

Pesticide registration legislation



Food
and
Agriculture
Organization
of
the
United
Nations



Pesticide registration legislation

by
Giuseppe Barberis
and
Jean-Pierre Chiaradia-Bousquet
Development Law Service
FAO Legal Office

FAO
LEGISLATIVE
STUDY

51

Food
and
Agriculture
Organization
of
the
United
Nations



Rome, 1995

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

M-16
ISBN 92-5-103137-1

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying or otherwise, without the prior permission of the copyright owner. Applications for such permission, with a statement of the purpose and extent of the reproduction, should be addressed to the Director, Publications Division, Food and Agriculture Organization of the United Nations, Viale delle Terme di Caracalla, 00100 Rome, Italy.

© **FAO 1995**

FOREWORD

Over the past few years "plant protection" legislation has been broadened to include a new area: pesticides. In their efforts to control plant pests and diseases, producers, traders and plant health services have been obliged to resort to certain chemical formulations, resulting in substantial increases in production. However, because of the hazards to which the use of these products may give rise and the possible extremely harmful consequences they may have on certain renewable resources and on the environment in general, appropriate statutory control systems have been established.

To complement the traditional legislative instruments for plant protection (setting up the plant health policing of the territory and border quarantine, appointing the responsible authorities and establishing their powers) it has become necessary to draw up specific rules governing the manufacture, formulation, labelling, transport and distribution of pesticides.

Occurring at a time when there is a general trend towards streamlining administrative procedures or liberalising trade, there are both quantitative and qualitative grounds that justify this trend.

Pesticide production and consumption are continually increasing, mainly because no other crop and harvest protection methods are available, or because those that do exist are inadequate or prohibitively costly. Economic interests are therefore constantly on the increase.

Yet consumers and users alike are extremely concerned about these products, and sometimes reject them.

The health-related and economic stakes are so high that governments have been led to enact legislation for the optimum control of both the quality and the use of pesticides. Since the essential element of control is the registration procedure it was felt useful and necessary to conduct a study of comparative law on this subject. This should enable the responsible authorities to draw on one single source when drafting or amending national legislation on this subject.

Since this paper has been drawn up on the basis of the legislative documents available in the archives of the FAO Development Law Service it does not claim to be a comprehensive treatise or a complete manual on current legislation. However, it does provide the reader with an overview of the general principles and the international legal instruments on which the necessary harmonisation of procedures must be based. Examples are given of national legislation that have been selected in terms of both technical and geographic criteria.

L.C. Christy
Chief, Development Law Service
Legal Office

TABLE OF CONTENTS

	Page
PART ONE - GENERAL PRINCIPLES	
1. INTRODUCTION	1
1.1 Terminology	1
1.2 Prerequisites for pesticide legislation	1
1.3 General principles for preparing legislation	3
1.4 Scope of national legislation	4
1.5 Institutional aspects	6
2. FAO'S WORK IN RELATION TO PESTICIDES	7
2.1 Technical and legal assistance	7
2.2 Survey of legislation on pesticide labelling	7
3. LEGISLATION	8
3.1 International Code of Conduct on the Distribution and Use of Pesticides	S
3.2 National legislation and pesticide registration	8
4. SCOPE OF THE LEGISLATION EXAMINED	9
4.1 Types of instruments	9
4.2 Scope of application	9
4.3 Application of the instruments to plant health substances	10
4.4 ...to veterinary products	10
4.5 ... to substances intended for the protection of inanimate objects	11
4.6 ... to substances intended for the protection of human health and hygiene	11
4.7 Specific pests	11
5. THE PRINCIPLES OF REGISTRATION	11
5.1 Purposes of registration	11
5.2 Registration and licensing	12
5.3 Registration of pesticides for export	12
5.3.1 General principles as defined in the Code	12
5.3.2 National legislation	13
5.4 The authority responsible for registration	13
5.4.1 Registration by a government officer: the Registrar	13
5.4.2 Registration by a Committee	14
6. REGISTRATION PROCEDURES	15
6.1 Submission of applications	15
6.1.1 Information to be submitted to the registration authority	16
6.1.2 Registration in stages	16

	Page
6.1.3 Conditional registration	18
6.1.4 Pesticide classification	18
6.1.5 Rejection of registration application	19
6.1.6 Withdrawal of registration	19
6.1.7 Import of non-registered pesticides in cases of necessity	20
6.1.8 Duration of registration	20
6.1.9 Fees	20
7. LABELLING AND PACKAGING	21
7.1 Labelling	21
7.2 Packaging	22
8. OTHER PROVISIONS	22
8.1 Advertising	22
8.2 Protection of property rights	23
8.3 Right of appeal	24
8.4 Registers	25
8.5 The pesticide trade: permits and licenses	25
8.5.1 Import/sales permits	25
8.5.2 Production and/or packaging permits	26
8.5.3 Use permits	26
9. ENFORCEMENT AND PENALTIES	27
9.1 Inspection	27
9.1.1 Qualifications of inspectors	27
9.1.2 The powers of the inspectors	27
9.2 Tests	28
9.3 Penalties	28
9.3.1 Main penalties	28
9.3.2 Ancillary penalties	29
PART TWO - NATIONAL LEGISLATION	
BELIZE	33
GERMANY	36
ITALY	45
IVORY COAST	53
THE REPUBLIC OF KOREA	60
LUXEMBOURG	67
MALAYSIA	75
SOLOMON ISLANDS	81
SRI LANKA	85

PART ONE - GENERAL PRINCIPLES

1. INTRODUCTION

1.1 Terminology

In the various legal instruments examined there is no uniformity in the use of terminology: the word "pesticide" is generally used, but such terms as "plant health products", "agro-pharmaceuticals" or even in the case of Brazil "agro-toxic products" are also used.

For FAO, the term pesticide means "any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products, or animal feedstuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies.. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport".

Registration means "the process whereby the responsible national government authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the purposes intended and not unduly hazardous to human or animal health or the environment".¹

This paper uses the definitions given by the International Code of Conduct on the Distribution and Use of Pesticides.

1.2 Prerequisites for pesticide legislation

The devastating effects on plants of diseases and pests have been known throughout history. Although some aspects of plant protection have long been the target of legal codification (such as plant quarantine), specific legislation to control pesticides is quite recent.

It should be borne in mind that the know-how required to develop and establish an effective plant protection system based on pesticides has only recently been mastered.

Administrative planning and law, the establishment of responsible and accountable institutions (i.e., an Inter-Departmental Pesticide Registration Committee), the use of rational agricultural practices, and the existence of an operational infrastructure all make a substantial contribution to plant protection in general. However, it is the economic interests and the legal aspects involved which are essential to pesticide control.

In effect, the powers of control given to the responsible authority may significantly curtail fundamental rights. For example, the administering entity's right to inspect places where pesticides are produced, formulated or stored, or its exercise of discretion in issuing pesticide permits, licences and registrations may significantly restrict the rights of persons to operate within the economic arena.

¹ International Code of Conduct on the Distribution and Use of Pesticides, article 2, "Definitions".

Without a basis in legislation, however, even under optimal technical conditions the responsible administrative entity cannot legally conduct its activities in a State where the rule of law prevails and where the sphere of public power is circumscribed by a Constitution (or equivalent fundamental text). In common law countries in particular, the administrative entity itself, its powers and actions will be subjected to varying levels of review and scrutiny by the judiciary both from a substantive and a procedural point of view.

Although pesticides remain essential tools to combat pests of plant cultures and harvests, they are also hazardous substances which should be controlled by the State's public power. Effective pesticide control relies on various legal norms which may be simple to understand but complicated to implement. These basic norms permits countries to, among others:

- (a) address disease and pest problems at the local, national or international levels;
- (b) create the administrative and technical infrastructure necessary to implement technical regulations elaborated at the national level, sometimes as a result of international directives and/or guidelines (notably those of FAO);
- (c) use, where existing technical knowledge permits, appropriate means to combat
- (d) diseases and pests;
- (e) introduce a climate of legal stability and confidence into trade in pesticides and protect the consumer with standards regulating the quality and processing of products intended for consumption;
- (f) hold liable, by indemnification or appropriate sanctions, those who violate existing legal standards.

For various reasons, however, legislation may not achieve the desired results. Sometimes this may be due to poor legislative drafting which makes the legislation unusable or subject to varying and conflicting judicial interpretations. Legislation also may not be adapted to the sociological and technological realities of the country and, in some cases, legal norms, however appropriate, may simply not be applied or implemented. Above all else, therefore, pesticide legislation should be related directly to the economic, social and legal situation of the country. If it is not, although it may be "legal", it will be neither appropriate nor implementable.

As with every other area of national legislation, pesticide legislation is drawn up according to the specific forms adopted in each country, depending on the legal system (civil-law, common law or Islamic law) and the government's economic policies.

It is therefore difficult to draft "model laws " for all countries. If the model is inflexible, there is a risk of introducing an alien element, in form or content, into a situation of legal homogeneity. Reference is nevertheless recommended to "guidelines " or "general technical principles " when preparing relevant national legislation.

It should be noted here that pesticide legislation is not designed primarily to impose new coercive, restrictive or punitive rules. Its main purpose is to improve the quality of life of the general population by contributing to increased food production and workplace safety while protecting the environment.

1.3 General principles for preparing legislation

Pesticide legislation is prepared when countries find it politically desirable, economically necessary and technically possible to institute a pesticide control system. Legislation is drafted on the basis of national legal norms applicable to the country by virtue of legislation adopted by its competent authorities and international legal norms incorporated into the country's domestic law according to the principles contained in its Constitution.

The general principle for drafting this legislation is that all legislation is adopted within the framework of the country's Constitution (or other fundamental legal text of similar nature and objectives) which sets out the functions and limits of public power and action,

The term "**legislation**" refers broadly to all legal texts which are promulgated by the legislative arm of the State exercising its legislative powers under the Constitution (see paragraph A. below) or by the executive arm of the State exercising either its delegated power from the legislative branch (see paragraph B. below) or its executive powers under the Constitution (see paragraph C. below).

- A. The term "*laws*" (enabling, principal, basic, framework, authorising legislation) refers only to those *texts adopted by the legislative branch*. This term includes a **Law, Statute, Decree, Ordinance** or **Act** adopted by the national legislature or its equivalent (Parliament, Congress, National Assembly, or military ruling council).

National laws usually take precedence over legal instruments, such as Municipal Ordinances or Bye-laws, which are adopted by the legislative branches of the country's political subdivisions or local authorities.

- B. The term "*subordinate legislation*" (subsidiary, enacting, implementing or delegated legislation) refers to all legal instruments *promulgated by the executive branch exercising delegated legislative power* (*regulations, orders, notices, rules, schemes, bye-laws, notifications, ordinances, instruments, directions, proclamations, determinations*).

The responsible executive body or its subordinate may also, under specified statutory authority, issue detailed statements such as a code of practice or a code of guidance. The legislation which authorises such a code determines the legal effect of the code (advisory or limited binding effect, admissibility in evidence, criterion in judicial or administrative review) and the consequences of its breach. In addition, procedural safeguards are usually included such as public participation or inquiry and review by the national legislature or responsible approving authority.

Other administrative legal texts (**Rulings, Circulars, Guidelines, Administrative Notes, Decisions**) are non-binding and not strictly speaking subordinate legislation. However, these non-binding legal texts assist the public entities involved to achieve the aims of the legislation and provide private entities with guidelines on how the competent authorities will act in enforcing and implementing the relevant legislation. These texts also contribute to the body of administrative law because courts and tribunals may rely upon such texts in reviewing administrative decision-making.

In some countries the executive branch of the State may, by virtue of its *executive powers under the Constitution*, issue legal instruments such as Executive Orders or Directives which achieve purposes similar to those of laws and subordinate legislation. The country's

Constitution and common law determine the legal effect and precedence to be accorded to such executive legal instruments.

International technical and legal norms which have been harmonised at the international level, such as FAO's guidelines, may be applied in a country through national legislation.

In this context, laws establish the general principles of a pesticide control policy, designate and empower appropriate authorities, establish obligations on the part of economic actors, and set out sanctions, directly or by reference to other texts. All other texts detailing these principles, especially the requisite technical standards on registration and labelling, fall within the realm of subordinate legislation.

Although identical texts among different States are not feasible or desirable, it is essential that, at least at the regional level, all national legislation in force is harmonised and that administrative procedures and control techniques are similar. This will ensure that national pesticide control systems are effective and do not constitute unjustifiable barriers to trade.

1.4 **Scope of national legislation**

It should be noted that, although pesticides are one element of plant protection, pesticides themselves may also be the object of separate legislation. In fact, in some countries plant quarantine and pesticide legislation are often separate texts. This is due to circumstances that are more historical (plant quarantine has been regulated for centuries) than technical or legal. In other cases a single plant protection law covers all technical components, including pesticides. Although it is not necessary to have only one plant protection law, it is essential to ensure that numerous, disparate legislative texts do not render the plant protection system ineffective.

Structure of legislative texts

Knowledge of a wide range of technical items is a prerequisite for drafting legislation which will establish an effective system of pesticide control. In effect, in this field the legislator or the competent authorities must often convert plans or measures prepared by technical staff into binding legislation. To this end, the principle of "progressive adjustment of norms" is applied. This means that standards are promulgated in more detail at decreasing levels of authority: legislative and/or executive power to responsible administrative entity.

The way in which each legislative text arranges these different topics varies widely. This depends not only on the characteristics of each legal system (Islamic, Roman or Germanic law and/or common law) but also on the interests and specific objectives of each country.

The general structure of a pesticide law in a common law country will usually include:

1. Short title.

2. Purpose of the Act²
 - this section sets out the general principles of controlling actors, substances and actions in the pesticide sector (i.e., registration, licensing, labelling, importation, formulation, distribution).
3. Interpretation.
4. Institutional organisation; functions; powers
 - this section creates and/or designates the responsible administrative authority (e.g., Inter-Departmental Committee for Pesticide Registration).
5. Appointment of officers/inspectors to enforce the Act; their functions and powers
 - this section empowers the administrative authority with inspection and analysis powers. In view of the importance of inspection to an effective pesticide control system and the potential for inspection to constrain individual liberties, the law must define exactly and specifically the powers of the officials responsible for controls. In general, these inspectors must identify themselves before exercising their powers, make inspection reports and, in accordance with the particular procedure of the country, inform the judge or the competent administrative authority of the offenses committed.
6. Pesticide registration and licensing schemes:
 - registration procedures and appeal, including treatment of proprietary information and post-registration monitoring;
 - licensing (or registration) procedures and appeals;
 - charges and taxes related to registration and licensing schemes, including those for pesticide analyses;
 - special aspects concerning manufacture and trade, including importation (licences, border inspections, certificates, rejection or destruction and compensation thereof), exportation and re-exportation.
7. Pesticide labelling requirements.
8. Provisions on special concerns in the country, such as marketing and advertising practices, disposal requirements, or training, as appropriate and applicable.
9. Offenses and administrative or penal sanctions, including limitation of designated authority and enforcing officers' liability where applicable.
10. Power to make regulations.³

² In some countries this statement of purpose appears as a preamble or as a final explanatory note to the law but not in the law itself. Common law principles of statutory interpretation in the country determine the legal effect of such a statement of purpose.

³ The drafting style of the country concerned will determine where to include in the law this section delegating the power to make subordinate legislation to central or competent local governmental authorities (Head of State, Head of Government, Minister, General Director).

11. Final provisions and repeal of contradictory and obsolete legislative texts.

Subordinate legislation usually includes details of the pesticide registration and licensing schemes, including forms to be used, and pesticide labelling requirements. Including forms in subordinate legislation facilitates the quick and effective implementation of the law by the administering agency, which is often beginning a series of new tasks under the pesticide control scheme and which may itself be a new entity in the government.

This method of preparing pesticide legislation has the following advantages:

- (a) It permits the use of the principle of delegation ("subsidiarity"), leaving subordinate officials sufficient discretion and independence to act; and
- (b) It favours the quick, effective and efficient operation of the public power (administration). Since the subordinate legislation is not as inflexible as a law, the government, the ministry or the competent authorities can quickly amend or adapt a particular provision without broaching the slow process of amending a law through the exercise of legislative power. Special care must be taken to draft a delegation of legislative power which is specific enough to implement the pesticide control scheme in a practical manner but not broad enough to result in subordinate legislation which is *ultra vires* the law.

Appropriate safeguards in legislation are needed to ensure that the competent authorities are accountable to the public and that powers delegated are in fact exercised. To do so, the basic pesticide law should provide criteria to guide the exercise of the authority's discretion, require some form of public consultation, ensure appropriate judicial or administrative review of the authority's actions, and set out a timetable for the promulgation of subordinate legislation (which, to expedite promulgation, should in fact be drafted during the drafting of the basic law).

In common law countries, the judiciary will play an essential role in determining how effectively the pesticide legislation is implemented, especially as it interprets the scope of administrative action, Constitutional limitations on the exercise of public power, compensation for public interference with private economic and other rights, and remedies. It is therefore imperative to take the judiciary's role into account in preparing any pesticide legislation, especially any legislative provisions on the legal effect of administrative actions and powers and the legal remedies available.

1.5 **Institutional aspects**

To adopt and implement appropriate measures in time, an efficient specialised administrative structure should be in place. This organisation or structure is not an end in itself, only the means to the specific objective of ensuring the appropriate use of pesticides.

In general, pesticide control is usually the responsibility of the minister in charge of agriculture. This minister is required to collaborate with other ministers, especially those of public health and external trade. Because of the potential risks involved, certain technical and administrative aspects of pesticide control are usually given to an inter-departmental body chaired by the minister of agriculture, such as a Committee on Pesticides. In association with the national plant protection service, this body coopts the expertise of other bodies or officer(s) from other ministries (public health, interior, industry, etc.) to complete its tasks. The establishment and operation of this structure vary according to the normal public administration practices in each country.

2. FAO'S WORK IN RELATION TO PESTICIDES

2.1 Technical and legal assistance

For many years, in implementation of the instructions issued by its governing bodies, FAO has been conducting comprehensive studies of chemical products for agricultural use, which soon became known as "pesticides". Drawing on the results of this research the Organisation subsequently set up a programme to provide assistance for national technical and legislative activities. This programme comprises four main components:

- in order to facilitate the work of the national authorities responsible for pesticide control, the Pesticides Management Group, belonging to the Plant Protection Service has drafted a number of technical guidelines to provide those concerned with methods for analyzing pesticide effectiveness and toxicity. These guidelines are essential instruments for establishing a control system and can serve as a model for drafting specific pesticide legislation;

- in view of the absence or inadequacy of national legislation in the developing countries it became necessary to draft an International Code of Conduct on the Distribution and Use of Pesticides (this Code, which is voluntary, lays down the principles with which governments, manufacturers, distributors and users of pesticides agree to comply. Although the study of the legal bases of pesticide registration does not require a detailed analysis of the articles of this Code, the general principles and certain recent developments are set out in paragraph 3.1 below);

- to complement this Code, FAO is implementing projects for assist its Member States to establish their own national pesticide registration systems or to prepare the necessary technical legislation (in this connection it should be remembered that the Code emphasised that "the development of national regulatory programmes is the first priority of FAO activities" in the field of pesticides);

- lastly, in view of the specific features to be borne in mind when drafting national legislation, and the specific technical features of pesticide control, FAO has been implementing a number of legal assistance projects at the request of certain member countries to help them draft basic legislation which form the basis of any effective pesticide control. This original legal assistance programme is under the responsibility of the Development Law Service of FAO's Legal Office.

2.2 Survey of legislation on pesticide labelling

An initial comparative law survey dealing with specific aspects of pesticide legislation was published in 1987. It examined the whole area of pesticide labelling legislation, with the aim of providing an overview of the principles of labelling set down in certain national pesticide (or plant protection) laws. As the author states, "the information included on package labels is the most important way in which consumers can be informed as to how to use pesticides most effectively". On this point, when the legislator lays down provisions regarding pesticide labelling, everything must be done to define all the details which must be stated on the labels in question in order to attain the desired objective.

To complete that first legislative study it was felt that a specific study on the methods and principles of pesticide registration would prove useful. And this is the purpose of the present study.

3. LEGISLATION

There are two sources of legislation governing pesticide control, and particularly pesticide approval and registration: (a) an intergovernmental legal instrument, the International Code of Conduct on the Distribution and Use of Pesticides; and (b) the domestic legislation of each country.

3.1 International Code of Conduct on the Distribution and Use of Pesticides

The International Code of Conduct on the Distribution and Use of Pesticides (hereafter called the Code) was adopted in Resolution 10/85 at the Twenty-third Session of the FAO Conference in 1985 and was the result of a long series of multidisciplinary studies conducted under the aegis of FAO.

The Code was designed to be a technical reference tool for manufacturers and the responsible national authorities; through the principles it lays down it (a) provides the business community and the administrative authorities with information for analysis and widely recognised evaluation methods; and (b) it makes up for the lack of adequate domestic legislation. As article 1.1 of the Code points out the objectives are "to set forth responsibilities and establish voluntary standards of conduct for all public and private entities engaged in or affecting the distribution and use of pesticides, particularly where there is no or an inadequate national law to regulate pesticides".

Two years after the adoption of the Code, in 1987, the Legal Office of FAO published a first study on pesticide legislation dealing with labelling.⁴

3.2 National legislation and pesticide registration

The essential part of all pesticide legislation relates to the administrative procedures for pesticide registration. Registration in the strict sense of the term is the process whereby the responsible statutory government authority approves a specific product.

Nevertheless, the following are also relevant:

- (a) measures which, while not being directly linked to registration, have implications in terms of the procedures, such as the infringement of provisions relating to advertising which normally entail the withdrawal of the registration certificate;
- (b) provisions which relate to the product but are linked to the registration conditions (e.g. rules regarding marketing, permits, etc.);
- (c) waivers to the registration principle (e.g. the import of non-registered pesticides for testing or research).

This study examines the administrative procedure for pesticide registration from the filing of the application to its withdrawal. It also examines the provisions governing of commercial activities involving the handling of pesticides, which are sometimes treated separately from the registration procedure proper.

⁴ FAO Legislative Study No. 43. "Pesticide Labelling Legislation" FAO, Rome, 1987.

No reference is obviously made here to labelling provisions, except where this is indispensable for the purposes of the study, for these have been dealt with comprehensively in the legislative study mentioned earlier.

4. SCOPE OF THE LEGISLATION EXAMINED

4.1 Types of instruments

In most cases instruments are promulgated in the form of laws. In many instances the basic law is followed by other instruments containing provisions for the application of the law.

However, some basic pesticide legislation may not be enacted in the form of a law, but take the form of delegated or secondary legislation for which provision has been made in a previously enacted law.

In these cases it is interesting to see the area providing the legal background for the pesticide control legislation, for two reasons:

- it reveals the legislator's primary concern;
- it makes it easier to construe certain provisions in the light of the basic underlying instrument.

For example, the legal basis for the pesticide legislation in the Solomon Islands is legislation on safety at work; in Papua New Guinea, the legislation was adopted in the wake of the enactment of the law on pollutants, and Italian pesticides legislation was passed in implementation of legislation of foodstuffs.

At first sight these might seem very substantial differences, because the juridical basis is quite different in each of the three cases: in the first case, the protection of workers, in the second the protection of the environment, and in the third the protection of consumer health.

4.2 Scope of application

According to the definition of the term "pesticide" given in the Code:

1. the Code not only applies to pesticides in the strict sense, but also to other categories of products (desiccation agents, fruit thinning agents, etc.);
2. the Code not only refers to plant health products but also includes veterinary products and substances to be used to control human disease carriers;
3. the Code also deals with pesticides to be used for the protection of inanimate products (foodstuffs, feedstuffs, wood, wood products);
4. the purpose of the Code is to protect products intended for human or animal consumption in every phase of food production.

The definitions of "pesticides" given in the texts examined here vary widely. However, their "lowest common denominator" is the fact that they are all plant health products.

It should also be noted that no one term is unanimously accepted to describe pesticides. Afghanistan, Belize, Ethiopia, Ivory Coast, Luxembourg, Malaysia, Myanmar and Sri Lanka use the term "pesticides". The Republic of Korea uses the term "agrochemical products"; Japan speaks of "agricultural chemical products"; while Italy prefers to speak of "phyto-pharmaceutical products and substances for protecting stored foodstuffs"; India has adopted the term "insecticides", and Canada "pest control products".

4.3 **Application of the instruments to plant health substances**

This is the field to which legislation is most widely applied.

All the legislation is designed to protect the nation's plants and national crop production.

Several laws also refer to products which, while not being intended to combat diseases of plants or plant products, are nevertheless intended for use in plant health protection.

However, the definition given in these laws usually includes plant growth regulators (Afghanistan, Ethiopia, The Gambia, Indonesia, Ivory Coast, the Republic of Korea, the Philippines, Solomon Islands, Sri Lanka), desiccants (Afghanistan, Ethiopia, The Gambia, Indonesia, Ivory Coast, the Philippines, Solomon Islands, Sri Lanka), fruit thinning agents (Afghanistan, Ethiopia, Ivory Coast), and agents to prevent the fall of fruit (Afghanistan, Ethiopia, Ivory Coast).

In other cases, although pesticide legislation also lays down provisions governing plant enhancing agents, they exclude them from the definition of "pesticides" and deem them to be completely distinct from them (Germany).

Legislation sometimes uses more generic terms, probably to designate the same products: "substances and preparations intended to enhance or regulate plant production" (Luxembourg) or "any other product intended to enhance or to help protect plants and plant products" (Italy).

Reference is even made in the definition of pesticides to substances produced by biotechnological research: "microorganisms and viruses as active agents in pest control" (Luxembourg). This is a reference to the notion of "integrated pest control", which has also been taken up in national legislation elsewhere (Germany).

4.4 **... to veterinary products**

Some of the legislation examined does not apply to veterinary products (Italy, the Republic of Korea, Luxembourg, Solomon Islands, Zimbabwe). When this is so, the countries have adopted specific legislation, in principle, to deal with these substances.

When the law applies to animal pest control products, their application is restricted solely to "domestic" animals (Sri Lanka). In other cases the law does not draw a distinction between different animals.

The veterinary products covered by the law are often those used to control pests on the bodies of animals (Afghanistan, Belize, Ivory Coast). But the law may either be non-specific in this regard (Malaysia) or it may expressly refer to substances intended for use against pests in animals (Ethiopia, Sri Lanka, Trinidad and Tobago).

4.5 **... to substances intended for the protection of inanimate objects**

These texts also apply to products to be used to protect inanimate products such as foodstuffs (Afghanistan, Ethiopia, Italy, Trinidad and Tobago), wood (Belize, Ethiopia, Sri Lanka, Ivory Coast, Trinidad and Tobago), clothing (Belize, Sri Lanka, Trinidad and Tobago), etc.

4.6 **... to substances intended for the protection of human health and hygiene**

Some legislation explicitly mentions these products. They contain provisions for products to be used to control:

- all forms of plant or animal life likely to affect public health (Sri Lanka);
- all forms of plant or animal life which may threaten public health or hygiene, including human ectoparasites (Trinidad and Tobago);
- human ecto- or endoparasites (Sri Lanka);
- human disease vectors (Ethiopia, Ivory Coast).

4.7 **Specific pests**

Some legislation provides a highly detailed list of the pests against which the products are to be used. They are generally insects, viruses, birds, weeds, etc., but the list may even include fishes (Sri Lanka), moluscs (Belize, Sri Lanka), snails (Myanmar), etc.

Legislation may also concentrate solely on specific crop pests such as fungi, insects and weeds (Republic of Korea), such that the law does not apply to products intended for use against rodents or birds.

5. **THE PRINCIPLES OF REGISTRATION**

5.1 **Purposes of registration**

Article 2 of the Code defines registration as "the process whereby the responsible national government authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the purposes intended and not unduly hazardous to human or animal health or the environment".

The purpose of registration is to ensure that pesticides, when used according to registered label directions, will be effective and efficient for the purposes claimed, and safe. Misused, pesticides can

certainly be harmful. Properly handled, they form an essential management tool in the production of food and fibre.

It should be noted that registration is very often only the final stage in a process covering several years. A phased-in procedure is preferable in the case of new products whose effectiveness, and above all whose risks, have not been proven, products that are already known but have not been used under specific conditions (e.g., certain climatic conditions) and have not been thoroughly tested.

Conversely one might feel that there is no point in registration by stages in the case of a pesticide whose active ingredient has been on the market for a long time already and whose effects, under similar conditions of use, are already well-known.

5.2 **Registration and licensing**

This is a very important point when registration merely relates to the product. But it could prove extremely important within the framework of a global pesticides registration policy to be able to control traders in pesticides, and also the facilities they use for this purpose.

Most countries' legislation provides that commercial activities relating to pesticides and the registration of pesticide products are two clearly distinct activities.

This twin approach is adopted by Afghanistan, Belize, the Cook Islands, Germany, Italy, Ivory Coast, Japan, the Republic of Korea, Luxembourg, Malaysia, Myanmar, the Philippines, Thailand, Trinidad and Tobago, etc.

However there is no absolute agreement on this point between the various legislations: some laws make no provision for licensing commercial activities involving pesticides (Solomon Islands, Pakistan).

5.3 **Registration of pesticides for export**

5.3.1 **General principles as defined in the Code**

Article 1.1 of the Code stipulates that its priority objective is to set forth the responsibilities of all the public and private entities engaged in or affecting the distribution and use of pesticides. Since the Code is primarily designed to make up for the lack of a national registration system, it describes and sets out the responsibilities of the various parties involved in the pesticides sector, and particularly the authorities responsible for registration.

It defines the responsible authority as the "government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and more generally for implementing pesticide legislation".

With regard to registration, the responsible authorities, namely governments must:

- "decide, and from time to time review, the pesticides to be marketed in their country, their acceptable uses and their availability to each segment of the public" (Art. 5.1.2);

- "strive to establish pesticide registration schemes and infrastructures under which products can be registered prior to domestic use and, accordingly, ensure that each pesticide product is registered under the laws or regulations of the country of use before it can be made available there" (article 6.1.2).

5.3.2 National legislation

The legislation may exclude pesticides intended for export from the statutory registration procedures.

In such cases, these laws do not ban the manufacture, formulation, etc. of non-registered pesticides provided that they are intended for the international market. In effect, the country's security requirements must co-exist with its commercial interests, and particularly those relating to exports. Furthermore, it is possible that a product may not be registered in a country simply because the pests against which it is intended for use do not exist there. In these cases the lack of registration does not mean that there are no hazards associated with the product, but simply because there is no reason to use it. In this case it would be absurd to impose an *a priori* ban on the manufacture of pesticide which might not be particularly dangerous.

However it is important to emphasise that the countries which do not subject pesticides intended for export to national legislation nevertheless insist on controlling over the facilities on which they are manufactured, or on conducting tests on the products themselves: this control can be indirectly effected in implementation of laws governing other Fields, such as environmental protection, worker protection, the control of hazardous or explosive substances, etc. In Italy it is the pesticides law itself that requires non-registered products intended for export to be manufactured in authorised facilities.

In this way the public interest is safeguarded without the need to subject pesticides intended for export to the provisions of the law.

It should be recalled that the new version of article 9 of the Code provides for a procedure to control the export of banned or severely restricted pesticides.

5.4 The authority responsible for registration

Article 6 of the Code provides that governments shall strive to establish pesticide registration schemes and infrastructures under which products can be registered prior to domestic use and, accordingly, ensure that each pesticide product is registered under the laws or regulations of the country of use before it can be made available there.

In countries with pesticide control procedures, the authority responsible for registration is sometimes an individual official (the Minister of Agriculture, the Minister of Health, or someone nominated by them, etc.) or a group of persons (a Committee).

5.4.1 Registration by a government officer: the Registrar.

The Registrar is generally appointed by the Minister of Agriculture, or he directly reports to the agriculture authorities (Solomon Islands, Sri Lanka). The Minister of Agriculture is sometimes

directly responsible for registering the product (Ethiopia, Ivory Coast). In Italy, the Minister of Health is responsible for registration, while in Luxembourg the Minister of Health acts jointly with the Minister of Agriculture when registering pesticide products.

5.4.2 Registration by a Committee

In other countries a Committee is directly responsible for registration (Germany, Belize, Malaysia).

This solution is adopted as a response to various needs.

First of all, the Registrar is subject to very powerful pressure on the part of applicants. This pressure might prevent the person responsible for registration from dealing objectively with applications, whereas such pressure is much harder to exercise on a group.

Secondly, a joint decision confers joint responsibility. The members of the Committee will therefore feel a greater sense of responsibility in the performance of their functions.

Thirdly, since the Committee has real powers the members will feel more committed to their work. As a result, the Committee will have a better chance of operating as the legislator intended.

As indicated on several occasions already, pesticide management not only relates to agriculture and veterinary medicine, but several sectors of public interest (the environment, public health, worker protection, foreign trade, etc.).

When products are registered, the interests involved must be taken into account and each authority will be required to express an opinion. This is why legislation in nearly every instance provides for the establishment of a Committee. Even when an individual official is appointed to register a product, he will normally be assisted by a Committee, acting in an advisory capacity.

Furthermore, the legislation examined does not always make it clear whether or not the opinions issued by the Committee are binding on the official responsible for product registration.

5.4.2.1 The composition of the Committee

The composition of the Committee is not always specified. In Myanmar, the Committee is composed of "suitable citizens" (section 3), while in Sri Lanka the Committee must be composed of two *ex officio* members and not more than 8 experts on pesticides or in pest control and scientific fields. None of these individuals must have any commercial interests vested in pesticide registration.

In other countries a different approach is sometimes adopted, and it is felt that the involvement of experts having an interest in the pesticide trade and pesticide use might actually be beneficial to the Committee (the Republic of Korea, Pakistan).

In Belize, even though the Minister of Agriculture is responsible for appointing the members, the main professional associations in the agriculture sector each propose a member.

Sometimes the laws provide a detailed list of the persons to sit on the Committee.

In several countries the Committee is also empowered to set up subcommittees to examine certain specific problems. Provision is often made for the Committee to specific issues to experts. In these cases, the experts attend the Committee meetings, but without voting rights.

5.4.2.2 The functions of the Committee

Obviously the functions of the Committee vary considerably, depending upon whether they have decision-making powers or a purely advisory status; in other words, whether the Committee has the final decision or not on the registration of a pesticide.

The Committee may normally request all the information it requires in order to reach a decision or an opinion (gathering analytical and toxicological data, controlling residues, carrying out product tests, etc.) with regard to product registration.

However the Committee's activities are not limited merely to deciding on or proposing registration for pesticides.

The Committee may also be given responsibility for laying down the conditions of use for any pesticide, offering its opinion regarding the withdrawal of registration, deciding on methods for inspecting the products, authorising pesticide imports for educational or research purposes, issuing licences, proceeding to classify products or issuing approval for facilities to be used for storage or sale, and in more general terms carrying out any other activity that may be required by the administrative authority to which the Committee reports.

Sometimes the law provides for the establishment of several committees according to the activities which they are required to perform. In Luxembourg, for example, there is a Committee to assist the responsible ministers, and it is consulted when registration applications are examined. Most of the members come from the Ministry of Agriculture, and there is also a Committee one of whose functions is to assist the Minister of Health when products are classified. Most of its members come from the Ministry of Health.

6. REGISTRATION PROCEDURES

6.1 Submission of applications

Applications are generally submitted by:

- an individual, or a public or private law corporation, wishing to market the products;
- an individual, or a public or private law corporation responsible for an agricultural undertaking wishing to use the product for crop or livestock protection (when the law also covers products for use with livestock). In these cases the undertaking must be large enough to make it worthwhile incurring the costs involved in registration;
- the government officer or agency responsible for the protection of public health (when the law also includes public health products).

6.1.1 Information to be submitted to the registration authority

Sometimes the basic legislative texts do not specify the information that is to be submitted by applicants to the authorities responsible for pesticide registration (Belize, Luxembourg). In these cases the list of information is normally set out in secondary legislative instruments. This approach has the advantage of making it easier to amend the list at a later date. For if the list requires updating and forms part of a basic law, it has to go through the legislative procedure again. Conversely, if a ministerial order specifies the data to be submitted by applicants, an equivalent statutory instrument is sufficient for any modifications that may subsequently become necessary. This can save a great deal of time.

However, the fact that the information to be submitted with applications for registration is set out in the basic law may also be taken to indicate the importance which the legislature of the country attributes to pesticide registration and to the consequences stemming from it.

It is always possible, however, for the basic legislation to state that the required information set out there is not exhaustive, and that supplementary information may be requested by the responsible authorities when the application is filed.

The information submitted must make it possible to establish the level of toxicity and the effectiveness of the product (Ivory Coast).

The more possibilities a country has of conducting a scientific appraisal of the product, the more detailed information it will be able to request. A procedure which might be particularly useful in the case of countries without adequate technical and scientific infrastructure to appraise the pesticide is to ask applicants for proof that the product is currently registered in countries which have already conducted such an appraisal.

However there are drawbacks with this approach because a pesticide's reaction often depends on the conditions of use, which may vary from one country to another (different soils or climate conditions, the degree of protection afforded to workers, etc.).

In some cases the information required by the authorities are taken directly from FAO guidelines (Afghanistan, Solomon Islands).

It is interesting to note the importance which the legislator attributes to labelling and packaging. Very frequently the law requires a copy of the label to be included with the application (Ethiopia, Italy, Ivory Coast, Malaysia, Sri Lanka) as well as a sample of the packaging (Ivory Coast, Malaysia, Sri Lanka).

6.1.2 Registration in stages

Such procedures have many advantages, both for the regulatory authority and for the manufacturer, in that they enable all parties to verify that the results of the laboratory or small scale trials are achieved in the field following wider use and thus allows any necessary modification to be made to the registration proposals before a full commercial registration is issued. During the phased registration stages, additional data that are required to enable both the authority and the manufacturer to evaluate the efficacy and possible side effects of the pesticide and to decide what additional testing, if any, may be necessary. It would be unrealistic to expect manufacturers to be able to provide the complete dossier to any registration authority before a submission could be considered.

6.1.2.1 Experimental authorization

Following the FAO guidelines, many countries' laws provide for experimental authorization (Afghanistan, Canada, Cook Islands, Ethiopia, Indonesia, Italy, Ivory Coast, Malaysia, Myanmar, Pakistan, Solomon Islands, Sri Lanka, Trinidad and Tobago, Zimbabwe).

However whereas FAO's guidelines consider experimental authorization as an integral part of the registration process, the legislation examined is more generic in this connection. It is therefore possible to conclude that even though the national authorities may grant experimental authorization bearing in mind above all the future registration of the product, the legislator did not intend to subordinate the needs of experimental work solely to the registration of the pesticide.

In some legislation the question of whether experimental authorization is granted for a limited period is not dealt with (Italy, Sri Lanka). Experimental authorization in other countries is granted for a limited period: two years in Afghanistan and Myanmar, one year in Indonesia, six months in the Solomon Islands and in Malaysia.

Some texts make express provision for renewing import permits for experimental purposes (Trinidad and Tobago).

This authorization may be subject to specific conditions. Sometimes even the import of non-registered products for experimental purposes is restricted to approved organisations or agencies (Ivory Coast, Sri Lanka).

Some legislation provides different procedures depending upon who is to use the pesticides for experimental purposes. In Italy and Trinidad and Tobago, a distinction is drawn between the use of pesticides by certain public agencies and the use of these products by third parties.

In some cases an *ad hoc* provision determines what is to be done with products to which the pesticide is applied. These may stipulate that the products:

- must not be marketed, even though the responsible authorities may waive this provision (Ethiopia, Malaysia, Zimbabwe), or used for human or animal consumption. In some cases the Committee is expected at all events to express its opinion (Italy);
- may be marketed, unless the Committee orders their destruction (Ivory Coast).

6.1.2.2 Provisional authorization for sale (PAS)

This type of clearance could be granted when most of the relevant registration data have been obtained. Some data, because of their very nature, can only be obtained when the scale of use of the pesticide is sufficient to demonstrate a measurable effect (or lack of one) on operators or on the ecology of the treated area. At this stage the product could be sold, but usually sales would be restricted to a certain quantity, perhaps over a specified period.

A PAS is provided in several countries (Afghanistan, Canada, India, Indonesia, Ivory Coast, Myanmar, the Philippines, Sri Lanka).

This authorization may be granted for a specific period of time: one year in Indonesia and Canada, two years in India and Ivory Coast, three years in Afghanistan and five years in Myanmar.

The legislation delegates the national authorities responsible for pesticide registration with the powers to lay down the conditions for granting a PAS. However a PAS may also be limited to specific categories of products (in the Ivory Coast only products which do not contain poisonous substances).

6.1.3 Conditional registration

In some countries registration may be subject to certain conditions (Germany and The Gambia, Italy, Malaysia, Luxembourg, Solomon Islands, Trinidad and Tobago).

Where it is possible to lay down conditions for pesticide registration, countries whose legislation does not make provision for PAS to hope to attain the same objectives (the use of the product solely for a specific geographical area, its use reserved to a particular category of approved users or for a specified period of time).

However the two systems must not be confused. In principle, a PAS is granted for a product that is not well-known (whether an existing product that has never been imported into the country before, or a brand new product) whereas conditional registration is granted for a product that is already known, but the responsible authorities deem it advisable not to issue a full commercial registration certificate for the time being.

At all events, even a product for which a PAS has been granted may subsequently be given conditional registration.

6.1.4 Pesticide classification

Pesticides are classified in terms of the risks to which they give rise, to distinguish between products in terms of the hazards that they represent. Depending upon the categories to which they belong, more or less strict rules governing marketing, use, etc. may be adopted. It is therefore advisable to deal with classification jointly with "conditional registration" because very often the stringency of the conditions on the import and/or use of the products depend upon their classification.

It should also be noted that the problem of classification has been dealt with in the Code in article 10.2.3 which provides that industry should use labels that "in international trade, clearly show appropriate WHO hazard classification of the contents or, if this is inappropriate or inconsistent with national regulations, use the relevant classification".

The WHO system just mentioned, which draws a distinction between "extremely hazardous", "highly hazardous", "moderately hazardous, and "slightly hazardous" and "not very dangerous", was approved at the Twenty-eighth World Health Assembly in 1975. Subsequently, acting on the advice of Member States, WHO added a number of guidelines regarding the classification of each pesticide (the first guidelines date back to 1978 and since then have been revised every two years).

At the European level it should be recalled that the Council of Europe has a "Committee of experts on pesticides", which was set up to carry out the systematic revision of a regular publication containing, inter alia, "recommendations on the classification and safety labelling of pesticides".

6.1.5 Rejection of registration application

The application for registration is generally rejected when:

- the applicant is unable to supply the information required to be able to properly assess the application;
- the risks outweigh the benefits to such an extent that registration is unjustified;
- the pesticide is not effective.

Even though an application may be rejected, this does not mean that a new application may not be submitted for the same product once the applicant is in a position to supply the required information.

The law may either require the reasons for rejection not to be revealed, or require the decision to indicate these reasons (Sri Lanka).

6.1.6 Withdrawal of registration

It should be recalled first of all that registration only applies to the pesticide which is actually submitted to the authorities and forms the basis of their decision. Any new formulation of the product normally requires a new registration application.

Most of the laws empower the responsible authorities to withdraw approval and registration of the product at any time.

In view of the hazards linked to these products, the national authorities must be able to ban any further marketing and use of the pesticide as and when new evidence about it emerges.

Several situations may give rise to a withdrawal of registration.

There are two types of withdrawal: technical withdrawal, and penalty withdrawal.

Technical withdrawal may be ordered, inter alia, in the following cases:

- when the protection of human or animal health or the environment make it necessary;
- when the pesticide is no longer the same as the product for which the registration had originally been applied;
- when the risks in terms of the benefits are such that registration can no longer be justified;
- when it has been shown that the pesticide is no longer effective;
- when the pesticide is no longer used.

Penalty withdrawal is applied mainly in the following cases:

- in the case of misconduct on the part of the registration holder (infringing the law, breaking the terms of registration, etc.);
- when the registration-holder fails to act for a certain period of time which the responsible authorities deem to be unjustifiably long (the Republic of Korea).

Some laws provide very little information on the subject of withdrawal. They merely make provision for it, laying down specific formal conditions, (Ivory Coast, Luxembourg, Solomon Islands). The decision justifying the withdrawal may in some cases be served on the holder (Ivory Coast, Luxembourg, Solomon Islands, Sri Lanka). Some countries give the person concerned the right of appeal against withdrawal (Malaysia).

6.1.7 Import of non-registered pesticides in cases of necessity

Some laws provide the possibility for importing non-registered products if the territory is unexpectedly infested by harmful organisms (Germany, Myanmar).

When the texts make no specific provision for this, and a pest has already invaded the country, reference is made to the section of the law which permits the introduction of pesticides for experimental purposes in order to be able to authorise the use of non-registered pesticides in cases of extreme urgency.

6.1.8 Duration of registration

Registration normally remains valid for a specific statutory period (Afghanistan, Ivory Coast, Solomon Islands, 5 years; Germany, 10 years; India, 2 years; Luxembourg and Myanmar, 10 years; Pakistan, Zimbabwe, Malaysia, 3 years).

However the law may either not directly lay down the period of registration, leaving this to be set out in the decision granting the application for registration (Sri Lanka) or it may not make any provision at all for a specific period to be established (the Republic of Korea, Fiji, Belize).

However, it should be recalled that the local authorities always control the products, and the legislation empowers them to withdraw registration at any time, particularly if they give rise to problems.

Under these circumstances the fact that the decision on registration is not subject to an expiry date is perfectly logical, for the national authorities may always withdraw registration from a product and consequently make it illegal to trade in it at any time.

Registration is generally renewable.

6.1.9 Fees

The registration procedure is subject to a fee to cover the administrative costs incurred by the authority when assessing the product.

Some legislation provides that the applicants must also pay the laboratory expenses incurred to examining the application.

Payment is normally made when the application is filed. However the payment of the laboratory tests may also be calculated in the form of a percentage levied on the volume of pesticide imported and manufactured, which is paid into a fund to cover the cost of conducting the tests (the Republic of Korea).

Various suggestions have been made that the fees charged to cover the registration procedure costs should be paid into the budget of the authority responsible for registration. Even though this would be ideal, it is not easy to implement because the law would have to make provision for the costs of the procedure to be paid to the responsible authorities. In principle at least, the finance authorities would oppose any waiver of a well-established principle under which all revenues must be paid into the central government budget indistinctly, for subsequent allocated in the new budget.

It should also be noted that in most cases the basic legislation does not directly indicate the fees to be charged. This is to avoid having to subsequently amend the law in order to adjust the fee to meet the national inflation rate. By leaving a lower-tier authority with the responsibility for establishing the fee to be paid (e.g., a minister) the authority can more easily adjust the fee to the national economic situation.

7. LABELLING AND PACKAGING

Provisions governing labelling and packaging form an essential part of the pesticide registration conditions.

In view of the importance of this aspect, the reader is referred to Legislative Study No. 43 which has already been mentioned.

The provisions relating to pesticide labelling will therefore not be examined in the section which analyses national legislation in part 2.

However a study of the registration procedures must necessarily touch on labelling provisions, for the sake of completion. It has therefore been felt advisable to provide a comparative analysis of the provisions relating to the external aspect of the product: labelling and packaging.

7.1 Labelling

Compliance with labelling legislation is normally a condition for granting (and maintaining) registration. Having a clear understanding of the labelling is essential before a pesticide can be properly used, and also to prevent accidents. Legislation therefore always deals with this issue.

Some legislation specifies the information that must be given on the labelling (the Republic of Korea, Sri Lanka). In other cases it merely indicates certain elements that are needed on the label and requests the applicant to prepare the label to ensure that there are "full" instructions for the user (Ivory Coast). Sometimes the features of the labelling can be set out in secondary legislation (Luxembourg, Malaysia, Solomon Islands), while the basic law merely lays down a general obligation to label the product (Malaysia). The applicant must also submit a specimen label in many cases (Italy, Ivory Coast, Malaysia, Sri Lanka).

Normally speaking, legislators are very sensitive to the language problem. They will normally require the labels to be written in the various languages used in the country (Sri Lanka, Luxembourg). However it should be recalled that the obligation to label a product in the national language may constitute a severe constraint on supplying the market properly with pesticides if the obligation is incumbent upon the manufacturer and if there is only a limited demand for the product in the country: in these cases the manufacturers will probably be unwilling to cover the extra costs in exchange for a very small return. This gives rise to the risk that such countries may not have an effective tool for controlling a particular pest.

7.2 **Packaging**

Packaging is the second point relating to the external aspect of pesticides.

A declarations explaining the packaging to be used (or a sample of the proposed packaging) must normally be submitted with the application for registration (Malaysia).

Packaging regulations often make reference to the very serious problem of repackaging. It is sometimes difficult to find small packages on the market, with the result that the consumer may not find it easy to procure supplies. The cost of packaging is also passed on to the buyer, and particularly in countries where controls are less stringent, pesticides are frequently sold in bulk without any compliance with the labelling and packaging conditions.

To deal with this problem legislation may require the products to be sold in their original packaging (Italy, Luxembourg), or the packaging to be previously approved (Malaysia, Sri Lanka), and prohibits the sale of pesticides in bulk or decanted (Ivory Coast). If the applicant wishes to request a waiver from this principle, prior written authorization is required from the Registrar (Solomon Islands), or the applicant must be an approved importer.

The legislation in countries which deal in greater detail with the problem of packaging (Luxembourg) also specifies the material to be used for packaging (and on its resilience both to corrosion caused by the product and to external agents) and the closure (sealing, a closure which will prevent loss after the product has been used several times, etc.).

8. OTHER PROVISIONS

8.1 **Advertising**

Not all the legislation deals with this issue. It is nevertheless very important, given the aggressive sales techniques used by manufacturers and the fact that the consumer's attention is very often influenced more by the advertising message than by the label.

Since the problems relating to pesticide advertising are so important, FAO devoted article 11 of the Code to this particular point.

More specifically, manufacturers must ensure, inter alia, that "advertisements 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, or official recognition or approval".

It should also be recalled that article 11.3 encourages governments to work with manufacturers in order to provide what it calls "public-service" advertising regarding the safe and effective use of pesticides. Advertising, according to the Code, could "focus on such factors as the proper maintenance and use of equipment, special precautions for children and pregnant women, the danger of reusing containers, and the importance of following label directions".

Many countries ban the advertising of non-registered pesticides (Belize, Ivory Coast).

The advertising of registered pesticides is authorised, even though certain conditions are imposed (e.g., the advertisement must simply mention the uses which are authorised in official legislation: Ivory Coast, Luxembourg).

Any misleading or untruthful information is prohibited.

Infringement of the provisions relating to advertising may in itself be sufficient for registration to be withdrawn. The provisions also express the legislator's concern regarding the dangers of untruthful or misleading advertising.

In some cases advertising methods are also set out in the legislation (the Republic of Korea, Malaysia, Trinidad and Tobago).

8.2 **Protection of property rights**

Pesticide producers must be certain that the information they submit to the national authorities with their application for registration is protected. In this connection FAO's guidelines regarding the registration and control of pesticides points out that it takes many years' work and huge investments for a company to design a new product or to be in a position to supply all the data relating to its safety and effectiveness for the purposes of registration. It would therefore be unfair if the authorities responsible for registration were to make it possible for the applicant company's competitors to acquire possession of the information submitted in good faith. Each applicant must be required to submit all the information needed to back the application, both by carrying out tests on their own account or obtaining authorization from the proprietor of the information to use the results of his tests.

Data protection is also useful in order to encourage research.

The Code deals with this point in article 6.1.3 where it requires governments to protect the proprietary rights to use of data.

The legislator must also take due account of this requirement on the part of the manufacturers. For this reason many laws make an *ad hoc* provision to protect the data submitted by applicants. Furthermore in many cases the lack of any reference to the confidentiality of the information does not mean that the system does not provide protection to the applicants, for the rights are already protected under a general system of data protection that rules out any need for specific provisions relating to the protection of pesticide data.

Legislation in the Malaysia, Pakistan, Solomon Islands, Sri Lanka, Tanzania and Trinidad and Tobago all make provision for the protection of the data submitted to them.

Sometimes the law has a specific section waiving the obligation of confidentiality in the case of legal proceedings (Pakistan, Sri Lanka) or an exception may be made to the principle where police and judicial enquiries make this necessary (Malaysia).

The law may also lay down a statutory deadline for the period of protection (in the Philippines, protection expires seven years after first registration).

Under certain conditions the law may also authorise the use of the application papers submitted by an earlier applicant (Germany).

8.3 **Right of appeal**

In some cases the law provides for a special appeal procedure against decisions of the responsible government authority (e.g., against the decision to grant registration or a provisional authorization for sale).

However, it is extremely difficult to imagine a more competent authority to hear an appeal on the merits, since the authority that has taken the contested decision (with regard, for example, to a registration application) is supposed to be the most competent on the subject (especially when the decision is taken by a Committee). It is evidently quite another matter when appealing on procedural or formal grounds.

Some legislation makes no provision for an appeal procedure. This does not necessarily mean that the applicant has no way of protecting his rights. It simply means that the general legal instruments available in the national system have to be examined. In legislation which does not expressly provide for an appeals procedure, all that is mentioned in some cases is that the reasons for the decision must be given (Ivory Coast): the rationale underlying this provision is probably the fact that the reasons for the decision will be used as the grounds for an appeal under the general legislation,

Some texts only refer to the appeals procedure (Belize) leaving a lower-tier authority with the responsibility of laying down the ways in which the right can be exercised. But normally the law at least indicates which authority has jurisdiction to take cognisance of the appeal. This is sometimes left to a panel under certain circumstances (Myanmar, Trinidad and Tobago).

With regard to the procedural aspects, legislation may require the payment of a fee (India), establish the deadlines for appealing (14 days in The Gambia, 10, 28 or 60 days in Trinidad and Tobago, depending on the instrument against which the appeal is made; 30 days in India, Italy and Myanmar; 60 days in Sri Lanka), or it may specify the documentation which can be submitted to the appeals body (Malaysia), etc.

Some laws specify that the decision handed down by the authority with jurisdiction to rule on it is final and binding, and that the matter cannot be pursued through the courts (Malaysia, Sri Lanka), or it may make provision for two instances of administrative appeal (The Gambia, Myanmar).

The body having jurisdiction to take cognisance of appeals may vary depending upon the instrument under appeal. In Trinidad and Tobago, for example, a waiver is provided to the normal appeals procedure when the decision under appeal refers to the registration procedure.

8.4 **Registers**

In some countries every registered pesticide must be recorded in a register kept by the government authority (Luxembourg). In some cases a register must also be kept for any licences issued by the authorities for the premises on which pesticides are marketed and for pesticide applicators (Belize).

These registers must always be kept up-to-date, but since in principle they are open for consultation by the public, they only contain the information that may be divulged without infringing any of the other provisions regarding confidentiality.

In other countries a register is required to be kept containing the quantities of the pesticides imported, manufactured or sold by the proprietor of a commercial enterprise (Italy, Luxembourg). This register contains all the transactions relating to the pesticide trade. Obviously this is for a completely different purpose altogether: the need for the authorities to be able to trace back a particular batch, product, or packaging, or to be able to trace the purchaser of the product, or to draw up statistics, etc.

8.5 **The pesticide trade: permits and licences**

As already indicated there are many countries in which pesticide registration is not in itself sufficient for a trader to begin marketing pesticides.

A permit (licence, authorization) may be necessary for this purpose.

Laws vary widely on this point.

There are three types of permits:

- for import/sale;
- for manufacture/packaging;
- for use.

In some cases the permits issued for these activities depend upon the type of product: the national authorities in some cases have already classified the products, and restrictions have been adopted depending upon that classification (Belize, Italy with regard to the conditions under which certain pesticides may be procured, Luxembourg). In other cases, although the country may have decided to classify the products, the permit is unrelated to that classification (Ivory Coast, Malaysia).

The law may require permit holders to inform the responsible authorities of any change (suspension, relinquishment, resumption) in their activities.

8.5.1 **Import/sales permits**

Import permits enable the responsible authorities to control the quantities of pesticides circulating in the country at any time, and hence enable them to assess the supply requirements.

Some countries place a general ban on the import of any pesticide without a permit; in other words, the import of pesticides is forbidden unless authorised in writing by the responsible authorities (Sri Lanka). Or the ban may be more specific, namely that certain particularly hazardous products may only be imported by persons meeting certain eligibility requirements (Luxembourg).

Imports for sale may be subject to approval by the responsible authorities.

Generally speaking, the authorities examine the applications in order to ensure that the applicant meets all the conditions required to guarantee the safe handling of the pesticides (sufficient technical know-how: Italy, Ivory Coast, Luxembourg; awareness of the hazards of pesticides: Malaysia). In particular they may inspect the premises on which the imported products are kept. Sometimes the premises themselves require authorization (Belize).

The registration authority is often responsible for issuing licences. But if the sales licence is mandatory for all pesticide retailers - whatever the pesticide sold - one can easily understand that there is a danger that the authority may not be able to cope with all the applications. In this case the responsibility may be devolved on officials at the regional level (Italy, Malaysia, Myanmar).

The seller may be required to comply with very stringent safety measures regarding the conservation of the products (Luxembourg).

8.5.2 Production and/or packaging permits

The manufacturing licence - like the sales licence - can only be granted if the pesticide has been previously approved and registered. However it should be remembered that some laws waive this principle in the cases of products intended for export.

The manufacture and/or packaging permit deals mainly with supervising the premises on which the pesticide is to be manufactured (Italy, Ivory Coast), the type of pesticide produced there (Italy) and the technical know-how in possession of the applicant (Italy, Malaysia).

8.5.3 Use permits

As far as use permits are concerned, some laws distinguish between use for "direct" commercial purposes (where the user applies pesticides as a professional activity and uses the products to protect his own crops). This is the case of the Ivory Coast where the pesticide use rules only exist for users having "direct" commercial interests.

Sometimes the specific provisions of the law regarding pesticide use are not based on the purpose for which they are used but on the pesticide classification (Luxembourg).

In some countries, however, the legislation not only refers to the purpose of use but also product classification (Belize, Italy).

9. ENFORCEMENT AND PENALTIES

Since this study deals with registration procedures in the broad sense of the term, it is not necessary for this first part of the study to examine in detail all the policing measures and the penalties for infringements of the law that are provided in the legislation.

However this aspect will be covered in the comparative study, since provisions relating to infringements form an essential part of pesticide legislation.

9.1 Inspection

The legislation examined may provide for the appointment of "sworn" agents (Ivory Coast) or "commissioned and sworn agents" (Algeria) who are responsible for enforcing the law. However, the law does not necessarily provide for the appointment of inspectors (Afghanistan, Tonga).

9.1.1 Qualifications of inspectors

Many laws lay down the qualifications required for inspectors. They must have an agriculture or science degree, and be familiar with chemistry and have sufficient field experience (India), or be sworn agents working for one of the ministries represented on the pesticides Committee (Ivory Coast). The Committee may be composed of 11 different ministries, or be "appointed" by the Minister of Agriculture (Sri Lanka).

They may also be police officers, customs officers, or public officials appointed specifically by the minister (Malaysia).

The law does not always lay down the qualifications of the inspectors who are nevertheless appointed on the basis of their "skills" or because they are "technically competent" (Belize, Canada, Trinidad and Tobago).

Inspectors may have the status of judicial police officers (Luxembourg) in the exercise of their functions.

Inspectors must carry an identification document (Canada, Malaysia). In Malaysia, anyone may refuse to comply with any request by an inspector who fails to give proof of identity.

9.1.2 The powers of the inspectors

Sometimes the inspectors must be given a warrant before they may operate. In other countries the mandate is optional (Trinidad and Tobago).

The scope of the powers of the inspectors varies.

They may normally inspect the premises and the sites to be used for the manufacture, sale, storage, or use of pesticides, and the vehicles to be used to transport them, and examine the products and inspect the registers and documents on the trade in pesticides.

In some countries, express provision is made for the inspector to visit farms and ensure that only appropriate products are being used on the crops, following sound agricultural practice (the Philippines).

In principle, the inspectors have the right to impound any products which are not in conformity with the statutory provisions.

The inspectors may request police help (Trinidad and Tobago), and they cannot be held responsible for any actions performed in good faith in the exercise of their functions (Sri Lanka, The Gambia).

In some cases the legislation requires that the persons on whose premises the inspection is being conducted must provide assistance (Canada, Germany).

9.2 **Tests**

Many laws lay down the procedure for testing products. The powers of the inspectors include taking samples for laboratory tests.

However, it should be noted that it is not always a prerogative of the inspectors to be able to procure samples and request them to be analyzed. In Malaysia and Tanzania, for example, any pesticide purchaser may request an analysis to be made of the product.

In principle, the sample must be divided into three equal parts and be labelled and sealed. One part is kept by the person from whom the sample is taken, one by the analyst and the third is given to the Registrar (Sri Lanka) or kept by the inspector (Malaysia, Tanzania).

In the case of litigation over the results of the tests, the court or the Registrar may proceed to analyze the samples of one of the other parties (Malaysia, Sri Lanka).

The test certificate setting out the results can be used in court as evidence, save where they can be shown to be unreliable (Belize, Canada, Malaysia).

This procedure is not universal, however. Sometimes the samples are divided into four parts. One part is kept by the person providing the sample, while the other three parts are all sent to the laboratory for analysis (Italy). The first analysis is carried out at the provincial level. If challenged, and a second analysis is carried out by the National Institute of Health (Istituto Superiore della Sanita).

9.3 **Penalties**

9.3.1 **Main penalties**

The penalties provided by the legislation are of two types: fines or criminal penalties.

The penalty obviously varies according to the seriousness of the offence.

Imprisonment can be up to a maximum of one year (Algeria, Belize, Myanmar, the Philippines), nine months in the Solomon Islands, six months in Afghanistan, three months in Luxembourg, and two years in Sri Lanka.

Some legislation does not establish penalties for infringements of the law (Ivory Coast). In these cases the general criminal law provisions apply (Ethiopia).

It should also be recalled that the imposing of the penalties provided by pesticide legislation does not mitigate liability if the conduct simultaneously constitutes another criminal offence. Sometimes this principle is explicitly provided by the law (Luxembourg).

Fines may sometimes be extremely high. However, a comparative analysis of this aspect serves no useful purpose here.

Imprisonment and fines may both be imposed.

9.3.2 Ancillary penalties

9.3.2.1 Withdrawal of registration or licence

In principle, the penalty for infringement can also involve the withdrawal of the registration or the licence. Withdrawal, which may at first sight seem to be a light penalty, is sometimes the most effective and acts as a major deterrent. The prospect of losing a licence, which would prevent a trader from pursuing his activities, could do more to deter him from infringing the law than the payment of a fine or even a prison sentence.

The withdrawal of the registration or licence can also be the principal penalty in the case of a minor infringement of the law.

9.3.2.2 Confiscation

Some legislation directly specifies the possibility of confiscating any products which are not in accordance with the statutory provisions (Afghanistan, Canada, Luxembourg, Malaysia, Solomon Islands, Sri Lanka, Tanzania).

However, once again, even if no provision for the confiscation of prohibited products is made by the pesticide law, this does not mean that general criminal law may not provide for their confiscation.

When a pesticide is confiscated it may be directly destroyed by the authorities themselves (Solomon Islands).

9.3.2.3 Other types of penalties

Ancillary penalties may also be imposed:

- the obligation to close the premises for a period of not more than three years (Luxembourg);
- the publication of the court orders or decisions in one or more daily newspapers at the expense of the liable party (Luxembourg).

PART TWO - NATIONAL LEGISLATION

This section examines the legislation of the following countries: Belize, Germany, Italy, Ivory Coast, the Republic of Korea, Luxembourg, Malaysia, the Solomon Islands, and Sri Lanka.

BELIZE

Legislation analyzed: Law No. 32 of 24 December 1985

1. SCOPE AND DEFINITIONS

The definition of pesticide provided by this Law refers to the definition of "pest". A pest is any insect, rodent, bird, mollusc, nematode, fungus, weed, microorganism, virus, animal ectoparasite and any other kind of plant or animal life which is harmful, dangerous or undesirable to crops, foodstuffs, wood, clothing or any other inanimate object.

One of these definitions which is worth emphasising relates to pesticides for restricted use. These are pesticides for which special precautions must be taken, to avoid any particularly harmful effects on the environment, and to the user.

2. LEGISLATION AND THE CODE

Although the definition given above is quite broad — in so far as it covers more than the range of mere plant protection products — a number of the elements set out in the FAO Code seem to be missing. The Belize law makes no reference, for example, to plant growth regulators, defoliant, or desiccants.

3. REGISTRATION

Prior registration of pesticides is necessary for any manufacturing, import, advertising or sales operations.

3.1 The Committee

An inter-departmental body, named the Committee, is responsible for registration. It is composed of a maximum of 14 members appointed by the Minister of Agriculture, four of which are chosen respectively by the Association of Citrus Planters, the Apiculture Industry, the Livestock Association and the Cereals Association. It should be noted that when the Minister appoints the members to the Committee he may consult any organisation deemed relevant in terms of pesticide control.

3.1.1 Functions (section 4)

The Committee is responsible, inter alia, for the following:

- 1) registering pesticides;
- 2) issuing licences to pesticide importers or manufacturers;
- 3) issuing authorization for the sale/use of pesticides for restricted use;
- 4) authorising and registering premises where pesticides for restricted use are sold;

- 5) classifying products into approved pesticides, pesticides for restricted use and banned pesticides;
- 6) any activity relating to the import, manufacture, packaging, preparation for sale, sale, disposal of surplus stocks and the use of pesticides, and for advising the Minister on all these activities;
- 7) any other activity required for the proper exercise of its functions.

In the exercise of its functions, the Committee must comply with the instructions issued by the Minister (section 5).

3.1.2 Committee Secretary (section 10)

The Secretary is appointed by the Minister, and must establish and keep up-to-date:

- (a) the Register of Approved Pesticides;
- (b) the Register of Licences issued to persons authorised to import or manufacture approved and registered products;
- (c) the Register of Authorised Importers or Manufacturers of pesticides for restricted use, with information on the premises approved and registered for the sale of these pesticides;
- (d) the Register of Approved Users. These registers are public.

3.2 Information to be submitted to the authorities

The request for registration must be in accordance with the specimen format laid down by the Committee (section 10.3). The Law does not provide any information regarding the data that must be submitted to the Committee. A list of approved pesticides, a list of pesticides for restricted use and a list of banned pesticides are given in schedules to the Law.

3.3 Expiry of registration or authorization (sections 4.2 and 12)

The Committee may at any time, with the permission of the Minister, ban the sale or use of any pesticide and order its destruction.

It is important to note that the Law does not state the conditions under which the Committee may impose this ban. Presumably the legislator had in mind the possibility of new information subsequently becoming available making it possible to better appraise the hazards of using a specific pesticide. However there is no explicit indication on this point.

The Law also provides that the Committee may order the suspension (for one year) or the withdrawal of registration or authorization obtained fraudulently.

3.4 **Duration**

The Law does not lay down any time limits on registration. It should nevertheless be recalled that the Committee may withdraw the registration of a pesticide at any time.

3.5 **Fees (section 9.3)**

A fee is charged for registration, the manufacturing or import licence, authorization to sell pesticides for restricted use, the authorization and registration of premises for the sale of pesticides and authorization to use the pesticides.

3.6 **Publication in the *Officiei Journal* (section 10.3 and 12.3b)**

The Committee is required to publish all its decisions regarding registration and authorization in the *Officiei Journal*. The copy of the Registers kept by the Secretary must also be published, and updated, in the *Officiei Journal*.

4. RIGHT OF APPEAL (section 20)

Anyone affected by any decision taken by the Committee may appeal to the Minister against that decision. However the Law does not provide any indication regarding the appeals procedure.

5 ADVERTISING

The Law authorises advertising for registered pesticides alone. Misleading or untruthful advertising which might create the wrong impression regarding the properties of the product, or which advertising that is inconsistent with the information supplied with the application, are prohibited.

6. PESTICIDE CLASSIFICATION

The Law draws a distinction between registered pesticides, pesticides for restricted use and banned pesticides. With regard to the pesticides for restricted use, section 8 bans the sale of any pesticide for restricted use save where the seller has been previously authorised and where the premises have been approved and registered for the sale. Sales must take place under the prescribed conditions. Except in the case of personal and non-commercial use, the user must be authorised by the Committee; if he is not directly authorised by the Committee, a pesticide for restricted use must only be used under the supervision of an authorised person.

7. LICENCES

A licence is required to manufacture, import or sell all pesticides.

GERMANY

Legislation examined: **The Plant Protection Act of 15 September 1986**

1. SCOPE AND DEFINITIONS

Under section 2 of the Law, pesticides (literally "plant health products") are substances intended for the following uses:

- (a) protecting plants against harmful organisms or damage of non-parasitic origin;
- (b) protecting plant products against harmful organisms;
- (c) protecting plants and plant products against animals, plants or microorganisms that are not harmful organisms;
- (d) acting on the vital processes of plants or plant products without providing nutrition (growth regulators);
- (e) preventing the germination of plant products;
- (f) mixing with the substances listed above under (a) to (e) with the intention of modifying their properties or effects, except for water, fats and plant growth stimulants;
- (g) killing plants or freeing or protecting land from certain types of vegetation, provided that the substances do not within the categories mentioned under points (a) or (d).

The products covered by this definition must not be confused with the plant stimulants to be used solely to enhance the plants' resistance to harmful organisms without having any harmful effect on man, animals or the environment.

The Law also provides a definition of harmful organisms: these are animals, plants and microorganisms at every stage of their development which are able to cause substantial damage to plants or plant products. Viruses and similar pathogens are equated with microorganisms; diseases which are not caused by harmful organisms are equated with harmful organisms.

Lastly, the Law provides a definition of the concept of "integrated pest management": the combination of procedures giving priority to biological, biotechnical and plant genetic methods of pest control, and cropping technology and rural engineering measures which reduce the use of chemical pesticides to the strictly necessary minimum.

2. LEGISLATION AND THE CODE

The Law only deals with pesticides for plant protection. Veterinary products and substances used to control human disease or animal disease vectors are dealt with in other legislation.

The Law also applies to plant stimulants: however these substances are not included in the definition of pesticides.

3. REGISTRATION (section 12)

Pesticides may not be marketed unless they have previously been registered. However, under section 11(1) this principle does not relate to the following:

- (a) pesticides for export or, in the case of imported products, those which are in a customs free zone or under the control of the customs authorities;
- (b) growth regulators to be used on cut ornamental plants;
- (c) products to be used to control plant microorganisms (a) in closed premises or in conduits on premises or in installations subject to inspection by work safety inspectors, or mine inspectors, or under atomic and health control authorities, or (b) in medical establishments.

Moreover, section 11(2) empowers the Biological Federal Institute (see below) to authorise the circulation or import of non-registered pesticides:

- (a) for the purposes of research, analysis or testing;
- (b) when there is an urgent need to control specific harmful organisms;
- (c) to be used on plants or plant products for export, except for foodstuffs and feedstuffs.

Seeds and crop substrates which contain pesticides, or on whose surface pesticides adhere may not be marketed or imported unless the pesticides in question have already been registered or if, in terms of their composition and effects, they can be equated with a registered plant protection product. Nevertheless the Law indicates exceptions for pesticides to be used for research or when it is necessary to act promptly to prevent a hazard.

3.1 The Federal Biological Institute (section 33)

The Federal Biological Institute (hereafter the Institute) is responsible for pesticide registration.

As an autonomous federal agency within the jurisdiction of the Federal Minister for Food, Agriculture and Forests (the Minister) the Institute is also responsible for:

- (a) informing and advising the federal government on matters relating to plant protection;
- (b) taking part in monitoring the registration process;
- (c) controlling plant protection treatment equipment;
- (d) helping to evaluate the substances in accordance with the statutory provisions governing chemical products.

The Institute may also control the following:

- (a) pesticides for which registration is not required;

- (b) plant stimulants and other substances to be used for plant production, other than pesticides.

The Institute is also required to publish a descriptive list of registered pesticides and plant protection treatment equipment.

Within the Institute a committee of experts has been set up, whose members are appointed by the Minister. The committee must be consulted:

- (a) before any decision is taken regarding pesticide registration;
- (b) before registration is withdrawn or revoked, except where delay would be dangerous.

3.2 **Submission of applications (section 12)**

Applications for registration may be submitted by:

- (a) the manufacturer;
- (b) the official representative of the distribution firm, whenever a plant protection product is marketed for the first time, or
- (c) the imponder.

Anyone who has neither residence nor a commercial agency in a Member State of the European Union may not request authorization unless they have appointed a representative who is resident or has a commercial agency there. The latter may represent the interested party in the registration procedure.

Section 17(1) empowers the Minister, acting jointly with the Federal Minister for Youth, the Family, Women and Health, and the Federal Minister for the Environment, the Protection of Nature and Nuclear Safety to regulate the pesticide registration procedure, particularly with regard to the type, the number and the status of the documents, as well as the size of the samples to be submitted to the responsible authorities, under regulations ratified by the Federal Council.

3.3 **Information to be submitted to the authorities (section 12(3))**

The application must provide the following information:

- (a) the name and address of the applicant;
- (b) the name of the pesticide;
- (c) the composition of the product, indicating the type and the quantities of all the ingredients, using their ordinary scientific name;
- (d) instructions on the fields of application;

- (e) instructions on the risks to human and animal health and on any other possible risks, particularly with regard to environmental pollution;
- (f) instructions on procedures to dispose of or neutralize the product;
- (g) an outline of the pattern of use;
- (h) markings designed for the recipients and the external packaging, or for the items included with the packaging;
- (i) details on the type of packaging;
- (j) information on the appropriate procedure for analyzing the product using commonly available equipment at an acceptable cost, and making it possible to reliably identify pesticide residues including the products of reaction and degradation which give rise to serious health hazards.

The application must be accompanied by the documents and samples required in order to show compliance with the statutory registration conditions (section 12(3)(2)).

The applicant is required to immediately notify the Institute of any changes made to this information (section 15(4)).

3.4 **Information already in the possession of the Institute (section 13)**

The Law authorises the use of any documentation submitted by previous applicants.

3.4.1 Products involving tests on animals

In the case of products involving tests on animals, the accompanying documents may not have to be submitted to the Institute where adequate information is already in its possession. If the information comes from a previous applicant, the Institute must notify that previous applicant: (i) of the information it intends to use for the benefit of the applicant; and (ii) the name and address of the applicant. Information provided by a previous applicant may not be used when the previously granted registration dates back more than ten years.

3.4.2 Products not requiring tests on animals

In these cases, documentation is not necessary when the Institute already has sufficient information available and, when this information is taken from the documentation submitted by a previous applicant who has issued written consent for that information to be used, or when the registration of the plant protection product submitted by the previous applicant dates back more than ten years.

3.4.3 Objections

The previous applicant has three months within which to object to the use of any information previously submitted. In the event of such an objection, the registration procedure must be suspended for five years following the submission of the registration application. This period may be extended for a maximum of ten years following the registration of the previous applicant's plant protection product.

If the applicant needs a shorter period of time to prepare all the documentation, the registration procedure need only be suspended for that shorter period.

In the event of an objection, if the plant protection product is registered before the expiry of the ten-year period in respect of the plant protection product registered by the previous applicant, using the information submitted by the latter, an indemnity equivalent to 50 percent of the amount saved as a result of having used that information may be claimed by the previous applicant. The previous applicant may restrain the new applicant from marketing the plant protection product until he has paid the indemnity or guaranteed payment of an equitable amount.

3.5 The outcome of the process (section 15)

The Institute registers the product when it is:

- (a) sufficiently effective in terms of scientific and technological know-how;
- (b) compatible with the conditions laid down with regard to the protection of human and animal health against the risks relating to the trade in toxic substances;
- (c) used for the purposes intended and according to sound professional practice, or when, after being so used:
 - it does not have any harmful effects on human or animal health, or on the water table; and
 - it does not have any harmful effects deemed to be unacceptable at the present state of scientific knowledge on the environment in particular.

The Institute issues its decision jointly with the Federal Office of Health on whether the conditions stipulated in (b) and (c) above have been met, and jointly with the Federal Office of the Environment in relation to the conditions set forth in paragraph (c), relating to the prevention of any damage which may be occasioned as a result of air and water pollution and any damage which might be caused by the residues of the plant protection product.

The Institute must issue jointly with the registration:

- (a) instructions ensuring the protection of human and animal health, and providing protection against any other harmful effects, particularly to the environment (establishing instructions for use, and particularly instructions regarding the correct use of the product, any harmful effects on human and animal health or on the environment, the precautions to be taken in the event of accident, ways of disposing of or neutralizing products adequately; provisions relating to packaging, ready-to-use mixtures, etc.);

- (b) the right to add, modify or complete the specifications.

In this connection the Institute may also lay down instructions for application where necessary to guarantee the protection mentioned earlier. In the instructions for use, these must be evidenced as being clearly distinct from any other instructions for use, using for example the following wording: "Methods for application imposed by the Federal Biological Institute for Agriculture and Forests", indicating the penalties for failure to comply.

The Institute may also require the registration-holder to provide any supplementary instructions, documents and samples needed to justify the required registration conditions whenever technological developments justify a review of the registration (section 15(5)).

3.6 **Duration of registration (section 16)**

Registration remains valid for ten years dating from the end of the year in which it is granted. It may be renewed. The Institute may also establish a shorter duration.

In principle, registration may be revoked at the request of the registration holder.

3.7 **Fees (section 37)**

For the administrative procedures performed pursuant to this Law the Institute charges fees and refunds of expenses. The Minister, acting jointly with the responsible authorities, lays down the services for which fees may be charged, specifying fixed or indicative charges. The public utility of the pesticides, plant health treatment equipment and plant health protection measures must be equitably taken into account when these fees are established.

3.8 **Publication in the Official Journal (section 17(2))**

The registration decision and the date on which registration lapses are published in the *Official Journal*. The same applies to the index regarding plant health treatment equipment (section 26).

4. **ADVERTISING (section 21)**

All advertising relating to the possibility of using the product for plants (or for plant products) apart from those for which the product has been approved or in quantities or concentrations or at intervals other than the quantities, concentrations or intervals for which the product has been approved is prohibited. It is also prohibited to suggest shorter pre-harvest intervals than those indicated in the instructions for use.

5. **RULES REGARDING MARKETING AND SALES (section 22)**

The Federal Government may issue regulations ratified by the Federal Council containing complementary provisions governing the nature and the scope of the professional know-how and skills required for marketing and selling the relevant products, together with the procedures for providing evidence of such know-how and skills.

If the Federal Government fails to act, the Länder governments may issue their own regulations. It should be noted that the Länder may act in place of the Federal Government under certain instances when the latter fails to take action (with regard to laying down the procedures for applying the product, or the nature and scope of the professional know-how of the applicators or the traders), and may issue regulations to supplement those adopted by the Federal Government (procedures relating to the issuance of the applicator's declaration).

The Law prohibits automatic distributors and any other form of self-service system for retailing pesticides.

6. RULES GOVERNING EXPORTS (section 23)

Products can only be exported if they bear a label specifying their characteristics, the type and quantity of the active ingredients, and the use-by date.

The recipients and the packaging ready for retailing must be accompanied by instructions for use stating the following:

- (a) the correct use of the product in terms of the purpose for which it is intended;
- (b) any harmful effects it may have on humans and animals, as well as on the environment;
- (c) preventive and first aid measures to be adopted in case of accidents;
- (d) the correct way of disposing of or neutralizing any unused quantities.

It should also be noted that if exported, international agreements must be taken into consideration, and particularly the FAO Code of Conduct.

Products intended for export which (i) are not registered, (ii) do not bear the statutory markings, and (iii) indicate instructions violating the rules governing advertising, must be kept separate from those intended for use within the framework of the Law, and consequently they must be made clearly distinguishable.

The Federal Minister of Food, Agriculture and Forests may, jointly with the other authorities concerned, ban the export of specific pesticides (or those containing specific substances) to countries outside the EEC where this is necessary in order to prevent serious hazards which cannot be eliminated in any other manner, particularly when they constitute a threat to people, animals or the environment.

Lastly, each year before 30th June, the pesticide manufacturer, the proprietor of a distribution firm or the person who places or facilitates the placement on the national market of imported pesticides must submit a declaration to the Institute for the previous solar year specifying the types and the quantities of the active ingredients contained in the pesticides being marketed.

7. CONDITIONS RELATING TO USE

The Minister may issue regulations ratified by the Federal Council and jointly with the relevant ministers⁵, banning, restricting or requiring a declaration for, or the possession of, authorization to use certain pesticides, or those containing specific ingredients, or when they are to be applied using specific equipment or procedures⁶.

In these specific cases, the Law may also enact conditions applying to (i) certain plant species on land whose soils have been treated with certain pesticides and (ii) using the pesticides and importing seeds, plants or crop substrates containing pesticides falling within the scope of specific regulations.

The Institute may then be empowered to issue authorization for taking the statements or declarations deposited.

The professional know-how and skills required must be justified upon request from the responsible authorities.

The Law also provides that pesticides may only be applied to open fields that are used for agriculture, silviculture or horticulture, and may not be used near or in the immediate vicinity of surface water or coastal waters.⁷

7.1 Professional applicator

Persons using pesticides on behalf of third parties⁸ are required to make a prior declaration to this effect to the responsible authorities, specifying the registered office of the application firm and the site where the operation is to take place.

7.2 Plant protection treatment equipment (sections 24 et seq.)

The Law also lays down provisions regarding plant protection treatment equipment. The equipment must therefore be designed to ensure that their use will not have any harmful effects upon human or animal health, or on ground water or the environment.

Before any plant health treatment equipment can be put on the market the manufacturer, the distributor or importer must deposit a declaration with the Institute attesting that the equipment complies with the statutory provisions.

⁵ When it is necessary to take urgent action the Minister may act without the prior agreement of the Federal Council and without liaising with the other ministers. In these cases, the measures will be valid for six months and can only be extended with the consent of the Council.

⁶ The governments of the Länder are empowered to lay down regulations under subsection 1(b) if the Minister does not use his powers over this matter.

⁷ The responsible authority may grant waivers to paragraph 2 whenever action is urgently needed to attain the purposes being pursued, and there is no other manner of doing so at an acceptable cost, and provided that there are no contrary public interests, such as the protection of animal and plant species.

⁸ Occasional voluntary services to help neighbours are excluded from this provision.

The Institute may waive the plant protection equipment declaration when the equipment is to be used for research, surveys, tests or display purposes.

The Institute keeps an index of the treatment equipment for which a declaration has been deposited.

The equipment may be inspected at any time by the Institute. If it is not in conformity with the statutory conditions, the Institute may order the equipment to be removed from the index, or if the infringements are of lesser importance, the manufacturer may be given a deadline by which to bring it into line with requirements.

Instructions for use must always be provided with the equipment. They must mention the name and address of the manufacturer, the name of the type of equipment and its field of application.

8. COLLABORATION OF THE CUSTOMS SERVICES

The Federal Minister of Finance and the customs offices appointed by him have a part to play in supervising the import, transit and export of pesticides. The Minister of Finance, jointly with the Minister of Agriculture, is responsible for regulating the details of the supervision procedure.

ITALY

Legislation analyzed: **Law No. 283 of 30 April 1962, amending a number of sections in the Health (Consolidation) Act dealing with foodstuffs.**

Section 6 of this Law provides that the production, trade and sale of plant health control products and agents for protecting stored foodstuffs require authorization of the Minister of Health.

Presidential Decree No. 1255 of 3 August 1968 ("Regulations governing the production, trade, and sale of plant health products and products for the protection of stored foodstuffs") was adopted to implementing this section.

1. SCOPE AND DEFINITIONS

Health protection agents (plant health control products and products for the protection of stored foodstuffs) include the following:

- (a) products to be used to control animal and vegetable organisms, microorganisms and viruses which are harmful to agricultural production and to the conservation of foodstuffs;
- (b) products intended to prevent damage caused by living organisms indicated in (a) above;
- (c) adjuvants;
- (d) certain toxic gases to be used for plant protection and for the protection of stored foodstuffs;
- (e) any other product intended to cause or participate in the action of protecting plants and plant products, or the protection of stored foodstuffs.

The Law excludes from this definition all mechanical instruments.

The production of health protection agents includes the formulating and/or packaging them.

2. LEGISLATION AND THE CODE

The definition given in the Regulations is limited to plant health control products. The substances intended for use as plant growth regulators, defoliant, desiccants, fruit thinning agents or to prevent premature falling of fruit, as well as veterinary products, lie outside the scope of application of the Regulations. These products nevertheless fall within the definition of the word "pesticide" as given in the Code.

3. REGISTRATION

All pesticides must be registered save where they are:

- (a) products designed for export. However these substances must be manufactured on registered premises, and the exporter must declare the composition to the customs services;
- (b) products in transit;
- (c) for experimental work. Nevertheless the use of any non-registered pesticide for experimental purposes must be notified in advance to the Ministry of Health (Regulation 36). State research institutions are exempt from making this communication, and the foodstuffs to which the non-registered product is applied must not be used for human or animal consumption. However, in the case of products whose active ingredient is already known, the Committee is required to express an opinion.

Applications for registration must be submitted to the Ministry of Health. The product is approved and registered by the Minister of Health acting on the opinion of the Commission.

3.1 The commission

A consultative Commission has been established at the Ministry of Health. It comprises 26 members (various officials of the Ministry of Health, Agriculture, Trade and industry, Labour, Finance, the National Institute of Health, and university professors). The Commission is authorised to call on experts.

The Commission is responsible for examining applications for registration and for the following:

- (a) indicating the class to which the pesticide belongs, or altering its class;
- (b) accepting or rejecting applications for registration, without proceeding to analyze the pesticide in question;
- (c) requesting and obtaining supplementary documentation, where necessary;
- (d) proposing the analytical and toxicological examination of the pesticide to be conducted by the National Institute of Health;
- (e) suggesting tests to be carried out on the product in conjunction with the Ministries of Agriculture, Health, and the National Institute of Health, in order to ascertain its effectiveness, its toxicity in relation to plants, and the amount of residues left on agricultural products and foodstuffs;
- (f) proposing technical rules relating to the active ingredients and the pesticides (formulation, concentration, colouring, labelling, intervals between the last treatment and harvesting or marketing, maximum residue limits, analysis methods, etc.);

- (g) laying down upper limits on residues and on the periods to be observed before harvesting or marketing;
- (h) issuing an opinion on the basis of the technical documentation relating to the methods of analysis submitted and proposed by the enterprises;
- (i) establishing methods of analysis both for control and monitoring, and for the residues of the active ingredients;
- (j) proposing that the National Institute of Health be requested to issue an opinion, even though the Regulations may not require this opinion.

The Minister of Health may also request the Commission to express its opinion on any other matter whatsoever.

3.2 **Information to be submitted to the authorities**

The application must indicate the following:

- (a) the name and forenames of the proprietor of the enterprise (the company name and the registered office in the case of a company). If the products are manufactured on premises owned by the applicant, he is required to submit information relating to the permit authorising production;
- (b) the name of product, the formulation of the product ready for use, and indications relating to the nature of the packaging;
- (c) the presumed classification of the products;
- (d) the upper limits on residues;
- (e) proposed intervals between the last treatment and harvesting or marketing of the foodstuffs, and any remedial treatment.

The application must also provide information on the active ingredients to make it possible to draw up a complete picture of their chemical and toxicological properties.

In the case of products containing microorganisms and viruses, the documentation must show that these microorganisms and viruses will have no harmful effects on humans or animals when the experimental applications have been completed.

An sample label or a photocopy of the instructions for use must be annexed to the application.

3.3 **Tests**

For the purposes of authorization and registration, the Minister of Health may request enterprises to submit specimens of pesticides to be tested by the National Institute of Health, and to submit reports on tests to ascertain their effectiveness and plant toxicity levels carried out by the Ministry of Agriculture.

3.4 **The outcome of the process**

The certificate of registration indicates:

- (a) the surnames and forenames of the proprietor of the enterprise or the company name and registered office in the case of a company;
- (b) the name and class of pesticide;
- (c) details regarding the production facilities and references to manufacturing permits;
- (d) information relating to limits or conditions of use or any other information deemed appropriate.

In a schedule, the aforementioned registration certificate must contain a specimen of the labelling and supplementary explanatory documentation which may accompany the product.

The registration certificate must be notified to the parties concerned through the Provincial Physician.

Permits for production or marketing may be made subject to conditions of use and be limited to a specific period of time. Registration gives the holder the right to market and sell the product.

Any changes made to the active ingredient or to the field of application of the pesticide, as well as any change to the labelling requires prior authorization from the Minister of Health. He may also request supplementary documentation to this end.

3.5 **Expiry of registration**

Registration is withdrawn whenever the composition of the pesticide no longer matches the composition set out in the application or when the product no longer complies with the registration conditions.

If the infringement only relates to one batch, and if only a small quantity is involved, the Ministry of Health may order the registration-holder to withdraw from the market all the samples which are not in accordance with the registration conditions, and then henceforth comply with the conditions of the registration certificate by a certain deadline.

Where this deadline is not respected registration is withdrawn. The withdrawal is published in the Official Journal. After being served with the withdrawal notice, the registration-holder must withdraw all the samples of the product from the market within thirty days. It is prohibited to market and sell any product which has been banned after fifteen days from the date the withdrawal of registration is published in the Official Journal.

It should also be noted that the health authorities may ban the public sale of any pesticide at any time, on health grounds, and order its temporary seizure.

3.6 Publication in the Official Gazette

The certificate of registration must be published in the *Official Gazette*.

4. REGISTERS

The registers are only required to be kept for the sale of class I and class II pesticides.

The register must indicate:

- (a) the name of the product, the registration number and the quantities, as well as the object of the transaction;
- (b) the date on which the merchandise is received and the date of sale.

5. PESTICIDE CLASSIFICATION

Italian law provide that pesticides may be grouped into four different classes depending on their toxicity levels and classified following the opinion expressed by the Commission.

6. PRODUCTION REGULATIONS

Pesticides may only be manufactured on premises authorised for this purpose by the Minister of Health.

Anyone interested in setting up a pesticide production facility for commercial purposes must submit an application to the Minister of Health giving the following information, *inter alia*:

- (a) information relating to the person responsible for managing the facility (1); (1). It should be noted that every facility must be under the personal responsibility of a chemist, an industrial chemist, a chemical engineer or a pharmacist. The Minister of Health may also require the registration-holder to be aided by other experts, depending upon the type of pesticide produced at the facility (section 7);
- (b) the type of pesticide formulation it is proposed to produce;
- (c) information on the premises on which the production activities are to take place.

When an enterprise has several production facilities, an application must be made for each one of them. Before granting authorization, the premises must be jointly inspected, together with the technical facilities and the security devices, by the Ministry of Health and the Ministry of Labour.

The Minister's authorization contains, *inter alia*, information regarding the pesticides for which production is authorised, and all specific production conditions.

The production permit also authorises the holder to market and sell the pesticide provided the product has been previously registered by the manufacturer, and that it is not directly sold to the public

on the premises used for production purposes (section 9(6)). Conversely, this is prohibited in the case of a pesticides manufacturer acting on behalf of third parties.

Whenever the address of the premises is changed, a new application for authorization must be submitted.

7. REGULATIONS GOVERNING MARKETING AND SALES

The proprietor of a commercial enterprise wishing to market and sell pesticides must submit an application to the health officer responsible for the territory on which the premises to be used for these activities stands.

The applicant must ensure that a person aged over 18 in possession of a practising certificate is in charge of the stores (or the premises where the products are sold). This certificate is issued by the officer of health following an interview between the officer and an official of the Ministry of Agriculture with the candidate requesting authorization, dealing with the following topics:

- (a) the use of pesticides in agriculture;
- (b) toxicity and the correct use of pesticides in agriculture from the health point of view;
- (c) prevention of poisoning;
- (d) notions of pesticide legislation.

The practising certificate is valid for five years, and is renewed upon application by the holder.

This interview is not required for persons who have a degree in agriculture, medicine and surgery, veterinary medicine, biology or pharmacology.

The application for authorization to market pesticides must contain the following indications, *inter alia*: (i) the address of the premises to be used for sale or to store the products; (ii) the class of pesticides which the proprietor intends to sell; (iii) the person in charge of the premises where the products are stored or sold.

The stores of enterprises authorised to manufacture pesticides are exempt from the procedures required for marketing whenever they do not directly sell the products to consumers.

The health officer issues authorization to market and sell pesticides after ascertaining that the premises where the pesticides are to be sold are appropriate for this purpose and that the proprietor of the enterprise (or the person responsible for sales) is in possession of the practising certificate.

The certificate must contain similar information to that set forth in the application for authorization, namely details of the premises and the store where sales are intended to be effected, the person responsible for the store, the class of products, etc.

Specific conditions may be laid down before granting authorization.

The health officer may also refuse to grant authorization, but must give reasons for so doing.

Appeals may be filed with the Provincial Physician within 30 days of the date of the communication. The appeal only seems to be granted under the terms of the Regulations, however.

8. CONDITIONS RELATING TO PURCHASERS

Class I and II pesticides may only be sold to persons holding authorization issued by the Provincial Agriculture Inspectorate. The pesticides sold must be used directly by the purchaser, who may also use them on behalf of third parties.

This authorization is only issued by the Provincial Agriculture Inspectorate after the applicant has been interviewed by a technical official of the Ministry of Agriculture, the Provincial Physician and a provincial officer of a national social security agency (ENPI).

The applicant must be able to show familiarity with the following:

- (a) the hazards relating to holding, conserving and handling a pesticide;
- (b) the procedures for the sound use of pesticides (from the point of view of health and agriculture);
- (c) the precautions to be followed to ensure that the pesticides are properly used.

The authorization remains valid for five years and is renewed following the same procedure.

The interview is not required for persons who have a degree or a diploma in agriculture.

When purchasing pesticides, the buyer must undertake to keep and use the product appropriately.

If the order for the purchase of pesticides is made in writing, the purchaser must ensure that a request is also signed by the mayor, or by the local police or Carabinieri chief, the Provincial Physician, the officer of health, an official of the Agriculture Inspectorate or a local official of the Ministry of Agriculture.

9. EXPIRY OF AUTHORIZATION

The Regulations also provide that authorization may be withdrawn (for production and marketing/sales) whenever the conditions on the basis of which authorization has been issued are no longer being observed.

However if the infringement is not serious the responsible authority may give the holder time to comply with the conditions laid down in the authorization. If this deadline is not honoured, authorization may be withdrawn permanently.

10. PROTECTION MEASURES

The Regulations specify that the public institutions organise refresher courses for persons selling or using pesticides, and ban the storing and sale of pesticides on any premises where foodstuffs are sold.

The same applies to the bulk sale of pesticides and sales carried out by market salesmen. The most hazardous pesticides (classes I and II) must also be stored in locked cupboards, or on specially designed premises.

IVORY COAST

Legislation examined: **Decree No. 89-02 of 4 January 1989 on the approval, manufacture, sale and use of pesticides**

1. SCOPE AND DEFINITIONS

The text applies both to pesticides for both agricultural and for veterinary use. Under article 2 of the Decree, pesticides are deemed to include all substances or mixtures of substances designed to repel, destroy or control pests, carriers of human or animal diseases and undesirable species of plants or animals which may cause damage or in any way prove harmful during the production, processing, storage, transport or marketing of foodstuffs, agricultural products, wood and wood products or animal feed, or which are required to be applied to animals to control insects, acaridae and other pests on their bodies.

The term also includes plant growth regulators, defoliants, desiccants, fruit thinning agents, agents to prevent the premature falling of fruit, substances applied to crops before or after harvesting and to protect products against deterioration during storage and transport.

2. LEGISLATION AND THE CODE

The term "pesticide" as defined in the Decree is almost identical to the definition given in the Code, except that it excludes substances (or mixtures of substances) that can be administered to animals to combat pests in their bodies; the Law of the Ivory Coast only considers products for treating parasites on their bodies.

3. REGISTRATION

Before a pesticide may be imported or manufactured it must be approved or a provisional authorization for sale must be issued for it.

However it is possible to import non-approved pesticides or pesticides that have not received a prior authorization for sale (PAS) for experimental purposes.

The import of these products for experimental purposes requires prior authorization from the Minister of Agriculture, at the proposal of the Pesticides Committee, and they may only be used by research establishments belonging to the Ministry of Scientific Research, and laboratories and research stations belonging to plant health control firms.

A declaration regarding their use must be made in advance to the Committee which may order the destruction of any crops that have been grown on land used as experimental fields.

Approval is issued by Decree of the Minister of Agriculture, acting on a proposal of the Pesticides Committee.

3.1 **The Committee**

The Committee comprises a representative of the Minister of Agriculture, acting as chairman, and members appointed by:

- (a) the Minister of Livestock Production;
- (b) the Minister of Waterways and Forests;
- (c) the Minister of Public Health and Population;
- (d) the Minister of Scientific Research;
- (e) the Minister of Industry and Planning;
- (f) the Minister of the Economy and Finance;
- (g) the Minister of Trade;
- (h) the Minister of Public Works and Transport;
- (i) the Minister of Defence;
- (j) the Minister of Internal Security.

The Committee has no decision-making powers but it examines all the applications for the decision-making authorities. It also proposes the approval and registration of pesticides (section 3) and the import for experimental purposes of non-authorised or provisionally authorised pesticides solely for the use of Ministry of Scientific Research establishments, and laboratories and research stations belonging to plant health control firms (section 9(3)), and the approval of pesticide retailers (section 12(2)) and applicators for these products (section 15(2)).

The Committee may also suggest amendments, suspensions or withdrawals of approval or provisional authorization (section 6(7)).

The Committee must be consulted whenever authorization is issued for the installation of any pesticide manufacturing and/or packaging establishment.

The Committee is nevertheless empowered to order the destruction of any crops grown on lands used as experimental fields (section 9(2)).

Whenever it deems it necessary, the Committee may also engage any person having some specific competence in a particular area to act in an advisory capacity.

3.2 **Information to be submitted to the authorities**

The application for approval of a pesticide is addressed to the Minister of Agriculture, and must be drawn up in French using the metric system, and provide an account of the toxicity and effectiveness of the product.

It must also indicate the following:

- (a) the trademark;
- (b) the product name proposed for the pesticide. This name must be different from the common standardised names of the active ingredients. It should not create to any confusion regarding use;
- (c) the exact quantitative and qualitative composition of the product, (including adjuvants), in a separate package, accompanied by samples;
- (d) the common name if any, the chemical composition and the proven physical or chemical properties of the active ingredient, as well as the conditions under which it will remain stable when stored;
- (e) adequate toxicological reports on the active ingredient and on the product as formulated (toxicological class, DL 50, poisoning risks and symptoms, antidotes and if possible advice to physicians);
- (f) the general features of the product (insecticide, fungicide, acaricide,...), uses, crops to be treated, conditions of use;
- (g) the form in which the product is presented;
- (h) the type, capacity and sealing system of the packaging;
- (i) the method of use, precautions to be taken by users, and counter-indications;
- (j) the periods for use before harvesting, grazing, slaughtering or consumption;
- (k) any incompatibilities with other pesticides;
- (l) the label design to be placed on the packaging, indicating not only the method of use, but also the date of manufacture and the use-by date, and the storage conditions;
- (m) reports on trials specific to the type of pesticide conducted by national or foreign research institutions;
- (n) copies of decisions regarding registration, authorization for sale, or restrictions on sale that may have been taken in other countries.

This list is not exhaustive. Any other information may be requested by the Committee which, at all events, has the sole responsibility for deciding on whether or not to accept the documents submitted.

3.3 **Tests**

The Committee may request the research establishments and responsible services of the ministries represented on the Committee as well as foreign laboratories to carry out any experiments

or tests and controls needed in order to appraise the documents submitted, and subsequently to monitor the approved products.

3.4 **The outcome of the process**

After examining the application and the documentation submitted with it, the Committee proposes one of the following four measures to the Minister of Agriculture: (i) approval; (ii) provisional PAS; (iii) the need for further studies to be conducted without PAS; or (iv) the rejection of the application (which necessarily implies the withdrawal of any PAS that may have been previously granted).

These measures are adopted in an officially approved form, and separate measures may be issued for the same speciality depending upon the uses for which it is intended.

Approval and PAS require the applicant to comply strictly with the initial proposals submitted to the Committee when filing the application for registration, to include any modifications which the Committee may have made to them.

When a product is found to contain poisonous substances no PAS may be granted, and when approval is issued the relevant declaration must mention the toxicological class.

Any change in the use and any extension to new uses is subject to obtaining prior approval.

For some pesticides for restricted use and pesticides which are dangerous to use, approval or the PAS may be issued for a limited number of named users.

The Law provides that if any of the agreed procedures are abandoned or if any waiver is made for any approved speciality or any or all of the agreed uses, this must be brought to the attention of the Committee which, where necessary, shall propose an appropriate amendment to the approval certificate.

3.5 **Expiry of registration**

The registration or PAS certificate may be modified, suspended or withdrawn by the Committee at any time, if it deems necessary.

The reasons for any decision to modify, cancel or withdraw the certificate must be given.

It is not clear from this legislation which authority is empowered to modify, suspend or withdraw registration. Since registration (or PAS) is issued by the Minister, it is presumably the Minister who is responsible for this procedure.

3.6 **Duration**

Approval is granted for five years, and any request for renewal must be submitted at least six months before the expiry of this period.

The PAS is granted for a period of two years, after which a final decision must be taken (acceptance or rejection).

3.7 **Fees**

The person to whom the approval is issued is required to pay for all the experimental work.

3.8 **Publication in the Official Journal**

Any measures adopted by the Minister are set out in the form of an "arrêté" and are therefore published in the *Official Journal*.

4. ADVERTISING

No advertising of approved pesticides or pesticides with a provisional agreement for sale may mention uses that are not set out in the official texts.

5. CONDITIONS RELATING TO MANUFACTURE

The Law provides that any pesticide manufacturing and/or packaging plant requires prior permission for installation for this purpose from the Minister of Industry and Planning, acting on the favourable opinion of the Minister of Agriculture issued after consultation with the Pesticides Committee.

6. CONDITIONS RELATING TO SALE

A pesticide seller is any individual or corporate person that procures pesticides to be marketed from the plant health control firms established in the Ivory Coast, legally recognised by the administrative authorities, or that imports these products.

Pesticide sellers are held liable for ensuring that the products purchased are approved or have been issued with a PAS.

Before dealing in pesticides, the seller must receive prior approval in the form of a joint 'arrêté' issued by the Minister of Trade and the Minister of Agriculture, acting on a proposal of the Pesticides Committee.

The applicant must:

- (a) demonstrate familiarity with general and practical knowledge relating to the specific features and the use of pesticides, either as a result of having taken a residential course with plant health control firms, or through vocational training or professional experience;
- (b) undertake to respect any quantitative or qualitative limits placed on imports;

- (c) possess premises on which to store pesticides during normal periods of use, which are locked, isolated from parts of buildings occupied by people or animals, and used exclusively for storing pesticides and agricultural equipment, with a notice affixed to the outside indicating the presence of hazardous substances;
- (d) be in possession of safety devices to detect leakages of toxic gas;
- (e) undertake to respect current plant health control regulations, and more specifically to sell only approved pesticides in their original hermetically sealed packaging;
- (f) undertake to engage in the distribution of pesticides as the main activity, and take any retraining or refresher courses that may be organised by the ministries and firms concerned;
- (g) undertake to submit to periodic medical examinations of the personnel.

Moreover, any middle-man between the consumer and the retailer acts under the liability of the retailer who has submitted a declaration to the Pesticides Committee and who guarantees compliance with the aforementioned conditions.

7. CONDITIONS RELATING TO USE

Any individual or corporate person who carries out the following on behalf of third parties is deemed a "pesticides applicator":

- (a) plant health protection;
- (b) treating stored foodstuffs;
- (c) chemical weeding;
- (d) cleaning agricultural product storage premises and facilities;
- (e) cleaning agricultural product vehicles and warehousing facilities;
- (f) cleaning public places, dwellings and animal shelters;
- (g) external parasite treatment of animals.

Like the pesticide seller, the applicator requires prior authorization in the form of an 'arrêté' of the Minister of Agriculture, acting on a proposal of the Committee.

The applicant must:

- (a) be in possession of general and practical know-how regarding the specific features and use of pesticides acquired either by in-house courses with specialised firms or by vocational training or professional experience;
- (b) possess appropriate and adequate facilities to protect the personnel against exposure to pesticides during dilution, application and storage;

- (c) possess efficient safety devices to detect any seepage of toxic gas;
- (d) possess a locked store to keep pesticides during the normal periods of use, separated from other parts of the buildings occupied by people or animals, to be used solely for storing pesticides and application equipment, with an external notice indicating the hazard;
- (e) undertake to require the personnel to submit to regular medical examinations;
- (f) undertake to comply with current plant health control regulations, and particularly only to use products which have been properly authorised for marketing.

The conditions with which the would-be user is required to comply in order to receive approval are therefore *mutatis mutandis* the same as those required for the seller, the only difference being that in the case of sellers pesticides must be the applicant's main field of activity, whereas for pesticide applicators the applicant does not need to show that it is his main activity.

8. TRANSPORT

Pesticides must be transported for marketing purposes under conditions that eliminate any risk of contamination. No explicit reference is made to the protection of foodstuffs.

9. DISPOSAL OF SURPLUSES

It should be noted, first of all, that it is forbidden to split any authorised packagings and that all bulk sales are prohibited (section 4). Moreover, after any pesticide application:

- (a) empty packages must be made unsuitable for any further use;
- (b) any pesticide residues must be disposed of taking all the necessary precautions.

10. LEGISLATION FOR IMPLEMENTATION

The Minister of Agriculture issues regulations for implementing the Decree jointly with the other relevant ministers.

THE REPUBLIC OF KOREA

Legislation examined: **The 1957 law on the handling of agricultural chemical products (although it actually deals specifically with pesticides) as amended by Law No. 3322 of 31 December 1980; and the subsidiary legislation for its implementation, Decree No. 11372 of 29 February 1984**

1. SCOPE AND DEFINITIONS

The Law does not apply to products intended for export.

The expression "agricultural chemical products", as used in the Law, includes all fungicides, insecticides and herbicides, used to control germs, insects, mites, viruses and any other animal or plant which is harmful to crops (including trees and agricultural and forest products), growth regulators and substances enhancing the effectiveness of pesticides. It should be noted that the substances used to control rodents are excluded from the scope of this Law.

2. LEGISLATION AND THE CODE

The Law does not deal with veterinary products, and only relates to plant health control products used against certain clearly defined pests (rodents are excluded). The definition of the word "pesticide" in the Code is more comprehensive.

3. PESTICIDE SUPPLIES (sections 3 and 4)

It should be noted firstly that the Law provides that in order to ensure balanced supplies of pesticides the Minister of Agriculture, Forests and Fisheries (hereafter the Minister) may require the professionals working in this sector as well as the national Federation of Agricultural Cooperatives - hereafter called the Federation - to establish a balance between supply and demand (section 3.1).

When the Minister acts through the Federation he may lay down price control measures (section 3.2).

The Law also provides that the government may grant subsidies or loans in order to ensure the balanced management of these products (section 4.3).

4. REGISTRATION (section 5.3)

A public notice (see below) must be issued for every pesticide before it is manufactured, imported or sold. Exceptions to this are imported pesticides to be used in laboratories or for scientific research.

The Minister is responsible for registration, which is carried out in stages.

4.1 **Tests and public notice (section 6 of the Law and articles 11 and 12 of the Decree)**

Anyone wishing to register a pesticide must request the Director of the Office for Rural Development (which reports to the Minister) to appraise the pesticide in terms of its effectiveness, effects, toxicity and residue content.

The Director may also proceed under his own powers.

With regard to the performance of tests, the Director may commission organisations appointed by the Minister, and particularly agriculture laboratories, research establishments or inspection firms.

The Regulations also provide the possibility to waive the tests regarding residues in the following cases, inter alia:

- (a) where there already exist results relating to the residues for the pesticides in question;
- (b) where the products are applied to crops that are not to be used for human or animal consumption.

Once the tests have been completed, the Minister issues a public notice which must contain the following information:

- (a) the type of product (e.g., acaricide) and its name;
- (b) the composition of the active ingredients;
- (c) the name and composition of the adjuvants;
- (d) the diseases and harmful insects to which the product may be applied, as well as the dosage;
- (e) the use-by date;
- (f) any other information which the Minister deems necessary.

Any manufacturer or importer of pesticides may acquire up to three hectares of land to carry out experiments with the products.

4.2 **The Committee**

The public notice is submitted to the Committee for Pesticide Management to be reviewed and for it to be "resolved upon" (resolution, decision, proposal).

The Committee comprises a maximum of 22 members, including officials from the Ministries of Agriculture, the Interior, Trade and Industry, Health and Social Affairs, the Rural Development Office and the Environment Office. Pesticide manufacturers and users may also sit on this Committee (article 4 of the Decree).

The Committee may also set up subcommittees.

The Committee is responsible for examining and deciding on the following issues:

- (a) public notices;
- (b) testing methods;
- (c) criteria relating to safety in the use and maintenance of pesticides;
- (d) methods for inspecting products;
- (e) any other matter submitted to it by the Minister.

The Law provides that the Committee shall be assisted by a Secretary and his Deputy.

4.3 **Import or manufacturing permits**

Before manufacturing, importing or selling pesticides that have formed the subject matter of a public notice, the applicant must be issued with a manufacturing or import permit issued by the Minister. It should be noted that the manufacturing permit also covers pesticide imports.

The application (under article 13 of the Presidential Decree) must provide the following information;

- (a) the name and address of the applicant;
- (b) the address of the factory or depot (or the place where repackaging is intended to be carried out in the case of imported pesticides);
- (c) the production plan and capacity (or, in the case of imports, the repackaging and storage capacity);
- (d) the work schedule.

The Decree lays down criteria to be followed by the Minister when appraising applications. The Minister is required to applications for permits particularly in terms of the future supply of and demand for pesticides, and must ensure that the applicant has not forfeited a similar permit in the previous three years: if so, the permit may not be issued.

The issue of a permit is subject to an inspection of the premises to be carried out by the responsible authorities. The applicant may nevertheless have the premises informally inspected both before submitting the application in order to ensure that they comply with the statutory conditions.

The permit-holder must inform the Minister of any change that may occur in the activities (the suspension of activities, the resumption of activities, the sale or modification of the facilities). This demonstrates the coordinating role which the public authority plays in order to ensure that pesticides are properly managed and that they are in adequate supply.

4.4 **The outcome of the process (registration in the strict sense)**

It is only after all of these procedures have been completed (tests, public notice, issue of a manufacturing or import permit) that the pesticide may and must be registered.

The Minister must be informed of any interruption, suspension or resumption of production.

4.5 **Information to be submitted to the authorities (section 5.1)**

The Minister issues an order laying down the information required to be submitted.

4.6 **Registration of commercial activities (sections 9,10 and 11)**

Sections 9, 10 and 11 of the Law provide that commercial activities must be registered for:

- (a) the production of active ingredients;
- (b) the sale of pesticides;
- (c) the application of pesticides.

The responsible authorities must be informed of any change in activities (suspension, cessation or resumption).

4.7 **Expiry (sections 12 and 13)**

A distinction must be drawn between the withdrawal of the manufacturing and import permit, the suspension of activities (even if partial), and the withdrawal of pesticide registration proper.

4.7.1 **The withdrawal of the manufacturing and import permit**

The manufacturing or import permit may be withdrawn:

- (a) if the manufacture, import or sale of products that have not been the subject of a public notice or have not been registered;
- (b) if the premises are transferred, rented or modified without prior approval from the Minister;
- (c) if activities are suspended for a period in excess of one year without informing the Minister thereof;
- (d) if an order suspending activities is violated;
- (e) if an order to integrate the facilities is violated.

The permit may also be withdrawn when the products manufactured have led to the withdrawal

of registration for a specific number of times: (withdrawals exceeding 30 percent of the registered pesticides in the case of manufacturers of less than 10 pesticides, 3 withdrawals if the number of pesticides registered are between 11 and 20, 6 (between 21 and 30), 9 (between 31 and 40), 12 (between 41 and 50), 15 (51 and over). These figures always relates to a two-year period.

4.7.2 Withdrawal of registration or suspension of permits

The Law also provides a number of cases justifying the withdrawal of registration or the suspension of the permit for a period of not more than two years.

Inter alia, the following may give rise to such a measure:

- (a) failure to commence activities after the issue of a permit (for more than one year);
- (b) infringement of the provisions of the Law relating to presentation, inspection (see below), and conditions of sale or use;
- (c) causing hazards to the environment or health.

The Law provides that if the permit or registration has been withdrawn on the grounds of an infringement under sections 12 and 13, no further application for a permit or registration may be submitted for a three-year period.

4.7.3 Duration

From an examination of the legislation, registrations or permits do not seem to have expiry dates. Nevertheless the supervision carried out by the authorities is always strictly enforced.

5. FEES (section 21)

A fee is charged for all applications for permits, registration or inspection (see below).

6. ADVERTISING (section 17)

Section 17 bans any advertising which makes untruthful or exaggerated claims.

7. PARTICULAR CONDITIONS

No product may be sold:

- (a) without indicating its name, its category (herbicide, fungicide, etc.), the percentage of active ingredients, use-by date, the insects or diseases against which it claims to be effective, etc.;
- (b) in bulk or repackaged without an import or manufacturing permit;

- (c) without the self-inspection certificate (see below);
- (d) if the packaging or labelling is defective;
- (e) after the use-by date.

Moreover, section 18 of the Law provides that in order to ensure that the pesticides are properly used, it may be necessary to classify the products. The Presidential Decree classifies them into "extremely toxic", "highly toxic" and "normally toxic" on the one hand, and pesticides causing residue-related problems (on crops, the soil and water) on the other.

The criteria relating to the proper use of the products - as are drawn up by the Minister of Agriculture - refer to the categories of users authorised to procure the products; the types of crops to which the products may be applied in terms of toxicity category; the methods of transport, storage, sale or use in terms of toxicity category.

8. PESTICIDE MANAGEMENT FUND (*sections 22 et seq.*)

The Law provides for the establishment of a Pesticides Management Fund to provide the resources needed to conduct all the tests to evaluate pesticides.

The management of the Fund, appointed by the Minister of Agriculture, must include both manufacturers and importers.

The Fund has its own financial resources. Every manufacturer or importer is required to pay 2 percent of their total sales revenues into the Fund's reserves every year. Nevertheless, revenues from the sale of products tested at the expense of the manufacturer or importer may be completely or partially excluded from this requirement.

The Fund is used to cover the following:

- (a) the cost incurred in testing and conducting the experiments needed for the issue of public notices;
- (b) the cost of training and safety campaigns regarding the use, handling and management of pesticides;
- (c) management costs.

9. INSPECTION (section 19)

This is one detail that deserves specific mention here, even though it does not fall within the scope of the institutional aspects of this survey. Section 19 provides that in addition to the inspections which the responsible authorities may conduct in the exercise of their own powers, the importer or the manufacturer must also have the products inspected before they are distributed, and submit a report to the responsible authorities. The importer or manufacturer may also request the authorities to inspect the products.

10. REGISTERS (section 20)

Operations relating to the manufacture, import, purchase or sale of pesticides or technical equipment must be entered in a Register and kept for two years.

LUXEMBOURG

Legislation analyzed: **The Law on the control of pesticides and plant health products, MX. A-No.9, 12 March 1968; the Regulation of the Grand-Duke on the control of plant health products *Mémorial A* No. 4, 9 February 1987.**

1. SCOPE AND DEFINITIONS

Pesticides are any substances and preparations intended to destroy or prevent the action of harmful animals, plants, microorganisms or viruses.

These products are subdivided into pesticides for agricultural use and pesticides for non-agricultural use.

The Law does not limit the definition of the word "pesticide" merely to products to be used in agriculture. The more specific term "plant health control products" is used in this case.

The following form part of the plant health control products category:

- (a) pesticides for agricultural use;
- (b) substances and preparations designed to enhance or to regulate plant production or to conserve plants or parts of plants;
- (c) substances and preparations intended to destroy weeds;
- (d) substances and preparations designed to destroy plant residues or to prevent undesirable growth;
- (e) microorganisms and viruses used in pest control;
- (f) wetting agents and adhesives designed to enhance the action of the substances and preparations indicated under points (a), (b), (c) and (d) above, in so far as they are marketed specifically for this purpose.

The Regulations for implementing the Law exclude the following from its scope:

- (a) medicines, drugs and radioactive preparations;
- (b) the transport of plant health control products by railways and by road, waterway, sea or air;
- (c) plant health control products intended for export outside the EEC;
- (d) transiting plant health control products;
- (e) fertilizers and conditioners;

- (f) plant health control products for scientific and experimental purposes to be used by an authorised person;
- (g) authorised additives in the food or food substances trade;
- (h) authorised additives in the animal feed trade;
- (i) plant health control products which are not registered in the Grand-Duchy, but which are authorised in another EEC Member State, requiring prior treatment of the plants or plant products in the exporting country using these plant health control products before they can be imported into the territory of the Grand-Duchy

2. LEGISLATION AND THE CODE

The definition set out in the Law is essentially the same as the one given in the Code. However the other spheres to which the Code refers in its definition (products for veterinary use, substances for the protection of human health) are not envisaged in this legislation.

3. APPROVAL AND REGISTRATION

The Law prohibits the possession, manufacture, import, delivery or transport for sale, the marketing or direct selling, assigning for consideration or without consideration or in exchange, of pesticides and plant health control products which are not approved and registered by a governmental agency.

The application for approval is submitted to the Ministers of Agriculture and Health, who are assisted in their duties by an Approvals Commission.

3.1 Approvals Commission

The Commission comprises six members appointed by the ministers having responsibility (three officials from the Ministry of Agriculture, of whom one acts as chairman, two officials of the Ministry of Health and one official from the Ministry of Labour, appointed by his Minister). The Regulations also provide for the appointment of six alternates.

3.2 The outcome of the process

A product can-only be approved if it is virtually certain that the quality is such that it is suitable for the purpose for which it is intended and that its proper use will not have harmful side effects. Harmful side effects include the following:

- (a) damage that might resulting from the use of these products in terms of public health or any other threat to the safety of the persons applying them, even if the required precautions are taken;
- (b) indirect harmful consequences on the quality of any foodstuffs;

- (c) reduced soil fertility, or harm caused to the water table, plants and animals who should be protected, provided this is disproportionate in terms of the intended result of using the product.

When granting approval, the Ministers of Agriculture and Health lay down, where necessary, special conditions to which the sale of the product is subject.

Each approved and registered product is given an approval number.

3.3 **Duration and expiry of approval**

The Ministers of Agriculture and Health may at any time give at least six months' prior notice of the suspension or the withdrawal of approval without incurring claims for damages against the State. However no prior notice period is required when the approval is suspended or withdrawn on the grounds of public health.

A reasoned decision for suspending or withdrawing approval is notified to the interested party. This shows that the ministers concerned have a wide margin of discretionary power with regard to withdrawing registration.

Approval is granted for a maximum of ten years.

3.4 **Fees**

Section 6 of the Law provides that fees be charged for submitting the application for approval, renewing approval, and for any applications to change the name or formulation of the product. The Law also provides that the cost of any chemical tests or physical/chemical tests, bioassays, toxicological tests and any other tests shall be paid by the applicant. The Regulations require the ministers responsible to determine these costs.

The Regulations also lay down the fees payable for the different types of application (registration, renewal, modification, denomination or formulation).

3.5 **Publication in the *Mémorial***

Each year, in the first quarter, the list of products approved the year before is published in the *Mémorial du Grand-Duché*.

4. REGISTERS

Approved products are recorded in a register kept by the Plant Protection Service kept by the Administration of Agricultural Technical Services.

Importers, manufacturers, preparers and sellers must also keep commercial and transport documents for a minimum of three years. They are required to exhibit them to anyone responsible for enforcing the Regulations.

5. ADVERTISING

Commercial advertising may not indicate any qualities or uses other than those set out in the certificate of approval.

6. CLASSIFICATION

6.1 Classes and categories

The Regulation lays down three classes (A, B, C) and several categories (highly toxic, toxic, corrosive, harmful, irritant, easily inflammable, fuels and explosives) for plant health control products, in terms of the hazards which they represent.

Class A includes the "highly toxic", "toxic" and "corrosive" products; class B includes the products which do not belong to class A and which fall into the categories of "harmful" or "irritant" products, while the other products fall under class C.

The Regulations also lay down the principles to be followed when deciding upon the classification and the category, and provide the symbols and the indications required for the various hazard categories.

The particular risks and precautionary advice relating to the use of the product for each hazard category that must be mentioned are laid down when the plant health control products are approved.

6.2 The Commission

The classification is established by the Minister of Health based upon the opinion of a commission composed of six members: three members, including the chairman, are appointed by the Minister in question, two are appointed by the Minister of Agriculture and one by the Minister of Labour.

In this case the composition and the chairmanship of the Commission is the exact opposite to the Commission examined in point 4.1 above, which is required to assist the Minister responsible for approval and registration: in this case the position of the Minister of Health prevails.

7. SPECIALLY APPROVED AND APPROVED SELLERS

7.1 Class A - Specially approved sellers

The import and sale of class A plant health control products are reserved exclusively to specially approved sellers, namely pharmacists who have a workshop open to the public and persons specially approved to this end by the Minister of Health. In order to qualify the latter must:

- (a) apply to the Minister of Health;
- (b) specify the place where they intend to practise their activity;

- (c) give proof that the premises or the equipment is appropriate, and undertake to permit inspection by any persons appointed to do so;
- (d) be in possession of a diploma as chemical engineers, agricultural engineers, or an equivalent qualification, or demonstrate that they possess the necessary know-how;
- (e) undertake to inform the Minister of Health fifteen days in advance of any change with regard to the eligibility requirements.

It should be noted that:

- (a) the specially approved seller may be authorised to market all class A products or only some of them (section 25);
- (b) class A products cannot be sold or given away free of charge except to sellers and users who are qualified to sell and use these products (section 26);
- (c) the specially approved seller may only be replaced by another specially approved seller. However, acting under his own responsibility, he may be assisted by persons over the age of 18;
- (d) the specially approved seller must be sure of the identity and the status of the purchaser of the product. The Regulations lay down the procedures to be followed here.

The specially approved seller is required to draw up a sales document, in duplicate, for the sale of every class A plant health control product, indicating the following:

- (a) the name and address of the responsible approved seller,
- (b) the number of the authorization certificate;
- (c) the name and address of the user;
- (d) the names and the quantities of the products sold;
- (e) a formula attesting to the fact that the user recognises that the seller has pointed out the dangers involved in handling the products and the precautions needed in order to use them;
- (f) the date and the signature of both parties.

At the moment of the sale, the seller places a label on the recipients and packages containing a class A plant health control product, with his name and address, and the number of the approval certificate.

Sellers must keep all the documents for three years.

7.2 **Class B - Approved sellers**

The import and sale of class B plant health control products is reserved (in addition to the specially approved sellers) to persons approved by the Minister of Health.

The eligibility conditions required to obtain authorization are the same as those laid down for the approval of sellers, with the sole exception that it is not necessary for the applicant to hold any of the following diplomas: chemical engineering, agricultural engineering (or the equivalent). Nevertheless the applicants must give proof of their know-how in this field, and particularly show that they have had at least three years practical experience in the field of plant health control products (section 31).

7.3 **Examination of applications**

Applications are examined by an official appointed by the Minister of Health.

7.4 **Delivery of products**

Plant health control products, which may not under any circumstances be divided up, must be given to the user in the original packaging.

With regard to their disposal, the packaging of class A plant health control products may not be re-used except by the manufacturer or the person holding the approval certificate, and only when they are recipients intended for re-use or refilling by the approval-holder for the sale of the same product.

8. SPECIALLY APPROVED USERS, APPROVED USERS, EQUIVALENT USERS

Just as the sellers are subject to control, the Regulations also provide that the users be controlled, and a distinction is drawn between specially approved users and approved users.

8.1 **Specially approved users**

The use of class A products set out in an *ad hoc* list is reserved to specially approved persons. Approval is granted by the Minister of Health acting on the Committee's proposal. It may be limited to the use of one or several products to treat a particular place or for a particular period of time.

In order to obtain this qualification, the applicant must submit all the necessary documentation to show his expertise in the field.

8.2 **Approved users**

Except for the class A products set out in the *ad hoc* list (cf. para. 13.1 above) whose use is reserved to specially approved users, any other products in the same class can only be used by users approved by the Minister of Agriculture and the Minister of Health.

Where the Regulations do not specify the conditions to be met by the specially approved user, it specifies the eligibility conditions that must be met by the approved user. The approved user must, in particular:

- (a) hold a decree in agricultural engineering (or an equivalent medical degree), chemical engineering, chemistry, pharmacology, agricultural-industrial engineering, or be a holder of a diploma in natural sciences;
- (b) hold a diploma or a certificate issued by a recognised educational establishment showing that the person concerned is in possession of the required knowledge;
- (c) justify to the Commission responsible for classifying products that he is in possession of the required knowledge regarding plant health control products (section 39).

8.3 **Equivalent users**

Section 41 establishes the category of "equivalent users", of the same status as the approved users. This category includes: (i) farmers, horticulturalists and viticulturalists, and (ii) researchers under the supervision of the authorities having technical responsibility.

8.4 **Product use**

Approved users and specially approved users may only be replaced by any other approved or specially approved user. However they may be assisted, under their own responsibility, by persons over the age of 18.

9. **RELEVANT CONSERVATION AND SAFETY MEASURES**

The sellers and users of classes A and B products are required to act in conformity with very stringent product safety and conservation rules.

9.1 **Sellers**

Specially approved sellers are required to keep the plant health control products containing highly toxic, toxic or corrosive substances in a locked cupboard or on premises specially set aside for these products, which are only accessible in the presence of specially approved sellers.

The premises must be dry and air-conditioned to ensure that the stored products are properly conserved.

These products and drugs or foodstuffs for both human and animal consumption can only be marketed simultaneously if these substances are stored, conserved and handled on completely separate premises from those on which the drugs or foodstuffs are handled.

Class B and C products must be stored in a cupboard or on special premises for this purpose.

9.2 **Users**

All users of classes A and B plant health control products are personally liable for

- (a) keeping the products in their charge, locked, in the original packaging, out of reach of unauthorized persons;
- (b) informing their colleagues on the safety and hygiene measures to be complied with when handling or using class A and B products.

MALAYSIA

Legislation analyzed: **Law No. 149 and the legislation for application, and in particular the Regulations governing the registration of pesticides (1976), the instrument governing exemption from registration (1979), the Regulations relating to the import of pesticides for educational and research purposes (1981), and the labelling Regulations (1984).**

1. SCOPE AND DEFINITIONS

According to the definition given in the Law pesticides are preparations used to destroy or to prevent the onset or spread of:

- (a) all fungi, parasitic plants or bacteria on plants, fruits, animals or other property, as well as all insects or diseases which affect or attack these;
- (b) any harmful animal, bird or plant, as well as weeds.

Domestic animals and all animals covered by wildlife protection legislation form part of the statutory definition of "animal".

The Law also lays down criteria for identifying a new product.

A pesticide is therefore identified in terms of the following:

- (a) its chemical name, its trademark and its commercial name;
- (b) its ingredients;
- (c) its formulation;
- (d) its manufacturer,
- (e) its technical features.

It is sufficient for even one of these elements to differ between two pesticides under comparison for the substances to be deemed to be different substances.

2. LEGISLATION AND THE CODE

The definition given by the Code is certainly more complete. However it should be stressed that the definition in the Law is not limited to plant health products: it also covers substances for veterinary use, and products to be used for the protection of other foodstuffs and "property".

3. REGISTRATION

All pesticides must be approved and registered before being imported or manufactured. The statutory definition of the term "manufacture" includes several operations linked to the manufacturing process such as the formulation, preparation, labelling or packaging of the product. One exception to the principle of prior registration is nevertheless made in the case of pesticides imported for educational or experimental purposes.

The Committee (see below) may issue a permit for educational or experimental reasons, in exchange for a fee, laying down any conditions it deems necessary. The Law provides that the Committee shall also lay down the conditions for disposing of surpluses.

In 1987 an instrument was adopted for applying the Law. Article 4(3) of this instrument provided, *inter alia*, that the permit would remain valid for six months.

3.1 The composition of the Committee

The Law makes no provision for the institution of a Registrar. The activities relating to pesticide registration are performed by a Committee for which the Law provides a complete list of the persons required to take part in its work. These are:

- (a) the Director-General for Agriculture, acting as chairman;
- (b) a senior administrator from the Department of Agriculture from Western Malaysia;
- (c) the Director of the Health Service;
- (d) the Director-General of the Chemistry Service;
- (e) the Director of the Institute for Agricultural Development and Research;
- (f) the Director of the Rubber Research Institute;
- (g) the Director-General of Veterinary Services;
- (h) the Head of Chemistry Applied to Pharmacy at the Ministry of Health;
- (i) the Director-General of Forests of Western Malaysia;
- (j) the Director of Agriculture of Sabah;
- (k) the Director of Agriculture of Sarawak.

The Law enables the Committee to invite other non-members to attend its meetings. These invitees do not have voting rights.

3.2 **The functions of the Committee**

The Committee is responsible for issuing and withdrawing pesticide registration. It may nevertheless authorise the import of non-registered pesticides for educational or experimental purposes. In general it is responsible for issuing pesticide manufacturing licences, and at the request of the Minister it submits its opinions, particularly on all draft instruments for the implementation of the Law.

3.3 **Information to be submitted to the authorities**

Anyone wishing to manufacture or import a pesticide must request approval and registration from the Committee. The application must include the following;

- (a) a statement giving the common name, if available, the commercial name, the chemical name, the chemical formula, as well as the name and the concentration of all the active ingredients in the pesticide;
- (b) the name and the concentration of any other ingredient forming part of the composition of the pesticide;
- (c) a report on the concentration of every other component of the pesticide;
- (d) a detailed toxicological report on all the substances in the pesticide, and on the pesticide as a whole;
- (e) the full wording that will appear on the label of the product, including instructions for use and the precautions to be taken during use, and the properties;
- (f) a report explaining the packaging procedures, or a sample of the packaging;
- (g) a report dealing with the effectiveness and the safety of the product;
- (h) a report on the methods for analyzing the pesticide, including information on the institutions that have conducted these analyses;
- (i) a report showing the methods used to determine the pesticide residues on the plants or the crops on which it is expected that the products will be used;
- (j) the applicant's registered office and the place where the applicant intends to store the pesticides, if a manufacturer,
- (k) the name and address of the factory or the building in which the applicant expects to manufacture the pesticide, and a summary description of the manufacturing methods.

The Committee may always request supplementary information, and where necessary change the information required for the labelling and packaging, and may also waive the need to supply some of this information with the application.

3.4 **Confidentiality**

All the information received is treated as confidential. However this is not merely limited to the technical information on the products but to all information submitted to the authorities in connection with the implementation of this Law.

An exception is made to the obligation to confidentiality when it is necessary to divulge information for the application of the Law or if the information is needed in legal proceedings.

3.5 **The outcome of the process**

The Committee registers the pesticide when it is satisfied that:

- (a) the information submitted is genuine;
- (b) the rules regarding labelling and packaging have been respected;
- (c) the pesticide is effective and safe for humans and animals, if correctly used according to the instructions, or if there is a risk this is offset by the advantages to agriculture of using it.

When the pesticide is registered, the Committee gives it a number and issues a registration certificate to the applicant.

3.6 **Expiry of registration**

The Committee may order the withdrawal of the registration of the pesticide:

- (a) when the registration-holder notifies the Committee that the product is no longer being sold or used;
- (b) when withdrawal is deemed necessary in view of the toxicity or ineffectiveness of the pesticide;
- (c) when the product no longer possesses the properties given on the labelling;
- (d) if the label is not in accordance with the provisions of legislation or regulations;
- (e) when specific registration conditions are being infringed;
- (f) where the applicant submits inaccurate data with the application for registration;
- (g) if the pesticide is no longer being used.

The Committee gives the registration-holder the opportunity to provide reasons for keeping registration before it is withdrawn (section 10(2)).

4. MANUFACTURING LICENCE

The Committee issues a manufacturing licence when:

- (a) the pesticide for which the licence application is submitted is registered in the name of the licence applicant;
- (b) the applicant has sufficient technical knowledge to be able to manufacture the product;
- (c) the applicant is in possession of the necessary technical facilities to limit the risks inherent in manufacturing the product.

5. SALES AND STORAGE LICENCE

This licence is issued by an Inspector appointed in different regions. The Inspector grants the licence when; (i) the pesticide for which the licence application is made has been approved and registered; and (ii) when the applicant has been informed of the dangers inherent when handling the pesticide.

The Law also provides, *inter alia*, that the licence must: (a) give the address of the premises where sale, or storage and sale is authorised; and (b) authorise the sale and storage of the pesticide for sale on the same premises.

6. DURATION AND EXPIRY OF LICENCES

The manufacturing licence remains valid for a period of three years and is renewable on each expiry date. The licence for sale and storage is granted for a period of one year.

The Committee (in the case of a manufacturing licence) or the Inspector (in the case of a sales or storage licence) may revoke/suspend or refuse to renew the licence when: (i) the application contains inaccurate information; and (ii) the licence-holder has infringed the conditions laid down when the licence was delivered, or with the provisions of the Law or other instruments on which the application is based. The licence-holder is entitled to give reasons to the authorities.

7. FEES

First registration, renewals and withdrawals or refusals to issue registration or to renew it must be published in the *Official Journal* giving all the information required to identify the product.

8. ADVERTISING

The Committee has issued instructions relating to advertising of pesticides. According to these instructions all pesticide advertising must comply with the conditions under which the products are registered and must not encourage consumers to overestimate the effectiveness of the products or to be misled regarding their nature.

The instructions also prohibit the use of such expressions as "non-toxic" or "harmless"...

9. RIGHT OF APPEAL

Like every decision taken by the Committee (or the Inspector) appeals may be lodged by applicants with the Minister. In the case of an appeal against a registration decision, or against a refusal to renew registration, the applicant may submit information to the Minister to supplement the data in the reports submitted to the Committee, provided that this information has also been submitted to the Committee at the same time.

The Minister's decision is final and binding.

SOLOMON ISLANDS

Legislation analyzed: **"The Safety at Work Act, 1982" and "The Safety at Work (Pesticide) Regulations, 1982**

Section 28(5) of the Act provides for the adoption of regulations banning the import, sale or supply of pesticides save where: (i) the pesticide has been registered in accordance with the Regulations in the meantime; and (ii) no pesticides have been imported, sold or supplied during the same year,

1. SCOPE AND DEFINITIONS

According to the definition, pesticides are any product intended for use against a pest, and composed of an active ingredient and an adjuvant.

The definition of pest is not exhaustive: it may apply to any animal or plant which is likely to cause harm or destruction.

Conversely, the definition of the formulated product is given in great detail. A formulated product is one which is sold, imported or distributed with the purpose of destroying or repelling any pest, or preventing its growth or mitigating its effects. Formulated products also include growth regulators, defoliant, desiccants and adjuvants.

2. LEGISLATION AND THE CODE

Even though the definition of "pest" does not exclude organisms which may be harmful to animal health, the explicit reference made to growth regulators, defoliant and desiccants (without any reference to products for veterinary use) would seem to restrict the application of *the* Law to plant health control substances alone.

The impression seems to be supported by the fact that the composition of the Committee does not include experts on veterinary pharmacology.

3. REGISTRATION

Any person wishing to import, sell or distribute a pesticide must be registered beforehand.

However, the Registrar (see below) may issue provisional authorization for the purposes of experimentation (section 6). This authorization is valid for six months, and the Registrar may impose any conditions deemed necessary.

3.1 The Registrar

The Law makes provision for the appointment of a Registrar, responsible for keeping the Register of all registered pesticides indicating:

- (a) their commercial name;
- (b) the name of the active ingredient of the pesticide as approved by ISO;
- (c) the type of formulated product;
- (d) the concentration of the active ingredient;
- (e) the date of registration and registration number,
- (f) the name and address of the person in whose name the product is registered.

In the performance of his duties the Registrar is assisted by a Committee.

3.2 **The Committee**

The following are members of the Committee:

- (a) the main government officer responsible for agriculture, acting as chairman;
- (b) the Registrar, acting as secretary;
- (c) a representative of the Government Pharmacist;
- (d) a government official who is an expert in industrial safety;
- (e) a government specialist who is an expert in public health and environmental protection;
- (f) public officials appointed by the Minister for Agriculture (at least three).

The Committee examines the product and advises the Registrar on its registration; where necessary, it can lay down conditions for the use of all pesticides in the country, and provide the Registrar with its opinion on the advisability of withdrawing registration.

The Committee is responsible for classifying products on the basis of their toxicity levels. The Regulations establish the basic criteria to be followed by the Committee when establishing this classification (Regulation 3.3).

The Committee is also responsible for hearing appeals (see below).

3.3 **Information to be submitted to the authorities**

All applications must be accompanied by the following information:

- (a) the common name using ISO (International Standards Office) terminology of the active ingredients;
- (b) the developed formula and the empirical formula of the pesticide;

- (c) the fusion, decomposition or boiling point of the product;
- (d) vapour pressure;
- (e) methods for analyzing the active ingredients in the case of formulated products and for establishing residues;
- (f) stability in relation to storage, density, flammability and pH;
- (g) appropriate toxicological data on the active ingredient of the pesticide or evidence showing that the product is presently registered in Australia, New Zealand, Hawaii, the United Kingdom, Japan or Fiji;
- (h) any other information which the Registrar or the Committee deem necessary.

This information very largely coincides with the information that FAO considers essential before registering a pesticide (see the FAO Guidelines for the Registration and Control of Pesticides).

The Registrar and the Committee must treat all the information received as confidential.

3.4 **The outcome of the process**

On receiving an application for registration, the Registrar must: (a) inform the Committee; and (b) act on the opinion of the Committee providing the prescribed information, by either registering the pesticide with or without conditions, or rejecting the application for registration.

If registration is granted, the Registrar must notify the applicant in writing of the number, the date and the conditions for registration.

If registration is refused, the Registrar must issue a written opinion and submit it to the applicant.

3.5 **Expiry of registration**

The legislation says very little about this. It merely provides that, acting on the opinion of the Committee, the Registrar may withdraw registration or provisional authorization for the pesticide. This decision must then be published in the Official Journal at least six months in advance. However, if the Committee deems it necessary, the six-month grace period may be denied. No details are given in the Regulations regarding the reasons *that* might justify the decision to withdraw registration (hazards connected with the use of the product, malpractice on the part of the registration-holder, etc.).

3.6 **Duration**

The registration of a pesticide is valid for five years. If any change is made to the formula, the registration automatically lapses, after which it may be renewed.

3.7 **Fees**

A fee is charged for all applications for registration or provisional authorization.

3.8 **Publication in the Official Journal**

It is the responsibility of the Registrar, as soon as possible after registration, to publish the following information in the *Official Journal*:

- (a) the commercial name;
- (b) the chemical identity of the active ingredients;
- (c) the name of the manufacturer,
- (d) the name of the person on whose behalf the pesticide has been registered;
- (e) the registration number.

3.9 **Right of appeal**

When a registration application is rejected or withdrawn, the party concerned may appeal to the Committee within one month.

The Committee alone is competent to hear the appeal.

SRI LANKA

Legislation analyzed: **Control of Pesticides Act, No. 33 of 1980"**

1. SCOPE AND DEFINITIONS

The Law applies (i) to active ingredients and formulations including adjuvants, and (ii) to adjuvants used to be mixed with the active ingredient.

According to the definitions of "pest", "pesticide" and "pesticide formulation" any substance is considered to be a pesticide which is intended to control:

- (a) insects, rodents, birds, fishes, molluscs, nematodes, fungi, weeds, microorganisms or viruses;
- (b) any other form of vegetable or animal life which is capable of affecting crops, stored products, foodstuffs, wood, clothing, cloth or any other inanimate object, or public health;
- (c) parasites on and in human and domestic animals' bodies.

This definition also includes growth regulators, defoliants, desiccants and adjuvants.

2. LEGISLATION AND THE CODE

The definition of the term "pesticide" is close to the one given in the Code.

3. REGISTRATION

All pesticides must be registered before they are manufactured, formulated, distributed, sold, put on the market or delivered, and also before they are packaged.

The Registrar (see below) may issue written authority to import non-registered pesticides - carried out by an approved organisation - for research purposes (section 14). It is prohibited to import any pesticide unless this is authorised in writing by the Registrar acting on an opinion issued by the Committee; the Law seems to treat registered and non-registered pesticides in the same manner in this connection; this provision makes it possible to check the amount of pesticides introduced into the country at any time, since the non-registered pesticides, like the registered pesticides, cannot be imported without prior authorization.

3.1 The Registrar

The Registrar is appointed by the government and is responsible for registering pesticides. He must be an expert on toxicological, biological and pest control issues.

In the performance of his duties, the Registrar is assisted by a Committee.

3.2 **The composition of the Committee**

The following are members of the Committee:

- (a) the head of the agriculture Directorate, *ex officio*;
- (b) the Registrar, *ex officio*;
- (c) eight experts in pesticide use, pest control or allied fields, appointed by the Minister and having no commercial interest in the pesticides sector.

3.3 **Information to be submitted to the authorities**

The application for registration filed with the Registrar must contain:

- (a) the name and address of the applicant;
- (b) the name and address of the manufacturer,
- (c) the proposed commercial name;
- (d) a copy of the label;
- (e) samples of the packaging;
- (f) a declaration from the manufacturer relating to the use, the strength, and the shelf life, as well as the effects of the product;
- (g) a declaration stating the composition of the pesticide, its chemical features, its net weight, stability, conditions of use and shelf life;
- (h) adequate toxicological data, including information on antidotes;
- (i) analysis methods;
- (j) methods used to determine the residues;
- (k) a report from a laboratory or experimental station, or on biological tests relating to the effectiveness of the pesticide;
- (l) at the request of the Registrar, any other information relating to the effectiveness or the safety of the pesticide.

Any information submitted to the Registrar is dealt with confidentially at the request of the applicant. An exception to this is the case in which the court of law deems that this information must be divulged.

3.4 **The outcome of the process**

Once the application has been filed the Registrar may;

- (a) register the product, issue a licence to the applicant and declare the pesticide "an approved pesticide" (section 9(1));
- (b) register the product and before issuing the licence issue a provisional permit to market the product and for its restricted use, in accordance with the conditions laid down in the permit;
- (c) reject the application, giving reasons for so doing.

4. LICENCES AND PERMITS

Acting on the opinion of the Committee, the Registrar may withdraw, suspend or modify the licence or provisional permit:

- (a) in the case of any infringement of the Law or the instruments for its application;
- (b) where this is felt necessary in the interests of the majority.

The Registrar must motivate his decision.

5. DURATION

The duration of the licence or the permit is set out in the document itself. The licence and the permit are renewable after a fresh examination of the features of the product.

6. FEES

All applications for a licence, and any appeal against a decision to reject, withdraw, suspend or modify a licence, is subject to a fee.

The relevant section of the Law also provides that in addition to these fees a tax may be imposed on the import, manufacture, formulation or packaging in order to set up a fund to be used to enforce the Law and the instruments for implementing it.

7. PUBLICATION IN THE OFFICIAL JOURNAL

All declarations relating to the approval of a pesticide and any decision to withdraw or suspend the licence or the provisional authorization must be published in the *Official Journal*.

8. ADVERTISING

All advertising must be in accordance with the approved labelling and with the registration conditions.

9. RIGHT OF APPEAL

Appeals may be filed against decisions to reject, withdraw, suspend or modify a licence or authorization.

The appeal must be filed with the Secretary of the Minister of Agriculture within sixty days from the date on which the decision was served on the person concerned.

The Secretary may confirm, modify or cancel the decision. The decision of the Secretary is final and binding.

10. SAFETY MEASURES

It is prohibited to: (i) store, transport or sell a pesticide when this might contaminate foodstuffs; (ii) store pesticides in bulk save in a store designed for that purpose, and provided that specific precautions have been taken locking the premises, affixing a hazard notice); (iii) harvesting or selling any product for which the intervals of use have not been respected, or which exceed the upper limits of residues prescribed.

FAO TECHNICAL PAPERS

FAO LEGISLATIVE STUDIES

- 1 Wildlife and national park legislation in Asia, 1971 (E*)
- 2 Wildlife and national park legislation in Latin America, 1971 (E* S*)
- 3 Vicuña conservation legislation, 1971 (E* S*)
- 4 Legal systems for environment protection: Japan, Sweden, United States, 1972 (E*)
- 5 Agrarian law and judicial systems, 1975 (E F S*)
- 6 Agricultural credit legislation in selected developing countries, 1974 (E)
- 7 An outline of food law, 1975 (E F S)
- 8 Legislación de aguas en América Central, Caribe y México - Vol. I, 1975 (S)
- 9 A legal and institutional framework for natural resources management, 1975 (E S)
- 10 Water law in selected European countries (Belgium, England and Wales, France, Israel, Italy, Spain, Turkey) - Vol. I, 1975 (E F S)
- 11 Fundamentos teóricos para una legislación tributaria en el sector agropecuario, 1975 (S)
- 12 International food standards and national laws, 1976 (E/F)
- 13 Derecho agrario y desarrollo agrícola: estado actual y perspectivas en América Latina, 1976 (S)
- 14 Legal and institutional responses to growing water demand, 1977 (E F S)
- 15 Systematic index of international water resources treaties, declarations, acts and cases by basin - Vol. I, 1978 (E/F/S)
- 16 Seed legislation, 1980 (E F S)
- 17 Water law in selected African countries, 1979 (E F S)
- 18 Reforma agraria y desarrollo rural integrado, 1979 (S)
- 19 Water legislation in South American countries, 1983 (E F S)
- 20 Legislation on wildlife, hunting and protected areas in some European countries, 1980 (E F S)
- 21 Legislation on coastal state requirements for foreign fishing, 1981 (E)
- 21 Rev. 1 Coastal state requirements for foreign fishing, 1983 (EFS)
- 21 Rev. 2 Coastal state requirements for foreign fishing, 1985 (ES)
- 21 Rev. 3 Coastal state requirements for foreign fishing, 1988 (EFS)
- 21 Rev. 4 Coastal state requirements for foreign fishing, 1993 (E)
- 22 Agricultural insurance legislation, 1981 (E S)
- 23 The law of international water resources, 1980 (E FS)
- 24 Irrigation users' organizations in the legislation and administration of certain Latin American countries, 1983 (ES)
- 25 Legislation on wildlife and protected areas in Africa, 1984 (E F)
- 26 The UN Convention on the Law of the Sea: impacts on tuna regulation, 1982 (E F)
- 27 Regional compendium of fisheries legislation - West Africa (CECAF Region), 1983 (E/F*)
- 28 Plant protection legislation, 1984 (E F S)
- 29 Législation on foods for infants and small children, 1983 (E*)
- 30 Water law in selected European countries (Cyprus, Finland, the Netherlands, Union of Soviet Socialist Republics, Yugoslavia) -Vol. II, 1983 (E)
- 31 The role of legislation in land use planning for developing countries, 1985 (E)
- 32 Agricultural census legislation, 1984 (E)
- 33 Legislation on productivity in agriculture: a comparative outline, 1985 (E F S)
- 34 Systematic index of international water resources treaties, declarations, acts and cases by basin - Vol. II, 1984 (E/F/S)
- 35 Regional compendium of fisheries legislation (Western Pacific Region) -Vols. I and II, 1984 (E)
- 36 Legislation controlling the international beef and veal trade, 1985 (E F S)
- 37 La législation forestière au Cap-Vert, en Ethiopie, en Gambie, au Mali et en Mauritanie, au Niger, au Rwanda et au Sénégal, 1986 (F)
- 38 The environmental impact of economic incentives for agricultural production: a comparative law study, 1990 (E F S)
- 39 Propiedad, tenencia y redistribución de tierras en la legislación de América Central y México, 1986 (S)
- 40 International groundwater resources law, 1986 (E F S)
- 41 Land tenure systems and forest policy, 1987 (E F)
- 42 Regional compendium of fisheries legislation (Indian Ocean Region) -Vols. I and II, 1987 (E)
- 43 Pesticide labelling legislation, 1988 (E F S)
- 44 La réforme du droit de la terre dans certains pays d'Afrique francophone, 1987 (F)
- 45 Legal aspects of international joint ventures in agriculture, 1990 (E)
- 46 The freshwater-maritime interface: legal and institutional aspects, 1990 (E)
- 47 The regulation of driftnet fishing on the high seas: legal issues, 1991 (E F)
- 48 Les périmètres irrigués en droit comparé africain (Madagascar, Maroc, Niger, Sénégal, Tunisie), 1992 (F)
- 49 Analyse préliminaire de certains textes législatifs régissant l'aquaculture, 1993 (F S)
- 50 Treaties concerning the non-navigational uses of international watercourses - Europe, 1993 (E/F/S)
- 51 Pesticide registration legislation, 1995 (E F)
- 52 Preparing national regulations for water resources management, 1994 (E)
- 53 Evaluation des impacts sur l'environnement pour un développement rural durable: étude juridique, 1994 (F)
- 54 Legislation governing food control and quality certification -Authorities and producers, 1995 (E F)

Availability: August 1995

Ar	- Arabic	Multil	- Multilingual
C	- Chinese	*	Out of print
E	- English	**	In preparation
F	- French		
P	- Portuguese		
S	- Spanish		

The FAO Technical Papers are available through the authorized FAO Sales Agents or directly from Distribution and Sales Section, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy.