, protective equipment, health monitoring, etc.) and to prevent use by children and other vulnerable groups; and
- ensure that the government has the authority to monitor workers' health and enforce provisions affording protection and reducing risk from pesticide use.

4.9 Advertising

Advertising can have a powerful effect on decisions to purchase and use a product, and thus any effective regulatory system for the management of pesticides must include clear advertising rules. Although many countries already have general legislation on false or

¹⁵ There are no established (UN-level) international standards for quality of protective gear. One could refer to EU or US standards. The most important point is that protective gear used actually provides the necessary protection to the risk posed by the pesticide being handled.

¹⁶ <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/>

misleading advertising, provisions directed specifically at pesticides are more effective. The Code of Conduct therefore stipulates that “*Governments should approve and implement legislation to regulate the advertising of pesticides in all media to ensure that it is in line with the conditions of registration as regards label directions and precautions, particularly those relating to proper maintenance and use of application equipment, appropriate personal protective equipment, special precautions for vulnerable groups and the dangers of reusing containers.*” (Art 11.1)

Because advertising of pesticides may take many different forms, legislation must have broad coverage to be effective, especially in developing countries with low literacy rates, where printed media account for only a small fraction of promotional activities. Advertising, for instance, should also include field demonstrations of specific products by anyone with an interest in selling such products. The Code of Conduct defines advertising as “*the promotion of the sale and use of pesticides by printed and electronic media, signs, displays, gifts, demonstration or word of mouth.*”

In addition to setting out a clear definition of advertising, the legislation should designate the authority responsible for enforcement. The FAO\WHO Guidelines on Pesticide Advertising (2010) provide detailed suggestions in this area. The guidelines recommend the designation of a responsible authority to promote awareness about advertising standards, receive complaints about violations and liaise with appropriate law enforcement officials to impose sanctions or penalties.

The pesticides legislation should prohibit advertising any unregistered or illegal pesticide; advertising any pesticide in a false or misleading manner; or advertising uses that are contrary to the conditions of the registration of the pesticide or contrary to its approved label instructions. Subsidiary regulations should be used to address specific words, phrases or claims that are prohibited in the course of advertising pesticides or pesticide products. National circumstances and the types of advertising recognized as problematic should be taken into account when elaborating these types of provisions.

Regulations could require that:

- all statements used in advertising are technically justified and do not contain any statement or visual presentation which, directly or by implication, omission, ambiguity or exaggerated claim, is likely to mislead the buyer, in particular with regard to the “safety” of the product, its nature, composition or suitability for use, official recognition or approval;
- pesticides which are legally restricted to use by trained or registered operators are not publicly advertised other than through journals catering for such operators, unless the restricted availability is clearly and prominently shown;
- advertising does not encourage uses other than those specified on the approved label;
- promotional material does not include recommendations at variance with national regulatory decisions;
- claims as to safety, including statements such as "safe", "non-poisonous", "harmless", "non-toxic", "environmentally friendly" or "compatible with IPM/ IVM," are not made on labels, pamphlets or other publicity material, with or without a qualifying phrase such as "when used as directed". [However, reference to use within specified

IPM/IVM programmes may be included if validated by the regulating authority, and the claim is qualified accordingly];

- advertisements do not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, use near food or use by or in the vicinity of children;
- advertising or promotional material draws attention to the appropriate warning phrases and symbols as laid down in the GHS and FAO/WHO labelling guidelines; advertisements and promotional activities should not include inappropriate incentives or gifts to encourage the purchase of pesticides.

For further guidance on provisions related to advertising, reference is made to article 11 of the Code of Conduct and the supporting technical Guidelines on Pesticide Advertising (2010).

Key Elements: Advertising

The pesticide law should:

- set out specific requirements for pesticide advertising;
- define pesticide advertising broadly to cover all forms;
- designate the authority responsible for enforcement;
- prohibit the advertising of unregistered or illegal pesticides, false or misleading advertising of pesticides and advertising contrary to approved uses or label instructions; and
- elaborate detailed requirements in subsidiary regulations.

4.10 Storage, transport and disposal

4.10.1 Storage

In most jurisdictions, pesticide storage is regulated under both pesticide legislation and other legal instruments addressing the storage of hazardous substances, or noxious activities or under chemicals legislation. It is therefore important that regulators pay attention to all potential legislation addressing general storage requirements before drafting the section on storage of the pesticide law.

Pesticide legislation should provide general storage requirements that apply to all pesticide storage. These may include: full separation of stored or displayed pesticides from food products or other consumables; adequate ventilation; impermeable floors; adequate protection against unauthorized access; availability on location of the necessary materials and equipment to deal with leakage and other emergencies; etc.. Further requirements can be established for pesticide storage above certain quantities or for a specific category of stores or products. Such a provision may require further safety measures and pose restrictions on the location of stores in order to minimize risk. This could apply to locations in habitation areas, near hospitals, schools or waterways. The legislation will likely differentiate on scale of storage, which varies from bulk storage by an importer to storage of small stocks at a village store. Facilities

where pesticides are to be stored in large quantities generally would require more stringent conditions, including provisions for the design of storage buildings, including impermeable flooring, facilities for easy loading and access in case of emergency. Requirements for the storage of large quantities of pesticides generally also include elements such as availability of firefighting equipment and other equipment to deal with emergencies; ventilation; ramps; security; and access to storage records and safety data sheets for products stored.

Specific procedures are required for obsolete pesticide stocks in storage. The law will generally require any person or entity with such stocks to notify the responsible authority regarding the specific amounts, types, locations and ages of the pesticide products that are no longer usable.

In addition to the above general requirements that apply to all pesticide storage, a license might be required for pesticide storage involving particular risks (see 4.5.3).

4.10.2 Transport

The transport of pesticide products and pesticide-related waste might be regulated under pesticide legislation and/or under other national legislation addressing the transport of hazardous substances. This may include transportation legislation that implements the relevant international standards, such as the United Nations Recommendations on the Transport of Dangerous Goods, the International Maritime Dangerous Goods Code and the Technical Instructions for the Transport of Dangerous Goods by Air. Revised national pesticide legislation thus might only refer to existing applicable legislation on transportation. But if there is no general transportation law, or if that law does not cover pesticides, the national pesticide law should include some basic provisions on transport.

The legislation should establish requirements for vehicles and containers used for transport of pesticides. It should also provide that pesticides are not transported in the same vehicles as passengers, animals, foodstuffs, animal feeds or other items meant for human consumption. The legislation should provide that where joint transport is unavoidable, the pesticides should be adequately physically separated with no risk of contamination of the other goods¹⁷. Vehicles carrying bulk quantities of pesticides should have the necessary hazard placards and should carry Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS) for the product(s) concerned. The legislation should also address the procedures applicable when there is a pesticide accident or spillage during transport.

Under the Basel Convention, any movement of hazardous wastes (which includes obsolete pesticides) should be accompanied by a movement document, and should adhere to generally accepted and recognized packaging, labelling and transport requirements. According to the convention, countries must also require proper documentation for such wastes in shipment, and prior consent must be obtained from every country through which the waste will pass before transportation begins.

¹⁷ . The Pesticide Storage and Stock Control Manual (1996) provides guidance on requirements for the transport of pesticides: <http://www.fao.org/docrep/v8966e/v8966e00.htm>

4.10.3 Disposal

The disposal of pesticides and pesticide-waste might already be partially covered under different legal instruments, including waste disposal, environmental protection or chemicals legislation. The disposal of empty pesticide containers, however, is usually specifically addressed in the pesticide law. The pesticide law should refer to, or designate, the national authority responsible for the disposal of pesticide waste and regulate that:

- the disposal of pesticides and pesticide waste should be conducted in compliance with instructions provided by the designated national authority;
- any spills or other emergencies related to pesticides should immediately be notified to the designated national authority.
- anyone witnessing any illegal dumping of pesticides, or finding a dumping site, has the obligation to notify the designated authority or the local police.

Thus, at a minimum, the national pesticide law should prohibit the following actions:

- pouring pesticides down drains or into water sources or drainage channels;
- burying pesticide-related waste; disposing of pesticide-related waste in general landfills instead of in approved landfill sites designed to prevent contamination; and
- burning pesticide-related waste, unless in an approved incinerator.

Exceptions may be made for certain types of containers, or containers that are rinsed in specific ways, which can be disposed of in ordinary landfills. Often, national legislation on waste disposal is already in place and should be taken into account.

Under the Code of Conduct, pesticide companies are encouraged to assist in the disposal of any banned or obsolete pesticides and used containers in an environmentally sound manner. The legislation could establish that the importer/distributor remains responsible for disposal costs for pesticides after confiscation for violations of legal requirements, or after stocks in the possession of the importer/distributor have become obsolete as a result of excessive importation or poor storage.

The Code of Conduct calls for measures to prevent the accumulation of obsolete pesticides, which often arises from excess donations or imports of pesticides to deal with emergencies, or from unused public health pesticides purchased for the purpose of vector control programmes. Other possible causes include: (1) products are banned while there still are quantities of it in store (e.g. certain POPs such as dieldrin, once used widely against locusts in Africa); (2) products are physically deteriorated due to prolonged or improper storage; or (3) stock is poorly managed, for instance due to poor record keeping. To prevent accumulation, legislation should in principle include provisions for phasing-out periods when pesticides are to be banned or de-registered, unless there is acute danger. Furthermore, legislation should include provisions requiring inventories of obsolete pesticide stocks or other measures to promote proper stock management.

Specific procedures are required for obsolete pesticide stocks in storage. The law will generally require any person or entity with such stocks to notify the responsible authority regarding the specific amounts, types, locations and ages of the pesticide products that are no

longer usable. The authority then determines the best course of action, which will depend on the disposal options available in the country.

Waste contaminated with, or consisting of, pesticides poses a particularly grave problem for many developing countries and countries with economies in transition, in that the correct treatment or disposal facilities are generally not available in these countries and users may have inadequate knowledge of the hazards posed by improper disposal. Legislation should require that any person or entity wishing to carry out disposal of pesticide-related waste seek authorization from the responsible authority and give notice of the disposal plan. Disposal, and remediation of contaminated sites, must take place in an environmentally sound manner, the details of which will be established in the legislation. Generally, this would be in environmental legislation or broader legislation on chemical or hazardous substances, not necessarily the pesticide legislation itself.

The Basel Convention is particularly relevant to the disposal of hazardous wastes, as it would apply to many, if not most, obsolete pesticide stores and pesticide-related wastes. Although the convention's primary objective is to prohibit the dumping of hazardous wastes in other countries and to control waste exports, it also contains obligations regarding domestic disposal. To comply with the Basel Convention, national legislation should prohibit removal of hazardous wastes to another country without the proper notification, receipt of permission through the country's focal point or responsible authority and proof that a contract has been concluded between the exporter and the disposer providing that such wastes will be managed in an environmentally sound manner. The legislation should also prohibit the import of hazardous pesticide wastes from another country without consent.

The Stockholm Convention addresses the identification and environmentally sound management of stockpiles, waste and contaminated sites containing POPs, and thus has to be taken into account when POPs are present among the pesticides to be disposed of. Some POPs containing waste have to be disposed of in such a way that the POPs content is destroyed or irreversibly transformed into non-POPs. Like the Basel Convention, the Stockholm Convention advocates waste prevention and minimization.

FAO has produced several tools and guidance documents that may be useful for the development of legislative provisions on disposal.¹⁸

Key Elements: Storage, Transport and Disposal

The pesticide law should:

- where relevant, refer to broader existing national legislation on storage, transport and disposal of hazardous materials and ensure consistency with this broader legislation;
- establish requirements for storage, transport and disposal of pesticides in so far these are not yet covered by broader legislation and thereby follow international standards for the transport of dangerous goods and the disposal of hazardous substances and wastes;
- designate the responsible authority(ies) for regulating, monitoring and enforcing

¹⁸ Environmental Management Tool Kit for Obsolete Pesticides - Volumes 1-4, Guidelines for the Management of Small Quantities of Unwanted and Obsolete Pesticides (1999), Guidelines on Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries (1996), Provisional Guidelines on Prevention of Accumulation of Obsolete Stocks (1995), Guidelines on the Management and Disposal of Used Containers (2007) and Guidelines on Management Options for Empty Pesticide Containers (2008)

provisions related to the storage, transport and disposal of pesticides in so far these have not yet been designated under broader legislation;

- prohibit the transport of pesticides in the same vehicle as passengers, animals, food or feed, or require physical separation in cases where joint transport or storage is unavoidable;
- include specific provisions on the disposal of empty pesticide containers. Usually these include prohibition of specific practices likely to pose risk to health or the environment;
- oblige persons responsible for storage, transport or disposal to immediately report incidences to the established authorities;
- for parties to the Basel and Stockholm Conventions, include requirements for the transport and removal of hazardous pesticide wastes and their disposal.

4.11 Information collection and monitoring

The collection of information about pesticides in a country is crucial because the details of current risks and incidents, as well as usage trends, can usefully inform policy choices, strategies and actions. For example, a programme that monitors which pesticides are causing problems (e.g. pesticide poisoning or environmental impact) can help determine whether a pesticide should continue to be registered for use or whether that use should be limited in some way. Furthermore, information on the risks associated with pesticide use can be used to build an effective public information campaign to raise awareness of those risks. It may also alter the decision to approve particular packaging or labelling, since either or both of these may increase or decrease the risks associated with a product. Similarly, evidence of rising or excessive use of pesticides on particular crops or in certain areas can provide guidance to agricultural strategies.

Pesticide legislation designates the responsible authority and assigns it the obligation to carry out monitoring and data collection, including collecting information and obliging others to keep and convey information. For example, the authority may have the power to require manufacturers, importers, distributors and sellers of pesticide products to keep records for a specified time period, to make their books and records available for inspection at all reasonable times and to report any incidents of health problems or environmental contamination resulting from pesticide use. These rules should be in accordance with the Guidelines on developing a reporting system for health and environmental incidents resulting from exposure to pesticides (2006), and should also take into account specific national circumstances.

Inspectors serve an important information-gathering function in a pesticide management system. They serve as the front line of enforcement of the pesticide legislation and, depending on the situation in the country, will visit manufacturers, importers, distributors, retailers and bulk users. Through their inspections, they will collect vital information about sale without license, sale of non-registered pesticides, labels that do not conform to the legal requirements, and other concerns such as adulterated pesticides, overstocking, mishandling, uses other than indicated on the label and mislabelling of pesticides. Such information should be used to identify issues that require further attention at policy or legislative level. It may also inform the process for registration and re-registration of pesticides.

The Rotterdam Convention requires pesticide incident reporting for certain pesticides (see below).

Key Points: Information Collection and Monitoring

The pesticide law should:

- assign responsibilities for monitoring and data collection with respect to pesticides;
- set out the powers and responsibilities of the responsible body, including the possibility to impose reporting requirements on manufacturers, importers, distributors and seller of pesticides.

4.12 Incident reporting

Regulatory frameworks for the control of pesticides generally contain provisions for the reporting of incidents. This can be directly under the pesticide law, or under broader chemicals law, or environmental, public health or labour legislation. Attention for consistency with other national legislation is thus important when including provisions on incident reporting in the pesticide legislation.

The legislation should specify when an event involving pesticides is considered an “incident.” These should include industrial and other accidents that involve pesticides and have an actual or potential negative impact on human health, the environment or crops (e.g. spills during transport, illegal dumping, fish die off due to water contamination, high number of poisoning cases within a community, etc.). Deliberate self-poisoning with pesticides as a means of committing suicide may require specific attention regarding incident reporting.

Legislation should establish a mechanism for pesticide-related incidents to be reported. Those involved should be obliged to report any significant spills, leakages or accidents during transport or storage of large volumes of pesticides to the relevant authorities. It should also establish responsibilities to provide and coordinate responses, including investigating pesticide incidents and monitoring the health of occupationally exposed individuals. Further, there can be provisions that require the local or national authorities to inform those parts of the public that might be at risk as a result of the incident, and/or to take other necessary measures to prevent harm.

The Rotterdam Convention requires reporting of incidents involving severely hazardous pesticide formulations. Guidance is provided in “*Guidance on monitoring and reporting pesticide poisoning incidents related to severely hazardous pesticide formulations.*”¹⁹

Labour law legislation may oblige employers to keep a record of incidents causing injuries to workers and to make such reports available to the pesticide authority. The health ministry or agency likely is obliged to keep records of all cases of poisoning by chemicals, including

¹⁹Forms for reporting on environmental incidents and for reporting on human health incidents related to severely hazardous formulations are available from the Rotterdam Convention website.
<http://www.pic.int/Implementation/SeverelyHazardousPesticideFormulations/SHPFKit/tabid/3114/language/en-US/Default.aspx>

pesticides, as reported to poison control centres or hospitals. The ministry of agriculture may collect field data through its plant protection or extension services. Such information will be useful in monitoring pesticide risks under actual use conditions. This could contribute to review and modification of the registration conditions, or even to cancellation of the registration of a pesticide. Similarly, the effects of pesticides on the environment should be monitored and any unacceptable adverse effects notified so that, if required, uses can be modified or even banned or severely restricted.

Key Elements: Incident Reporting

The pesticide law should:

- specify which events constitute an “incident”; and
- establish a mechanism for the reporting of pesticide-related incidents by all relevant authorities and parties in a manner that it is consistent with other legislation, such as labour or public health laws.

4.13 Inspection

A reliable inspection system for pesticides serves a number of purposes. Inspection of places where pesticides are sold can help ensure vendors’ compliance with legal provisions concerning the registration, import/export, storage, packaging, labelling and advertising of pesticides. Inspections at border points can prevent the entry of prohibited pesticides, such as products that have not been registered (including banned pesticides), are not properly packaged or labelled, or whose shelf-life has expired. Inspections at the place of manufacture can ensure that facilities have safety systems in place and follow associated procedures to provide a safe working environment and to ensure products meet the required standards. Inspections at the workplace or farm can contribute to the proper use of pesticides, preventing harm to human health and the environment. The inspection system also allows the responsible authority to collect information relevant for its evaluation of applications for licenses to carry out certain activities in relation to pesticides, and for it to determine whether license holders are meeting license conditions.

The national pesticide law generally designates the national authority (or authorities) responsible for inspection. There could be different authorities responsible for different subjects of inspections. For example, even where the ministry responsible for agriculture is assigned overall enforcement authority under the law, it may wish to rely on customs officers at border points if there are not sufficient ministry employees to serve at those remote locations. Along the same lines, the ministry of environment may play a relevant role in inspections related to pesticide waste or disposal and the ministry of health in incident reporting. If different authorities are involved in pesticide inspections, clear mechanisms for coordination should be established.

The law should further provide for the appointment of qualified persons to act as pesticide inspectors, and establish the mandate of inspectors and the procedures for inspection. The latter can be detailed in subsidiary regulations.

The establishment of the mandate for inspection is important. In many countries inspections have limited effect because the powers of the inspectors are not sufficiently defined.

Inspectors are the main point of contact between the government and the pesticide industry and between the government and pesticide vendors and users, and thus their powers must be clearly defined in legislation. Inspectors must have the power to enter a variety of locations, including private premises used for the storage of pesticides (which are not used as dwelling places), to stop and search vehicles, persons and containers, in order to ascertain that all aspects of the legislation are being complied with. Because these powers can be very similar to those of police and may therefore affect personal liberties, the pesticide law should clearly outline the parameters of the inspectors' powers.

Other inspection powers include the ability to take samples, to seize equipment, products and documentation, to ask questions, to request and review purchase and sales records, to take photographs and to shut down operations. The latter can include administrative measures such as the closure of an establishment or the precautionary suspension of a license in case of violation of requirements attached to the license. In some countries the law allows inspectors to issue spot fines. If spot fines are allowed there should be adequate safeguards against abuse of power. Legislation may, for instance, include a provision that stipulates that inspectors operate in teams and that written notices and receipts are issued. The law may also include specific penalties for inspectors who abuse their power or accept money informally. The law should require inspectors to display their identification card when carrying out their duties, and permit them to request the presence and assistance of the police where needed. Secondary legislation may enumerate in more detail inspectors' duties and responsibilities, and may outline procedures for how inspectors should carry out inspections, take and mark samples and submit them for analysis. These last rules are designed to ensure that the samples can be properly admitted and used in a court of law. The FAO\WHO Guidelines for the Quality Control of Pesticides (2011)²⁰ provide useful guidance.

Seizing of banned or counterfeit pesticides may be necessary to prevent these from being sold. However, one should be aware that after seizing such products, these need to be stored somewhere safely and eventually they will need to be disposed of. As many countries do not have appropriate disposal facilities for hazardous waste, it is important to provide clear instructions to inspectors and local authorities on what to do with seized products. Although this generally will not be prescribed at the law level, it is important to develop a collection, storage and disposal scheme when inspectors are empowered to seize pesticide products.

In addition to the inspection corps, the law should establish a mechanism for the designation of official analysts and laboratories that will carry out the required analysis of samples taken under the law. Usually the minister or the responsible authority is given the power in the law to designate the official laboratories and to appoint official analysts. In many countries there is a trend to rely on private or university laboratories and their staff for some or all of these functions, and therefore this should be allowed under the law. Official laboratories may also be assigned on a regional basis, which can be helpful in regions where individual countries do not have the resources to establish and maintain their own laboratories at the required standards. Secondary legislation may set rules for the operation of the laboratories as well as for how official analysts should receive and analyse samples and communicate the results.

²⁰ http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Quality_2011.pdf

Further guidance on inspection is provided in the Guidelines on Licensing and Inspection of Pesticide Retailers (2015).²¹

Key Elements: Inspection

The pesticide law should:

- designate the national authority (or authorities) responsible for inspection;
- provide for the appointment of qualified inspectors;
- define the powers of inspectors and ensure that these are adequate to enable the inspectors to fulfil their duties.
- provide procedures and criteria for inspections. Criteria should be linked to licensing requirements;
- provide procedures and requirements for sample taking, as well as provisions for the designation of official laboratories for analysis of samples; and
- provide clear and effective procedures for intervention if irregularities are found during inspections.

4.14 Offences and penalties

Except in countries where offences and penalties are contained in a separate law, the pesticide law will contain enforcement provisions consisting of a list of offences, the penalties associated with each violation and the applicable procedures once an offence has been committed. Enforcement provisions play an essential role in ensuring compliance with the pesticide law. The Guidelines on Compliance and Enforcement of a Pesticide Regulatory Programme (2006) are a useful source of information on enforcement issues in the pesticide context.

4.14.1 Offences

The first task is to establish the offences under the law. These should include actions not only by the industry, distributors and users, but also by persons acting officially on behalf of the responsible authority. Some of the possible offences that can be stipulated in legislation include:

- manufacturing, importing, storing, distributing, selling or using a pesticide that has not been registered;
- selling or distributing a pesticide that does not meet the specifications as stated when the product was registered or a pesticide that is adulterated or counterfeit;
- performing any function for which a license is required without having obtained that license;

²¹ Expected to be published in 2015

- failing to comply with any conditions of registration or licensing;
- violating the packaging, re-packaging, labelling, advertising, storage, use or disposal requirements;
- supplying a pesticide in a container that has deteriorated or been damaged;
- selling or distributing a pesticide without an approved label attached to it;
- detaching, altering or destroying any label on the container of a pesticide product;
- using a pesticide in a manner that is not consistent with the approved label;
- advertising in a false or misleading way;
- making false or misleading statements or providing false or misleading information in an application for registration or licensing or in required reports or records;
- participating in the illegal traffic of pesticide products (including transporting pesticide-related waste across an international border);
- making shipments contrary to the import decisions of a country under the Rotterdam Convention or under the Basel Convention;
- improper disposal of pesticides by manufacturer, importer, distributor, retailer or bulk users.
- failing to report incidents related to pesticides that are subject to mandatory reporting, or otherwise failing to keep required records; and
- hindering or impeding an inspection or assaulting an inspector.

Offences by officials such as inspectors or officers of the registration authority could include:

- accepting, rejecting or otherwise acting on any application for registration or for a licence for any reasons other than those listed in the pesticide legislation as applicable criteria;
- participating in any administrative decision in which the individual has a personal interest including a familial relationship or financial stake;
- knowingly disclosing any confidential information acquired in the course of official duties, except in limited circumstances (e.g. court proceedings);
- otherwise abusing their power.

After an offence has been identified, the next step would be to decide the severity of the offence. Most countries distinguish between administrative and criminal offences, where criminal offences might be included in Criminal Codes.

In some countries, the answer may already be provided for in the constitution (or in other countries, the criminal code); the answer may also be a function of the country's international commitments. For example, the Basel Convention requires that parties consider illegal traffic in hazardous wastes or other wastes a criminal activity.

In other jurisdictions, it may be possible to define some types of offences as administrative violations, meaning that the power to prosecute violations is vested in the administrative agency, not a judicial body. Thus the responsible authority would have the power to take administrative action to punish certain kinds of violations. Such administrative sanctions

could include small fines and administrative measures such as the withdrawal of registration or license.

4.14.2 Penalties

Having defined the offences and their level of severity, the legislation must then outline the applicable penalties. Options for penalties include monetary sanctions (fines) and administrative measures (suspension or revocation of registration or a licence). Other sanctions might include requiring the offender to pay the cost of clean-up, disposal or other necessary measures to mitigate the damage caused by the offence. Imposition of a term of imprisonment is permissible for criminal offences, if so provided in legislation.

Different penalties may be assigned to different offences according to the severity of the offence or its consequences. Aggravating factors, which would increase a penalty, could apply in certain circumstances, such as where the offence caused irrevocable damage, permanent disability or death of an individual or in case of repeated offence. It is important to ensure that the level of the penalties is high enough to be a deterrent, but without becoming disproportionate to the offence committed.

It is not recommended to provide actual amounts of fines in the law, because these then would remain at the same level for years or decades while their deterrent value declines due to inflation. A common solution to avoid quantifying fine levels in the law is a system whereby the pesticide legislation establishes the categories of violations, in reference to a neutral economic parameter, such as a cost-of-living index or the monthly salary of a civil servant of a particular grade, to calculate the fine level. In this way, a minor offence might for instance be defined as one quarter the monthly salary of a civil servant from a medium management level, while a serious offence might attract a penalty equivalent to ten times that same monthly salary. The advantage of using such neutral parameters is that it does not name particular amounts, and thus the penalties can be expected to rise over time. Another solution is to include the possibility for the amount to incorporate inflation rates.

4.14.3 Rights and appeals related to enforcement procedures

The law should next set out the procedures applicable once an offence has been committed (unless this is governed by a criminal or administrative procedure code). The main purpose of the procedural rules is to guarantee constitutional or other basic legal rights. Procedures regarding notice, the right to a hearing and the right to appeal a negative decision are designed to protect an individual's rights, particularly the right to due process and to a proper defence. Thus, in most countries, the legislation requires that once a violation has been committed, the offender is served notice to inform him or her of the facts, the date and nature of the offence and the assessed penalty. Notice is served prior to the imposition of a penalty so as to afford the accused a reasonable opportunity to object, either in writing or in person.

The legislation should also include provisions for appeals against negative administrative decisions of the responsible authority. For example, the law should permit an applicant for registration to appeal a negative decision by the authority, for example to deny or suspend registration or a licence, within a specified time period. The law should indicate which party or body will hear the appeal (such as the head of the responsible authority, the minister responsible for enforcement of the pesticide law or a specially created appeals board). In some jurisdictions the appeals are heard in the regular court system.

4.15 Miscellaneous and Final provisions

Pesticide laws usually contain provisions covering issues that do not fit into any of the categories already addressed. For example, miscellaneous provisions may address liability issues, stating that inspectors or officials are not liable for anything done in good faith in the performance of their functions under the law. Other provisions may specify the liability of corporate officers in the case of a corporation committing an offence.

4.15.1 Presumptions

The law may also specify legal presumptions applicable under the law, although this will depend on the legislative practice of the country, since in some countries presumptions will be contained in a civil procedure or criminal procedure law. Typical presumptions include the presumption that a certificate of analysis purporting to be signed by the director or head of an official laboratory shall be accepted as evidence of the facts contained in it; the presumption that a package that bears the name and address of a manufacturer was manufactured by that person; and the presumption that all the contents of a container or consignment from which a sample was taken are the same as the sample.

4.15.2 Repeals, savings and transitional clauses

When drafting a new pesticide law, it is important to explicitly refer to any existing law or legal provisions that are repealed by the new law as well as those saving clauses that would limit the scope of repeal of prior legislation.

The new pesticide law may also include some transitional provisions to ensure a clear transition between the previous and the new system in manner that guarantees that all newly registered products meet the requirements of the new law and products registered under the former system will smoothly be aligned to these new requirements. Such transitional provisions may, additionally, define the validity of product approvals, or licenses granted, under the previous legislation, and where relevant, provide a timeframe for adjustment. It is routine to include a clause that renders anything that is inconsistent with the new law as superseded.

4.15.3 Power to make regulations

Most pesticide laws include a provision listing the many subject matters that the minister (or other person in whom the power has been vested, such as the head of the responsible authority or the pesticide registration board) may address through regulations in order to carry out the purposes of the law. Depending on local practice, the list of regulations may be extremely detailed or it may simply give broad outlines of the kinds of topics that may be addressed. In either case, the power to make regulations is rarely limited, since the law usually contains a general statement that the relevant authority may make all regulations deemed necessary to achieve the purposes of the law.

Among the many topics normally addressed in such subsidiary regulations are the organization and functioning of the pesticide registration board established in the main law;

date requirements and procedures for pesticide registration; detailed labelling requirements; detailed procedures for the issuance and repeal of licences, including the criteria to be used by the responsible authority in the licensing decisions; functions/responsibilities of inspectors and how they should go about their work inspecting consignments and taking samples; and the organization of the pesticide testing scheme for quality control. Regulations may also define the qualifications of inspectors and analysts operating under the pesticide law, as well as training requirements for commercial operators.

4.15.4 Implementing legislation

The decision regarding which issues to include in primary legislation (the law) and which to include in secondary legislation (regulations) varies by jurisdiction. As a general rule, the law should be kept as basic as possible and establish principles, mandates and responsibilities, while the details should be included in the regulations and other lower-level instruments. In this way, changes necessary to keep pace with scientific and other advancements or changes in the local context can be more easily made through ministerial rather than parliamentary action.

The dividing line between what is to be included in the parliamentary-level law and what should be in the secondary legislation (also referred to as subsidiary legislation or implementing legislation) depends on the legislative tradition of the country, but some general observations can be made. First, as already noted, elements that are likely to change should not be part of the main pesticide law. These would include provisions based on the state of scientific or technological knowledge, as well as any provisions that depend on a particular set of circumstances. Therefore, it would not be advisable for the main law, in establishing the membership of a Pesticide Board, to include too detailed a list of members (especially if the list has been developed with particular people in mind), since with time, those very people may move to different jobs within the same institutions or to different positions altogether. If the law identifies the membership too closely, future ministers or heads of the responsible authority would nonetheless be bound by those provisions. By the same token, the specific minister, ministry, department or division will not generally be named in the main law, since portfolios may change. Generally, the law will refer to the “minister responsible for agriculture” or the “minister responsible for health” rather than listing the full name of the ministry.

In practice, secondary legislation, such as regulations, often tend to include detailed rules on registration, labelling, permits, licensing procedures, inspection and enforcement, import/export, advertising, disposal, storage and the like.

Secondary legislation should not conflict with the main pesticide law. Terms defined in the parent law should not have different definitions in the regulations, and procedures set out in the principal legislation should be used as the framework for the more comprehensive procedures in the secondary legislation. Likewise, secondary legislation, should not regulate aspects that go beyond the scope of the parent law, or other laws. Topics like sanctions for environmental contamination, food safety, levels of fines, taxes, etc. may already be regulated under other laws.

Every effort should be made to ensure that the pesticide regulations comprehensively cover the subject in a manner that these could be maintained if for some reason the parent pesticide

law would be repealed. This could for instance be the case if pesticide legislation is integrated into broader chemicals legislation.

Key Elements: Offenses, Penalties and Miscellaneous Provisions

The pesticide law should:

- define the actions that will be considered as offences, including special offences for public officials;
- determine proportional and deterrent fines and include mechanisms to adapt the fines if their value declines;
- regulate rights related to enforcement procedures, including appeals procedures;
- take into consideration national legal presumptions and, if necessary, complete these presumptions;
- include transitional clauses that facilitate a smooth transition between the old and the new legislation;
- recognize the power of the authority to approve implementing regulations;
- define the date of entry into force.

5. Considerations in designing national legislation

5.1 International framework

A number of international agreements address pesticides directly and most countries are contracting parties to one or more of these. Other agreements affect pesticides management only indirectly. Further there are voluntary instruments that affect pesticide directly or indirectly. All of these instruments together contribute to an international framework for pesticide management that covers some of its most important aspects.

This section provides an overview of binding agreements and non-binding instruments that are relevant to pesticide management and should be taken into consideration when drafting pesticide legislation.

5.1.1 Binding international agreements

Rotterdam Convention

The growing world trade of chemicals during the 1960s and 1970s raised concerns about the risks linked to the use of hazardous chemicals. These concerns eventually led to the adoption in 1987, by the UNEP Governing Council, of the London Guidelines for the Exchange of Information on Chemicals in International Trade. The Prior Informed Consent (PIC) procedure was added to the London Guidelines in 1989. Its aims were to help importing countries learn more about the potential hazards of chemicals being shipped to them, establish a decision-making process on future imports and encourage exporting countries to take measures to prevent the export of unwanted pesticides. In 1998, the PIC procedure was

incorporated into a legally binding instrument, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam Convention). The Convention entered into force in 2004 and applies to pesticides as well as industrial chemicals.

Except for a few obligations relating to domestic production and use, the Convention mainly governs the import and export of chemicals. The PIC procedure is a mechanism for formally obtaining and disseminating the decisions of importing countries regarding hazardous chemicals. In essence, export of any chemical listed in Annex III should respect the decision taken by the importing country. The goal is to protect human health and the environment through the exchange of information about hazardous chemicals (including pesticides), enabling countries to make informed decisions about imports and exports of such substances.

Two types of chemicals are eligible to be “listed” in Annex III of the Rotterdam Convention, which makes them subject to the mandatory PIC procedure: “banned or severely restricted chemicals” (including pesticides), and “severely hazardous pesticide formulations.” Once a chemical is listed in Annex III, all parties to the Rotterdam Convention must implement the PIC procedure with respect to that chemical. Parties must also implement appropriate legislative and administrative measures to ensure that they will meet import and export obligations for chemicals subject to the Convention. The Convention also requires that the legislative and administrative measures applied to imports be no more restrictive than those applied to domestically produced goods. At the end of 2014, Annex III of the Rotterdam Convention listed 47 substances, of which 29 banned or restricted pesticides (active ingredients) and 4 severely hazardous pesticide formulations.²²

Stockholm Convention

The Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention), which entered into force in 2004, is aimed at eliminating the production and use of chemicals that are deemed to be persistent organic pollutants (POPs). POPs are organic compounds that become widely distributed throughout the environment and remain intact for long periods of time, accumulate in the fatty tissue of living organisms and are found at higher concentrations at higher trophic levels, and are toxic to humans and wildlife. In many ways, these are some of the most highly dangerous chemicals, although their effects may be seen only in the long term.

There are three different lists of chemicals under the Convention. Annex A is for chemicals that are to be eliminated, Annex B for chemicals to be restricted and Annex C for chemicals that are unintended by-products of certain production processes and are to be reduced. At the end of 2014, 26 substances, of which 16 pesticides, were listed in these Annexes. The most up-to-date list can be found at the Convention’s website²³. Many of these chemicals are also listed under the Rotterdam Convention.

Article 3 of the Convention contains detailed prohibitions on Annex A chemicals and sets out the contracting parties’ obligations to eliminate the production, use, import and export of these chemicals. It also outlines restrictions on the production and use of Annex B chemicals. Imports of chemicals for the purpose of environmentally sound disposal are exempted. There are also specific production and use exemptions for chemicals listed in both Annex A and B.

²² <http://www.pic.int/TheConvention/Chemicals/DecisionGuidanceDocuments/tabid/2413/language/en-US/Default.aspx>

²³ <http://chm.pops.int/TheConvention/ThePOPs/ListingofPOPs/tabid/2509/Default.aspx>

For example, Annex B chemicals (e.g. DDT) may be produced and used for so-called “acceptable purposes,” i.e. disease vector control in accordance with Part II of that annex. Parties to the convention therefore need to prohibit the production and use of most listed chemicals under Annexes A and B at national level. The Convention also establishes requirements for POPs stockpiles and wastes.

Basel Convention

The Basel Convention on the Transboundary Movement of Hazardous Wastes and Their Disposal (Basel Convention), which entered into force in 1992, regulates the international shipment of hazardous wastes. Although not specifically directed at pesticides, it does address obsolete pesticides and substances that may be by-products or waste products from pesticides. As such, this Convention is useful for national governments seeking to prevent the dumping within their borders of waste products such as obsolete pesticides, especially where governments may lack the capacity to manage these waste products in an environmentally sound manner.

The Basel Convention targets “hazardous wastes,” which belong to any category contained in Annex I and exhibit one or more of the characteristics listed in Annex III. Annex I includes “Wastes from the production, formulation and use of biocides” (pesticides). It particularly applies to obsolete pesticide stocks that require disposal. Annex III includes “Substances or wastes liable either to cause death or serious injury or to harm human health if swallowed or inhaled or by skin contact” and “Substances or wastes which, if they are inhaled or ingested or if they penetrate the skin, may involve delayed or chronic effects, including carcinogenicity”²⁴.

Under the Basel Convention, parties may generally prohibit the import of hazardous wastes, or may prohibit imports of specific types of hazardous wastes or specific shipments of hazardous wastes. Exporting states may only move hazardous wastes across borders after having provided prior written notification to the importing state and received written consent. Although implementation of the Basel Convention has mainly been focused on the trans-boundary movement of wastes, the Convention imposes many other obligations relevant to the development of national legislation. Parties must ensure the availability of adequate disposal facilities, establish criminal penalties for violations of the convention and require proper labelling, packaging and documentation for hazardous wastes in shipment.

Montreal Protocol

The Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) so far only addresses one specific type of pesticide (methyl bromide, which depletes the ozone layer). Developing countries have been given a grace period, while industrialized countries were scheduled to eliminate production of methyl bromide by January 2005, with certain exceptions: for pre-shipment, quarantine and emergency uses and for “critical uses” authorized under the protocol (the so-called “critical-use exemptions”). These apply, for example, where technically and economically feasible alternatives are not immediately available. The exemptions are intended to be temporary and strictly limited derogations from the phase-out of methyl bromide. A number of developing countries have agreed to phase out methyl bromide on a faster timetable.

²⁴ <http://www.basel.int/Portals/4/Basel%20Convention/docs/text/BaselConventionText-e.pdf>

ILO conventions

Several International Labour Organisation (ILO) conventions address the safety and health of workers in contact with chemicals at their workplace in general and in agriculture in particular. These conventions have varying rates of ratification. Those with a low rate still may have an impact beyond a simple calculation of the number of states that have ratified. ILO conventions are negotiated and agreed among governments, unions and industry.

The convention that most clearly addresses the safety and health of workers exposed to pesticides is the C184 Safety and Health in Agriculture Convention (Agriculture Convention), which was adopted by the ILO Conference in 2001 and which entered into force in 2003. The convention is intended to close the gap often found in national legislation which does not generally address the protection of agricultural workers through occupational health and safety legislation. Therefore, many people exposed to pesticides during their daily work are not covered. Usually, only those employed under contracts of employment are entitled to the full protection provided under the legislation, while informal labourers are not.

ILO Convention No. 182 on the Worst Forms of Child Labour of 1999 has a high rate of ratification and calls upon governments to act to eliminate the worse forms of child labour. Article 3.d. identifies “work which, by its nature or the circumstances in which it is carried out, is likely to harm the health, safety or morals of children” as a worst form of child labour. This should include the application of pesticides, not least because of the increased vulnerability of children to the toxic effects of many pesticides.

According to ILO’s tripartite approach, the Agriculture Convention imposes responsibilities on employers, strengthens the rights of agricultural workers and places obligations on governments. Governments have to develop a coherent national policy on safety and health in agriculture, consult employers and trade unions, establish a responsible authority, specify the rights and duties of employers and workers, ensure that there is a system of inspection and establish an inter-sectoral coordination mechanism.

The Workplace Convention is more general than the Agriculture Convention, applying to all kinds of economic activities related to (hazardous) chemicals in general, which would include pesticide products. It addresses the protection of workers from harmful effects of chemicals at the workplace, covering any activity that may expose a worker to a chemical. This includes the production, handling, storage, transport, disposal and treatment of waste chemicals, as well as the release of chemicals resulting from work activities and the maintenance, repair and cleaning of chemical equipment and containers.

Chemical Weapons Convention

The Chemical Weapons Convention (CWC) aims to eliminate an entire category of weapons of mass destruction by prohibiting the development, production, acquisition, stockpiling, retention, transfer or use of chemical weapons by States Parties²⁵. All States Parties have agreed to chemically disarm by destroying any stockpiles of chemical weapons they may hold and any facilities which produced them. States Parties have also agreed to create a verification regime for certain toxic chemicals and their precursors (listed in Schedules 1, 2 and 3 in the Annex on Chemicals to the CWC²⁶) in order to ensure that such chemicals are only used for purposes not prohibited. Some pesticides may chemically be closely related to compounds on

²⁵ <http://www.opcw.org/about-opcw/member-states/>

²⁶ <http://www.opcw.org/chemical-weapons-convention/annexes/annex-on-chemicals/>

that Annex, which may have implications for production, importation and storage of large volumes of these pesticides or for obsolete stocks containing these pesticides.

5.1.2 Non-binding international instruments

Non-binding legal instruments (often called “soft law” instruments) include plans of action, declarations, Codes of conduct, guidelines and technical standards. These instruments are designed to promote international harmonization, and they are usually elaborated and drafted by experts. Although they are not legally binding, some have influenced and continue to considerably influence national pesticide legislation.

Code of Conduct on Pesticide Management

The International Code of Conduct on Pesticide Management (Code of Conduct) is the only international instrument addressing the main elements of pesticide management throughout the pesticide life cycle. It aims to provide a reference framework for governments and the pesticide industry and other stakeholders.

The Code of Conduct, which was originally adopted in 1985 by the 23rd Session of the FAO Conference, was subsequently amended in 1989, fully revised in 2002 and updated in 2013. It is supported by a comprehensive set of technical guidelines that provide more detailed guidance on specific aspects of the pesticide life-cycle²⁷. These guidelines are an important reference for design of pesticide legislation, particularly the secondary legislation. Particularly the guidelines on registration, data requirements for registration, labelling, provide important guidance for formulation of legislation.

Unlike a binding convention or treaty, the Code of Conduct is voluntary. Nevertheless the Code of Conduct has been widely adopted by national governments and, together with its supporting technical guidelines, is widely being used to shape pesticide legislation.

The Code of Conduct actually provides specific suggestions on how to design national legislation on pesticide management. In particular, Article 6, entitled “Regulatory and technical requirements,” urges governments to create the necessary national legislation to regulate pesticides and to provide effective enforcement, and outlines the areas in which regulation is necessary (See box in introduction). The Code of Conduct also identifies other governmental programmes necessary for the creation of a comprehensive pesticides management framework. Among other things, as already noted, it encourages Integrated Pest Management.

Codex Alimentarius standards

The Codex Alimentarius Commission (CAC), a joint body of FAO and WHO, elaborates harmonized food standards which are recognized by the World Trade Organization (WTO) through the Agreement on the Application of Sanitary and Phytosanitary Measures. Most relevant to the management of pesticides are the standards for maximum residue limits (MRLs) established by the Codex Committee on Pesticide Residues (CCPR). The CCPR is a subsidiary body of CAC, entrusted with the preparation of the MRLs to be adopted by CAC.

²⁷ <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/>

The CCPR establishes MRLs for pesticides and for chemicals similar to pesticides which can be contained in specific food items and animal feed; considers methods of testing for MRLs; and prepares priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). As of September 2014, MRLs had been established for more than 271 active ingredients. Some governments have adopted Codex MRLs as legally binding standards, usually through subsidiary instruments under their basic food laws, which is advisable where a country wishes to ensure that its national standards comply with the international consensus on MRLs.

Globally Harmonized System

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is an internationally agreed tool for chemical hazard communication, incorporating harmonized hazard classification criteria and provisions for standardized label information and Safety Data Sheets (SDS). The scope of GHS is broad, covering all chemicals, including pesticides. GHS was developed as a result of Agenda 21, agreed in 1992 at the Rio Conference on Environment and Development. It was endorsed by ECOSOC (the United Nations Economic and Social Council) as an international voluntary standard available for adoption by countries.

The ultimate goal of GHS is to ensure that information on chemical hazards, including pesticide hazards, is made available to workers and consumers in a harmonized and comprehensive format, on labels and in Safety Data Sheets, in countries around the world.

Regarding pesticides, GHS classification replaces the WHO Classification of Pesticides by Hazard. The main difference is that GHS adds chronic human toxicity and environmental toxicity to the acute human toxicity, which was the sole basis for the WHO Classification. As such it is more comprehensive. An increasing number of countries is choosing to adopt GHS classification as a binding standard through national legislation.

5.1.3 Meeting supra-national obligations

There are different ways that countries can choose to meet their legal obligations under international and regional instruments to which they are parties. Treaty obligations can be incorporated by reference in national laws, i.e. the national law states explicitly that the treaty obligations are effective national law. Treaty obligations can also be transposed into national laws. This option reproduces the text or crucial requirements from the international or regional instrument directly in the national legislation. A third option is to adjust national legislation to be consistent with the international instrument, taking into account national policies, institutions, resources, implementation and enforcement. This latter option tends to be the most effective and actually will be required in many cases. This is because the provisions of many international instruments are quite general, leaving each country free to determine exactly how the obligations will be implemented. This is the case with most of the non-legally binding international instruments examined in this text. The Code of Conduct, for example, has provisions governing all aspects of the pesticide life cycle. While the Code itself mainly enumerates the goals of this approach, specific mechanisms for achieving those goals are provided by the supporting technical guidelines.

Agreements such as the Rotterdam or the Basel Conventions (see 5.1.1) introduce specific prior notification and reporting obligations that should be integrated in national export procedures and their enabling legislation. As another example, an international instrument may require a party to monitor pesticide incidents that affect human health. This broad

provision would need to be implemented by each signatory country in the most appropriate fashion. One country might establish reporting requirements under the national pesticides legislation for all members of the pesticide industry, with penalties or loss of an operating licence in case of failure to comply. Another country might create an agency to oversee the collection and dissemination of such information. National action is required, and each country will have its own rules and practices to determine the desirable strategy for its national context.

5.2 Regional initiatives

The Code of Conduct encourages regional harmonization of pesticide registration requirements, procedures and evaluation criteria (art 6.1.8 – see box in Introduction). In the last 10 to 15 years, there has been a trend toward greater regionalization of regulatory activities related to pesticides. In many cases, the fact of similar legal systems and traditions has facilitated the adoption of regional arrangements.

Regional approaches have several advantages, among them the fact that they can facilitate trade opportunities by ensuring that national pesticide control systems do not constitute barriers to trade in the region, and that they enable sharing of often scarce expertise and financial resources. The character and legal nature of regional instruments differ. Some are legally binding on the member states of the respective regional organization, while others are non-binding. Some examples of regional arrangements are outlined below.

The Organization for Economic Co-Operation and Development (OECD) runs a Pesticides Programme which develops Guidelines for the Testing of Chemicals reflecting the international consensus on the best testing methods for the safety of chemicals including pesticides. Once adopted by the OECD Council, they are binding on the OECD member states that do not abstain from them.

Because the same pesticides are often tested in more than one country (and this is taking place in countries with limited resources), the OECD Council adopted a binding Decision in 1981 stating that data generated in one OECD member country in accordance with OECD Testing Guidelines and Principles of Good Laboratory Practice must be accepted in other member countries. Analytical data for a pesticide in one member country is thereby accepted by the responsible registration authority with respect to the same pesticide in another OECD country. A later Council Decision in 1989 monitors GLP compliance and establishes a framework for international cooperation among monitoring and data-receiving authorities. In 1997 another decision authorized non-member countries of OECD to participate in the mutual acceptance of data.

Some regional bodies have adopted regional-level pesticide legislation.

In the European Union, the European Parliament and Council approved Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. The Regulation lays down approval criteria for active substances at “community level”, while the authorisation to place plant protection products on the market remains the responsibility of Member States according to agreed “Uniform principles”. It also introduces the principle of mutual recognition, which enables the holder of an authorisation to place the product on the market in another Member State insofar as the

agricultural, plant health and environmental conditions are comparable in the regions concerned. Regulation (EC) 528/2012 of the European Parliament and of the Council specifically regulates the “making available on the market and use of biocidal products”.

Another Regulation of the European Parliament and of the Council is aimed at harmonization of national rules on the classification, packaging and labelling of substances and mixtures. In 2011, Regulation 1107/2009 came into force. It introduced new hazard criteria and established a new approach to authorizations that distinguishes between different climate zones²⁸.

In Western Africa, the Committee on Drought Control in the Sahel (known by its French acronym CILSS) established a Common Regulation for Pesticide Registration in the nine CILSS member states. It provides for the registration of all pesticides entering the Sahel Region by a central committee of experts, called the Sahelian Pesticide Committee, which pools scarce expertise from the participating countries. Similarly, the Andean Community issued Decision 436/1998 which establishes harmonized procedures for the registration and control of chemical pesticides for agricultural use and regulates their use and correct handling.

Regional collaboration in pesticide registration may require adaptation of national pesticide legislation. For instance, if a regional registration authority has been established and has been given the power to approve or reject registration of active ingredients or formulated products, this then may need to be recognized in national legislation. The extent of this depends on what has been agreed and the legal effect of regional legislation on national legislation²⁹.

In addition to registration, other areas that would benefit from regional collaboration include: sharing information on efficacy trials among countries with similar conditions; harmonized data requirements for registration; harmonized label formats and requirements; mutual recognition agreements to facilitate regional trade; regional databases on registered pesticides; information exchange on incidences of fake, counterfeit or substandard pesticides and, regional level collaboration in pesticide quality control. This last point can be important given the high numbers of developing countries without adequate laboratory facilities for pesticide quality control. Finally, regional meetings can facilitate information exchange on many aspects of pesticide management, notably on pest management and health and environmental risks under prevailing circumstances of pesticide use.

5.3 National context

Pesticides legislation needs to be tailored to national context and circumstances: each country should work within the context of its own basic legal framework and traditions. The type of

²⁸ This new Regulation led to cancellation of a high proportion of existing authorizations. Many substances did not receive support from the industry when the review process was conducted while others were cancelled because they did not meet the new hazard criteria. As more registrations come up for renewal, it is expected that more products will get cancelled.

²⁹ Some regional organizations have the capacity to enact legislation at the regional-level with direct effect and immediate applicability in national legislation. Countries that are members of these regional organizations would not technically require a national legal reform to implement the regional-level legislation. In other cases, adaption would be required. However, even in cases where regional legislation automatically becomes applicable at the national level, a revision of national legislation would nevertheless contribute to legal transparency and facilitate implementation.

legislation that will be developed or revised in a particular country will depend on a number of factors:

5.3.1 Constitution

The first question is what is the fundamental legal text (usually a Constitution) underpinning the draft pesticide law. The Constitution, or other fundamental law, sets out the functions and limits of public power and action. The provisions of the Constitution usually describe the national legal system and determine how international law should be incorporated into national law.

The Constitution normally creates a list of citizens' individual rights. Substantive provisions relevant to pesticides might consist of constitutional rights to health, a clean environment, adequate food and water and the right to take part in decisions affecting one's community. In drafting national laws, it may be useful to refer to these rights, for example by stating in a preamble or statement of purpose that the pesticide law is intended to promote and protect human health or a clean environment.

In nations with a federal government structure, the Constitution may provide for a division of powers among the different levels of government. If some of the powers are granted solely to one level of government, this may affect the assignment of powers within the pesticide law. Provisions on decentralization are particularly relevant for pesticide inspection and control and licensing mechanisms.

5.3.2 Other national legislation

After the Constitution, the next area to be examined is the national legislation in force. Most countries already have a legal and institutional framework addressing pesticide management. Before developing new pesticide legislation, it is essential to identify and analyse the existing legal provisions affecting the different stages of the pesticide life cycle. This helps determining the types of changes that will be necessary and that can be undertaken.

The review should begin with specific pesticide legislation already in force, as well as provisions under other laws that are directly or indirectly affecting the many aspects of pesticide management at all stages of the pesticide life cycle. Because pesticide management is cross-sectoral, much other legislation will be relevant. The review should cover legislation on environmental protection, public health, occupational health, water, food safety, plant protection, general chemicals management, transportation and disposal of hazardous substances in order to determine whether and how existing provisions govern pesticides. The review of these other laws is carried out for the purpose of determining how those provisions relate to the proposed new pesticide law and where there may be any conflicts. Legislation regarding the government structure and powers may also be relevant, such as a decentralization law devolving inspection and enforcement authority to the regions.

Besides reviewing the legislation in force, it also is important to collect field information concerning pesticides in consultation with stakeholders, such as the agricultural extension service. It should then be determined why these issues exist and why they have not yet been addressed. This may provide useful insights in shortcomings in the existing legislation or the institutional capacity to enforce it.

As mentioned in section 4.1.2, it is generally recommended that countries enact a pesticide law that applies to all pesticide use within a country and to all stages of the pesticide life cycle. If a country pursues this legislative strategy, the Attorney General's Department, or similar office, generally will have to carefully review the other pieces of related legislation (e.g. transportation, environmental, labour) and make recommendations for which provisions should be repealed so as to avoid any conflict with the new pesticide law. Assuming that the legal system allows it, the new pesticide law could conclude with a statement to the effect that "All provisions conflicting with the provisions of this law, wherever they may be found, are hereby repealed", or "The provisions of this law supersede all conflicting provisions in other effective laws in [insert country name]."

5.3.3 *Policies*

In every country, a variety of policies, strategies and priorities affect the development of the legal framework relevant to pesticide management. An important policy with implications for pesticide regulation is the overall agricultural policy; others include environment, public health, protection of workers and more specifically the promotion and development of Integrated Pest Management and Integrated Vector Management approaches and the availability of biopesticides and other non-chemical alternatives to hazardous pesticides. Because of the many sectors that have a stake in pesticide management it is important that mechanisms are put in place to encourage effective inter-sectoral collaboration. Good governance policies, such as access to information, participation in decision-making, transparency and accountability will also affect the legislative design. In some situations, governments are obligated to incorporate certain policies in their national legislation, while in others they may simply choose to do so.

As an example, many countries have embraced the decentralization of government responsibilities and the devolution of powers to provincial or lower levels of government. The purpose is to ensure public participation in decision-making and to promote more effective management of resources, since local authorities are generally more familiar with their regulatory needs and resources. In practice, the existence of a decentralization policy or decentralization law might mean that in any new pesticides law, local authorities might be given the power to regulate on certain defined issues, such as carrying out inspections and issuing licences to pesticide sellers or operators, while the central authority might retain a broader policy-making role.

Other policy influences on national legislation include international trade and regionalization. Regional agreements and standards adopted by major trading partners are especially important to small and developing nations because they assist in establishing transparent and uniform standards and fostering relationships with trading partners. The desire to join regional organizations, such as the European Union, MERCOSUR or CARICOM, may spur countries to update their legislation and ensure its conformity with regional standards. There may also be an overall policy on the integration and participation of the country in the global economy and in international organizations, which might affect the design of the national pesticides law.

Of course, the principal policy which should be considered in the development of pesticides legislation is pest and pesticide management policy. Countries considering updating or enacting new pesticides legislation should first develop a national pest and pesticides management policy, after broad consultation and through close collaboration among

governmental and non-governmental stakeholders. This ensures that the legislation that is drafted captures the goals and objectives of the policy.

5.3.4 Implementation

A thorough analysis of the legal framework consists not only of an assessment of the legal system and a review of the relevant legislation and policies in force. It is also important to assess how exactly the law is applied and the ways in which it influences the behaviour of individuals and institutions. Often, there are gaps between the objectives and policy goals of a law and what is actually achieved once it is enacted. This kind of analysis is important because if the reasons the current legislation governing pesticides is not enforced are not addressed in the first place, then any new laws and regulations are unlikely to work any better.

For example, the effectiveness of a new pesticide law may be undermined by the failure of officials or institutions to devote sufficient resources or energy to its implementation. In many cases this is due to a simple lack of resources or capacity. It may also be related to the manner in which the new law has been formulated and adopted. For instance, response to advocacy or pressure of interest groups, such as pesticide companies, donors with a specific interest or NGOs, may have influenced the formulation of the pesticide legislation. Implementation may also be compromised by corruption, a problem that governments may be unable or unwilling to combat with the necessary vigour.

In some cases, legislation may be difficult to implement because of the failure to anticipate the pragmatic details of putting the law into effect. There are many examples of well-drafted laws that have been enacted without sufficient attention paid to the country's resources and its level of development and which, as a result, have proven difficult to implement. For example, in many countries the resolution of legal disputes is the responsibility of a court system that is overburdened and underfinanced, while alternatives to the traditional court system may be few or non-existent. As a result, even good pesticide laws may not be properly enforced for lack of judicial mechanisms. As another example, a pesticide law may create various boards, committees and procedures in an attempt to coordinate and structure pesticide management in the country, but these may require financial or human resources that the government does not have. Having legal requirements that are not implemented or in practice are unlikely to be enforced can undermine the whole legislation. It is therefore important to carefully match requirements with what institutional infrastructure is achievable in the national context.

Both the quality of a law and its successful implementation will depend in large part on the effective consultation of stakeholders in its preparation. In the pesticides area, stakeholders include governmental and non-governmental actors, central and local authorities, manufacturers, farmers, consumers, scientific and academic interests, the tourism industry and many private sector organizations. By helping create a consensus in favour of the law, broad participation improves compliance and fosters a sense of "ownership." By contrast, the absence of widespread understanding and support (both by those being regulated and those doing the regulating) can seriously undermine implementation.

6. Final remarks

The cross-sectoral nature of pesticide management calls for a comprehensive life cycle approach, covering all steps from registration to disposal. Primary legislation, the pesticide law, provides the regulating authorities with adequate powers, allocates responsibilities and establishes institutional mandates on a firm ground. The law can also establish new rights and impose new obligations. The law provides the basis for the system of registration of pesticides and licences, formalizes cooperation between public and private actors and establishes a mechanism for the settlement of disputes.

A solid legal framework for the control of pesticides must reflect a country's international obligations while addressing the country's particular circumstances. A review of national pesticide legislation should take into account the international and regional instruments which the country has formally signed, those it has voluntarily adopted and those it is intending to sign. The main law and its accompanying secondary instruments should reflect the economic and social situation as well as any specific features of the country, such as the crops grown, pest and vector problems, dietary patterns, toxicity of the required pesticides and the risks associated with their use, level of literacy, climate and the environmental situation. Properly weighing and considering these factors should help to ensuring the creation and enactment of a well-designed legal framework for pesticides tailored to national needs and appropriate to the national context.

A modern pesticide law and a comprehensive legislative framework for pesticides, although essential, cannot alone meet the goals of adequate pest and vector management and pesticide risk reduction. Governments must also establish and implement policies and programmes aimed at risk reduction which should involve the following steps: (1) reducing reliance on chemical pesticides and eliminating overuse; (2) encouraging the use of less hazardous and more selective products; and (3) ensuring proper use. These measures, underpinned by a solid national legislative framework, can assist in achieving sound management of pesticides, while reducing human and environmental risks and contributing to sustainable agricultural development.