

Pesticide labelling legislation

FAO
LEGISLATIVE
STUDY

43



FOOD
AND
AGRICULTURE
ORGANIZATION
OF THE
UNITED NATIONS

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by

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Legal Office

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FOREWORD

The use of pesticides in agriculture is widespread at the present time and can be considered beneficial, generally speaking, as it serves not only to raise productivity but also to reduce post-harvest losses. However, pesticides are toxic substances to a greater or lesser degree, and their employment entails a definite risk to the health of humans, domestic animals and livestock, and can also lead to the pollution of the environment.

For these reasons, most States have enacted legislation for the purpose of providing maximum safety to the user of pesticides, as well as to furnish due guarantees to the consumer of food products. Such legislation consists normally of a set of regulatory provisions governing the authorisation and registration of pesticides, marketing, labelling and so on, together with the necessary mechanisms of enforcement.

Among all these provisions, particular importance attaches to those concerning labelling. Indeed, the correct labelling of pesticides ensures that the user is in possession of the necessary information, not only regarding the contents of the package (identity of the product, composition, net contents etc.), but also regarding the precautions to be taken for its application or handling, as well the measures to be adopted for avoiding risks to the health of humans, animals and plants, and to the environment. Pesticides on the market should therefore always have labels containing all the required information, including if necessary pictograms which can be easily understood by illiterates or persons of modest cultural level. The product label is often the only available means of communicating to the user such data as the precautions to be taken, instructions for use, warnings as to how to avoid intoxication, and so on.

The present study has been prepared on the basis of the legal texts available in the Legislation Branch. The texts consulted were thus limited

to those held in the archives at the time of writing, and they may not always be complete or currently operative in their entirety. This survey does not, in any case, claim to be either an exhaustive treatise or a complete manual on the legislation in force on the subject. It aims to provide various examples of how the legislator has implemented in positive law the standards for pesticide labelling. The reader is also offered a rapid panorama of initiatives in the international field designed to achieve harmonization of the legislation under examination.

The Legislation Branch wishes to express its appreciation to the Pesticides Group, the Plant Protection Service for its collaboration in the preparation of this survey. The cooperation of Dr. Luis Bombín, Legal Officer of this Branch, is also gratefully acknowledged.

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TABLE OF CONTENTS

Page

PART I

LABELLING IN PESTICIDE LEGISLATION

1	THE IMPORTANCE OF PESTICIDE LEGISLATION	3
1.1	<u>General introduction</u>	3
1.2	<u>The function of pesticide legislation</u>	5
1.3	<u>Objectives</u>	6
1.3.1	Control of the suitability of pesticides	6
1.3.2	Protection of pesticide users	6
1.3.3	Protection of the consumer	7
1.3.4	Protection of crops (treated and untreated)	7
1.3.5	Protection of livestock and domestic animals	7
1.3.6	Protection of the environment	8
1.3.7	Protection of the interests of exporters	9
1.4	<u>Scope</u>	10
1.4.1	Subjects considered for pesticide legislation	10
1.4.2	Related fields and marginal areas	10
2.	BASIC CONCEPTS OF PESTICIDE LABELLING	12
2.1	<u>Introduction</u>	12
2.2	<u>What is a label</u>	13
2.3	<u>Leaflets</u>	13

	<u>Page</u>
2.4 <u>Information to be carried on the label</u>	14
2.4.1 Classification	14
2.4.1.1 Directions for use	14
2.4.1.2 Mandatory and additional information	17
2.4.2 Languages	18
2.4.3 Other-factors affecting the understanding of labels	19
2.4.3.1 Presentation of information	19
2.4.3.2 The use of standard phrases	19
2.4.3.3 Excess information on labels	20
2.4.4 Illiteracy	20
2.5 <u>Information from other sources</u>	21
2.5.1 Advertising	21
2.5.2 Other promotional systems	22
2.5.3 Educational campaigns	22

PART II

ANALYSIS OF POSITIVE LEGAL SYSTEMS

1. IN THE INTERNATIONAL FIELD	25
1.2 <u>Recommended provisions</u>	26
1.2.1 FAO	26
1.2.1.1 The International Code of Conduct on the Distribution and Use of Pesticides	27
1.2.1.2 Guidelines of Good Labelling Practice for Pesticides	33
1.2.2 Recommendations and initiatives from other international organizations	34
1.3 <u>Mandatory regulations: the EEC</u>	36
1.3.1 Council Directive No. 78/631/EEC	36
1.3.2 Other related provisions	38

	<u>Page</u>
2. A SURVEY OF NATIONAL LAWS	39
2.1 <u>General considerations</u>	39
2.2 <u>Laws and regulations</u>	40
2.3 <u>Comparative study of national legislation</u>	42
2.3.1 Texts analysed: their scope	42
2.3.2 Authorization and registration	44
2.3.3 Labelling	45
2.3.3.1 Definitions	45
2.3.3.2 The characteristics of labels	46
2.3.3.3 Mandatory information	46
2.3.3.3a Product identification	46
2.3.3.3b Instructions for use	48
2.3.3.3c Warnings (as to potential hazards)	49
2.3.3.3d Other information	50
2.3.3.4 Optional information	51
2.3.3.5 The language in which information must appear	52

PART III

SURVEY OF LEGISLATION IN SELECTED COUNTRIES

Belgium	55
Canada	63
Chile	69
Ecuador	77
France	83
Germany (Federal Republic)	87
The Netherlands	95
New Zealand	103
Spain	107
The United States of America	117
ANNEX: Resolution 10/85 of the FAO Conference: International Code of Conduct on the Distribution and Use of Pesticides	127

PART I

LABELLING IN PESTICIDE LEGISLATION

1. THE IMPORTANCE OF PESTICIDE LEGISLATION

1.1 General introduction

From time immemorial, man has used chemicals to combat parasites and other pests. The Greeks, for example, used sulphur against mange and used other similar products to fight plant diseases 1/. In ancient Egypt and China, compounds based on arsenic or mercury were used for this purpose. Such primitive pesticides generally consisted of inorganic substances. Later on, organic derivatives from certain plants (e.g. nicotine from tobacco) began to be used.

It was not, however, until these last few decades that a huge quantitative and qualitative increase took place in the use of pesticides, especially in the agricultural field. The "qualitative" aspects of this increase need to be emphasized, since not only the tonnage produced per annum should be taken into consideration, but also the number of active ingredients and principles that have been discovered and marketed, as well as the vast range of formulae and methods of application that have been developed. A marked increase has also taken place in the number of people who are involved - in one way or another as users or as ultimate consumers of the products treated or their derivatives - in the handling or use of pesticides 2/.

As regards the immediate future, according to the forecast made in the FAO report "AGRICULTURE: Toward 2000", a sustained increase is to be expected in the use of pesticides in the coming decades 3/. This increase 4/ will take place in spite of the efforts that are sure to be made to develop feasible systems for integrated pest control, and also of genetic improvement of crop species that will make them more resistant to - and, if possible, immune from - certain parasites and other pests. It is also necessary to insist on the point that pesticides should be used only when pest damage exceeds the economically significant threshold. If the damage is only secondary, there is no need to use them.

Setting aside such controversies as are motivated by emotional rather than scientific factors, these forecasts indicate that, as was recognized at the World Food Conference in 1974, greatly increased use of fertilizers and pesticides is among the measures essential for achieving the massive expansion needed in food production. Pests destroy up to one-third of the world's food crops during growth, harvesting and storage. In developing countries, crop losses can be even higher.

To sum up, it may be confidently stated, without being exhaustive, that the use of pesticides in agriculture, veterinary practice, public health services, as well as industry and housing, has resulted in:

- (i) better protection of harvests against unforeseeable losses caused by plant diseases and pests;
- (ii) lessening of the problem of disease transmitted by humans and animals through vector-borne and other sources of contagion; and
- (iii) in general, increase in the quantity of the foods available.

Nevertheless, the use of pesticides to improve agricultural production and the health of humans, animals and plants should be subject to certain limitations: although pesticides do achieve the object of effectively combating organisms capable of destroying or placing at hazard man's food, health and environment, it is also certain that, under some circumstances and at concentrations above a certain threshold, they, like virtually every chemical, may have physiological effects on other organisms living in the environment, including man himself. Whether the effects occur or not is simply a question of dosage and of proper use.

Nor should it be forgotten that most pesticides are obtained from non-renewable natural resources. Waste of these resources must be avoided through sustained efforts to conserve them, make the best use of them and reduce contamination of the environment to a minimum. In the world of modern technology and trade, the challenge of protecting crops and livestock from insects, diseases, weeds, and other pests without hazard to people, animals or their environment require the combined and sustained efforts

of scientists, technicians, and administrators; of producers, processors, and distributors; of industry and government; and of nations working together to establish and administer sound, acceptable standards of food safety and environmental quality 5/. Among the measures to be adopted to achieve these ends is coherent application of adequate and effective economic and social legislation in each country, a subject to which further attention will be given later.

1.2 The function of pesticide legislation

Experts and specialists, as well as most international organizations, have successfully insisted that one of the most effective ways of achieving wide availability and the most correct marketing and use of pesticides to improve agriculture without any negative effect on public health, is for each State to have appropriate laws controlling such products and an infrastructure adequate to apply the laws and regulations in force 6/.

It should be noted here that, while the provisions of many specific laws show a tendency to de-regulation 7/, in the pesticide sector nearly every country has decided to establish (or maintain or complete) strict mandatory legislation controlling the manufacture, sale and use of pesticides. Such legislation must be based on standards that establish a safe-use pattern for each chemical. This pattern must be described on the labels of each product and the labels be subject to government approval. In addition, safety limits should be established by law for pesticide residues in food and feed 8/.

This clear choice of mandatory legislation (and it is characteristic of laws that they be mandatory) does not exclude - as a fuller understanding of the risks and benefits of the use of pesticides is attained - the co-existence of voluntary systems 9/ of control which complement such legislation in order to ensure that these products are not damaging to public health, beneficial organisms, and the environment.

Nor is it enough to rely on adequate laws for ensuring the necessary control of pesticides and their correct distribution and use. The

achievement of these objectives is helped considerably by other factors that may sometimes be essential for application of the pertinent legislation. Examples are: voluntary control of the quality and purity of pesticides, technical and practical standards for their manufacture, advertising campaigns to encourage their safe and effective use, the education and training of their users by means of agricultural extension and inspection services, the circulation of educational materials, etc.

In short, the official policy of each State should aim at protecting the people and the environment from excessive exposure to harmful substances, but also at preserving and increasing the wide variety of products that have proved useful in increasing the food supply, protecting human health and improving trade and living standards.

1.3 Objectives

Legislators usually have the following objectives in drafting pesticide laws 10:

1.3.1 Control of the suitability of pesticides

Adequate legislation correctly applied can ensure that pesticides placed on the market are suitable ("of good quality" in common usage) and can also eliminate fraud regarding the amounts of active ingredients, the suitability of their packages, the truthfulness of advertising material, etc.

1.3.2 Protection of pesticide users

Pesticide users are exposed to immediate hazards: on opening the container, applying the product, cleaning the equipment used and handling any unused remainder or empty package. It is also most important to know when, how and in what quantity the product should be applied and how to obtain the greatest benefit from the money invested. Among other things legislation can require that the labels with which pesticides are marketed should contain clear and adequate instructions for their use and warnings and understandable symbols to indicate the hazards involved,

instructions against reuse of containers and their safe destruction or decontamination.

1.3.3 Protection of the consumer

Pesticides must be applied in such a way that consumers of foods deriving from agricultural products are protected from any adverse effect on their health due to an excessive level of pesticide residues. The safety of food is of fundamental importance for both the public and health authorities, who demand that food products contain the least possible amount of chemical residues and that suitable tests be available for judging whether such residues are hazardous to the consumer. Pesticide legislation, in requiring manufacturers to test all products prior to marketing to obtain a basis for establishing the maximum residue limit (MRL) and to indicate on the label the "safety interval" 11/ between the last application of the product and harvest and in requiring farmers to observe this interval, fulfils its function of protecting the consumer. Food laws should also include appropriate regulations to establish the maximum tolerable concentrations of residues. This is necessary in order to protect consumers against residues that may occur due to unfavourable conditions or imprudent or improper use of pesticides in the cultivation of food crops 12/.

1.3.4 Protection of crops (treated and untreated)

It is essential to avoid completely - or, at worst, minimize - damage to plants from pesticide treatment. The vulnerability of crops being treated requires careful consideration of the phytotoxicity of each and every chemical before use or authorization for use 13/. The possibility of non-target species being affected by spray drift, run-off, carry-over in soil or contamination of spray machinery necessitates the most careful evaluation and adequate precautions 14/.

1.3.5 Protection of livestock and domestic animals

The main hazards to livestock and domestic animals arise from inadvertent consumption of recently-treated feed, contamination from

fumigation or ingestion of rat poisons or similar substances 15/. All this is independent of the danger to their integrity deriving from directly-applied compounds, their feed, or the environment in which they live. The susceptibility of some animal species to individual pesticides may be quite high and the need for adequate precautions must be assessed in advance. Account should also be taken of the fact that even if an animal does not die or sustain obvious injury, pesticide contamination may later result in unacceptable residue levels in milk, meat, etc. intended for human consumption.

1.3.6 Protection of the environment

There is no need to insist here on the great importance of maintaining a sound and healthy environment, i.e. soil, water and the atmosphere. Acute contamination of these basic natural resources due to the action of pesticide residues or other contaminants may affect not only the safety of food products but also other ecological values such as waterways, the preservation of wildlife and recreational activities in the open air. Thus, to quote an example, it is essential to pay special attention to such a valuable resource as water16/. Pesticide residues that can be carried over great distances, such as those persisting in running water, are a serious danger to the drinking water supply, while herbicides, defoliant, etc., endanger water used for irrigation 17/. Fish from contaminated waters, especially lakes, can also accumulate pesticides and be found to contain such high residue levels as to render them unfit for human consumption 18/.

It is obvious that, at a time when most countries are concerned with the protection and management of such resources in order to enhance the living standards and security of mankind, not only pesticide legislation but also that referring specifically to water, fisheries, food products, or concerning the environment in general, must take these considerations into account, since they are interrelated.

1.3.7 Protection of the interests of exporters

Most countries are trying to increase their exports of food products. Especially in the developing countries, such exports may provide a guaranteed and indispensable source of foreign currency and have a highly favourable effect on the national economy, provided care is taken not to upset home markets or indirectly to cause a rise in prices that would have an adverse effect on less well-off consumers. Nevertheless, if an importing country rejects goods exported by a country as contaminated or failing to comply with legislation in force on maximum pesticide residue limits, the exporters may incur very high losses, with consequent damage to the country's economy. A rejected consignment represents a loss of precious foreign currency as well as serious damage to the industry and the financing institutions. The fact that one country has rejected a particular product may also have unfavourable repercussions on trade with other countries.

Pesticide legislation, especially that requiring labels to include information on safety intervals and all general instructions for - directly or indirectly - preventing food products of vegetable (and also, in some cases, animal) origin from containing unacceptable amounts of pesticide residues, are important safeguards for the interests of a country's exporters as well as of those of agencies or private firms trading internationally in food.

It must also be emphasized that countries should do everything possible to establish systems for the inspection of foodstuffs in order to meet the risks to health represented by the use of chemicals in agriculture and food processing and to prevent contamination of the environment. As has already been pointed out, any shortcomings in this field may lead to progressive restriction of markets and a decrease in food exports for failure to comply with the regulations in force in the importing countries 19/. It is also essential to achieve harmonization in this field of national legislation and see to it that such legislation does not constitute a non-tariff barrier to trade.

1.4 Scope

1.4.1 Subjects considered for pesticide legislation

As will be shown in greater detail in Section 2 of Part II (with reference to positive legal systems in countries that have been studied) pesticide legislation normally covers the following subjects: scope and purposes; definitions 20/; pesticide classification; authorization and registration of active substances and/or formulations; requirements to be complied with by manufacturers regarding storage and marketing of pesticides and related materials; packaging and labelling; their application and relative practices; exports and imports; inspection and control; responsibilities; penalties, etc.

1.4.2 Related fields and marginal areas

It should be pointed out that certain legal provisions regarding related fields may directly or indirectly affect - without specifically regulating - production, distribution, marketing and use of pesticides in general or of certain products in particular. Logically enough, any such provisions will remain outside the field of pesticide legislation (and therefore do not, in principle, strictly concern this survey). Nevertheless, they need to be included in what have been termed related fields. This relation may be of two kinds. It will be substantial and necessary if the objective is to affect the manufacture, composition and quality, marketing or use of pesticides. The most obvious example here is that of provisions which - within the field of food law - control pesticide residues in food products and their maximum limits. Regulations on animal feed, labelling of chemically-treated seeds, the environment (water and air pollution, etc.) must also be included under this term, including financial legislation specifically applicable to pesticides (price regulations, etc.).

When such measures are introduced to cover specific legal situations that could possibly, though not necessarily, influence production, distribution and use of pesticides, the connection may be completely

accidental. Such is the case with general penal, financial and administrative measures concerning brands, advertising (in general), unfair competition, etc.

Regarding related fields 21/, they may be considered to include, within the general field of pest control legislation 22/, all provisions dealing with matters or substances considered by the legislation itself to be distinct from pesticides in the strict sense of the term. For example, fertilizers and, in some cases, dangerous chemicals in general, in countries that include fields related to those under consideration under their general pesticide laws.

Nevertheless, if the legal definition of pesticide includes substances intended for use as plant regulators, defoliants, dessicants, or agents for preventing the premature fall of fruit, these should not be considered as related but included as part of this survey.

2. BASIC CONCEPTS OF PESTICIDE LABELLING

2.1 Introduction

As stated in sections 1.4.1 and 1.4.2 above, the field of application of pesticide legislation is very broad and concerns many matters. In order to limit this study to just one of these matters, labelling was chosen, a choice which is justified by the range and importance of the subject. There can, indeed, be no doubt that 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. Thus, when establishing labelling requirements for pesticides, the law-maker has to ensure that the audience can understand the message and, at the same time, must determine how much detail is necessary to achieve the desired objective of motivating the user to use pesticides properly and take reasonable and practical precautions when handling them 23/.

It must be emphasized that it is essential that the instructions on labels should be clear and intelligible even to the least educated user. According to the available statistics, most cases of incorrect use or of abuse of pesticides occur in the developing countries 24/, and fatal or non-fatal accidental poisonings, - "the silent epidemic" as they have been called - are on the increase 25/. The number of such accidents could be reduced if only users were able to understand and prepared to carry out the recommendations and instructions included on pesticide labels. Both at national and international levels, considerable effort has gone into research, co-ordination and sharing of experience for the purpose of ensuring that pesticides are marketed with labels that communicate to end-users, clearly and concisely, the essential requirements for their safe and effective use. Aware of the importance of this matter, most countries have now enacted specific regulations on the subject or included them under their pesticide laws or those referring to agriculture in general. Some countries, nevertheless, are still without any such legislation, while others have the requisite provisions but lack the proper infrastructure for their application. Illiteracy, as will be shown later, constitutes a

serious obstacle to attaining the objective set by the legislator in regulating the matter of labelling.

2.2 What is a label

Although reference will be made, in subsection 2.3.5.1 and the survey of individual countries in Part III, to a number of definitions of the words "label" and "labelling", included in the legislation of countries under consideration, the present section will deal with the general concept as contained in the relative international guidelines.

The "Guidelines on Good Labelling Practice for Pesticides" (FAO, Rome, March 1985), taken as an example, furnish the following definition; "A label is the written, printed or graphic material firmly attached to a container" 26/. This, to all intents and purposes, coincides with the definition given in: "Pesticides" (Council of Europe, Strasbourg, 6th Edition, page 119).

The "International Code of Conduct on the Distribution and Use of Pesticides", adopted by the FAO Conference on 28 November 1985 27/. extends this definition thus: "any written, printed, or graphic material that is attached to a pesticide or written, printed or attached to its immediate container or included in the package or outer wrapping for use or retail distribution".

By extension, "labelling" may be defined as the sum of data, suggestions and information appearing on the label of a pesticide or else on the leaflet or prospectus that accompanies it.

2.3 Leaflets

In certain cases, the package of a pesticide may include a leaflet amplifying the information on the label or containing mandatory information that should have been on the label but was omitted because, e.g, of the limited size of the container.

It may also happen that the products concerned require more detailed information as to their use and the space on the container is insufficient. Rather than make the label illegible by reducing print size, label information may be presented on the container and on a separate leaflet 28/.

When a leaflet is used, the following statement must appear in bold capital letters on the main panel of the container label 29/:

"READ THE ATTACHED LEAFLET BEFORE USING THIS PRODUCT"

It should also be pointed out that, in every case, hazard symbols, product name, safety precautions, first-aid instructions and the name and address of the manufacturer, distributor or agent must appear on the leaflet as well as on the container, so the user can easily match the two separate components of the label 30/.

2.4 Information to be carried on the label

2.4.1 Classification

2.4.1.1 Directions for use

The information on pesticide labels must include indications that can be classified under the following four headings:

(i) Indications for identifying the product

One of the most obvious aims of information on pesticide labels is to enable both purchasers and users to identify its contents, composition, quality, etc., and distinguish it from other available products. Such information includes:

- The "product name": the label must contain the "descriptive name" (trade name of the product, together with a description of its use) 31/.

- "Declaration of the active ingredients": the names of all active ingredients using, as far as possible 32/, common names approved by the International Standards Organization (ISO), together with the minimum guaranteed amount of each active ingredient.
- "Declaration of the solvent": where a solvent is present, the concentration should be stated if the solvent significantly contributes either to the hazards inherent in its use, or to the flammability of the product 33/.
- "Summary of uses": consisting of a brief statement summarizing the use of the product 34/.
- "The net weight or volume of the product in the container".
- "Name and address of manufacturer, distributor or agent".
- "Identification number of the batch or consignment of the product".
- "Official register": in countries with legislation so requiring, a reference to, or the number of, the approval of the product must be included.

(ii) How, when and where to use the product

Directions for use on pesticide labels must clearly indicate how the product can be effectively and safely used. Such information should include;

- "Instructions": these must clearly indicate how, when and where the product can be legally and safely used with maximum efficiency and minimum risk. They must include any warnings intended to prevent incorrect or inappropriate use of the product 35/; crop, situation, pests, weeds or diseases for which the product has been officially approved and registered; and also application dosage and explanatory notes on the effective use of the product on each crop, situation,, pest, weed or disease, including timing and method of application.

- The "safety interval" refers to a statement of the period which should elapse between the last application of the production and: harvest of plant products; grazing of treated areas; slaughter of treated animals for consumption; feeding produce to domestic animals; conservation, preserving, or sale or utilisation of treated products; preserving or sale or utilisation of produce for human use such as milk, honey or eggs; and the sowing or planting of new crops.
- "Date of formulation" and/or "expiry date" 36/: is necessary only in the case of products that may deteriorate under likely storage conditions.
- "General instructions" include information essential to the proper use of the product in all the circumstances listed in the Instructions. They give practical advice on preparing, mixing and applying the product; storage and disposal of surplus or unwanted chemicals; mention of compatibility of the product with other products, where appropriate; and any special recommendations on storage conditions for the container and product. References to good agricultural practice can also be included under this heading 37/.

(iii) Information on potential hazards

The suggestions under this heading are designed to provide clear information to users on handling products with the minimum of hazard, and include:

- "Hazard symbols" which must appear on the label, using the appropriate graphic symbols that warn of danger, together with clear and concise indications as to the degree and kind of such danger. Such indications shall comply with a classification of pesticides according to their inherent hazards, preferably based on that proposed by WHO.
- "Safety precautions": labels must include standard statements designed to inform the user clearly how to handle the product with a minimum of hazard 38/ (e.g. the protective clothing to be worn, what to do in case of contamination, etc.).

- "Warnings": as to the steps to be taken to avoid harmful effects on beneficial insects such as bees, and on beneficial organisms which may be utilized in an integrated pest management programme, etc.
- "First-aid instructions and advice to doctors": these statements should indicate what to do in case of poisoning 39/. Appropriate special additional information regarding symptoms, special tests and antidotal measures are to be added where necessary for particular products.

(iv) Legal requirements and other mandatory information

Included in this final section is a further quotation from the already frequently mentioned "Guidelines on Good Labelling Practice for Pesticides" (FAO, Rome, March 1985):

- "Legal liability": certain products or active constituents may come within the scope of national legislation regarding control and safe use of hazardous or poisonous substances. The label may therefore have to state this, and also include other legislative requirement, e.g.: "THE REQUIREMENTS OF THE... (LAW)... APPLY TO THIS PRODUCT" 40/.

It should also be added that regulations may sometimes require additional information on transport by road, rail, sea or air. Certain countries have specific regulations or codes of practice for aerial use of pesticides, and such regulations usually lay down that, in addition to information on the special ways of making such applications (which must be clearly stated in the general instructions section) there shall also be a reference on the label to the special authorizations that are needed and the relevant legal requirements.

2.4.1.2 Mandatory and additional information

A distinction may be made between:

- (i) "mandatory information": i.e. that which, according to the legislation in force, must of necessity appear on the label of all pesticides; and

- (ii) "additional information": besides the information prescribed in the relevant regulations, the manufacturer or distributor may wish to add further items to the label 41/. In such cases, great care must be taken to ensure key information is not cramped, reduced in print size, or overwhelmed by other information not essential to the needs of the user.

As regards additional information, it should be remembered that to ensure satisfactory communication between the supplier, and the purchaser or user through the pesticide label, it is essential that all label information is accurate and free from statements which cannot be substantiated, or which could mislead. Words which describe the product as "SAFE", "HARMLESS", "NON-TOXIC", "NON-POISONOUS" or "NON-INJURIOUS" in respect of risks to humans or animals should not be used either with or without qualifying phrases such as "when used as directed". Nor should use be made of superlatives such as "the best", "most effective", "superior control" or "unrivalled" 42/.

2.4.2 Languages

The information contained on labels must, logically enough, be in the official language of the country concerned and/or, whenever applicable, the language normally spoken in the area where the pesticide in question is to be distributed and used. Where the label is required to be printed in more than one language 43/, each language must have its own complete label. Translations must convey the same meaning in each language. Only in extremely rare circumstances will there be sufficient space on a single label for two complete sets of information in separate languages. This shortage of space can be overcome by having the primary language on the container label, with other languages on an attached leaflet 45/.

It is, in any case, essential to state in this section that, in spite of all these general rules on the language - or languages - to be used in the mandatory and additional information on labels, there are users who are unable to understand either the language in which the label is written or, indeed, any written text. The problem of illiteracy is dealt with later, in section 2.4.4.

2.4.3 Other factors affecting the understanding of labels

2.4.3.1 Presentation of information

Whenever possible, the label should be set out in clearly-headed or distinct blocks making deliberate, but not excessive, use of colour in print or background.

Label information should be readable horizontally 46/ when the container is in its normal standing position. When containers are intended for retail sale the labels must be wholly visible when they are stacked for display in the place where they are on sale.

Lastly, it is worth noting that labels must frequently be read by people who have poor eyesight or limited reading skills or under adverse lighting conditions. The largest print possible should therefore be used, taking into consideration the maximum label area and the amount of information required for that area.

2.4.3.2 The use of standard phrases

Regarding information on hazards or safety precautions, there is a growing tendency to recommend (or establish as mandatory under the legislation in force) that standard phrases should be used such as are available on lists that can be supplied on request. The use of such phrases should be based on the following principles:

- the number and length of the phrases should be reduced to a minimum;
- only those standard phrases should be used which serve to warn of hazards and/or indicate safety precautions;
- whenever possible, positive precautions should be included;
- other information should be given only for special products or uses, or when there is no adequate standard phrase; and
- safety precautions must be separated from the directions for use.

2.4.3.3 Excess information on labels

It is essential to avoid using small print in order to include more information, lest important parts of labels be obscured or transferred to other graphic material. Optional information on labels should not exceed the limits established by the legislation in force; and when the words, phrases or other printed information are chosen, the ability of the less well-educated users to understand should be taken into consideration by seeing that maximum clarity is achieved with the minimum of words 47/.

2.4.4 Illiteracy

If the principles outlined in the above subsections are followed, pesticide labels will contain the essential information concisely expressed. Nevertheless, in some cases, especially in the developing countries 48/, communication of these ideas may be hindered by language difficulties and the level of illiteracy.

Illiteracy is, in fact, a difficult barrier to overcome: the use of symbols or drawings only partially alleviates the problem since many of these (with the exception of the skull and crossbones) have little meaning for an illiterate, unless he has been previously instructed as to their meaning. For this reason, one of the actions taken in application of the FAO "International Code of Conduct on the Distribution and Use of Pesticides" (see below, section 1.2.1.1 in Part II) has been the preparation of pictograms and posters with images for pesticides, with the aim of providing a clearer idea of the directions and safety precautions to be observed when applying them 49/.

It will also be necessary - as already mentioned in 1.2 - to establish appropriate educational programmes designed to improve knowledge already acquired and provide training to new pesticide users. In order to penetrate to the remotest rural areas, it will be essential to make use of the various kinds of audiovisual teaching aids including, naturally enough, massive use of radio and television which become more useful and important in proportion to the degree of illiteracy of the audience.

Any campaign to provide information on the hazards involved in the use of pesticides should have the double objective of communicating the basic requirements for their safe and effective use to users in general, and illiterates in particular. Such campaigns can make use of various kinds of communication: long or short announcements on radio and television, lectures in rural communities, the showing of documentary films, etc. Support activities of all kinds - including the teaching of general safety precautions in schools - can be included to help achieve the desired results.

Under certain conditions, legislation to limit the use of extremely hazardous pesticides to duly authorized personnel (paying attention to training, ability and professional qualifications) or to teams under supervision, may minimize the problems caused by the poor education or illiteracy of some users or their employees.

2.5 Information from other sources

Although, because of their immediacy, labels are the best way of conveying information, manufacturers and distributors may devise other means of conveying messages about pesticides to prospective purchasers. These usually consist of advertising material of different kinds, aimed at boosting pesticide sales.

2.5.1 Advertising

It may be in the interest of pesticide manufacturers (and others involved in the production-use chain) to try to boost sales through advertising campaigns. These usually consist of announcements in trade journals, although other methods can also be used, such as advertisements on television and radio, in general-interest magazines and at the place of sale 50/.

All advertising material for potentially toxic products should be given special attention, especially if it is likely to contradict the information supplied on the label, or counteract its preventive effect 51/.

2.5.2 Other promotional systems

Apart from advertising as such, other sales promotion systems may be used, such as: distribution of free samples, lectures in rural centres, exhibitions and trade fairs, demonstrations, etc. Everything stated in the above section with reference to advertising - of which, in the widest sense, these are variations - may apply here too.

Special mention should be made of concealed advertising (e.g., in the form of subsidized articles in trade journals, etc.) which appears to users as supposedly impartial, reliable and scientifically accurate information. Total prohibition of such material is essential.

2.5.3 Educational campaigns

Mention has already been made, in section 1.2 and subsection 2.4.4, of some examples of this sort of campaign. It should be added that pesticide legislation is so complex, and its erroneous application can cause such serious harm to people, animals and the environment that it is advisable to complement its promulgation and publication in the country's Official Gazette (the legal requirement for its entry into force) with appropriate campaigns for the divulgation of its contents, including the obligations it creates for manufacturers, importers, traders, users, etc. 52/.

PART II

ANALYSIS OF POSITIVE LEGAL SYSTEMS

1. IN THE INTERNATIONAL FIELD

There exists an important international trade in pesticides. Among the factors contributing to it is the fact that the producer countries are few, and that, in the developing countries, which are importers of these products, there is a growing need for such products. That is why international harmonization has become desirable ^{53/}, especially in the sphere of requirements for the registration of pesticides, including labelling, which is the subject of this survey.

Such harmonization can be brought about either through legal instruments whose provisions are binding on all States or through "recommended" standards.

Regarding binding provisions, a distinction has to be made between those established by international treaty, and those which have been worked out by consensus and whose binding nature depends on subsequent acceptance through notification (as is the case of the standards adopted within the framework of the Codex Alimentarius). In either case, it is incumbent on States that accept a standard to adopt such legal or administrative procedures as may be required to render application of the standard mandatory under national law.

The mandatory nature of an international standard can also be limited by a suspensive clause, under the procedure known in English-speaking countries as "opting out". This consists in making a standard mandatory yet allowing any State that so wishes to notify its non-acceptance or "reservation" within a certain period of time. On expiry of this period, any State that has failed to send such notification shall be deemed to have tacitly accepted the standard. Such a procedure is thus said to be a "potentially mandatory standard".

Because recourse to the traditional method of international treaties ^{54/} may mean that a number of years elapse before ratification, and taking into consideration the fact that, in the meantime, technical progress will have been made such as to render legal provisions devised in this way

obsolete even before they become applicable, the choice of "optional" or "non-mandatory" standards, is becoming more and more frequent. These "recommended" standards are adopted in the form of recommendations the content of which is intended to be incorporated in national law to the extent to which governments deem this to be appropriate.

Examples of the two alternatives can be found in the International Plant Protection Convention of 1951 (revised in 1979), which laid down among other things, the form of certificates that were required to accompany imports of plants and plant products, and the International Code of Conduct on the Distribution and Use of Pesticides (1985) reference to which will be made in the following section 55/.

Lastly, it is clear that harmonization may be fostered by other optional measures such as the elaboration and circulation of criteria or guidelines with a view to having them incorporated in national laws; or even the devising of "model" laws. It should be pointed out here that, in this field, guidelines have proved to be an excellent source of harmonization - as will be shown in subsection 1.2.1.2 and section 1.2.2 - and, because pesticide legislation is bound to be directly related to the social, economic and juridical situation of each individual country, model laws have been found to be of little use. In starting from a rigid model, there is always the risk of introducing a foreign body, in either form and content, into homogeneous system. For this reason - even when starting from the guidelines mentioned or from general technical principles - the social and juridical context and economic conditions within which a particular law will have to operate in a given country must also be borne in mind.

1.2 Recommended provisions

1.2.1 FAO

Since 1959, FAO has been working on an active international programme for the effective use of pesticides in agriculture 56/. This programme has been concerned with three main themes: pesticide residues in crops and the environment as well as food; pest resistance to pesticides; and

international standardization of specifications, registration requirements and standards for the application of pesticides 57/.

Regarding the subject of this study, the most recent, and also the most pertinent, legal instrument approved by FAO has been the "Code of Conduct" to which reference will be made below.

Other guidelines and recommendations, of an earlier date, serve to complement the content of this Code. In addition to the guidelines on labelling (to be discussed in 1.2.1.2), there are the "Guidelines for the Registration and Control of Pesticides" (FAO, Rome, March 1985, 43 pages) which have had an important indirect effect on national pesticide legislation as well as the "Guidelines for the Packaging and Storage of Pesticides", Rome, 1985.

1.2.1.1 The International Code of Conduct on the Distribution and Use of Pesticides

The FAO Conference, at its twenty-third session in 1985, adopted, by Resolution 10/85 58/, the "International Code of Conduct on the Distribution and Use of Pesticides". This text, which is not binding, is described, in article 12.7, as a "dynamic text", one of the fundamental functions of which is to "serve as a point of reference, particularly until such time as countries have established adequate regulatory infrastructures for pesticides" 59/.

Article 1.1 of this Code states that its 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".

Article 1.5 states that the standards of conduct recommended by this Code aim to:

- (i) encourage responsible and generally accepted trade practices;

- (ii) assist countries which have not yet established controls designed to regulate the quality and suitability of pesticide products needed in that country and to address the safe handling and use of such products;
- (iii) promote practices which encourage the safe and efficient use of pesticides, including minimizing adverse effects on humans and the environment, and preventing accidental poisoning from improper handling;
- (iv) ensure that pesticides are used effectively for the improvement of agricultural production and of human, animal and plant health 60/.

Article 2 includes a number of definitions (active ingredient, advertising 61/, banned, common name, distinguishing name, distribution, environment, extension service, formulation, hazard, integrated pest management, label 62/, manufacturer, marketing, maximum residue limit, packaging, pesticide, pesticide industry, pesticide legislation, poison, poisoning, product, protective clothing, public-sector groups, registration, repackaging, residue, responsible authority, risk, severely restricted, toxicity, trader and use pattern). One of the most important for our purposes is that of "pesticide" which is defined as "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, dessicant, 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 transport and storage".

The Code defines pesticide legislation as: "any laws or regulations introduced to regulate the manufacture, marketing, storage, labelling, packaging and use of pesticides in their qualitative, quantitative and environmental aspects".

Article 6.1 (Regulatory and technical requirements) states that governments should (6.1.1): "take action to introduce the necessary legislation for the regulation, including registration, of pesticides and make provision for its effective enforcement".

It is of particular interest to this study to point out that article 2, cited above, defines "label" as: "the written, printed or graphic matter on, or attached to, the pesticide; or the immediate container thereof and the outside container or wrapper of the retail package of the pesticide". And that article 3 ("Pesticide Management") states, among other things, that: "Manufacturers and traders should observe the following practices in pesticide management, especially in countries without legislation or means of implementing regulations:

- (i) supply only pesticides of adequate quality, packaged and labelled as appropriate for each specific market;
- (ii) pay special attention to formulations, presentation, packaging and labelling in order to reduce hazard to users, to the maximum extent possible consistent with the effective functioning of the pesticide in the particular circumstances in which it is to be used;
- (iii) provide, with each package of pesticide, information and instructions in a form and language adequate to ensure safe and effective use;
- (iv) retain an active interest in following their products to the consumer, keeping track of major uses and the occurrence of any problems arising in the actual use of their products as a basis for determining the need for changes in labelling, directions for use, packaging, formulation or product availability".

With reference to "reducing health hazards", article 5 recommends that industry should make every reasonable effort to reduce hazards and that the provisions for achieving this should include "using clear and concise labelling" (article 5.2.2.5).

Article 10 (on "Labelling, packaging, storage and disposal") specifically recommends that all pesticide containers should be clearly labelled in accordance with applicable international guidelines, such as the FAO guidelines on good labelling practice 63/. In this respect, article 10.2 states that: "industry should use labels that:

- (i) include recommendations consistent with those of the recognized research and advisory agencies in the country of sale;
- (ii) include appropriate symbols and pictograms whenever possible, in addition to written instructions, warnings and precautions;
- (iii) 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.
- (iv) include, in the appropriate language or languages, a warning against the reuse of containers and instructions for the safe disposal or decontamination of empty containers;
- (v) identify each lot or batch of the product in numbers or letters that can be read, transcribed and communicated by anyone without the need for codes or other means of deciphering;
- (vi) are marked with the date (month and year) of formulation of the lot or batch and with relevant information on the storage and stability of the product.

Lastly, it should be mentioned that the Code devotes ample space to advertising 64. Article 11 recommends that: "Industry should ensure that:

- (i) all statements used in advertising are capable of technical substantiation;
- (ii) 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;
- (iii) pesticides which are legally restricted to use by trained or registered operators are not publicly advertised through journals other than those catering for such operations, unless the restricted availability is clearly and prominently shown;
- (iv) no firm or individual in any one country simultaneously markets different pesticide active ingredients or combinations of ingredients under a single distinguishing name;
- (v) advertising does not encourage uses other than those specified on the approved label;
- (vi) promotional material does not include use recommendations at variance with those of the recognized research and advisory agencies;
- (vii) advertisements do not misuse research results or quotations from technical and scientific literature; and scientific jargon and irrelevancies are not used to make claims appear to have a scientific basis they do not possess;
- (viii) claims as to safety, including statements such as "safe", "non-poisonous", "harmless", "non-toxic", are not made, with or without a qualifying phrase such as "when used as directed";

- (ix) statements comparing the safety of different products are not made;
- (x) misleading statements are not made concerning the effectiveness of the product;
- (xi) no guarantees or implied guarantees - e.g. "more profits with...", "guarantees high yields" - are given unless definite evidence to substantiate such claims is available;
- (xii) advertisements do not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, use near food, or use by or near children;
- (xiii) advertising or promotional material draws attention to the appropriate warning phrases and symbols as laid down in the labelling guidelines 65/;
- (xiv) technical literature provides adequate information on correct practices, including the observance of recommended rates, frequency of applications, and safe pre-harvest intervals;
- (xv) false or misleading comparisons with other pesticides are not made;
- (xvi) all staff involved in sales promotion are adequately trained and possess sufficient technical knowledge to present complete, accurate and valid information on the products sold;
- (xvii) advertisements encourage purchasers and users to read the label carefully, or have the label read to them if they cannot read".

Article 11 ends with a recommendation to governments to: "work with manufacturers to take advantage of their marketing skills and infrastructure, in order to provide public-service advertising regarding the safe and effective use of pesticides. This advertising could focus on such

factors as 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".

1.2.1.2 Guidelines on Good Labelling Practice for Pesticides

These guidelines (to which the International code of Conduct on Distribution and Use of Pesticides makes direct reference in article 10.1) have, as their main objective, to facilitate the preparation of pesticide labels that will communicate to the end-user - in clear and concise form - the essential requirements for their safe and effective use. To this end, specific advice is provided on label layout, designed for both industrial personnel and State authorities responsible for registration of pesticides. Some examples are also included of labels for each category of product according to the WHO hazard classification system, as well as detailed instructions explaining every aspect of how to arrange the information on the labels.

Pesticide labels are defined as: "the means of achieving a consistently high standard of communication from supplier to purchaser" 66/. and on this point it is recommended that the label should provide information on:

- (a) what is in the container and the hazard it represents;
- (b) what safety precautions are necessary when handling and using the product and first-aid treatment where appropriate;
- (c) how, when and where to use the product in the container;
- (d) how to mix the product;
- (e) how to clean up equipment, and how to store or dispose of unwanted surplus products;
- (f) what legal responsibilities are involved;

- (g) the name and address of the manufacturer, distributor or agent;
- (h) registration approval;
- (i) the compatibility with other products where appropriate;
- (j) date of manufacture/formulation.

Section 2 of these guidelines concerns the application of pesticides. First, there are examples of how to arrange the information on the label with the aim of providing graphic illustration of the recommended principles and ideas (each example illustrates a different layout suitable for the information required on the label). There are examples of: one-panel, two-panel and three-panel labels and of label leaflets 68/.

1.2.2 Recommendations and initiatives from other international organizations

Interest in the international trade in pesticides and toxic chemicals has also been shown by other international organizations, especially in the exchange of information in this field, through recommendations that directly or indirectly affect the labelling of these products. The United Nations Environment Programme (UNEP), for example, keeps an international register of potentially hazardous chemicals in Geneva 69/. UNEP and WHO are completing a joint project to produce assessments on chemicals in relation to human health and the environment, and to circulate the results. On the same lines, UNEP, WHO and ILO jointly publish environmental health standards in the field of toxicology.

Because of its important contribution to the international harmonization of legislation on pesticides in general and their labelling in particular, attention must be drawn here to the WHO proposal for classification of pesticides on the basis of the hazard they entail to the health of users 70/. The system, which classifies pesticides as: "extremely hazardous", "highly hazardous", "moderately hazardous" and "slightly hazardous", was approved at the 28th World Health Assembly in 1975. On the

suggestion of the Member States, WHO later produced some guidelines on the classification of each pesticide (first issued in 1978, and revised annually ever since). It should be emphasized that article 10.2.3 of the "International Code of Conduct on the Distribution and Use of Pesticides" expressly cites this system of classification. There is thus room for hope that it will continue to have an increasing influence on national legislation and international trade.

The Organization for Economic Cooperation and Development (OECD), through its Environment Committee, has also been taking an interest in chemicals since 1971. A programme on these questions - which may have an influence on the labelling and packaging of pesticides - has been worked out with reference to policy and legislative harmonization within the framework of the Special Programme for the Control of Chemicals 71/.

With regard to Europe, attention is drawn to the work carried out by the Council of Europe, especially on the approval, classification and labelling of pesticides. Under this international organization, a "Partial Agreement" on social and public health matters was concluded in 1959. Among the bodies set up to deal with public health questions is an "Experts' Committee on Pesticides" 72/. charged with periodical revision of a publication dealing, among other things, with "Recommendations for the Classification and Safety Labelling of Formulated Pesticides" 73/.

To conclude this section, mention should be made of certain non-governmental organizations that are collaborating in the necessary process of legislative harmonization in this field, by means of publicity campaigns, participation at international experts' meetings, and so on: "Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques" (GIFAP), the "Confédération Européenne des Associations des Pesticides Appliqués" (CEPA), and the International Organization of Consumers' Unions (IOCU).

1.3 Mandatory regulations: the EEC

1.3.1 Council Directive No. 78/631/EEC

Within the EEC, the basic text for harmonization of pesticide labelling is Council Directive 78/631/EEC on the approximation of the laws of Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides), of 26 June 1978 (Official Journal of the European Communities, No. L 206 of 29 July 1978, page 3) 74/.

Before examining the contents of this Directive, brief reference should be made to the special juridical nature of EEC Directives of this kind: these are legal instruments imposing an obligation on the States to which they are addressed 75/ to abide by certain set objectives, whilst the choice of the ways and means of attaining such objectives is left to the discretion of each Member State within a given period. A Directive is usually issued by the Council of Ministers, although the Commission may also issue Directives for certain matters. The difference between Directives and Regulations of the Community 76/ is that, while the former apply directly without any need for national legislation, Directives require specific action by the State concerned in order to come into force. When a State receives a Directive, it may have to amend or enact a national law 77/.

Thus, Directive 78/631/EEC 78/, adopted within the framework of article 100 of the EEC Constituent Treaty, has as its primary object the elimination of the existing differences in the legislation of Member States that may constitute an obstacle to the free circulation of pesticides within the Common Market.

Article 2 reads:

"For the purposes of this Directive 'pesticides' shall mean preparations designed:

- (i) to destroy organisms harmful to plants or to plant products or to protect plants and plant products from such organisms; or

- (ii) to improve or regulate plant production with the exception of fertilizers and soil conditioners; or
- (iii) to preserve plant products, including wood preservatives, in so far as there are no other Community provisions specifically relating to preservatives, except those products which are applied to surfaces and do not contain preserving substances which penetrate into the plant product; or
- (iv) to destroy undesired plants; or
- (v) to destroy parts of plants or to prevent undesired growth; or
- (vi) to render harmless or to destroy, or to give protection against, harmful organisms which do not attack plants, and undesired organisms".

Article 3 of the said Directive deals with the classification of pesticides, and article 5 with the requirements for packaging.

Article 6 refers to labelling and provides that all packaging must show the following clearly and indelibly 80:

- (a) trade name or designation of the preparation;
- (b) the name and address of the holder of the authorization for the pesticide and the registered number of the preparation;
- (c) the name and amount of each active substance contained;
- (d) the name of each very toxic, toxic, harmful or corrosive substance contained in the preparation, excluding active substances;
- (e) the net quantity of the preparation given in legal units of measurement;
- (f) the batch number;

- (g) the symbols and indications of the dangers of the preparation;
- (h) an indication of the special risks, deriving from these dangers; and
- (i) for very toxic, toxic or harmful pesticides, the indication that the packaging must not be re-used except in the case of containers specifically designed for re-use, recharging or refilling by the manufacturer or distributor.

Articles 7 and 8 complete the labelling requirements (language etc.)

1.3.2 Other related provisions

Among the mandatory provisions adopted by the EEC in this field, mention should be made of Directive No. 67/548/EEC (amended) to regulate the active ingredients of the formulations dealt with by Directive No. 78/631/CEE already mentioned. Other directives relevant to this study are No. 73/173/CEE, of 4 June 1973 (solvents), as subsequently amended; and No. 77/728/EEC, of 7 November 1977, as subsequently amended.

It may be added in conclusion that, towards the middle of 1986, the Commission submitted a proposal to the EEC Council for Regulations on the import and export of certain dangerous chemicals, and including specific instructions on packaging and labelling 83/.

2. A SURVEY OF NATIONAL LAWS

2.1 General considerations

This section, which deals with national legislation on pesticides in general and labelling in particular, is based on the documentation available in the Legislation Branch of FAO. The legal texts consulted are those of: Belgium, Canada, Chile, Ecuador, the Federal Republic of Germany, France, the Netherlands, New Zealand, Spain and the United States. In certain cases - especially in the "Comparative Survey of Selected Countries" - reference is also made to provisions in the enactments of Belize, El Salvador, India, Sri Lanka, Thailand and Trinidad and Tobago, with explanatory notes to specify the sources. It should be noted that this survey naturally concentrates on legislation in force; however, considering its informative nature and the limited amount of material available in the Legislation Branch archives, the possibility has not been excluded of referring to certain legal provisions that may not be complete or fully implemented.

Although attention has been focussed in this study on legislation dealing with pesticide labelling, it was considered desirable - in both the present section and the chapter on selected countries in Part III - to refer briefly to the scope and other requirements of general legislation on the subject, as well as to provisions regarding registration and authorization of pesticides. It should, nevertheless, be pointed out that these references are only intended to serve as an introduction to the subject or to mention such matters as specific definitions and classifications of pesticides which determine the greater or lesser strictness of labelling requirements or as provisions which make it mandatory to include specimens of proposed labels in requests for registration. In no case is it claimed that this information on scope and registration adds up to an exhaustive study of either subject, neither of which is included in the specific aims of this publication.

With these reservations, and before embarking on the comparative analysis of legislation in the countries concerned, the section that follows will refer to the different forms (Laws and Regulations) such provisions may take.

2.2 Laws and regulations

The establishment of legal rules governing pest control necessitates constant reference to certain basic principles and numerous technical elements (biological, toxicological, etc.). The main function of the legislator often is, in fact, to give binding force to technical standards, lists of required information (recommended phrases, and other similar requirements which have been worked out by experts on the subject).

The fact that legal rules governing these matters are of a technical - and frequently interdisciplinary - nature explains why they are usually promulgated as subsidiary legislation under enabling acts. This is justified by the fact that, in a modern state, it cannot reasonably be expected that the legislature should enact each and every one of the very large number of rules that are now required for the proper functioning of society.

For its part, the Executive, in order to perform the numerous and ever more complex functions that are entrusted to it, finds that it is obliged to lay down legal rules supplementary to those of the legislature. The Executive has a technical competence and flexibility of action that no legislative chamber can be expected to possess. Such chambers are generally composed of large numbers of individuals and this means that the amount of legislation that can be enacted is never very extensive because it usually requires the fulfilment of complicated meeting, debating and voting procedures.

In practice, the Legislature will enact basic provisions. Its role is to establish guidelines and principles for the ordering of society. The task of the Executive is to apply or implement these guidelines.

These considerations lend support to a fundamental distinction, namely, that obtaining between "laws" in the strict sense of the term - which are the legal provision enacted by the Legislature - and what are usually referred to as "regulations". The latter are laid down by the Executive, i.e. by the administrative arm of the State of which the Government is the central and most important part 84/.

In a modern State, the Administration is there to serve general interests, always under the strict control of the Legislature. Whilst maintaining this subordinate role, it is reasonable that the Administration should have certain rule-making powers, i.e. possess powers to make regulations.

It should come as no surprise, therefore, that in a modern State, government regulations should play a role of exceptional importance within the legal system taken in its entirety. There are so many of them and they go into such minute detail that there is a regulation or a number of regulations for practically every sector of human activity. Generally speaking, the broad outline of the law of a country is embodied in the enactments of the legislature. How these are developed and worked out in detail is, on the other hand, left to regulations issued by the Administration.

In a field such as plant health (or that of the control, manufacture and marketing of chemicals), the following pattern is frequently adhered to, precisely because it is of an eminently technical nature:

- the basic law, which establishes general principles, scope, structure and basic concepts, the delegation of the power to make regulations, and, generally, the penalties and sanctions;
- regulations (laid down by the appropriate delegated authority, which may be either general or specific) in which cross-reference may be made to other standards of a technical nature 85/;
- orders or rules in application of the above regulations or related provisions.

One of the advantages of adopting this pattern is that it is flexible enough 86/ to cover requirements dictated by the rapid development of technology and the progress of knowledge in the field. Experience has shown that, in order to have an effective, practical and flexible administration, the law should establish general principles, allowing as need arises for the bringing into force of regulations adaptable enough to deal with the changes that so frequently occur 87/.

2.3 Comparative study of national legislation

2.3.1 Texts analysed: their scope

As was pointed out in 2.1, despite the fact that the basic theme of this study is pesticide labelling, it was deemed advisable to make brief mention - both here and in the survey of selected countries in Part III - of the scope and application of the provisions analysed.

As a result of research carried out prior to preparing this study, a very wide interpretation of the term pesticide was chosen, based originally on the definitions of "pesticide" and "pesticide legislation" in article 2 of the FAO "International Code of Conduct on the Distribution and Use of Pesticides" 88/. It includes both pesticides for plant protection and those intended for application to animals (raised as livestock) and also those for environmental or domestic use, including pesticides for use in the food industry and for personal hygiene.

However, the study of positive legislation led to the discovery that few countries have an "all-embracing" idea of pesticides 89/. In many cases, the provisions examined refer only to certain specific kinds of pesticide.

Canada may be taken as an example of one of the few. There, the law defines a "control product" as: "any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling, any pest...". In the United States, too, the

Federal Insecticide, Fungicide and Rodenticide Act gives an all-embracing definition of pesticide. The definitions included in the legislation of the Netherlands and New Zealand are equally wide, and the competent authorities in New Zealand are also empowered to declare substances to be pesticides under the law.

In Spain, the technical and public health regulations in force controlling the manufacture, marketing and use of pesticides, specify, in article 1, that their "object is to define the meaning of the word 'pesticides' and to lay down the rules governing their manufacture, storage, marketing and use and in general their regulation from the technical and public health viewpoint, whether they are produced domestically or imported, and also to suggest standards for the setting of maximum residue limits in or on products intended for food" 90/. A general definition of "pesticide" is given in article 2.1 and will be quoted in the appropriate section of Part III. It goes on to make a distinction between: "pesticides for use in pest control" (or phytosanitary products) 91/; "pesticides for cattle raising" 92/; "pesticides for use in the food industry" 93/; "pesticides for environmental use" 94/; "pesticides for personal hygiene" 95/ and "pesticides for domestic use" 96/.

In other countries, on the contrary, the laws examined have more restricted and specialized scope. This applies to the Federal Republic of Germany where the "Act to Protect Crops" of 1986 refers exclusively to "pest control products", and to Chile, where Resolution No. 1.179 Ex., of 14 August 1984, specifies - in the title, too - that its range of application is limited to: "pesticides for agricultural use", which Resolution No. 1.178 Ex. (also dated 14 August 1984) defines at length, in article 1, and allows for the possibility of the Agricultural and Cattle Breeding Service adding, by an appropriate administrative resolution, other substances to those listed. In Belgium, to quote another example, the law makes a distinction between "pest control products", which are basically pesticides for use in agriculture, and "pesticides for use outside the field of agriculture". In Ecuador, Decree No. 2331, of 21 December 1983, applies exclusively to "pesticides and similar products for agricultural use", which are defined respectively in articles 2 and 3 97/. Regarding France, a number of relatively heterogeneous provisions were examined that have been amended and improved over the years. They all focus on the concept of a "pest control

product for agricultural use", and have thus been amended from time to time to adapt them to new conditions, especially those relating to modern agricultural technology.

Another question is whether or not the definition of "pesticide" should include substances intended for use as plant growth regulators, defoliants, dessicators, agents for thinning fruit, and also as substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport (see section 1.4.2 of Part I). Such products are included in the legal definitions of pesticides in Belgium, Chile, the Federal Republic of Germany, the Netherlands, New Zealand and the United States, among others.

In Ecuador, substances used as defoliants, dessicants or growth regulators are included in the definition of "similar products" (article 3 of Decree No. 2331 of 21 December 1983), whereas in Spain, the definition of "pesticides" in general includes substances intended to "improve or control plant production, with the exception of nutrients and soil conditioners" (article 2.1.b of the technical and public health regulations approved by Crown Decree No. 3349/1983 of 30 November) and also those that serve to "destroy parts of plants or prevent their undesirable growth" (Ibidem, article 2.1.e).

2.3.2 Authorization and registration

It needs to be stated in this section that, in practically all the provisions examined, countries require prior registration or authorization of pesticides as an indispensable condition for their marketing. This is the case in Belgium, Canada, Chile, Ecuador, France, the Federal Republic of Germany, the Netherlands, New Zealand and the United States.

Without going any further into the question - which is of only marginal interest to the main subject of this survey - it is noted that, in certain cases, exceptions are made to this general rule: e.g. products that are to be used exclusively for experimental purposes or, under some circumstances, for export. Belgium and Chile are two examples of countries allowing exceptions of this kind.

As will be pointed out, whenever applicable, in the surveys of individual countries in Part III, applications for authorization or registration must, under certain circumstances, be accompanied by specimens of labels intended for use in marketing products in order to enable the competent authority to effect prior control and/or grant approval.

2.3.3 Labelling

2.3.3.1 Definitions

Some of the provisions examined include a precise definition of what is meant by a "label" for a particular purpose (and, in some cases, of "labelling", too). Such definitions do not differ a great deal from one to another, and so a few examples will be adequate for this section. Readers are referred to the relevant passages of Part III and to the provisions enacted in the different countries.

Under Canadian law, a "label" is defined as "any legend, word, mark, symbol or design applied to, affixed to, included in, belonging to or accompanying any control product". In the United States, the following definition is given: "the writing, printing or graphic material that appears on, or has been affixed to, a pesticide... or any of its containers or packages". The definition of a label according to the legislation in force in New Zealand is very similarly phrased. The same may be said of the definitions of a "label" included in the laws of other countries not included in the special studies in Part III: Belize, "any inscription, word or mark affixed to, included in, belonging to, or accompanying a container" 98; India: "any written, printed or graphic matter on the immediate package and on every other covering in which the package is placed or packed and includes any written, printed or graphic matter accompanying the insecticide" 99; Trinidad and Tobago: "any legend, word or mark, symbol or drawing applied to, attached to, included in, belonging to or accompanying any control product or the container thereof" 100, etc.

2.3.3.2 The characteristics of labels

In practically all of the legislation studied, there are provisions concerning the requirement for labels to be perfectly affixed to (or integrated into) the package of the pesticide, and for their text to be clearly visible and legible by ordinary people under normal conditions 101/.

In most cases, there are detailed rules as to size requirements (usually with reference to minimum label dimensions). The laws of Belgium, Ecuador, the Netherlands and Spain may be quoted as examples.

2.3.3.3 Mandatory information

Reference was made to this sort of information in Part I, subsection 2.4.1.2. Mandatory information is undoubtedly one of the most important aspects of this study, since it is by making it obligatory for certain matter to appear on labels that legislators can protect users, livestock and domestic animals and also achieve the other objectives they have set themselves 102/.

An analysis follows of the function of such information (identification of the product, instructions for correct use and warnings as to the hazards involved in application). It is by no means always possible to make such clear distinctions, since there are cases where the information in question can serve two separate, though complementary, purposes. Some examples will be found in 2.3.3.3.d ("Other information") or wherever pertinent.

2.3.3.3.a Product identification

A very important part of the information to be included under this heading is what is known as the "name of the product". The distinctive function of "trade denomination", which enables purchasers to distinguish

one product from another, is evident from the fact that it has been made mandatory in all the legislations examined. In many cases, it is also laid down that such information shall appear on the label exactly as established at the time of authorization and/or registration of the pesticide.

In the majority of the enactments studied (Belgium, Chile, Ecuador, France, the Federal Republic of Germany, the Netherlands, Spain and the United States) a further mandatory requirement is that labels should include a "declaration of the active ingredients" made in the manner prescribed in the legislation of the respective countries.

There is also an obligation to include the net contents of each container, in weight or volume, whichever applies. This is included under the laws of Belgium, Canada, Chile, Ecuador, the Netherlands, New Zealand, Spain and the United States.

Regarding the obligation to include the "name and address of the manufacturer, distributor or agent", this is prescribed in the provisions in force in Belgium, Canada, Chile, Ecuador, France, the Federal Republic of Germany, the Netherlands, New Zealand, Spain and the United States, with some slight variations (e.g. as to whether an individual or body corporate has obtained registration of the pesticide, etc.).

Inclusion of the "identification number of the lot or batch of manufacture", which allows the competent authorities to trace defective or dangerous consignments, etc., and producers and distributors to detect other anomalies of any kind, is specifically required in Chile, Ecuador, the Netherlands and Spain.

A further piece of information allowing for rapid identification of a product, as well as an assurance that it has been duly authorized, is the inclusion on the label of the "official registration number". This information, under different names as provided in the different laws and regulations, is required in "Belgium, Canada, Chile, Ecuador, France, the Federal Republic of Germany, the Netherlands, New Zealand, Spain, the United States, etc.

The "summary of uses" (mentioned in subsection 2.4.1.1 of Part I) should be implicitly included in the name of the product, or inserted beside the list of active ingredients, or else mentioned in the instructions 103/. Under Belgian law, e.g., mandatory information on labels must include "the purpose for which the product is to be used", and also: "the uses for which it has been authorized". In Chile, the regulations in force require mandatory inclusion on labels of a "brief summary of the main uses of the product". Similar provisions are found in the New Zealand Pesticides Act.

To complete this section, it should be pointed out that the legislation in force in some countries requires the inclusion on labels of further identifying information, especially for extremely hazardous and highly hazardous products. This applies to Canada, where the class to which a product belongs must be stated (e.g. "RESTRICTED" or "DOMESTIC"), and to Chile, where the regulations require information as to what sort of product the package contains ("Insecticide", "Fungicide", etc.), and the chemical group to which it belongs.

In the Netherlands, labels must carry "the toxicological classification of all the components which are dangerous for humans or for those animals the preservation of which is desired".

Lastly, in the United States of America, labels must include in addition to the information already mentioned, the factory registration number preceded by the phrase "EPA EST".

2.3.3.3.b Instructions for use

For the user to be able to apply pesticides effectively - without risk and to obtain the best results - labels must include clear and concise information as to how they should be used. Such information usually includes the doses to be applied and other similar indications, and is required in Belgium, Canada, Chile, France, the Netherlands, New Zealand, Spain and the United States of America.

Another important piece of information that needs to be mentioned is the expiry date (or else the date of formulation, from which the former can be deduced) of a pesticide. Reference is made in this respect, e.g., to the laws of the Federal Republic of Germany which make it mandatory to include this on labels of pest control products with limited duration. In Belgium, too, labels must state the latest date for use, in the case of products which can be preserved for only a limited period. This must include the year and month and, when appropriate, the information prescribed in the document of authorization. In Chile, labels have to include the expiry date ("fecha de vencimiento") which must, in Ecuador, be followed by the date of manufacture. Regulations in force in Spain require, when appropriate, information as to the expiry date.

To complete this general picture, it must be stated that the regulations in force in the Netherlands require, for pesticides with withdrawal dates, inclusion on the label of the phrase: "to be used before..." followed by the date on which the specified period elapses (calculated from the date of formulation).

Regarding the "safety interval" 104/, its mention is mandatory in, e.g., Belgium

105/, Chile 106/ ("periodo de carencia"), Ecuador ("íntervalo última aplicación) and Spain, ("plazo de seguridad").

The provisions examined also contain other requirements of different kinds, such as information on methods for rendering residues or excess quantities harmless; a reference to the prohibition against reusing packages which have contained very toxic or harmful products, etc. These may be included in the category of "general instructions" (see, inter alia, the chapters devoted to Canada, Chile, Ecuador, the Federal Republic of Germany and Spain).

2.3.3.3.c Warnings (as to potential hazards)

Paragraph (iii) of subsection 2.4.1.1 of Part I has already dealt in some detail with the value of "hazard symbols" and of statements as to the appropriate "precautions" that are required to be included on pesticide labels. The fact that virtually all the texts studied provide that these

should be made mandatory - in different ways and with slight variations - confirms both their utility and the fact that legislators (not to mention experts and technicians) attach great importance to them.

The information dealt with in the preceding sections is generally completed by specific "warnings" such as those required in Chile: "Do not store with foods", "Keep out of the reach of children and irresponsible persons", etc.; Ecuador: "This product may be fatal if swallowed", "Poisonous if inhaled", etc., and Trinidad and Tobago 107/: "Keep out of the reach of children", etc.

This section concludes with a reference to "Instructions for first-aid and advice to doctors", the function of which is obvious. Such instructions provide that, when necessary, appropriate action has to be taken to counteract the effects of poisoning. Labels are required to include the relative information as to the antidotes that exist and suitable action to be taken without undue delay (analyses, diagnosis, etc.). This is required by the pertinent laws and regulations in force in, e.g., Belgium, Canada, Chile, Ecuador, El Salvador 108/, the Federal Republic of Germany, Spain, Sri Lanka 109/ and Thailand 110/

2.3.3.3.d Other information

Finally, mention should be made of other items of mandatory information with complementary functions.

In Canada, as a general warning, labels are required to include, the advice to read the label before using the product, while Chile provides for the inclusion of the notice "Before using, read the entire label"; in the legislation of Ecuador, Trinidad and Tobago, among other countries, there are provisions making similar warnings mandatory.

Canada also requires the inclusion of a warning under the heading "NOTICE TO USERS", "this control product is to be used only in accordance with the directions on this label. It is an offence under the Pest Control Products Act to use a control product under unsafe conditions". The law in the United States of America includes a similar warning stating that it is

"a violation of Federal law to use this product in a manner inconsistent with its labelling".

The regulations in force in Chile make it mandatory for pesticide labels to indicate the countries or economic areas that are export markets for Chilean plant products, and that permit the use of the pesticide in question, or that have established tolerances for the residues, in respect of the species for which the pesticide is recommended.

2.3.3.4 Optional information

Generally speaking, the legislation surveyed adopts a restrictive stance toward information of this kind. To give an idea of what is meant, the legislation in force in Belgium and Spain prohibits the use on labels of phrases such as "non-toxic", "unharmful" or anything of the sort.

Labels in Canada are allowed to include additional information about pest control products, and also any other drawings or graphic symbols, always provided that they do not detract from or impede the understanding of the mandatory information. The inclusion on labels of the following declaration is also authorized; "Seller's guarantee shall be limited to the terms set out on the label and, subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition".

If desired, labels in Chile may also include the trademark of the firm 111/.

In Ecuador, it is expressly forbidden to state that a pesticide has been recommended by any body under the Ministry of Agriculture and Livestock; or to make any claims that may lead one to believe in the efficacy of a particular product for controlling a pest against which it has not been appropriately tested, or registered.

Regulations in the United States of America forbid the inclusion on labels of false or misleading statements regarding the composition of the product and its efficacy, or any false or misleading comparison with other

pesticides, or any statement directly or indirectly implying that the pesticide is recommended by any agency of the Federal Government. Label disclaimers which contradict or detract from labelling statements required by the legislation in force are also prohibited and also all claims as to the safety of the pesticide or its ingredients, including statements such as "safe", "non-poisonous", "non-injurious", or "non-toxic to humans and pets" with or without such a qualifying phrase as "when used as directed".

Although many more examples could have been quoted, a final reference in this section may be the legislation of the Netherlands which prescribes that: "No particulars shall appear on or with the packaging which might create an inaccurate or misleading impression of the nature, composition, possible uses or harmfulness of the pesticide".

2.3.3.5 The language in which information must appear

As is logical, the general rule is that the text of the label must appear in the official language of the country. This is prescribed in the laws and/or regulations of, amongst other countries: Chile, Ecuador, the Federal Republic of Germany, the Netherlands and Spain.

There may, however, be other requirements:

In the United States of America, all texts which are to be included in the label shall appear in the English language. The regulatory authority may nevertheless require, or the applicant may propose, additional texts in other languages when considered necessary to protect the public.

In Belgium, it is laid down that information or indications on labels must appear in both the national languages. Regulations in force in Canada state that information on labels must be in English or French or in both languages. In Sri Lanka, the Sinhalese, Tamil and English languages must be used 112/.

PART III

SURVEY OF LEGISLATION IN SELECTED COUNTRIES

BELGIUM

LEGISLATIVE TEXTS

- Act controlling Pesticides, Raw Materials for Agriculture, Horticulture, Forestry and Livestock Raising. - 11 July 1969. - Moniteur Beige, 17 July 1969.
- Crown Order on the Storage, Marketing and Use of Pesticides and Plant Protection Products. - 5 June 1975. - M.B. No. 211, 28 October 1976, page 1391.
- Crown order amending the Crown Order of 5 June 1975 on the Storage, Marketing and Use of Pesticides and Plant Protection Products. - 19 February 1985. - M.B. No. 52, 13 March 1985, page 3149.
- Crown Order amending the Crown Order of 5 June 1975 on the Storage, Marketing and Use of Pesticides and Plant Protection Products. - 15 July 1985. - M.B. No. 242, 18 December 1985, page 18489.

Scope and general requirements

Section 4 of the Act of July 1969 includes the following definition of pesticides (as regards their application): "products intended to cause the destruction or prevent the action of harmful animals, plants, micro-organisms, and viruses" and distinguishes between:

- (i) products for use outside the agricultural sector; and
- (ii) "any substance intended to protect plant production and livestock raising, such as agricultural pesticides and other plant protection products" 113/.

Article 1 of the Crown Order of 5 June 1975 further classifies pesticides (substances and preparations intended to bring about the destruction or prevent the action of harmful animals, plants, micro-organisms and viruses) as:

- "plant-protection products" which, in turn, include agricultural pesticides, and also substances and preparations intended to improve or control plant production and to preserve plants, parts of plants or plant products 114/ (and also micro-organisms and viruses considered as active agents in combating parasites); and
- "non-agricultural pesticides", which are defined as substances and preparations, and also micro-organisms and viruses, intended for use outside the agricultural field for combating and eliminating animals and micro-organisms that damage houses, buildings, means of transport, swimming-pools, refuse dumps and sewers; treating materials and objects for combating or repelling animals, plants or micro-organisms; for combating or repelling by suitably treating the soil and waterways; organisms that may cause disease in humans or animals; and combating or repelling the ectoparasites of domestic animals.

Article 2 (1) of the said Crown Order (amended by article 4 of the Crown Order of 25 July 1985) lays down 115/ that this provision shall not apply to substances governed by the regulations controlling fertilizers and soil conditioners, unless they contain a plant-protection product or a pesticide for non-agricultural use designed for export to a State which is not a member of the EEC, always provided that each consignment is clearly marked "export" and stored in a separate place with the same identification 116/.

Authorization and registration

Mention must here be made of the fact that article 4 of the Crown Order of 5 June 1975 lays down the general principle that: "it is forbidden to market, purchase, offer for sale, display or place on sale, possess, prepare, transport, sell, deliver on payment or free of charge, import or

use plant-protection products that have not previously been authorized by the minister for Agriculture". Article 8 of the said Order lays down an identical provision for what are referred to as "pesticides for non-agricultural use", although, in this case, authorization is by the Minister for health.

Such authorizations shall last for a maximum of ten years and are renewable indefinitely for successive periods of a maximum of ten years.

Article 11 of the said Crown Order of 5 June 1975 (as amended by article 5 of the Crown Order of 25 July 1985) lays down that authorization or approval shall be personal but may be transferred, provided that the transfer is approved by the responsible Minister after hearing the opinion of the Authorization Committee, or, if appropriate, the High Commission for Public Hygiene.

The requirements and procedures for requesting such authorizations, and their approval, are set out in detail in articles 12 to 17 of the Crown Decree of 5 June 1975 (as amended in 1976 and 1985) and also in Appendix I, which includes a model form for such requests.

Article 2 (2) of the said Crown Order (also amended by article 4 of the Crown Order of 25 July 1985) specifies those cases for which it is not mandatory to request authorization: products for use for exclusively scientific purposes or research, and also those intended for export to Member Countries of the EEC 117/.

Lastly, in section 8 (1) 3 and 4 of the Act of 11 July 1969, penalties are prescribed for: "anyone who by means of announcements, posters or any other kind of advertising, or by using brands, seals, labels, certificates, containers, trade names, symbols, documents or any other kind of indication, simulates or falsely alleges that a pesticide has been controlled and approved by the competent authority; and for anyone who, without obtaining authorization, imports, manufactures, holds or places on the market a pesticide for which authorization is mandatory.

Packaging

Both plant-protection products and non-agricultural pesticides shall be packed in containers designed to prevent the loss of any of their contents 118/.

Such packaging must be made of materials that are not susceptible to attack by the contents or liable to form harmful or dangerous compounds with the contents. Packaging and fastenings must be strong and solid throughout so as to ensure that they will not come apart and will safely withstand normal handling. Containers with fastening devices must be so designed that the container can be repeatedly refastened so that the contents cannot escape 119/.

It should be added that containers must, when necessary, comply With the provisions of the Crown Order of 14 April 1978 with reference to aerosols.

Labelling

Article 18 of the Crown Order of 5 June 1975 lays down that the containers of plants-protection products and non-agricultural pesticides must bear the following information in both the national languages:

- (i) name and address of the individual or body corporate that obtained authorization;
- (ii) the trade name of the product exactly as stated on the authorization certificate;
- (iii) indication of all active ingredients using their common or chemical names, as indicated on the authorization certificate;
- (iv) the contents of each active ingredient, as Stated on the authorization certificate 120/;

- (v) the words "authorization number", followed by the number that appears on the relevant certificate;
- (vi) the purpose for which the product is intended and the manner in which it is presented, and also the uses for which it has been authorized;
- (vii) the dosage and method of application, as well as the counter-indications, if any 121;
- (viii) the weight of the contents of the container, for solid products, aerosols and volatile or viscous liquids, and the volume of the contents for other liquids (using the metric system in either case) 122;
- (ix) the reference code of the consignment 123;
- (x) for products of limited duration, the expiry date for use, stating month and year, and, when appropriate, the information required by the authorization certificate;
- (xi) the symbols and indications of the dangers of the product, as specified in articles 22 and 23 (a skull and crossbones for toxic and very toxic products; a Saint Andrew's cross for harmful and irritant products; ebullient acid for corrosive products; a flame for flammable products and a flame inside a circle for explosive products) 124;
- (xii) an indication of the special risks, using the standard phrases as found in Appendix IV (amended) of the Crown Order 125;
- (xiii) the safety precautions to be observed and measures for the protection of the health of users and anyone else concerned using the standard phrases as found in the said Appendix IV 126;

- (xiv) first-aid instructions and advice to doctors 127/;
- (xv) information as to an appropriate method for rendering harmless packages and residues or surpluses after treatment;
- (xvi) any other information made mandatory by the authorization certificate, especially, when appropriate, the withholding period and toxicological group;
- (xvii) the names of all the very toxic, toxic, harmful and corrosive substances contained in the preparation, excluding active ingredients that exceed 0.2 percent of the overall weight for toxic and very toxic substances, and 5 percent for harmful and corrosive substances. The names of solvent falling into the "harmful" category must be included when their concentrations exceed those established in detail by the pertinent regulation 128/;
- (xviii) a prohibition of reuse of a container that has been used for very toxic or harmful products, except in the case of containers expressly designed to be reused, recharged or refilled by the holder of an authorization 129/.

All the above information must appear in a clearly visible manner, in easily readable and indelible lettering on the container of the product. Whenever the packaging consists of two or more layers, the above information must appear on each layer, including the collective container when there is one 130/.

The minimum established sizes for labels are 131/:

- 52 mm x 74 mm for containers with a capacity of less than or equal to 3 litres;
- 74 mm x 105 mm for containers with a capacity greater than 3 litres but not exceeding 50 litres;

- 105 mm x 210 mm for containers with a capacity greater than 50 litres but not exceeding 500 litres;
- 148 mm x 210 mm for containers with a capacity greater than 500 litres.

Article 24 of the Crown Order of 5 June 1975 (amended by article 14 of the Crown Order of 25 July 1985) lays down that the colour and presentation of the label and, when there is no label, of the packaging, must be such that the danger symbol and its orange-yellow background stand out clearly.

Lastly, it is important to mention that section 8 (1) of the Act of 11 July 1969 prescribes, among other things, penalties for anyone who counterfeits a trademark, seal, label, container, name, symbol, document, indication, etc., provided for by the implementing regulations, or for anyone who uses such means to mislead as to the origin, quality or guarantee of a pesticide, etc. Along these lines, article 18 bis of the Crown Order of 5 June 1975 (included under the terms of article 9 of the Crown Order of 25 July 1985) also prohibits the appearance on the labels - or packages - of plant protection products or non-agricultural pesticides, such information as "non-toxic", "harmless" or anything of the sort.

CANADA

LEGISLATIVE TEXTS

- Pest Control Products Act (Chapter P-1Q). - 25 November 1972. - Amended, September 1982. Separate publication.
- Pest Control Products Regulations: - Ibidem (Amended, 8 December 1983 - "Gazette du Canada" Part II, Vol. 117, No. 24).

Scope and general requirements

The following definition of "control product" in the English text and "produit antiparasitaire" in the French, is found in section 2 of the Pest Control Products Act: "any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means of directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest, and includes:

- (a) any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added; and
- (b) any active ingredient used for the manufacture of a control product".

It must also be stated that section 3 of the Regulations exempts certain control products (which are governed by the Food and Drug Act).

The definitions 132/ appearing in the said section 2 describe "pest", in the English text and "parasite" in the French, as: "any injurious, noxious or troublesome insect, fungus, bacterial organisms, virus, weed, rodent or other plant or animal pest, and includes any injurious, noxious or troublesome organic function of a plant or animal".

The Pest Control Products Regulations also include a number of definitions designed to facilitate their interpretation; "certificate of registration, applicant, device, active ingredient, residues 133/, seed, registrant and others" 134/.

To conclude this introductory section, section 3(1) of the Pest Control Products Act establishes the following general principle: "No person shall manufacture, store, display, distribute or use any control product under unsafe conditions". This principle is extended by section 3 (3) which states that failure to comply with the regulations shall be deemed contrary to subsection 1 of the said section 3.

Authorization and registration

Section 4 (1) of the Pest Control Products Act (and section 6 of the Regulations) prohibit the importation into and sale in Canada of products that have not been registered as prescribed.

Sections 7 to 25 of the Regulations give detailed instructions on the application, issue, duration and renewal of registrations, including temporary registrations, and list reasons for refusal and pertinent charges.

Section 26 states that every registrant shall keep a goods-in and goods-out register in which all quantities of control products stored, manufactured or sold by him shall appear.

Lastly, it should be noted that section 10 of the Regulations specifically lays down that: "every application for a certificate of registration shall be accompanied by five copies of the proposed label for the control product or reasonable facsimilies thereof" 135/.

Packaging

This subject is governed by section 46 of the Regulations. Basically, it is laid down that: "The package for every control product shall be

sufficiently durable and be designed and constructed so that it will contain the control product safely under practical conditions of storage, display and distribution".

To this effect: "Every package shall be designed and constructed to permit:

- (i) the withdrawal of any or all of the contents in a manner that is safe to the user; and
- (ii) the closing of the package in a manner that will contain the control product satisfactorily under practical conditions".

Labelling

Section 3 (2) and (3) of the Pest Control Products Act prohibits the packaging, labelling or advertising of any control product in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety or contrary to the regulations in force. This prohibition is confirmed by section 4 (1) (concerning importation into and sale in Canada) of the said Act and also by section 27 (1) of the Regulations which establishes that: "No label shall be used on a control product unless it has been approved by the Minister and, unless the Minister otherwise directs, every label shall show the information required by sections 28 to 38".

The word "label" (used in both the English and French versions) is defined in section 2 of the Pest Control Products Act as: "any legend, word, mark, symbol or design applied or attached to, included in, belonging to or accompanying any control product".

Regarding information that must be included on labels, section 31 of the Regulations establishes that "display panel" 136/ of control products with the primary purpose of controlling, destroying, preventing, mitigating,

attracting or repelling any pest, shall show:

- (i) the product name of the control product, descriptive of the physical form and purpose of the control product and also the common name of its active ingredient, when established, and may include a distinctive brand or trademark [section 27.2.a 137/];
- (ii) the product or class designation of the control product. It shall be shown in capital letters and be "RESTRICTED" 138/, "DOMESTIC" 139/, or such other words may be need to indicate the product class designation as may be acceptable to the Minister 140/ [section 27.2.b 141/];
- (iii) information respecting the nature and degree of hazard inherent in the control product. This shall be identified by the appropriate precautionary symbols and signal words selected from Schedule III of the Regulations 142/ together with a statement respecting the nature of the primary hazard to which the symbol relates [section 27.2.c];
- (iv) a statement directing the user to read the label before using the product 143/ [section 27.2.d];
- (v) a guarantee statement consisting of the word in capital letters "GUARANTEE" 144/ followed by a colon, followed by the common name of the active ingredient of the control product or, where a common name has not been designated, the chemical or other name of the active ingredient, followed by the contents of the active ingredient, the viscosity, specific gravity, particle size or such other property or specification determined by the Minister to be necessary for guarantee purposes [section 27.2.e];
- (vi) the registration number of the control product, set out in the following manner: the word and abbreviation in capital letters "REGISTRATION No." 145/, followed by the words in capital letters "PEST CONTROL PRODUCTS ACT" 146/ [section 27.2.f];

- (vii) a declaration of the net quantity of the package expressed by volume, when the product is liquid or gas or is viscous, by mass when the product is solid or pressure-packed, in terms acceptable to the Minister [section 27.2.g];
- (viii) the name and postal address of the registrant, and of the registrant agent, if any [section 27.2.h];
- (ix) the directions for use of the control product, including dosage rates, timing of application and use limitations [section 27.2.i];
- (x) information identifying any significant hazard respecting the handling, storage, display, distribution and disposal of the control product. The information shall include instructions respecting procedures to alleviate the hazard and, when required by the Minister, instructions respecting decontamination procedures and disposal of the control product and its empty packages [section 27.2.j];
- (xi) information identifying any significant hazard to things to which the control product is intended to be applied, or to the health of the population, plants, animals or the environment [section 27.2.k];
- (xii) instructions in first aid, under the heading in capital letters "FIRST AID INSTRUCTIONS" 147/, setting out the practical measures to be taken in the event of poisoning, intoxication or injury caused by the control product [section 27.2.1];
- (xiii) toxicological information essential to the treatment of persons who are poisoned, intoxicated or injured by the control product. The information shall be under the heading in capital letters "TOXOLOGICAL INFORMATION" 148/, and include an antidote and remedial measures; a description of the symptoms of intoxication; and the ingredients not mentioned in the guarantee statement 149/ that may affect the treatment [section 27.2.m]; and

- (xiv) a notice to the user of the control product, under the heading "NOTICE TO USER" 150/: "This control product is to be used only in accordance with the directions on this label. It is an offence under the Pest Control Act to use a control product under unsafe conditions".

Section 27 requires the information mentioned in (i), (ii), (iii), (iv), (v), (vi), (vii), (viii) to be shown on the face of the package while the rest may be shown on a secondary panel.

Sections 28 and 30 151/ establish what is mandatory on labels for control products that are devices - information under (v), (viii), (ix) (x) and (xii) - and for those which, while not primarily intended for controlling pest, have such properties - information under (i), (ii), (iii), (vi), and (viii) - on the principal display panel and that under (v), (vi), (ix) and (xi) on the secondary.

In certain cases, subject to approval by the Minister for Agriculture, this information may be included on an attached leaflet 152/. In such cases the label shall include the words: "READ THE ATTACHED BROCHURE (OR LEAFLET) BEFORE USING" 153/.

Regarding "voluntary labelling", section 36 154/ states that: "Subject to the approval of the Minister, additional information relating to the control product and any graphic design or symbol may be shown on the label if it does not unreasonably detract from or obscure the information required to be shown on the label".

Section 37 authorizes registrants to include on the label the following limitation of warranty statement: "Seller's guarantee shall be limited to the terms set out on the label and subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition".

Lastly, section 39 of the Regulations reads: "The information on every label shall be printed in either the English or French language or in both".

CHILE

LEGISLATIVE TEXTS

- Decree-Law No. 3.556 laying down provisions for the protection of agriculture. - 29 December 1980. - Diario Oficial de la República de Chile No. 30.866, 9 February 1981, page 817.
- Resolution No. 1.777 Ex., establishing the toxicological classification of agricultural pesticides. - 14 August 1984. - D.O. No. 31.959, 28 August 1984, page 3952.
- Resolution No. 1.178 Ex., providing for the registration of agricultural pesticides. - 14 August 1984. - D.O. No. 31.959, 28 August 1984, page 3953.
- Resolution No. 1.179 Ex., prescribing information that shall appear on labels for agricultural pesticides. - 14 August 1984. - D.O. No. 31.959, 28 August 1984, page 3954 155/.
- Resolution No. 938 Ex., completing Resolution No. 1.179, prescribing information that shall appear on labels for agricultural pesticides. - 21 July 1986. - D.O. No. 32.529, 23 July 1986, page 3622.

Scope and general requirements

Article 1 of Resolution No. 1.178 (1984) states that (for the purposes of this Resolution): "agricultural pesticides shall be any trade formulation of insecticides, miticides, nematocides, molluscicides, rodenticides, bird poisons, fungicides, bactericides, herbicides, defoliants, dessicants, plant regulators, conditioners, attractants, mammal poisons, repellants and other substances that the Agricultural and Livestock Service shall declare, by resolution ex., to be for agricultural use". This is a much more specific

and detailed definition than the one of "pesticide" in article 3 (k) of Decree-Law No. 3.556 (1980) which reads: "any chemical, organic or inorganic compound or natural substance used against weeds or diseases or pests potentially able to cause damage to organisms or things".

The said Decree-Law also describes "pest" as: "any organism, living or of a special nature, the existence and dispersion of which constitutes a serious hazard to the protection of plants and their products".

Authorization and registration

Article 2 of Resolution No. 1.178 lays down the general principle that: "any individual or body corporate may import, manufacture, formulate, market or use an agricultural pesticide provided it is entered in the Register of Agricultural Pesticides kept in the Plant Protection Division" 156/.

Registration of an agricultural pesticide that has been formulated with an active ingredient tested or used in the country shall be valid for five years, and may be renewed for similar periods, provided a request is made a minimum of thirty days before its expiry date. If renewal has not been requested within the specified period, the registration shall lapse and the product may no longer be marketed until reregistered as for the first time 157/.

Any pesticide containing an active ingredient that has not been tested or used in the country, but for which antecedents for registration originating from official bodies abroad are presented, shall be granted provisional registration until the applicant shall have demonstrated, by means of experiments performed or supervised by recognised public or private experimental Agencies, its efficacy for the purposes for which it is intended. A pesticide under provisional registration may be marketed, but there shall be clear indication on the label as to the provisional nature of its registration. Any such registration shall have a maximum duration of three years, at the end of which time, or sooner if desired, the applicant shall register the product finally for the purposes the efficacy of which have been demonstrated, or else renew the provisional registration for only one further period 158/.

If, on the contrary, an agricultural pesticide contains an active ingredient that has not been tested or used in the country, and there exist no official antecedents abroad for its use, it shall be registered as an experimental pesticide. Any such registration shall have a duration of one year, and may be renewed for similar periods, provided a request has been made for this one month before the expiry date. Experimental pesticides shall be used only for experiments until the results of their experimental use shall justify final registration 159/.

Article 15 of Resolution No. 1.178 lays down that, in order to assess information provided to obtain registration for pesticides formulated with an active ingredient for which no other products have been finally entered in the Register of Agricultural Pesticides, a Registration Committee for Agricultural Pesticides shall be set up within the Agricultural and Livestock Service including, when this is deemed necessary, specialists from the Ministries of Agriculture and Health, and from public and private Universities or Research Institutes. The said Committee may invite the attendance at its discussions of a technical representative from the firm applying for registration, if it is considered that he will do no more than provide additional or clarificatory information as requested regarding the pesticide in question. The said Committee shall make its report prior to issue of a certificate of registration for such a pesticide 160/.

Every agricultural pesticide entered in the Register of Agricultural Pesticides is to be assigned a number that must be included on its label. The applicant receives a certificate testifying to its registration and a copy of his request for registration, with the antecedents, duly stamped by the Plant Protection Division. Such documents must be kept and shown on request for any necessary controls 161/.

Entry of a pesticide in the Register of Agricultural Pesticides does not dispense the holder from his responsibilities under the legislation in force in respect of the registered product. No such registration shall be taken as a guarantee of the efficacy of the registered product, nor shall the Plant Protection Division or the Agricultural and Livestock Service become a party to responsibilities of the holder for the said product 162/.

It is important, lastly, to mention that article 6 of Resolution No. 1.178 provides that agricultural pesticides manufactured or formulated for export only are not required to be registered.

Labelling

Article 32 of Decree-Law No. 3.557 expressly lays down that pesticides must be distributed in closed containers with labels bearing, in indelible lettering, the composition of the product, directions for its use, the necessary safety precautions and the name of the manufacturer or importer.

Resolution No. 1.179 extends this provision, establishing that labels for agricultural pesticides shall be written in the "Spanish language" and include the following information 163:

1. "Identification"
 - 1.1 The trademark of the firm, if desired, no greater in size than 4 percent of the area of the label.
 - 1.2 The trade name of the product.
 - 1.3 The classification ("Insecticide", "Fungicide", etc.) and formulation ("Wettable powder", "Emulsifiable liquid", etc.).
 - 1.4 The ISO number of each active ingredient and the proportion in which it is found in p/p or p/v, whichever applies; the chemical name of each ingredient, shown in brackets or indicated by an asterisk under the declaration of inert ingredients and their proportion.
 - 1.5 The hazard symbols and warning statements according to the toxicological classification of the pesticide:
 - 1.5.1 for extremely hazardous pesticides, a skull and crossbones in black and the words "DANGER POISON";

- 1.5.2 for highly hazardous pesticides, a skull and crossbones in black and the words "HARMFUL POISON";
- 1.5.3 for moderately hazardous pesticides, the word "HARMFUL"; and
- 1.5.4 for slightly hazardous pesticides, the word "CAUTION".
- 1.6 A brief summary of the main uses of the product.
- 1.7 The net content of the container.
- 1.8 In clear lettering, the phrases: "Read all the label before using" and "Destroy the container as soon as empty".
- 1.9 The registration number with the phrase: "Entered in the Register of Agricultural Pesticides under the No...".
- 1.10 The name and address of the manufacturer and importer.
- 1.11 Identification of the batch of manufacture and expiry date of the product.
- 2. "Safety precautions"
 - 2.1 The chemical group, especially of extremely toxic and highly toxic products.
 - 2.2 Precautions to be taken to avoid risk to the people handling or applying the product, third parties, domestic animals, fauna, flora and the environment.
 - 2.3 The symptoms of poisoning, first-aid instructions, antidotes and advice to doctors.
 - 2.4 In clear lettering, the phrases: "Do not store with foods", "Keep out of reach of children and irresponsible persons" and "In case of poisoning call a doctor".

- 2.5 Storage precautions.
- 2.6 The minimum time between application of the product and entry to the treated area.
- 3. "Directions for use"
 - 3.1 The common name of the pest or disease that may be controlled, or the effect that may be obtained.
 - 3.2 The period of application.
 - 3.3 The number of applications and interval between them as appropriate.
 - 3.4 The doses, using the metric system and with reference to the trade formulation.
 - 3.5 The time that must be allowed to elapse between application and harvest, use or consumption (withdrawal period), seeding or planting, or seeding or planting of the subsequent crop, when applicable.
 - 3.6 An adequate method for preparing dispersion or dilution.
 - 3.7 The incompatibilities and plant toxicity.

Article 2 of Resolution No. 1,179 lays down that the surface of the label shall be divided into three equal vertical panels into which the information as above must be divided as follows 164/:

- (i) left panel, safety precautions;
- (ii) centre panel, identification;
- (iii) right panel, directions for use.

Labels shall be on a white background, using black lettering. No other colour shall appear, with the exception of the firm's trademark and the

border that contains the toxicological classification 165/ to which reference is made below.

The toxicological classification 166/ must appear on the label in the form of a strip of colour filling the lower border which shall have a width of 15 percent of the height of the label. The colours must conform to the pesticide classification system 167/, as follows:

- (a) Category I 168/, extremely hazardous, colour red (tone Pantone red 199-C).
- (b) Category II 169/, highly hazardous, colour yellow (tone Pantone yellow-C).
- (c) Category III 170/, moderately hazardous, colour blue (tone Pantone 293-C).
- (d) Category IV 171/, slightly hazardous, colour green (tone Pantone 347-C).

It is important to point out, lastly, that - in order to help agricultural workers ensure that plant products intended for export do not exceed the tolerance limits established in exporter countries - Resolution No. 938 172/ lays down that: "pesticide labels shall indicate the countries or economic areas that are export markets for Chilean plant products, in which the use of the pesticide on plant species for which their use has been recommended is permitted, or for which tolerance limits have been established". When applicable, information shall also be provided as to the residue tolerance established by the said countries or economic areas.

The information referred to in Resolution No. 938 may be included on the label in the "instructions for use" section, or on a supplementary label attached to the container near the label, or on a separate label attached to the marketable unit.

The legal implications of the information included on labels are confirmed by article 34 of Decree-Law No. 3.557, which establishes a specific obligation binding on purchasers or users of pesticides; "that

they shall be used according to the technical requirements set out on the label, adopting the safety precautions indicated on it and respecting the intervals that must be allowed to elapse between the final application and harvest". Only with express authorization from the Agricultural and Livestock Service of the Ministry of Agriculture may they be used in any other way.

ECUADOR

LEGISLATIVE TEXTS

- Decree No. 374, promulgating the Act to Prevent and Control Environmental Pollution 173/. - 21 May 1976. - Registro Oficial No. 97, 31 May 1976, page 6.
- Decree No. 2331 approving the Regulations governing the manufacture, formulation, importation, marketing and use of pesticides and related products for use in agriculture. - 21 December 1983. - R.O. No. 649, 28 December 1983, page 1 174/.

Scope and general requirements

Article 2 of Decree No. 2331 defines "pesticides" (plaguicidas) as: "any chemical, inorganic, organic or biological substance, for use alone, in combination or mixed, to prevent, combat or destroy, repel or mitigate: insects, fungi, bacteria, nematodes, mites, molluscs, rodents, weeds or any other form of life that may be directly or indirectly damaging to crops, plant products and plants in general". Article 3 establishes that the term "similar products" shall include: "any substance or mixture of substances added to a pesticide to augment its toxic or biological characteristics, facilitate its dispersal, diffusion or attachment to the surface to which it is applied, stabilize the solution and, in general, anything that may contribute to improving the efficacy of the pesticides applied. And also any substance or mixture of substances for use as defoliant, dessicant or growth regulators" 175/.

Authorization and registration

Article 18 of Decree No. 2331 establishes the general principle that: "any individual or body corporate desiring to import, manufacture, or market

agricultural pesticides 176/ shall have obtained prior registration under the National Plant Protection Programme" 177/.

To obtain the said registration, interested parties must present an appropriate request in quadruplicate containing the information set out in article 19 of the said Decree (including clear and detailed information as to the purposes for which the product is intended, and especially: directions for use, dosage, season and frequency of application; and deadline for the last application before harvest) plus the documents referred to in article 20, of which attention is drawn to: "six samples of labels used for the different presentations of the product and the form in which they are to be printed ..." 178/.

Packaging

It is expressly established by article 41 of Decree No. 2331 that agricultural pesticides and similar products shall be offered for sale to the public: "only in original manufacturer's packages or in those as repacked locally by authorized importers 179/, manufacturers 180/, formulators 181/ and distributors...".

Labelling

The general requirements for labelling are to be found in paragraphs (a), (b), (c), and (d) of article 41 of Decree No. 2331, and may be summarized as follows:

- texts and inscriptions shall be in the Spanish language;
- all the mandatory graphic reproductions and symbols shall be clearly visible and easily readable by anyone with normal eyesight;
- the ink, paper and adhesive used for producing and applying labels shall be of such quality as to resist the action of atmospherical agents and handling under adequate storage and transport conditions;

- the labels shall be printed in black lettering on a white background, and no other colour shall appear apart from those identifying the registered trademarks 182/ and the toxicological classification system;
- label sizes shall be proportional to the size and shape of the packages, according to the following specifications 183/;
 - (i) containers holding up to 4 litres, or 5 kg. shall carry a label covering 100 percent of the lateral surface of the container (if all the mandatory information will not fit into the label, the inclusion of an attached leaflet, carrying all such information, shall be obligatory);
 - (ii) for containers of the same capacity, but not cylindrical in shape, the label shall fill 100 percent of the larger lateral surfaces;
 - (iii) containers with a capacity greater than 4 litres, or 5 kg. but not exceeding 19 litres, or 25 kg. shall carry labels covering at least 25 percent of the appropriate surface 184/; and
 - (iv) containers with a capacity greater than 19 litres, or 25 kg, shall carry labels of a minimum size equal to those for containers of up to that capacity.

Regarding mandatory information on labels, article 41 of Decree No. 2331 lays down that it shall be included in three sections or panels, and that it shall read as follows with reference to the four toxicological classes or categories 185/:

1. LEFT PANEL:

"READ THE LABEL BEFORE USING THE PRODUCT"

Safety precautions and directions for use

- (a) Protective clothing suitable for handling the product during its preparation and loading into the application instruments;

(b) Safety precautions during use and application of the product.

First aid

Action to be taken in case of poisoning by oral, dermal or inhalatory contamination.

Antidotes and medical treatment

"In case of intoxication, take the patient to a doctor, who should be given a copy of this label".

Provisions for protecting the environment: storage and handling of the product

Guarantee statements

Advice to purchasers

2. CENTRAL PANEL

Trademark of the company (manufacturer)

Registered name and registration number of the product

Pesticide classification

Kind of formulation

Active Ingredient

(Chemical and common name).....%

Inert ingredients.....%

Grammes/kg of active ingredient

Grammes/litre of active ingredient

"This product may be fatal if swallowed".

"Poisonous if inhaled. May cause damage to eyes".

"Do not store in living quarters. Keep out of reach of children and domestic animals, and away from food. Destroy this container after using the product".

NET CONTENTS:

Name and address of manufacturer/formulator

Lot number

Date of manufacture

Expiry date

3. RIGHT PANEL

Preparation of mixtures and instructions for use

CROP: Common and scientific names; PEST: Common and scientific names; DOSE: International unitary system; FREQUENCY OF APPLICATION: when applied; INTERVAL AFTER LAST APPLICATION.

Compatibility and Toxicity

Registration number

Ministry of Health

Ministry of Agriculture

Distributor

Address

Regarding toxicological classification 186/, article 41(f) lays down that this shall be shown on labels in the following colours: red for "Extremely Toxic" products; yellow for "Highly Toxic"; blue for "Moderately Toxic" and green for "Slightly Toxic". The colour 187/ shall be applied in the form of a band along the base of the label, of a width equal to 15 percent of the label's height.

The name of the pertinent class or category (Extremely, Highly Toxic, etc.) shall appear immediately above the line limiting the category-indicating colour.

The following must also be included:

- with the classification "Extremely Toxic", a skull and crossbones inside the red band, in black and large enough to occupy its entire width, with the words DANGER POISON;
- with the classification "Highly Toxic", a skull and crossbones inside the yellow band, with the words CAUTION POISON;
- with the classification "Moderately Toxic", there shall be no skull and crossbones inside the yellow band, just the word HARMFUL;
- with the classification "Slightly Toxic", there shall likewise be no skull and crossbones inside the green band, just the word CAUTION.

No label, leaflet or advertisement for pesticides and similar products shall include statements to the effect that they are recommended by the Ministry of Agriculture and Livestock, since it is forbidden to assert anything that may lead to the belief that a given product is effective against a pest for which it has not been adequately tested and registered 188/.

Lastly, attention is drawn to the fact that article 49 of the said Decree No. 2331 lays down expressly that: "when using pesticides, the instructions contained on the label must be followed" and also any others issued, on his own responsibility, by any professional agricultural expert, with the intention of preventing pollution of water sources or supplies or damage to adjacent crops or domestic animals belonging to third parties.

FRANCE

LEGISLATIVE TEXTS

- Act regulating Agricultural Pesticide Control Products. - 2 November 1943.- Journal officiel de la République française, 4 November 1943 189/.
- Decree codifying various administrative regulations and decrees of the Council of State on pharmacological matters. - 26 November 1956 190/.
- Act No. 1139 amending the Act of 2 November 1943. - 22 December 1972.
- Decree No. 682 applying the Act of 2 November 1943. - 1 August 1974. - J.O., 4 August 1974.
- Decree No. 541 applying article 2 of the Act of 12 July 1977 controlling chemicals and with reference to agricultural pesticide control products. - 3 July 1979. - J.O., 5 July 1979, page 1620.
- Order regulating the importation of agricultural parasite control and similar products. - 16 August 1979. - J.O. No. 208 N.C., 8 September 1979, page 7702.

Scope and general requirements

The opening articles of the Decree of 11 May 1937, the Act of 2 November 1943 and the Order of 16 August 1979 define respectively the fields of application of the said provisions.

The pertinent field of application focuses on a concept of pesticide control products developed over the years by the quoted legislative texts and distinguishing those intended for agricultural use from those for other uses 191/.

Authorization and registration

Section 1 of the Act of 2 November 1943 (amended by Acts Nos. 1139 of 22 December 1972, and 595 of 13 July 1979) lays down the general principle that registration of pesticide control products shall be mandatory. In particular, Section 9 of the said Act prohibits all advertising of unregistered products 192/.

Section 7 of the said Act requires the labels of pesticides control products to include the date of registration and registration number.

Labelling

French law requires that pesticide control products which do not contain poisonous substances shall carry the following mandatory information on the label:

- the name of the product (which may be either its chemical name or a common name approved by AFNOR) 193/;
- the name and address of the manufacturer 194/;
- the contents of useful elements 195/;
- nature or information as to the mixtures of the said elements 196/;
- dosage and the use for which authorized 197/;
- the number of the authorization for sale (this expression covers both authorized and provisionally authorized products) 198/;
- safety precautions to be taken by users 199/; and
- counter indications detected during testing that have been entered in the authorization register 200/.

Labels for toxic products 201/ shall carry all the above mandatory information and, in addition, the name of the toxic substance in question on an orange-red background. The name of the active ingredient in hazardous products 202/ shall be clearly shown on a green background.

The Decree of 11 May 1937 and Act of 2 November 1943 authorize labels to carry the following "optional" information:

- the selling price;
- the name and address of the consignee;
- the name, firm, trademark and address of both manufacturer and seller;
- detailed instructions for the use of the product;
- safety precautions to be taken during storage; and
- when applicable, any pertinent mark of conformity.

The Acts of 4 August 1905 and 2 November 1943 and Decree of 3 July 1979, lay down special requirements for copper-based products, and an Appendix to the Decree of 26 November 1956, establishing restrictions on trading in certain articles and substances, lists additional requirements for certain toxic products 203/.

Regarding imported products, article 3 (a) of the Order of 16 August 1979 establishes that the following information shall appear, in the French language, on their packages or labels:

- the trade name;
- the name of the owner of the trademark;
- the number of the authorization for sale or importation;
- the composition of the active ingredients;

- the uses, dosage and instructions for use;
- the safety precautions to be adopted by users, and counter indications, if any.

It must be added that section 2 of the Act of 2 November 1943 204/ forbids any mention, in advertisements for pest control products, of uses or methods for use not included in the act of authorization of the product in question. Article 5 of Decree No. 79 of 3 July 1979 adds that, if an advertisement refers to products containing substances particularly hazardous to humans and the environment, it shall include a statement to the effect that it contains such substances. Lastly, a circular from the Quality Controller of the Ministry of Agriculture, of 2 March 1980, extends and interprets the said provisions 205/.

GERMANY (FEDERAL REPUBLIC)

LEGISLATIVE TEXTS

- Act protecting against hazardous substances (Act on Chemicals). - 16 September 1980. - Bundesgesetzblatt I No. 58, 25 September 1980, page 1718.
- Act protecting crops (Plant Protection Act). - 15 September 1986. - Bundesgesetzblatt I No. 49, 19 September 1986, page 1505.

Scope and general requirements

The recent Plant Protection Act is designed to 206:

- "1. Protect plants, especially crops, against noxious organisms ("Schadorganismen") and against damage of non-parasitic origin.
2. Protect plant products against noxious organisms.
3. Avoid damage caused by muskrats (Ondatra zibethicus L.).
4. Avoid hazards, especially to human and animal health and also the environment, caused by the use of plant protection products "Pflanzenschutzmittel" or by application of other plant protection devices".

The term plant protection product ("Pflanzenschutzmittel") includes all substances intended for:

- (a) protecting plants against noxious organisms "Schadorganismen" and against damage of non-parasitic origin;

- (b) protecting plant against noxious organisms;
- (c) protecting plants and plant products against animals, plants, or microorganisms that are not noxious organisms;
- (d) acting on the vital processes of plants, without providing nutrition;
- (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.

Water, fertilizers as defined by the Fertilizers Act, and substances intended to strengthen plants, are excluded from the meaning of the term "plant protection product". Plant protection products are held to mean any substances, other than those included under the letters (a) and (d), intended to act as plant killers or to free or keep free specific areas from plants 207/.

The term "noxious organisms" "Schadorganismen" is defined as: "animals, plants and microorganisms, in all stages of development, that may cause considerable damage to plants and plant products, including muskrats. Viruses and other similar causes of disease shall be treated as microorganisms; diseases not caused by noxious organisms shall be treated as noxious organisms" 208/.

Authorization and registration

The Federal Minister for Food, Agriculture and Forestry is empowered to: "prohibit, limit or make subject to a permit or notification of use" the use of certain plant protection products, the use of plant protection products which include certain substances in their composition, and the use of plant protection products the handling of which requires specific instruments or procedures. In execution of this power, the Minister may lay down that permits shall be issued by the Federal Biological Institute ("Biologisches

Bundesanstalt") or that notification shall be sent to the said Institute 209/. The Federal Biological Institute is an independent federal agency registered with the Ministry of Food, Agriculture and Forestry 210/.

Distribution or importation of plant protection products is permitted subject to authorization by the Federal Biological Institute. Such authorization is not required in the following cases:

1. plant protection products that are intended for export or, after being imported, are stored in a free port or are under customs control;
2. growth regulators intended for use on cut ornamental plants;
3. products intended for use against vegetable microorganisms in enclosed areas or in tubes in factories and establishments under public health control.

The Federal Biological Institute may permit the marketing or importation of unauthorized plant control products under the following circumstances:

1. if they are intended for research purposes;
2. if delay may be prejudicial to combating certain noxious organisms;
3. if the plant control products are for use on plants or plant products intended for export, with the exception of human foods and animal feeds 211/.

Authorization may be requested by the manufacturer, a distributor intending to distribute a plant control product for the first time, or an importer. Requests must include:

1. the name and address of the applicant;
2. the name of the plant control product;

3. information as to the composition, using normal scientific terminology;
4. information on the uses of the product;
5. information as to hazards that may ensue to humans and animals, and any other hazards, in particular to the environment;
6. information as to the procedure for obtaining effective elimination or neutralization;
7. a draft of the directions for use;
8. the symbols intended to be used on containers and outer packages, or on anything added to the package;
9. information as to the nature of the packaging;
10. information as to an appropriate method for analysis such as can be carried out with instruments in common use and at reasonable cost, by means of which a reliable assessment can be made of the residues of the product 212/.

Authorizations shall lapse 10 years after the end of the year in which they were issued and are renewable. In certain cases, the Federal Biological Institute is empowered to impose a shorter duration 213/.

Before 30 June of each year, the manufacturer, producer, distributor marketing a plant control product for the first time, or anyone who has placed on the free market imported plant control products, shall inform the federal Biological Institute as to the classification and quantity of all substances subject to this act delivered to persons resident In the national territory, and as to all exported plant control products 214/.

The Federal Biological Institute shall publish a descriptive list of all authorized plant control products (The Plant Control Products List),

providing information as to their important characteristics and suitability for use in set environments, soils and climates 215/.

Labelling

A preliminary list of basic rules for the labelling of plant control products is found in the Chemicals Act of 1980 216/. The provisions of this Act with reference to labelling are, in fact, also applied to marketing of plant control products that are not substances or preparations under the terms of the said Act 217/. The federal Government is empowered, by the Chemicals Act of 1980, to issue an order making mandatory identification as hazardous any substances which, if placed on the market, may cause considerable risk to human life or health, or to the environment 218/. It is also empowered to issue regulations governing the labelling of such substances 219/.

The Plant Control Protection Act of 1986 adds further specific instructions regarding labelling of plant control products. Manufacturers, distributors and importers are permitted to distribute such products only provided that there is indication on containers and packages of the following information, in the German language in clearly visible, easily readable, indelible lettering:

1. the name of the product;
2. the authorization number;
3. the name and address of the manufacturer or distributor, resident in a Member Country of the European Community, and those of the importer;
4. the active ingredients according to quality and quantity;
5. for plant protection products of limited duration, the expiry date;

6. directions for use. These must include information on:
 - (a) their efficacious utilization for the purposes proposed;
 - (b) possible adverse effects on the health of humans and animals, as well as any other possible adverse effects, especially on the environment;
 - (c) safety precautions and emergency measures in case of accident;
 - (d) efficacious elimination or neutralization;
7. prohibitions and limitations, if any, issued by Ordinance of the Minister for Food, Agriculture and Forestry, referring to the plant protection product in question 220/.

It is pointed out that the information included under the numbers 1 to 7 above does not apply to plant protection products intended for export or those that have been imported and are lying in a free port or are under customs control 221/.

Regarding the marketing or advertising of plant protection products, it is forbidden to use any information that may suggest that such products are suitable for use on other plants or plant products, in larger quantities, or at different times or with safety intervals inferior to those specified in the directions for use. This provision does not apply to plant protection products intended for export 222/.

Specific regulations cover the labelling of plant protection products intended for export 223/. These must include on the container and packaging the following information, in clearly visible, easily readable, indelible lettering:

1. the name of the plant protection product;

2. the active ingredients according to quality and quantity;
3. for plant protection products of limited duration, the expiry date.

They, too, must be accompanied by directions for use, including information on the following:

- (a) their efficacious utilization for the purposes proposed;
- (b) any possible adverse effects on the health of humans and animals and also on the environment;
- (c) their efficacious elimination or neutralization.

Products intended for export must comply with all international agreements, and in particular must be in conformity with the FAO "International Code of Conduct on the Distribution and Use of Pesticides".

THE NETHERLANDS

LEGISLATIVE TEXTS 224/

- Act establishing new regulations for the marketing and use of pesticides (Pesticides Act). - 12 July 1962. - Staatsblad van het Koninkrijk der Nederlanden, Text 288, 7 August 1962, page 727.
- Decree establishing regulations for applying articles 13, 14 and 15 of the Pesticides Act of 1962 (Pesticides Decree). - 25 July 1964. - Stbl., Text 328, 25 August 1964, page 835. (Subsequently amended by the Decrees of 20 March 1973, and 7 September 1983).
- Act amending the Pesticides Act of 1962. - 5 June 1975. - Stbl. 1975, No. 381.
- Order on the composition, classification, packaging and labelling of pesticides. - 22 February 1980. - (Amended by Order J 1806 of January 1982).
- Order on the Authorization of Pesticides. - 28 November 1980.

Scope and general requirements

Section 1(1) of the Pesticides Act defines "pesticides" - for the purpose of the provisions laid down by or pursuant to this Act - as: "being understood to mean any substance or mixture of substances, as well as micro-organisms and viruses, intended for use in:

- (a) controlling or repelling animals which may cause injury to plants and parts of plants;
- (b) preventing or controlling plant diseases;

- (c) preventing or controlling unwanted growth of plants or parts of plants in places other than those referred to in section 1 (2) (b), and destroying foliage;
- (d) regulating or stimulating the growth of plants or parts of plants, not including fertilizers within the meaning of the Fertilizers Act of 1947;
- (e) preventing the decay of plant products intended for use as animal fodder;
- (f) controlling or repelling insects and mites, occurring on or in the presence of animals, by external application, as well as controlling or repelling slugs that can be intermediate hosts for organisms causing disease in animals, the preservation of which is desired;
- (g) treating buildings used to house animals, dunghills and cellars for liquid manure, means of transport for animals or milking equipment, in order to control or repel insects, mites viruses or micro-organisms or products derived through conversion by the latter.

Article 1.2 extends this definition, establishing that "pesticide" shall also be understood to mean substances 225/ intended for use in:

- (a) controlling or repelling animal or plant organisms or viruses which may cause injury to plant products, not being parts of plants as referred to in section 1 (1) (a), or to products of animal origin designated by the Minister concerned by Order to be published in the Government Gazette;
- (b) controlling or repelling animal or plant organisms or viruses in or on:
 - (i) building and other premises, not used to house animals or as nurseries for plants;
 - (ii) domestic water supply and water used for that purpose, for example on campgrounds.

- (iii) refuse dumps;
- (iv) vehicles, ships and aircraft, not used for the transport of animals;
- (v) materials, apparatus and utensils;
- (c) controlling or repelling animals which may cause diseases in or transmit diseases to man, insofar as the provisions of the Medicines Act are not applicable to the pesticide in question;
- (d) controlling or repelling animals, other than those referred to under (c), for the prevention of nuisance to man.

Authorization and registration

Section 2 (1) of the Pesticides Act establishes the following principle: "it is prohibited to sell, stock, store or use a pesticide which is not authorized in accordance with this Act". Section 3 (1) goes on to establish that: "a pesticide shall only be authorized if:

- (a) the content of the active substance or substances and the other constituents, the colour, form, finish, packaging, and specifications and information on or with the packaging comply with the general rules laid down by the Minister concerned by order to be published in the Government Gazette;
- (b) on the basis of prior tests, it can be assumed with reasonable certainty that the pesticide is suited to the purpose for which it is intended and that if used for the proper purpose and as prescribed and recommended, no harmful side-effects will be caused by the pesticide or its conversion products;
- (c) in the case of pesticides ready for use, the content of the active substance or substances does not exceed the requirements for its intended purpose.

Packaging

Article 2 of the Pesticides Decree prohibits the sale of unpackaged pesticides and also the storage and sale of pesticides not in the packaging in which they were first put into circulation in the Netherlands.

The packaging and fastenings used for pesticides must meet the following requirements 226/:

- (a) they must be so designed and constructed that none of the contents can escape;
- (b) the composition of the material used in packaging and fastenings must not be susceptible to attack by the contents or liable to form harmful or dangerous compounds with the contents;
- (c) all elements of the packaging and fastenings must be so well-constructed that they will not come apart and they must be able to withstand normal handling;
- (d) containers with a fastening device meant to be used more than once must be designed so that the container can be repeatedly refastened by the user without any of the contents escaping.

The packaging must also be sealed in such a way that it cannot be opened without damaging the seal.

Labelling

Articles 7, 8 and 9 of the Order of 22 February 1980 establish that the following information must appear on the packaging:

- (a) the name of the pesticide and the words "authorization number", followed by the authorization number and the capital letter "N";
- (b) in the case of pesticides authorized as the result of an application, the name and address Of the person who first put the

product into circulation in the Netherlands if different from the applicant;

- (c) in the case of pesticides authorized by the Minister on his own initiative, the name and address of the person who first brought the pesticide into circulation in the Netherlands;
- (d) the name of the active substance or substances and the concentrations thereof, expressed:
 - (i) for liquids, in grams per litre (at 20° C);
 - (ii) for gases, in volume percent;
 - (iii) in all other cases in mass percent 227/;
- (e) the name of substances other than active substances if these may be considered very toxic, toxic, harmful to health or corrosive 228/;
- (f) the quantity of the pesticide in the container, expressed in units of mass or volume, with the proviso that in the case of pesticides in spray cans the contents shall be expressed in units of volume;
- (g) the safety advice and special risks associated with the use of the pesticide, as stated in the application for authorization, with due regard to the provisions of Appendix II;
- (h) the batch number or other indication by means of which the data relating to the preparation or the origin of the pesticide in question may easily be traced in the records of the manufacturer or importer;
- (i) the danger symbols (skull and crossbones, St. Andrew's cross, ebullient acid, flame, flame over a circle or exploding bomb) in accordance with the provisions of Appendix II;
- (j) the rules and instructions for use;

- (k) where limited shelf-life was specified when the product was authorized the words "to be used before", followed by the date on which the period specified elapses (calculated from the date of preparation);
- (L) the toxicological classification of all the components which are dangerous for humans or for those animals the preservation of which is desired.

The prescribed particulars must either be printed directly onto the packaging and surrounded by a border, or must appear on a label attached to it. In any case the said label or printed notice must be attached in such a way that it is clearly visible and can be easily read when the packaging is set down in the normal way (article 10 of the Order of 22 February 1980).

Article 11 (1) of the said Order 229/ lays down that all labels or printed notices must meet the following minimum size requirements according to contents:

- (i) 3 litres or less: 52 mm x 74 mm;
- (ii) greater than 3 litres but not exceeding 50 litres: 74 mm x 105 mm;
- (iii) greater than 50 litres but not exceeding 500 litres: 105 mm x 148 mm;
- (iv) greater than 500 litres: 148 mm x 210 mm.

If the packaging is so small that all of the prescribed particulars cannot reasonably be accommodated, use may be made of a label securely attached to the packaging or of a leaflet enclosed in the packaging 230/, on condition that:

- (a) at the very least the following information shall appear on the packaging: the name of the substance, the authorization number and batch number, the danger symbol if prescribed, and a note referring the user to the enclosed leaflet or attached label; and

- (b) all of the prescribed particulars with the exception of the batch number must appear on the enclosed leaflet or attached label.

If the packaging consists of material which comes into direct contact with the pesticide, surrounded by a wrapper, and if this material can be pulled apart without being damaged, the prescribed particulars must be placed both on the wrapper and on the packaging material inside it 231/.

Regarding the language to be used on the label, article 12 of the Order of 22 February 1980 establishes that: "all prescribed particulars must appear in the Dutch language and must be clearly legible and indelible".

Lastly, it is provided that no particulars shall appear on or with the packaging which might create an inaccurate or misleading impression of the nature, composition, possible uses or harmfulness of the pesticide 232/. Further, the design and colour of the label (whether stuck on the packaging or attached to it by some other method), the enclosed leaflet or the packaging itself, must be such that the danger symbols clearly stand out.

NEW ZEALAND

LEGISLATIVE TEXTS

- Pesticides Act of 1979 (An Act to make better provision for the regulation and control of the sale and use of pesticides, and to consolidate and amend the Agricultural Chemicals Act of 1959) - 19 October 1979. - Acts 1979, No. 26.

Scope and general requirements

Section 2 of the Act of 1979 includes definitions of "pesticide" and "pest". Pesticide means: "any substance or mixture of substances represented by the proprietor (manufacturer or importer as the case may be 233/) as suitable for the eradication or control of any pest, whether by way of modification of behaviour or development or otherwise; and includes any substance or mixture of substances represented by the proprietor (manufacturer or importer) as suitable for use as a plant growth regulator, or a defoliant or a dessicant; and also includes any substance declared under section 7 of the Act to be a pesticide ..." 234/.

Pest means:

- "(a) any unwanted mammal, bird, reptile, amphibian, fish, insect, arthropod, mollusc, nematode or other worm, plant or fungus, not being an organism living on or in man or any livestock; and
- (b) any bacterium or virus affecting plants; - and includes any other organism from time to time declared under section 6 of this Act to be a pest for the purposes of this Act".

Authorization and registration

Section 21 of the Act establishes the general principle that pesticides are not to be sold unless registered, or unless authorized by an experimental use permit issued under section 25 of the Act.

Section 22 of the said Act lists the documents, reports and other information that must accompany each request for registration.

If the Pesticides Board (provided for in section 12, the functions and responsibilities of which are established by section 13, and include assessment of and making decisions on applications for registration of the pesticides mentioned above) is of the opinion that any label submitted with an application for the registration of a pesticide is misleading, inaccurate, inadequate or otherwise not in conformity with the provisions of this Act or any regulations made thereunder, it may require the proprietor to amend or modify a label (section 38 (3)). Only when the Board is satisfied that the label is in conformity with the provisions of this Act and any regulations made under this Act shall it notify the proprietor in writing that the label has been accepted (section 38 (4)).

Packaging

The first paragraph of section 38 establishes that pesticides shall be marketed in appropriate containers, unless the Board (referred to in the preceding paragraph) expressly authorizes their sale "in bulk" for economic reasons, provided this can be done safely.

The exception referred to above is provided for by section 37, which also establishes (in paragraph 4) that each lot sold "in bulk" shall be delivered with an invoice in duplicate, signed by the seller, stating that a permit has been given under this section, setting out the particulars required to be shown on the label accepted by the Board in respect of the registration of the pesticide.

Labelling

Pesticide labels must show the following particulars clearly and distinctly (section 38):

- (a) the name and address of the proprietor (manufacturer or importer as the case may be 235/), and the name or trade name of the pesticide;
- (b) the number of the certificate of registration or (as the case may require) the number of the permit relating to the pesticide;
- (c) such particulars of the chemical composition of the pesticide as may be required by the Board;
- (d) the preventive or remedial properties claimed in respect of the pesticide, and advice for its use;
- (e) such mandatory directions as to the use or application of the pesticide as may be required by the Board;
- (f) such precautionary advice as may be required by the Director-General of Health for the purpose of safeguarding the health of human beings;
- (g) such precautionary advice as may be required by the Board for the purpose of safeguarding the health of livestock and beneficial animals 236/;
- (h) such precautionary advice as may be required by the Board for the purpose of avoiding damage to beneficial plants, or to the environment generally;
- (i) such other particulars as the Board may direct in any particular case;
- (j) the symbols and information required by the Toxic Substances Act of 1979 237/; and

- (k) the net weight or the net quantity of the pesticide contained in the package (stated in a manner approved by the Board) 238/.

Regarding advertising, section 20 of the Act includes a number of restrictions and, in particular, the fact that a statement shall be included to the effect that the pesticide has been registered for restricted use (paragraph 2) and that no advertisement shall be made for a pesticide the use of which is subject to an experimental use permit (paragraph 3).

SPAIN

LEGISLATIVE TEXTS

- Crown Decree No. 3349/1983, approving the Technical Health Regulations concerning the manufacture, marketing and use of pesticides. - 30 November 1983. - Boletín Oficial del Estado No. 20, 24 January 1984, page 1850 239/.

Scope and general requirements

Article 1 (1) of the Technical and Public Health Regulations for the manufacture, marketing and use of pesticides states that object of these regulations is to: "define what is meant by pesticides and lay down rules for their manufacture, storage and use and, in general, for the technical and public health control of such products, whether produced in the country or imported, as far as public health is concerned, and also to lay down the basic requirements for establishing maximum limits for the residues permitted in or over products intended for food". Article 1 (4) excludes from the field of application of these regulations:

- (a) medicines, narcotics and radioactive products;
- (b) the transportation of pesticides;
- (c) pesticides in transit through Spain, under customs control, that do not undergo processes of transformation or modification; and
- (d) field research into pesticides prior to registration, which shall be authorized by the Ministries of Agriculture, Fisheries and Food and of Health and Consumption.

Article 2 of these Regulations includes a number of definitions, the following of which are selected as examples:

- "Pesticides" are: substances or active ingredients, and also formulations or preparations containing one or more of these, intended for any of the following purposes:
 - (a) combating or preventing the action of agents harmful to plants or plant products;
 - (b) improving or controlling plant production, with the exception of nutrients and those intended as soil conditioners;
 - (c) preserving plant products, including protection of wood;
 - (d) destroying weeds;
 - (e) destroying parts of plant or preventing their undesirable growth;
 - (f) rendering inoffensive, destroying or preventing the action of other harmful or undesirable organisms, excepting those that attack plants.
- "Pesticide residues" are: their remains and those of any toxic products, their metabolization or degradation, that are found in or on human foods and animal feeds.
- "Safety interval" is: the period of time that must elapse between the application of a pesticide to plants, plant products or animals and their harvesting or exploitation or, when applicable, their placing in treated areas or enclosures.

Distinction is also made between "pesticides for use for plant protection" (or "plant protection products") [article 2 (9)]; "pesticides for use with livestock" [article 2 (10)]; "pesticides for use in the food

industry" [article 2 (12)]; "pesticides for use for personal hygiene" [article 2 (13)]; and "pesticides for domestic use" [article 2 (14)].

Article 3 of the Regulations refers to classification of pesticides as follows:

- regarding their degree of toxicity 240:
 - (a) slightly dangerous;
 - (b) harmful;
 - (c) toxic; or
 - (d) very toxic;
- regarding other effects:
 - (a) corrosive;
 - (b) irritant;
 - (c) easily flammable; and
 - (d) explosive.

Authorization and registration

Pesticides intended for use inside the territory of the Spanish State may be manufactured and/or marketed only if entered in one of the following registers:

- (a) for plant protection products, the Official Register of Plant Products and Equipment of the Pest Control and Inspection Service;

- (b) for pesticides for use with livestock, the Register of Veterinary Products of the State Office for Agricultural Production;
- (c) for pesticides for use in the food industry, the General Register of Foods of the State Office for Public Health;
- (d) for pesticides for use for the environment and for personal hygiene, The Register of Authorizations and Special Registrations of the State Office for Drugs and Medicines.

Prior to entry in the respective Registers, the hazards to humans shall have been authorized by the State Office for Public Health, which shall, at the petition of the Responsible Agency of the pertinent Official Register, establish:

- (a) the toxicological classification of the pesticide;
- (b) whether the pesticide is corrosive, irritant, easily flammable or explosive (in accordance with the provisions of article 3 (1) 2 of the Regulations);
- (c) the hazard symbols and a statement of particular hazards and the safety precautions for their use (article 9 (2)); and
- (d) whether or not it is to obtain authorization as a pesticide for domestic use, laying down, if so, the maximum capacity of its containers.

In accordance with the provisions of article 5; "for a formulation to be registered ..., its active ingredients shall have been authorized for that purpose, there being established by the act of registration standards of purity, for analysis and other pertinent specifications, such as the toxicological classification and, when appropriate, the maximum residue limits...".

For the authorization or rejection of an active ingredient, the results must be taken into consideration of long- and short-term toxicological research into mutagenesis, carcinogenesis, teratogenesis and allergy sensitivity, and also into anything else that may produce any direct or indirect harmful effect on human health.

Packaging

Pesticides must be marketed in appropriate containers and, when necessary, packaged according to the regulations in force governing the transportation of dangerous good.

Pesticide packaging must meet the following requirements:

- (a) the packaging must be so designed and constructed that its contents cannot escape;
- (b) the materials constituting the packaging and fastenings must not be susceptible to attack by the contents, or liable to form harmful or dangerous compounds with the contents;
- (c) the packaging and fastenings must be strong and solid throughout, so as to ensure that they will not come apart and will safely withstand normal handling. They may be of glass only for those pesticides the act of authorization of which expressly allows this;
- (d) they must be provided with a guaranteed seal which shall be irreparably destroyed on opening for the first time, and a fastening device so designed that the container can be repeatedly refastened so that the contents cannot escape; and
- (e) the packages for marketing of pesticides for domestic use must be provided with childproof closures.

Article 10 (3) 8 expressly lays down that: "empty packages that contained pesticides classified as harmful, toxic or very toxic must be destroyed or buried or, if applicable, returned to the manufacturer".

Labelling

Article 9 of the Regulations is entirely devoted to the labelling of containers and lettering on packages of formulations, and requires the inclusion of specific information, necessarily in the official language of the Spanish State.

Distinction is made between:

- (a) products in large containers, not addressed specifically to the user, which shall abide by the requirements of the regulations in force controlling transportation of dangerous goods, and must, in each case, include 241;
 - (i) the trade name;
 - (ii) the net contents expressed in legal units of measurement;
 - (iii) the registration number in the appropriate Official Register;
 - (iv) the name and address of the firm or holder of the act of entry in the appropriate Official Register;
 - (v) identification of the batch of manufacture, it being at the discretion of the holder of the act of entry in the Official Register to decide on the form or code of the said identification. It is mandatory that the necessary documentation for localization and identification of each batch shall be made available to the competent State Office;

- (vi) the names of the active ingredients that are part of the formulation and their amounts expressed:
- as a percentage by weight for pesticides which are solids, aerosols, volatile liquids (maximum boiling point 50° C) or viscous liquids (lower limit 1 Pa. s at 20° C);
 - for other liquids: as a percentage by weight and in grams per litre at 20° C;
 - for gases: as a percentage by volume;
- (vii) the name of each very toxic, toxic, harmful or corrosive substance contained in the preparation, excluding active substances, in concentrations of more than 0.2% in the case of very toxic and toxic substances, 5% in the case of harmful substances and 5% in the case of corrosive substances.

and (b) products packaged in units ready for sale to the user, the labels 242/ of which must include, in addition to the information described above for products in large containers, the following:

- (i) the following symbols and indications of danger (drawings of which appear in an appendix to the Regulations) which must be in black lettering on an orange-yellow background:
- Explosive: an exploding bomb.
 - Easily Flammable: a flame.
 - Very Toxic: a skull and crossbones.
 - Toxic: a skull and crossbones.
 - Corrosive: a design showing ebullient acid.
 - Irritant: a Saint Andrew's cross.

It is unnecessary to include the symbol for irritants when that for corrosive, toxic or very toxic substances is included;

- (ii) indications as to the nature of the special risks deriving from the use of the pesticide (from among those shown in Appendix 2 of the Regulations);
- (iii) indications as to the safety advice concerning the use of the pesticide (from among those shown in Appendix 3 of the Regulations);
- (iv) the antidote and advice to doctors in case of intoxication or accident;
- (v) directions for use, including the safety interval and other precise instructions for correct utilization;
- (vi) the expiry date;
- (vii) in the case of there being a double package, indication of the number and kind of units contained; and
- (viii) for very toxic, toxic or harmful pesticides, the indication that the packaging must not be re-used except in the case of containers which are specifically designed for reuse, recharging or refilling by the manufacturer or distributor, with precise instructions for its destruction or return 243/.

Article 9 (4) establishes, in general, that when all the above indications appear on the label, that label must be firmly affixed to one or more surfaces of the packaging so that the particular can be read horizontally when the package is set down normally. The surface or minimum dimensions for labels must be established jointly by the Ministry of

Agriculture, Fisheries and Food and Health and Consumption, and must not be inferior to the following:

Capacity of the packaging:	Size (in millimetres)
- less than or equal to three litres:	52 x 74
- greater than three litres but not exceeding 50 litres:	74 x 105
- greater than 50 litres but not exceeding 50 litres:	105 x 148
- greater than 500 litres:	148 x 210

Each symbols must cover at least one tenth of the surface area of the minimum label as referred to in the above paragraph, but not be less than one square centimetre.

The colour and presentation of the label, or, when appropriate, of the packaging must be such that the danger symbol and its orange-yellow background stand out clearly.

In cases where it is evidently impossible to include on the container or label the required information, it may be supplied to the user in some other appropriate manner which shall be duly indicated on the label.

Lastly, it is laid down by article 9 (3) that a general prohibition exists against: "the inclusion on labels of indications such as non-toxic', 'not dangerous', or any similar indications that may lead to error or confusion".

Regarding the control of products intended for export and imported products, article 11 of the Regulations lays down 244/. that:

- (a) pesticides intended for export failing to comply with the technical and public health requirements of the said Regulations must be packaged and labelled in such a way that they are unmistakably identifiable as such, so as to avoid any possibility of their being marketed or used within the national territory;
- (b) pesticides manufactured abroad must abide by the present Regulations if they are to be marketed and used within Spanish territory.

THE UNITED STATES OF AMERICA

LEGISLATIVE TEXTS

- Federal Insecticide, Fungicide and Rodenticide Act 245/. - 7 United States Code (USC), Chapter 6, Subchapter II, article 136.
- Regulations for the enforcement of the Federal Insecticide, Fungicide and Rodenticide Act. - 7 Code of Federal Regulations (CFR) 162.

Scope and General requirements

The Act defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest 246/, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant or dessicant". Excluded are new animal drugs and animal feeds [7 USC 136 (u)]. This definition is duly extended in 40 CFR 162.3 (ff) with examples and further definitions of particular classes of pesticide.

"Active ingredient" 247/ is defined as follows [7 USC 136 (a) and 40 CFR 162.3 (c)]:

- (i) in the case of a pesticide other than a plant regulator, defoliant, or dessicant, an ingredient which will prevent, destroy, repel or mitigate any pest;
- (ii) in the case of a plant regulator, or an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behaviour of ornamental or crop plants or the product thereof;

- (iii) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from the plant; and
- (iv) in the case of a dessicant, an ingredient which will artificially accelerate the drying of plant tissue.

Authorization and registration

All of the following are expressly prohibited by 7 USC 136a (a): the distribution, sale, offering for sale, possession for sale, despatch, delivery for despatch, or receiving and supplying, or offering to supply, of a pesticide which has not been registered with the Environmental Protection Agency (EPA).

Labelling

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device 248/ or any of its containers or wrappers 249/ and "labelling" means all labels and all other written, printed, or graphic matter 250/:

- (a) accompanying the pesticide or device at any time; or
- (b) to which reference is made on the label or in literature accompanying the pesticide or device (excluding publications of the EPA and other Official Agencies).

The definition in 7 USC 136 (n) of the term "ingredient statement" is a statement which contains:

- (a) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and
- (b) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

It is laid down by 40 CFR 162.10 that the contents of a label must show clearly and prominently the following:

- (i) the name, brand or trademark under which the product is sold 251/;
- (ii) the name and address of the producer, registrant, or person for whom produced 252/;
- (iii) the net contents 253/;
- (iv) the product registration number, preceded by the phrase "EPA Registration No." or "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears 254/;
- (v) the producing establishment number, preceded by the phrase "EPA Est.";
- (vi) an ingredient statement which contains the name and percentage by weight of all inert ingredients, and if the pesticide contains arsenic, a statement to that effect 255/;
- (vii) warnings and precautionary statements consisting of the signal word "Danger" and, the word "Poison" if the product was assigned to Toxic Category I; the word "Warning" if to Toxic Category II; and the word "Caution" if to Toxic Category III or IV. Labels must also bear the statement "Keep out of reach of children" and other indications as found, for each case, under 40 CFR 162.10 (h) (2);
- (viii) directions for use, expressed clearly and concisely, including the following indications: or on over what the product must be applied (e.g. plants, animals, etc.); the pests on which the product may be used; dosage; method of application including instructions for its disposal, if required; frequency of and intervals between applications to obtain effective results without causing adverse effects on the environment; specific

limitations on re-entry into treated areas in accordance with the provisions of 40 CFR 170; instructions for storage; the necessary safety interval, etc. The phrase: "It is a violation of Federal Law to use this product in a manner inconsistent with its labelling" must also be included 256. It is laid down by 7 USC 136 (ee), that this phrase means: "to use any registered pesticide in a manner not permitted by the labelling", but the term shall not include applying a pesticide at any dosage, concentration or frequency less than that specified on the labeling, mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labelling, or using any method of application that is not prohibited by the labeling; and

- (ix) the use classification ("General" or "Restricted") in accordance with the provisions of 40 CFR 162.10 (j), which must appear immediately below the heading "Directions for Use", referred to in the preceding paragraph.

It is laid down in 7 USC 136 (c) (1) that the term "adulterated" applies to any pesticide if: "its strength or purity falls below the professed standard of quality as expressed on its labeling..." While 7 USC 136 (q) lays down that a pesticide is misbranded if:

- (a) its labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
- (b) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator of the EPA pursuant to section 136w (c) (3) of this title;
- (c) it is an imitation of, or is offered for sale under the name of, another pesticide;
- (d) its label does not bear the registration number assigned under section 136e of this title;

- (e) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (f) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a (d) of this title, are adequate to protect health and the environment;
- (g) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a (d) of this title, is adequate to protect health and the environment; or
- (h) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon, the following: "not Registered for Use in the United States of America".

Pesticides are also misbranded if: a) the label does not bear an ingredient statement; b) the labeling does not contain a statement of the use classification under which the product is registered; or c) a label bearing the indications that are mandatorily required to appear on it.

It must also be pointed out that, extending the provisions of section 2 (q) (1) (A) of the Act, 40 CFR 162.10 (a) (s) lays down that a pesticide shall be considered misbranded if its labeling is false or misleading in any particular. Examples of statements which constitute misbranding include:

- (i) a false or misleading statement concerning the composition of the product;

- (ii) a false or misleading Statement concerning the effectiveness of the product;
- (iii) a false or misleading statement about the value of the pesticide for other purposes;
- (iv) a false or misleading comparison with other pesticides;
- (v) any statement directly or indirectly implying that the pesticide is recommended by any agency of the Federal Government;
- (vi) the name of a pesticide which contains two or more principal active ingredients if the name Suggests one or more but not all such active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
- (vii) a true statement used in such a way as to give a false or misleading impression to the purchaser;
- (Viii) label disclaimers which negate or distract from labelling statements required under the Act and these Regulations;
- (ix) claims as to the safety of the pesticide or its ingredients, including statements such as "safe", "nonpoisonous", "noninjurious", "harmless" or "nontoxic to humans and pets", with or without such a qualifying phrase as "when used as directed"; and
- (x) other statements such as: "contains all natural ingredients", "among the least toxic chemicals knbwn", or "pollution approved".

It is expressly laid down in 40 CFR 162.10 (2) (i), that all words statements, graphic representations, designs or other information required on the labeling by the Act or the Regulations must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs or graphic matter on the

labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Regarding the language to be used, 40 CFR 162.10 (3) lays down that: "all required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling".

ANNEX

Resolution 10/85 of the FAQ Conference

International Code of Conduct on the Distribution
and Use of Pesticides

Resolution 10/85 of the FAO Conference

THE CONFERENCE,

Recognizing that increased food production is a high priority need in many parts of the world and that this need cannot be met without the use of indispensable agricultural inputs such as pesticides,

Noting that FAO's study entitled "Agriculture: Toward 2000" foresees a steady increase in the worldwide use of pesticides,

Convinced that such growth in pesticide use is likely to take place in spite of necessary intensive parallel efforts to introduce biological and integrated pest control systems,

Acknowledging that pesticides can be hazardous to humans and the environment and that immediate action must be taken by all concerned, including governments, manufacturers, traders and users, to eliminate as far as possible and within the scope of their responsibility, unreasonable risks, not only in the country of origin but also in the countries to which pesticides may be exported,

Being aware that the requirements for the safe and proper use of pesticides in some developed countries have led to the adoption of complex systems of regulations and of enforcement mechanisms, but that many other countries have neither such mechanisms nor the necessary legislation, regulations or infrastructures to control the import, availability, sale or use of pesticides,

Convinced that additional efforts are needed to enable such countries to control pesticides more effectively and to assess the hazards which could result from their use or misuse,

Recognizing that a voluntary International Code of Conduct, based on internationally agreed technical guidelines, would provide a practical framework for the control of pesticides, especially in countries that do not have adequate pesticide registration and control schemes,

Noting that such a draft Code was reviewed by the Committee on Agriculture at its Eighth Session, and endorsed by the Council at its Eighty-eighth Session,

Having further noted the conclusions and recommendations of these bodies,

1. Hereby adopts a voluntary International Code of Conduct on the Distribution and Use of Pesticides as given in the annex to this Resolution;
2. Recommends that all FAO Member Nations promote the use of this Code in the interests of safer and more efficient use of pesticides and of increased food production;
3. Requests governments to monitor the observance of the Code, in collaboration with the Director-General Who will report periodically to the Committee on Agriculture;
4. Invites other United Nations agencies and other international organizations to collaborate in this endeavour within their respective spheres of competence.

(Adopted 28 November 1985).

NOTES

- 1/ See Fitzwater, "31,927 years of Pest Control", Harcourt-Brace-Jovanovich, Cleveland, 1972.
- 2/ See Segura Roda and Izard Granados, "Plaguicidas y Medio Ambiente: difícil equilibrio entre riesgo y beneficio", AMBIENTE Y RECURSOS NATURALES, Buenos Aires, 1984, page 44.
- 3/ See FAO, "AGRICULTURE: Toward 2000", Rome, 1981, pages 69 and 71.
- 4/ It is to be noted that the use of herbicides is expected to increase at a proportionately much higher rate than that of insecticides and fungicides, and also that this increase will be more rapid in those countries with developed agriculture (Ibidem).
- 5/ See "Guidelines for the Registration and Control of Pesticides", FAO, Rome, 1985, page 1.
- 6/ See, among other documents, the "Report on the Second Intergovernmental Meeting on International Harmonization of the Requirements for the Registration of Pesticides", FAO, Rome, 1982. Attention is also drawn to article 3.1 of the FAO "International Code of Conduct on the Distribution and Use of Pesticides" (to which further reference will be made below in 1.2.1.1 of Part II) which states that; "Governments have the overall responsibility and should take the specific powers to regulate the distribution and use of pesticides in their countries". This principle is more precisely defined in article 6.1.1 of the Code which states that: "(Government should:) take action to introduce the necessary legislation for the regulation, including registration, of pesticides and make provisions for its effective enforcement...".
- 7/ Defended by the most opposed sectors of the doctrine and applied in communities and countries with distinctly different social and economic systems.

- 8/ See "Guidelines for the Registration and Control of Pesticides", FAO, Rome, March 1985, page 3.
- 9/ "Soft law", to use terminology in vogue in North America (see Calais-Auloy, "Implementing the Consumer-Supplier dialogue through Soft Law", JOURNAL OF CONSUMER POLICY, Vol. 7 No. 2, Special edition, June 1984, page 111 and ff).
- 10/ Readers are advised that the order in which the different subjects are treated, certainly heterogeneously chosen, does not indicate any sort of priority or value judgement. It is also recalled that other authors have presented different "lists" of proposed objectives including some that have not been quoted or excluding others that have. Of special interest is the opinion of Glasser who lists as the principle objectives of legislation controlling pesticides: 1) the protection of persons who may remain exposed to serious risk during their manufacture, formulation, packaging, transportation and storage; 2) to ensure that correct containers are used, bearing information as to the classification as to danger, and to avoid direct contamination of human food and animal feed at all stages from manufacture or formulation to their use in the field; 3) to protect persons who may be exposed to risk on opening containers, on diluting concentrated products to obtain adequate doses for treatment or for use at a later stage; 4) to warn, Whenever necessary, about unintentional contamination of untreated crops, animals, soil or waterways; 5) to protect purchasers against low-quality products or misleading information On labels and advertisements for pesticides; 6) to protect consumers of treated food or feedstuffs by ensuring that pesticides are correctly applied and establishing adequate safety intervals between application and harvest and, whenever necessary, providing specific indications. This measure is designed to ensure that pesticide residues - whenever there are any remaining in food or feedstuffs - are of an acceptable level and do not constitute any risk to the consumer; and 7) to ensure that the consequences of the above requirements do not give rise to any restrictions that may impede the development of new pesticides (see "Pesticides and Human Welfare", Oxford University Press, Oxford, 1976, page 228 and ff).

- 11/ Or "pre-harvest interval". The term refers to the declaration of the time that must be allowed to elapse between the last application of the product and the harvesting of plant products, the use for pasture of treated areas, the sacrifice for use as food of treated animals, feeding treated products to domestic animals, storage, sale or use of products such as milk, honey or eggs for human consumption, or the seeding or planting of the following crops, etc.
- 12/ See Gérard, "An outline of Food Law", FAO, Rome, 1975, pages 45 and 49.
- 13/ See "Guidelines for the Registration and Control of Pesticides", FAO, Rome, March 1985, page 3.
- 14/ See Segura, "Control y Registro de Plaguicidas", AGRICULTURA, No. 640 page 883 (paragraph 2.2.5).
- 15/ Ibidem, paragraph 2.2.6.
- 16/ With reference both to surface and underground watercourses.
- 17/ See document No. 103 of the Council for Agricultural Science and Technology (CAST), "Agriculture and Groundwater Quality", Ames, Iowa, March 1985, page 38 and ff.
- 18/ See Cabanellas, "Contaminación de los productos alimenticios", RQNE, No. 69, November 1982, page 17 and ff.
- 19/ See Moses and Henderson, "Guidelines for the establishment of an efficacious national system for the inspection of food", FAO/WHO Rome, 1976, page 2.
- 20/ Which not only facilitate the interpretation of acts and regulations but also, frequently, indirectly limit the field of application. E.g. the definition of "pesticide" (which may include or exclude pesticides for non-agricultural use, or extend the meaning to include defoliant, growth regulators, etc.).

- 21/ Regarding the legislation controlling pesticides under study.
- 22/ See Bombín, "Plant Protection Legislation" (Legislative Study No. 28) FAO, Rome, 1983, 171 pages.
- 23/ See "Guidelines on Good Labelling Practice for Pesticides", FAO, Rome, March 1985, page 1.
- 24/ See the article referred to in note 18.
- 25/ See Wasilewski, "Poisoning from pesticides in Asia: the silent epidemic", CIID REPORT, Ottawa, January 1987, page 18. At a recent meeting of experts organized by WHO, it was reported that a reasonable estimate of the number of cases of intoxication from pesticides worldwide annually is 1 100 000. Of these, 20 000 are fatal (see Brader, "Problems of Pesticide usage in the tropics", communication to the 2nd International Conference on Plant Protection in the Tropics, Kuala Lumpur, March 1986, page 7).
- 26/ See page 3 (paragraph 3.1) of the above publication.
- 27/ See 1.2.1.1 of Part II of this study.
- 28/ One of the problems created by the use of leaflets is to see that they do not become separated from the pesticides to which they refer. As will be seen in Part II of this study, some legislations make, it mandatory that they should be connected with the label itself in one way or another.
- 29/ See "Guidelines on Good Labelling Practice for Pesticides" (FAO, Rome, March 1985), paragraph 7, pages 14 and ff, on the arrangement of information on labels.
- 30/ See page 14 of the document quoted in the previous note for an example of a label leaflet.

- 31/ E.g. " SMITH'S WEEDKILLER". (Most of the examples quoted in this section are taken from "Guidelines on Good Labelling Practice for Pesticides", FAO, March 1985, 36 pages).
- 32/ When no name has been recommended by the ISO, that approved by a local Standardization Agency or Association should be used.
- 33/ In such cases, the label must bear the standard symbols to indicate flammability, and also phrases warning of the hazard involved in using the product.
- 34/ E.g. "FOR CONTROL OF POST-EMERGENT ANNUAL BROADLEAF WEEDS IN CEREALS" (see note 31). When information on labels or leaflets as to recommended uses for a product is amplified, this must be done clearly and distinctly, with names, terms or descriptions that indicate precisely to the user which pests, weeds or diseases the product is intended to be used against.
- 35/ E.g. "Do not use on sandy soils" or "Do not apply when rain is imminent".
- 36/ The expiry date is also known as the "withholding period".
- 37/ See Appendix 2.2 of "Guidelines on Good Labelling Practice for Pesticides", FAO, Rome, March 1985, pages 28 and 29.
- 38/ Ibidem, Appendix 2.1.
- 39/ Ibidem, Appendix 1.3, page 27.
- 40/ See note 31.
- 41/ Such as indemnity clauses or a declaration of the possession of a patent.

- 42/ Competent authorities may opt for other legislative solutions regarding such optional information; forbid it altogether, authorize only if already approved for each case at the time of registration of the pesticide (and its label), lay down different general principles (veracity, clarity, that it shall not overwhelm mandatory information, etc.) on which optional information shall be based, etc.
- 43/ In the case of bilingual countries, for example.
- 44/ See "Guidelines on Good Labelling Practice for Pesticides", FAO, Rome, March 1985, paragraph 8.3 (page 16).
- 45/ Ibidem.
- 46/ The use of both horizontal and vertical texts on a single label causes confusion.
- 47/ See Kanouse and Hayes-Roth in "Cognitive Considerations in the Design of Product Warnings" in "Product Labelling and Health Risks", Cold Spring Harbor Laboratory, 1980, page 149.
- 48/ And, sometimes, in developed countries, where farm work is done by immigrant labourers who may not know the language spoken in the country, many of whom may be illiterates.
- 49/ Such pictograms are being tested in the field to find out how far they are understood, especially by farm workers with a low standard of literacy (see the document COAG/87/3, Supp. 1, FAO, Rome, November 1986, page 12).
- 50/ As will be seen in 1.2.1.1 of Part II, the FAO "International Code of Conduct on the Distribution and Use of Pesticides" contains an extensive definition of "advertising" (including those aspects treated in this section 2.4.2 and the subsequent 2.5.2).

- 51/ No referenae is made in this section to advertising material contained on labels and leaflets, since this must be taken to be included under "optional information", which was considered in section 2.4.1.2. It is repeated here that any such authorization whould be considered as restrictive for the reasons given in that section as well as other negative effects (excessive information, the inadvisability of certain indications, etc.)
- 52/ No reference is made here to the means that may be used to this end, or to other characteristics or methods of such campaigns, since what there is to be said can be found in sections 1.2 and 2.4.4, already quoted.
- 53/ In the international field, standardization [which may be defined as the legal establishment of certain precise and verifiable requirements (the sum of which is called the "standard")] may take form of "unification" - which consists in replacing by a single rule those ruels that are in force in different countries - or "harmonization" - which consists of arranging such rules adequately.
- 54/ According to this method, the rule that is the result of negotiation and agreement between different countries should be included in a multilateral treaty which is then, after signature and before coming into force, submitted for ratification by a set number pf signatory States.
- 55/ Both these legal provisions were elaborated and approved by FAQ.
- 56/ See the FAO document, COAG/83/8, Rome, November 1982, paragraph 21.
- 57/ Ibidem.
- 58/ Included as an Annex to this study.

- 59/ See the "International Code of Conduct on the Distribution and Use of Pesticides", FAO, Rome 1986, 30 pages. Introduction, page 1.
- 60/ "The Code is designed to be used, within the context of national law, as a basis whereby government authorities, pesticide manufacturers, those engaged in trade and any citizens concerned may judge whether their proposed actions and the actions of others constitute acceptable practices" (article 1.6).
- 61/ To which reference will be made below.
- 62/ Idem.
- 63/ To which more detailed reference will be made in the following section.
- 64/ Defined, in article 2, as: "the promotion of the sale and use of pesticides by print and electronic media, signs, displays, gift, demonstration or word of mouth".
- 65/ Reference is made to "Guidelines on Good Labelling Practice for Pesticides", FAO, Rome, March 1985, which will be considered below.
- 66/ See paragraph 3.3 of the said Guidelines (FAO, Rome, March 1985).
- 67/ Ibidem, paragraph 3.2.
- 68/ As already indicated at the end of section 1.2.1, FAO has prepared other documents, the diffusion of which has played an important role in the "indirect" harmonization of national laws. The already quoted "Guidelines for the Registration and Control of Pesticides" (FAO, Rome, March 1985, 42 pages) include a model; "Plan for Establishing a Registration Organization". It is recommended in article 6.1.1 of the "International Code of Conduct on the Distribution and Use of Pesticides" that: "Governments should take action to introduce the

necessary legislation for the regulation, including registration, of pesticides and make provisions for its effective enforcement", following as far as possible, "the FAO guidelines, taking full account of local needs, climatic conditions and the availability of pesticide application equipment".

- 69/ It should be added that UNEP is preparing some guidelines for the interchange of information on potentially toxic chemicals in international trade.
- 70/ See the "WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 1986-87", WHO, Geneva, 1986, 37 pages, (document VCB/86.1, Rev. 1).
- 71/ See "Control of Chemicals in Importing Countries", OECD, Paris, 1982, 195 pages.
- 72/ The name was not adopted until 1977, although the working group in question has existed since 1956 (see "Pesticides", 6th edition, Council of Europe, Strasbourg, 1984, page 6).
- 73/ Ibidem, page 113 and ff.
- 74/ See Volume XXVIII, No. 1, June 1979, of the FAO "Food and Agricultural Legislation", page 54.
- 75/ The addressees of directives may be one or more, or all, the Member States. In certain cases directives may create individual rights in persons subject to the law of the Member State receiving the directive.
- 76/ A community regulation may be defined as a legal act of a general nature, binding in every respect on, and directly applicable to the laws of, each Member State without thereby requiring the intervention of any national body. It confers rights and obligations on individuals which the latter may invoke before the respective national courts.

- 77/ To avoid deviations or alterations in the objectives indicated by Community Directives (which are the privileged instrument of the policy of approximation and harmonization of national laws), the Commission supervises their putting into practice within the internal legal system, by means of a check that is usually made two years after the Directive has been sent to its addressees. See Capelli, "Le Direttive Comunitarie", Giuffrè, Milan 1983, page 9 and ff.
- 78/ Amended by directives Nos. 81/187/EEC ("DOCE" No. L 88, 2 March 1981, pages 29 and 30) and 84/291/CEE ("DOCE" No. L 144, 30 May 1984, page 1).
- 79/ For the time being, whenever no other specific Community provisions exist applicable to such preservatives.
- 80/ This information is presented schematically since, as already explained with reference to the legal nature of Directives, what is important is national law enacted to apply them.
- 81/ For a product not subject to authorization, the name and address of the manufacturer, or anyone introducing it on the market, is sufficient.
- 82/ According to the provisions of Directive No.67/548/ECC and Appendix V to Directive No. 78/631/EEC.
- 83/ See "DOCE" No. C/177, 15 July 1986, page 5 and ff.
- 84/ This general pattern may be subject to variations of detail in one or more countries.
- 85/ Without going too deeply into the matter, it may be stated that referential rule-making consists in referring to or incorporating a rule that is outside the legal system under discussion, whether the rule is international, national or issued by a non-government or even private agency, usually of an associative nature. It is generally used to avoid having to include in the regulations in question

excessively technical or too detailed provisions, variable factors, etc. This legal technique is often resorted to in the field of legislation studied here, which is both international and has its share of technical material, it is frequently used in order to refer to rules for the classification of pesticides, standard warning phrases or directions for use, etc.

86/ Or "adaptability".

87/ Inclusion in basic enactments of very detailed provisions regarding classification of pesticides, labelling requirements, etc., is inadvisable for the following reasons; i) the law becomes too lengthy, inconvenient and not sufficiently flexible; ii) the longer a provision is, the less comprehensible it becomes to those to whom it is addressed, including those responsible for its application and those to whom it applies; iii) it is much more difficult to amend a law than to revise a regulation, especially if it concerns technical matters referring to pesticides and their active ingredients which may frequently vary.

88/ See paragraph 1.2.1.1 of Part II.

89/ The liberty is taken here of repeating that definitions of "pesticide" included in acts or regulations limit the field of application of the provisions.

90/ This particular Regulation is binding on manufacturers of, traders in, applicators and firms treating pesticides and, in general, their users and, when applicable, importers (article 1.2).

91/ Article 2.9 of the Regulation cited.

92/ Ibidem, article 2.10.

93/ Ibidem, article 2.11.

94/ Ibidem, article 2.12.

- 95/ Ibidem, article 2.13.
- 96/ Ibidem, article 2.14.
- 97/ It is to be noted that article 6 of Decree No. 2331 defines "pesticidas" (sic) as "all plaguicidas in general and similar products".
- 98/ See the Act Controlling Pesticides of 1985, section 2.
- 99/ See the Act Controlling Insecticides of 1968, section 3.4.
- 100/ See Act No. 42 of 1979 on pesticides and toxic substances, section 2.
- 101/ In some cases - see Part III of this study - detailed provisions are laid down with reference to dissemination (in 2 or 3 sections) of the information on labels, and also on the colours to be used, generally in relation to the different categories of product and hazards they involve, as will be seen in the following sections.
- 102/ See section 1.3 of Part I.
- 103/ This will be considered below.
- 104/ See paragraph 2.4.1.2 of Part I.
- 105/ Once established as such.
- 106/ The legislation in force expressly requires mention of the time that must be allowed to elapse between application and re-entry into the treated area.
- 107/ See Regulation TTS 21 10 500 Part 8, 1980 (under the terms of the Standardization Act of 1972).

- 108/ See the Regulations applying the Act Controlling Pesticides, Fertilizers and Stockbreeding Products of 1980, article A3.
- 109/ See Act No. 33 Controlling Pesticides of 1980, section 8 (f).
- 110/ See the Act Controlling Poisonous Products of 1967, section 21.7.
- 111/ For purposes of "identification".
- 112/ See Act No. 33 Controlling Pesticides of 1980, section 8 (1).
- 113/ See section 1 (2) of the Act of 11 July 1969, which includes agricultural pesticides and other plant control products under the heading of "raw materials" for agriculture, under the terms of the said Act.
- 114/ The term "plant control products" also includes substances and preparations intended for the destruction of pests, lichens and algae; for combating or eliminating plants, or parts of plants, and also for preventing or limiting their unwanted growth; for combating or eliminating ectoparasites on livestock, including pigeons, etc.
- 115/ Excepting as provided for in Chapter VI of the Crown Order of 25 July 1985.
- 116/ Inapplicable either to: plant protection products and pesticides for agricultural use in transit, under customs control, always provided they undergo no transformation; substances and preparations controlled by the legislation on medicines, including antiseptics and surgical disinfectants; additives authorized for trade in foodstuffs when used as such; and additives authorized for feed and other animal nutrition products.
- 117/ Provided they are clearly marked "export (EEC)" and stored apart with identical markings.

- 118/ See article 21 of the Crown Order of 5 June 1975, amended in 1985.
- 119/ Ibidem.
- 120/ See article 8 of the Crown Order of 25 July 1985.
- 121/ Ibidem, article 8 (b)
- 122/ Ibidem, article 8 (c)
- 123/ Ibidem, article 3 (d)
- 124/ Ibidem, articles 8 (e), 12 and 13.
- 125/ Ibidem, articles 1 and 8 (f)
- 126/ Ibidem, articles 1 and 8 (g)
- 127/ See article 25 of the Crown Order of 5 June 1975.
- 128/ Ibidem, article 18 (15) and article 8 (h) of the Crown Order of 25 July 1985.
- 129/ See article 8 (i) of the Crown Order of 25 July 1985.
- 130/ See article 19 of the Crown Order of 5 June 1975.
- 131/ Ibidem.
- 132/ Also in the same provision there is, e.g., the definition of label referred to below.
- 133/ Which are defined as "the ingredients of a control product that remain after the control product has been used and includes substances resulting from degradation or metabolism".

- 134/ Such, for example, as "display panel" and "aire d'affichage", respectively, which will be referred to in the section dealing with labelling.
- 135/ See also section 13 (2) (b) of the Regulations in question.
- 136/ "Display panel" (see note 134) is defined in section 2 of the Pest Control Products Regulations as: "part of a label applied on or affixed to the package for a control product but does not include a leaflet or brochure unless it is part of the label".
- 137/ Of the Regulations.
- 138/ "RESTRICTED" and "RESTREINT", respectively.
- 139/ "DOMESTIC" and "DOMESTIQUE".
- 140/ Controlling Agriculture.
- 141/ Of the Regulations.
- 142/ Which are: "danger"/"danger" (an octagon); "warning"/"avertissement" (a Square); "caution"/"attention"; "poison"/"poison" (a skull and crossbones); "corrosive"/"corrosif" (a damaged hand in a receptacle); "flammable"/"inflammable" (a flame) and "explosive"/"explosif" (an exploding bomb).
- 143/ Which reads: "READ THE LABEL BEFORE USING" or "LIRE LE LABEL AVANT L'EMPLOI".
- 144/ "GUARANTEE" or "GARANTIE".
- 145/ "REGISTRATION No." or "N" "D'ENREGISTREMENT".
- 146/ "PEST CONTROL ACT" or "LOI SUR LES PRODUITS ANTIPARASITAIRES".

- 147/ "FIRST AID INSTRUCTIONS" or "PREMIERS SECOURS".
- 148/ "TOXICOLOGICAL INFORMATION or "RESEINGEMENTS TOXICOLOGIQUES".
- 149/ See paragraph (v).
- 150/ "NOTICE TO USER" or "A L'ATTENTION DE L'USAGER".
- 151/ Also of the Regulations.
- 152/ See section 33 of the Pest Control Products Regulations.
- 153/ "READ ATTACHED BROCHURE (or LEAFLET) BEFORE USING" or "LIRE LE DEPLIANT (ou LA FEUILLE) CI-JOINT AVANT UTILISATION".
- 154/ Of the Regulations.
- 155/ Resolution No. 1541 of 5 October 1982, published in the D.O. of 16 October of the same year is no longer in force.
- 156/ Entry in the register is obtained through an application in triplicate for each product, including the antecedents as indicated in articles 7 (1) and 7 (2) (of Resolution No. 1.178) as well as the documents as prescribed in article 7 (3) (Ibidem), with the exception of those for testing or use in the country if they are pesticides for provisional registration or for experimental use, in which case the information stated in article 8 (Ibidem) shall be included. It shall, in every case, be the responsibility of the applicant to have checked the veracity of the antecedents that are supplied. It should be pointed out that, included in the documents listed in the said article 7 (3) are: i) a model of the label with which the product will circulate in the country; and ii) labels and leaflets with which it circulates in the country of origin (if these are in different languages from Spanish, English or French, a translation into Spanish must be included).

- 157/ Resolution No. 1.178, article 3.
- 158/ Ibidem, article 4.
- 159/ Ibidem, article 5.
- 160/ Listing of pesticides with active ingredients for which other products on the same basis have Already been finally registered in the country shall not require intervention by the said Committee, unless, according to the judgement of the Agricultural Protection Division, special circumstances obtain.
- 161/ Resolution No. 1.178, article 16.
- 162/ Ibidem, article 18.
- 163/ Article 1 of the said Resolution.
- 164/ In those special cases where this division cannot be made because of the shape and/or size of the packages, the Agricultural Protection Division shall issue appropriate instructions (Ibidem, article 3).
- 165/ Ibidem, article 4.
- 166/ See Resolution No. 1.177.
- 167/ Resolution No. 1.179, article 5.
- 168/ See Note 165.
- 169/ Ibidem.
- 170/ Ibidem.
- 171/ Ibidem.

- 172/ Which is, in this sense, complementary to Resolution No. 1.179.
- 173/ Section 22 of the Act lays down that the use of substances such as: pesticides, herbicides, fertilizers, defoliant, detergents, radioactive and other materials the use of which may cause contamination shall be limited, regulated or prohibited.
- 174/ See Volume XXXIII, No. 2, December 1984, of the FAO "Food and Agricultural Legislation", page 4.
- 175/ It should be added that article 6 of Decree No. 2331 refers to the definition of "pesticidas" (sic): "all pesticides in general and similar products".
- 176/ See the above note.
- 177/ Which, under the terms of article 17 (e) of the said Decree, is competent, among other things, to: "approve packages and the information on labels, brochures, leaflets, bulletins and other instructive or advertisement information on pesticides and similar products in accordance with the rules laid down by the (...) Regulations and any others established by the Ecuadorian Institute of Standardization (INEN), for the purpose of guaranteeing the veracity of information on the use of the product, and also for the preservation of health".
- 178/ See article 20 (c) of Decree No. 2331.
- 179/ See article 7 of Decree No. 2331.
- 180/ Ibidem, article 4.
- 181/ Ibidem, article 5.
- 182/ In no case shall the trademark of the firm exceed 4 percent of the total area of the label.

- 183/ See article 15 of Decree No. 2331.
- 184/ In no case shall the size be smaller than that of labels used for containers of 4 litres or 5 kg.
- 185/ See article 15 of Decree No. 2331.
- 186/ Ibidem.
- 187/ The colours red, yellow, blue and green must be of the internationally-adopted tones.
- 188/ See article 42 of Decree No. 2331. The provision in question also provides that the National Plant Health Programme may confiscate or prohibit the use of labels, leaflets or advertisements that do not abide by the provisions of the Regulations, without detriment to the penalties incurred by those responsible for the infringement.
- 189/ Amended in 1963, 1972, 1974, 1976 and 1979.
- 190/ Amended and completed in 1958, 1962 and 1974.
- 191/ See Fournier and Bonderf, "Les produits antiparasitaires à usage agricole", TEC & DOC, Paris, 1983, page 259.
- 192/ See also the Order of 7 October 1974 on the authorization of the plant control products in question.
- 193/ See article 3 of the Decree of 11 May 1937.
- 194/ Ibidem.
- 195/ Ibidem, article 1.
- 196/ Ibidem.

- 197/ See section 7 of the Act of 2 November 1943 (amended by Act No. 1139 of 22 December 1972).
- 198/ Ibidem.
- 199/ Ibidem.
- 200/ See the Act; of 22 December 1972.
- 201/ Corresponding to class A. See the Decree of 26 November 1956 and other pertinent provisions.
- 202/ Class B (Ibidem).
- 203/ It should be noted that the Decree of 5 July 1985 on the application of pest control products states (article 2) that acaricides dangerous to bees and other insects useful for pollination, shall include in the table the following: "Produits dangereux pour les abeilles et autres insectes pollinisateurs".
- 204/ Amended by Act No. 1139 of 22 December 1972.
- 205/ For the future development of pesticide labelling regulations, see page 268 of the work quoted in note 191 for some general considerations.
- 206/ Act Protecting Crops (Plant Protection Act) of 1986, section 1. Henceforward referred to simply as the Plant Protection Act of 1986.
- 207/ Plant Protection Act of 1986, section 2, No. 9.
- 208/ Ibidem, section 2, No. 7.
- 209/ Ibidem, section 7 (1).
- 210/ Ibidem, section 33 (1).

- 211/ Ibidem, section 11.
- 212/ Ibidem, section 12.
- 213/ Ibidem, section 16.
- 214/ Ibidem, section 19.
- 215/ Ibidem, section 33 (4).
- 216/ Act Protecting against Hazardous Substances (Act on Chemicals) 16 September 1980.
- 217/ Plant Protection Act of 1986, section 20, which refers to sections 13-15 of the Act on Chemicals.
- 218/ Act on Chemicals of 1980, section 13 (3).
- 219/ Ibidem, section 14 (2) 1.
- 220/ Plant Protection Act of 1986, section 20 (2).
- 221/ Ibidem, section 20 (3).
- 222/ Ibidem, section 21.
- 223/ Ibidem, section 23.
- 224/ See the publication of the Ministry of Housing, Town Planning and the Environment (July 1984) with the English-language versions of the same.
- 225/ And also their mixtures, micro-organisms or viruses.
- 226/ Article 5 of the Order of 22 February 1980.

- 227/ Including the propellant, when dealing with aerosol pesticides.
- 228/ In accordance with the standards established by Appendix II and article 7 (e) of the said Order of 22 February 1980.
- 229/ Of 22 February 1980.
- 230/ Ibidem, article 11 (2)
- 231/ Ibidem, article 11 (3)
- 232/ Ibidem, article 13.
- 233/ See the definition of "proprietor" in section 2 of the Act.
- 234/ The term pesticide does not include fertilizers or medicaments for animals, according to the provisions of the Act on medicines for animals of 1967.
- 235/ See note 233.
- 236/ Including birds, fish, livestock, beneficial insects and organisms in the soil.
- 237/ See section 38 (6).
- 238/ See section 38 (9).
- 239/ See the complete text of the said provision in the FAO "Food and Agricultural Legislation", Volume XXXIV, No. 2, December 1985, page 4 and ff.
- 240/ The toxicological classification of pesticides into categories of slightly dangerous, harmful, toxic and very toxic is made basically according to their acute toxicity, expressed in DL 50 (a dosage 50 percent lethal) by oral or dermal route for female rats, or CL 50 (a concentration 50 percent lethal) by inhalation for female rats, in accordance with the standards laid down in article 3.2.

- 241/ Article 9 (1) These requirements are also applicable to packaging in general.
- 242/ Without detriment to the different specific regulations.
- 243/ Pesticides for domestic use shall include, in addition, the phrase "Authorized for domestic use" in clearly visible lettering.
- 244/ With the exception of the provisions of international agreements ratified by Spain.
- 245/ Amended by the Federal Act controlling pesticides in the environment of 1972 (Publication L. 92-516, 86 Stat. 973).
- 246/ "Pest" is defined as: "1) any insect, rodent, nematode, fungus, weed or 2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator of the Environment Protection Agency (EPA) declares to be a pest under section 136w (c) (1)" [7 USC 136 (A)].
- 247/ See the definition of "inert ingredient" in 7 USC 136 (m) and 40 CFR 162.3 (A).
- 248/ According to the definition in 7 USC 136 (n).
- 249/ 7 USC 136 (p) (1).
- 250/ 7 USC 16 (p) (2).
- 251/ The said information must appear on the front panel of the label - [40 CFR 162.10 (b)].
- 252/ As provided for in 40 CFR 162.10 (c).
- 253/ According to the specific rules established in 40 CFR 162.10 (d).

254/ In no case shall this information suggest that the product is recommended by the EPA.

255/ See 40 CFR 162.10 (g).

256/ See 40 CFR 162.10 (i).

