

MODEL PESTICIDES BILL
for countries in the Caribbean region

Draft for Consultation

July 2020

MODEL PESTICIDES BILL

FIRST DRAFT FOR CONSULTATION

(July 2020)

Editorial note

This document presents a Model Pesticides Bill for countries of the Caribbean region. It has been formulated based on:

- A thorough analysis of pesticide legislation in countries of the region, to analyze gaps and particular concerns on pesticide management;
- Records from regional meetings on pesticide management, including considerations on a potential regional-level registration mechanism based on voluntary recommendations, informed by current activities of the Technical Working Group formed under CAHFSA;
- A review of legislation from other countries, in particular countries with similar characteristics, to provide lessons and useful examples;
- Drafting by a team of lawyers including a regional and an international legal consultant hired by the Project, and supervision by the Legal Office of the FAO;
- Provisions of the International Code of Conduct on Pesticide Management (CoC);
- the FAHO/WHO Guidelines on Pesticide Legislation (GPL) and Guidelines on Pesticide Registration (GPR).

This Model Pesticide Bill has the objective to serve as basis for countries to revise their national pesticide legislation in order to minimize the risk posed by pesticides to human, animal and environmental health. This will contribute to strengthen national legislation as well as to foster harmonization throughout the Caribbean Region.

Countries of the region may want to take into consideration the advantages of harmonized legislation in this area, especially in matters such as registration, licensing, labelling and packaging, as well as waste disposal. These include harmonized risk reduction, and improvement of trade flows in both pesticides and agriculture products.

Note: **points highlighted in yellow** are references to other sections of the law that might need to be revised if articles are deleted/added after a review of this document, until a final version is agreed upon. Along the same lines, text included between squared brackets might be subject to national discussion and amendment.

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PESTICIDES BILL, 20[]

An Act to regulate all pesticides, including pesticides for agricultural, human health and other uses, at every stage of their life cycle, including the disposal of pesticide waste, with the objective of protecting human, animal and plant health and the marine and terrestrial environment, and promoting sustainable agricultural production in [country X].

[DATE]

Justification: this section sets the aim of the law aligned with the provisions of the CoC and recommendations of the GPL of regulating all pesticides through all of their life-cycle, with a view to protect human, plant and animal life from risks posed by pesticides.

PART I

PRELIMINARY

Short title and commencement

1. (1) This Act may be cited as the **Pesticides Act, 20[]**.
- (2) This Act shall come into force on a day to be fixed by the Minister by Order published in the *Gazette*.

Interpretation

2. In this Act —
 - “Active ingredient” means the part of the product that provides the pesticidal action;
 - “Advertising” means the promotion of the sale and use of pesticides by printed and electronic media, signs, displays, gifts, demonstration or word of mouth;
 - “Adulterated pesticide” means a pesticide in which —
 - (a) any constituent has in whole or in part been omitted or abstracted;
 - (b) any substance has been substituted wholly or in part of it;
 - (c) any substance has been added to it or mixed or packed with it so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is;
 - (d) damage or inferiority has been concealed in any manner;
 - (e) any constituent exceeds the amount stated on the label or permitted in the regulations;
 - (f) its nature, substance or quality has been affected.
 - “Banned pesticide” means a pesticide all uses of which have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a

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pesticide that has been refused approval for first-time use, or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment

“CAHFSA” is the Caribbean Agricultural Health and Food Safety Agency, an institution of the Caribbean Community (CARICOM)

“Commercial name” (or trade name) means the name under which a pesticide is marketed, including the trademark.

“Common name” means the name assigned to the active ingredient of a pesticide by the International Organisation for Standardization (ISO) to be used as a generic or non-proprietary name only for that particular active ingredient;

“Concentration” means the proportion of the active ingredient in a pesticide;

“Container” means any object used to hold a pesticide product;

“Convention” includes an international agreement, bilateral agreement or other arrangement relating to a pesticide to which [Member State] is a party;

“Disposal” means any operation to recycle, neutralize, destroy or isolate pesticide waste, used containers and contaminated materials;

“Distribution” means the process by which a pesticide is supplied through a trade channel to a local or international market;

“Efficacy” means the degree of effectiveness at the dose rate, frequency and duration of use, and by the route of administration claimed by the manufacturer;

“Environment” includes surroundings, including water, air, soil and their interrelationship as well as all relationships between them and a living organism;

“Exposure” means any contact between a living organism and one or more pesticides;

“Formulation” means the combination of various ingredients designed to render the product useful and effective for the purpose claimed for the envisaged mode of application;

“GHS” means the Globally Harmonized System of Classification and Labelling of Chemicals developed by an international team of hazard communication experts for adoption by Member States of the United Nations;

“Hazard” means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences;

“Inspector” means a person appointed or designated as an inspector under this Act;

“International Organization for Standardization (ISO)” means the Organization established on the 23rd day of February 1947 to develop international standards for adoption by at least 164 of its Member States including (Member State);

“Highly Hazardous Pesticide” means a pesticide that —

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- (a) is acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as by WHO or GHS or their listing in relevant international binding agreements or conventions; and
- (b) appears to cause severe or irreversible harm to health or the environment under conditions of use;

“Label” —

- (a) means the written, printed or graphic matter on, or attached to a pesticide or its immediate container; and
- (b) includes the outside container or wrapper of the retail package of the pesticide;

“Life cycle” means all the stages a pesticide might pass through from production to its degradation in the environment after use, or its destruction as an unused product. The life cycle includes manufacture, formulation, packaging, distribution, storage, transport, use and final disposal of a pesticide product and/or its container.

“Manufacture” means to prepare, compound, formulate, mix, make or otherwise treat a pesticide with a view to its sale and use;

“Manufacturer” means a corporation or other entity in the public or private sector (including an individual) engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product;

“Member” means a member of the Board;

“Minister” means the Minister with responsibility for [Agriculture/ Environment / Health];

“Ministry” means the ministry with responsibility for [Agriculture/ Environment /Health];

“Obsolete” in relation to a pesticide, means a pesticide —

- (a) the registration of which has been cancelled under this Act; or
- (b) that has become unusable due to having been degraded or expired;

“Packaging” means the container together with the protective wrapping used to carry a pesticide product through wholesale or retail distribution to a user;

“Personal protective equipment” means any clothes, materials or devices that provide protection from pesticide exposure during handling and application. In the context of this Code, it includes both specifically designed protective equipment and clothing reserved for pesticide application and handling.

“Pest Control Operator” means a person who applies a pesticide as a profession;

“Pest” —

- (a) means any species, strain or biotype of a plant, an animal or a pathogenic agent, injurious to a plant and plant product, material or the environment; and

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- (b) includes a vector of a parasite or pathogen of human being and animal disease and an animal causing a public health nuisance;

“Pesticide” means any substance, or mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth;

“Pesticide management” means the regulatory and technical control of all aspects of the pesticide life cycle, including production (manufacture and formulation), authorization, import, distribution, sale, supply, transport, storage, handling, application and disposal of pesticides and their containers to ensure safety and efficacy and to minimize adverse health and environmental effects and human and animal exposure;

“Poison” means a substance that can cause disturbance of structure or function, leading to illness, injury or death when absorbed in relatively small amounts by human beings, plants or animals;

“Poisoning” means occurrence of damage or disturbance caused by a poison, and includes intoxication.

“Registration” means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of scientific data aimed at demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment under the conditions of use in the country or region.

“Repackaging” means the authorised transfer of a pesticide from a commercial package into another, usually smaller container for subsequent sale;

“Responsible authority” means the government agency or agencies responsible for regulating pesticides and more generally for implementing pesticide legislation;

“Residue” means any specified substances in or on food, agricultural and other types of commodities or animal feed as well as in environmental media including soil, air and water resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, breakdown products, reaction products and impurities considered to be of toxicological or ecotoxicological significance. The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g. environmental contamination) as well as known, authorized uses of the chemical;

“Risk” means the probability and severity of an adverse health or environmental effect occurring as a function of a hazard and the likelihood and the extent of exposure to a pesticide;

“Rotterdam Convention” refers to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, signed on 10th September 1998 and in force since the 24th February 2004;

“Severely restricted pesticide”—

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- (a) means a pesticide virtually all use of which has been prohibited by final regulatory action to protect human health or the environment, but for which certain specific uses remain allowed; and
 - (b) includes a pesticide that has, for virtually all use, been refused for approval or been withdrawn by industry either from the market or from further consideration in the domestic approval process, where there is clear evidence that this action has been taken to protect human health or the environment;
- “specification” means the parameters and criteria defining the physical appearance and physical and chemical properties of technical and formulated pesticides linked with hazard and risk profiles;
- “Stockholm Convention” refers to the Stockholm Convention on persistent organic pollutants (POPs), signed on 22 May 2001 and in force since the 17th May 2004;
- “toxicity” means a physiological or biological property which determines the capacity of a chemical to do harm or produce injury to a living organism by other than mechanical means;
- “Tribunal” means the Pesticides Appeals Tribunal” established under this Act;
- “Vehicle” includes a motor vehicle as defined in [applicable legislation] and any vessel, aircraft, container or trailer.
- “WHO” means the World Health Organisation.

These definitions clarify terms used in the Law, most of which are drawn from the CoC. The definitions ensure that key terms in the Law are interpreted accurately and consistently. They may slightly differ from the common understanding of a term or serve to specify a concrete meaning; for example, the definition of “advertising” includes promoting the sale and use of pesticides through gifts and word of mouth because shopkeepers, particularly in rural areas, may informally promote pesticides in these ways. In other cases, definitions are used to simplify and clarify the text.

Definitions should be consistent with the terminology in relevant international agreements, including the CoC as well as that of related national legislation. Secondary instruments should always use the same definitions as the primary legislation they are designed to implement. These definitions might be used as a minimum standard by national legislators and adapted as suitable to national circumstances and legal framework. Of note, the definition of registration envisions the possibility of regional registration as currently discussed by regional authorities in the Caribbean.

Scope

3. (1) This Act applies to any pesticide intended for production, import into, use in, or export from [Member State] whether for an agricultural, a forestry, veterinary or a public health use.
- (2) This Act applies to all stages of the pesticide life cycle, from production to the disposal of pesticide waste.
- (3) This Act binds the (State/Crown).

Some jurisdictions include an exception to the requirement of registration for certain insecticides, such as household pesticides. Even if the country decides to follow this option, it is recommended

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not to exclude these pesticides completely from the scope of the Act, to make sure they are subject to similar requirements in terms of storage and disposal. If the registration of these products deserves an expedite simplified procedure, this can be done by introducing fast-track registration options for low-hazard products.

PART II ADMINISTRATION

Responsible authority for pesticide management

4. (1) The primary responsibility for the administration and implementation of this Act lies with the Ministry responsible for [agriculture]. Hereinafter the Ministry.

(2) The Ministry responsible for [agriculture] will have the responsibility to coordinate the implementation of this Act in close collaboration with the Ministries of health and environment

Functions of the Minister

5. (1) The Minister shall have the following functions:
- a) Supervise and facilitate the implementation of this Act;
 - b) designate a [unit/service] at the Ministry to act as Pesticide [authority/division/unit/service] – hereinafter [“Pesticide Authority”]
 - c) designate the Chief of the Pesticide authority, to be responsible for the implementation of this Act;
 - d) designate a Registrar from among the Ministry staff, to be responsible for handling registration applications, keeping the Pesticides Register, and serving as Secretary to the Pesticides Registration Board;
 - e) approve pesticide risk reduction measures necessary to protect human, animal, plant, marine and environmental health;
 - f) designate the official laboratory(ies) for the purposes of this Act;
 - g) approve any fees and other payments payable to the Government under this Act
 - h) coordinate with other competent authorities of [the country] the implementation of all international, regional and bilateral conventions, agreements and other obligations relating to pesticides;
 - i) liaise with the competent authorities in neighbouring states and regional organizations concerning matters related to pesticides;
 - j) liaise with the authorities in CARICOM, including the [regional pesticide registration body];
 - k) approve and amend the implementing regulations to this Act, as necessary.

(2) The Minister may call upon other government units or officials as appropriate to assist in the implementation of this Act.

Most countries in the region invest the Ministry of Agriculture as the responsible authority for pesticide management, though in some countries also the Ministries of Health and Environment are designated as such.

It should be noted that, with regards to approving and amending the implementing regulations, the designation of this competence to the Minister would depend on the country legislation. In some countries, regulations will be approved by a Council of ministers. In the case of pesticides it is useful that the ministries of health and environment participate in the development of the regulations.

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The Minister also designates a Pesticide Authority, with functions and powers to undertake the day-to-day implementation of pesticide management activities envisioned by this Act, as described in the section below.

Keeping with the inter-ministerial nature of comprehensive pesticides regulation, the Minister is given the ability to call upon other government units or officials as appropriate to assist in implementing the Law.

Functions of the Pesticide Authority

6. (1) The Pesticide Authority shall implement the functions related to pesticides management determined in this Act, including, but not limited to:

- (a) facilitate and coordinate the day-to-day implementation of this Act;
- (b) keep and maintain registers provided for under this Act, and make these publicly available;
- (c) approve, issue, modify and revoke licenses under this Act;
- (d) establish and keep an inventory of pesticides in [country];
- (e) implement and monitor pesticide risk reduction measures approved by the Minister, to protect human, animal, plant, marine and environmental health;
- (f) promote measures to reduce reliance on pesticides, such as promoting Integrated Pest Management and Integrated Vector Management;
- (g) monitor the trade and use of pesticides, and the collection of statistics in relation thereon;
- (h) promote public awareness and organize training relating to the use of pesticides, the dangers involved and the safeguards required for their proper use;
- (i) by delegation of the Minister, any other function related to pesticide risk reduction, or that may be necessary, for the achievement of the purpose of this Act.

PART III

PESTICIDE REGISTRATION

Pesticide Registration Board

7. (1) A Pesticide Registration Board (hereinafter “the Registration Board”) is hereby established as an inter-ministerial body under the coordination of the Minister, which shall be responsible for the registration of pesticides in [country].

(2) The Registration Board shall be composed by an odd number of members and be composed of:

- (a) representatives from the government authority responsible for agriculture, covering at least the areas of crop protection and veterinary services;
- (b) representatives from the government authority responsible for health, covering at least the areas of vector control and public health services;
- (c) representatives from the government authority responsible for the environment, with knowledge of pollution control and waste management;

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(3) The Registration Board may seek consultation from relevant independent experts with knowledge on certain technical aspects of pesticides, either on an *ad hoc* basis or by establishing working groups.

This section establishes the Pesticides Registration Board, responsible for the decisions on pesticide registration. It is recommended that the Registration Board is composed by a limited number of members (not more than 9), representing the key interests of health (vector control and toxicology, occupational health and safety), agriculture (animals and plants) and environmental protection. These are the three interests that should be at the basis of every decision on registration, and these should be taken in a manner that is expedite, based on science and independent. Involving other representatives (other interests) in the decision making would dilute the relevance of the objectives of health, environmental protection and agricultural production.

For this same reason, the private sector should not participate in the Registration Board, to preserve its independence, and members should demonstrate they have no conflict of interest, or disclose any potential conflict of interest.

Functions of the Pesticide Registration Board

8. (1) The functions of the Registration Board include the following —
- (a) Make decisions on registration, [based on the recommendations of the regional registration body];
 - (b) [prepare dossiers, make questions and otherwise liaise with the regional registration body as necessary;]
 - (c) Upon request, advise the Minister on matters related to the implementation of this Act as well as others that might be required;
 - (d) Assume other tasks as necessary for the purposes of this Act.

As currently envisioned under the project and LoA with CAHFSA, the procedure created here aims to have the national Pesticide Registration Board making a final decision, after evaluation of registration requests at regional level and recommendations to be issued by the regional pesticide registration body. This, at the moment, is the TWG working under the auspices of CAHFSA, which is earmarked to be the Technical Secretariat of the CGPC.

Countries will have the right to abide by the recommended decision or not, as the national Pesticides Registration Board will have ultimate control over the registration of pesticides. This is an advantage as the Board will draw on national expertise on the main areas of interest, and also for the country to retain sovereignty over the final decision on registration, while benefiting from the regional expert advice.

In some countries, the Registration Board is charged with the task of defining the criteria for the issuance of licenses. In this model, such function has been given to the Pesticide Authority.

Operation of the Pesticide Registering Board

9. (1) The functioning of the Registration Board shall be defined by regulation under this Act, and include as a minimum:

- (a) The detailed composition, including the number of members and their profile;

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- (b) decision-making processes;
- (c) detailed definition of conflict of interest, disclosure requirements and disqualification rules for internal members and external experts;
- (d) procedure for selecting the chairperson;
- (e) rules on consultation to external experts or institutions;
- (f) number and frequency of annual meetings and conditions for convening extraordinary meetings.

Sometimes the definition of the functioning of the Registration Board is already included in the law. As there are plans for harmonization of the pesticide registration procedure at the regional level, leaving this to a regulation here would allow to make changes in the procedures of the Board to accommodate any recommendations from the regional level.

Disclosure of interest

10. (1) If a member of the Registration Board or a close relative, associate of that member or a person who has an influence on that member, has or intends to acquire, directly or indirectly a personal or financial interest in an application for registration, a license or a permit, or to another matter which is the subject of a proceeding or deliberation, that member must —

- (a) as soon as possible disclose the interest; and
- (b) not be present or participate in a proceeding or deliberation of the Registration Board in relation to the matter.

Pesticides Advisory Committee

11. (1) The Minister may, in consultation with the Registration Board, establish a Pesticide Advisory Committee, to represent the position of different pesticide stakeholders and provide advice on matters related to the pesticide life cycle;

(2) The Pesticide Advisory Committee may be composed by representatives of public and private entities, industry, civil society, experts or academic institutions with an interest in pesticide management.

(3) Matters related to the nomination, appointment and removal of members of the Advisory Committee will be determined by regulation to be issued under this Act.

An advisory body is a proper space where representatives of a broader range of stakeholders can be gathered, without posing a conflict of interest in the processes of registration and licensing or diluting the interests of health, environment and agriculture. This includes the private sector (NGOs, the pesticide industry, academia) as well as other public institutions with an interest on pesticide management).

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Administrative and financial support

12. (1) The Ministry, through the Pesticide Authority, shall provide the Registration Board with the staff, and administrative support necessary to carry out its functions.

(2) The members of the Registration Board will not receive other salary or fee in addition to their regular salary, but may receive daily allowances or cost recovery support for costs incurred in the exercise of their functions, as defined by the Ministry.

Registration requirement

13. (1) No person shall manufacture, formulate, pack, repack, label, import, export, re-export, advertise, keep, store, sell, distribute, apply or use a pesticide in [country] unless the pesticide is registered under this Act.

(2) The Registration Board may issue a special permit, by request or *ex officio*, authorising a pesticide that has not been registered or has been registered for another use in [country] if the pesticide is —

(a) intended to be used for —

(i) purposes of scientific research; or

(ii) an overriding national interest, in the case of emergencies;

(b) in direct transit through [country] and has the necessary permit to enter the country of final destination.

(3) A special permit issued under subsection (2) must specify —

(a) the period of its validity;

(b) the maximum quantity of the pesticide covered by the special permit;

(c) requirements for storage and disposal of the pesticide and pesticide waste; and

(d) any other condition as considered appropriate by the Registration Board to protect human, animal or plant health and the environment.

(4) A special permit issued under subsection (1), for importing a pesticide, applies only to the importation of a single consignment of the pesticide.

This provision provides the basic requirement that all pesticides must be registered in order to be introduced into, be sold or used, or be otherwise handled or dealt with in the country. This article also contains an exception to the registration requirement, allowing unregistered pesticides to be imported or formulated for specific research purposes or emergency situations, for transit through the country or to address new pests or temporary problems of availability or affordability of products on the market.

Pesticides Register

14. (1) The Minister shall establish a Pesticides Register to be kept by the Registrar. The contents of the Register shall be published on the Ministry's website and in a newspaper with national distribution.

(2) Each entry in the Pesticides Register shall include the name and address of the registrant and at least the following information:

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- (a) scientific name of the active ingredient;
- (b) active ingredient content (%);formulation;
- (c) classification;
- (d) trade name;
- (e) toxicity class;LD50 mg/kg (Acute Oral)
- (f) country of origin;
- (g) purpose(s) and use(s) for which the pesticide is approved (crop/animal pest or disease vector);
- (h) any conditions or restrictions on registration, including a reduction in duration or on the manufacture, storage, transport, import, packaging, repackaging, labelling, distribution, sale, use, or disposal imposed under according to this Act; and
- (i) other information as included in Regulation.

(3) Each pesticide in the Pesticides Register shall have an accompanying product file containing the supporting materials prescribed pursuant to section 16.

List of banned pesticides

15. (1) The Minister may approve a list of banned pesticides to be developed and regularly updated by the Registration Board on the basis of the relevant international conventions and good practices.

(2) Pesticides included in the “List of Banned Pesticides” cannot be the subject of an application for registration.

(3) The Registration Board may decide to include a pesticide in the “List of Banned pesticides” at any time, *ex officio*, upon request or following a request for registration, when:

- (a) the product is included in Annex A of the Stockholm Convention or another reference international convention;
- (b) a recommendation to prohibit the product has been issued by the [regional pesticide registration body / CAHFSA];
- (c) the product may otherwise pose an unacceptable risk to human, animal or plant health.

Application for registration

16.

(1) An application for pesticide registration must be made to the Registrar in the form and accompanied by the fee stipulated by regulation under this Act.

(2) Data requirements to be included in the application form shall include:

- (a) the applicant’s company details;
- (b) trade name of the pesticide;
- (c) common name of the pesticide;

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- (d) formulation;
 - (e) proposed use (crop/pest combinations);
 - (f) the manner of its use (including mixing instructions, use instructions, application method and rates);
 - (g) withholding periods;
 - (h) co-formulants;
 - (i) chemical properties and toxicological data;
 - (j) reports of efficacy trials conducted in the country or under conditions similar to those in the country;
 - (k) reports of residue trials;
 - (l) reports on risk to human health and the environment;
 - (m) proposed warnings, hazard symbols and pictograms;
 - (n) type of packaging;
 - (o) information on how the pesticide will be stored and handled and how used containers and any surplus will be disposed of;
 - (p) first aid instructions;
 - (q) a sample label.
- (3) If an application submitted is incomplete, the Registrar shall notify the applicant by writing requesting further information. If the applicant does not provide the information requested within the prescribed time, the application shall be rejected.
- (4) The rejection of an application under subsection (2) shall not bar an applicant or another person from making a subsequent application in relation to the registration of that pesticide.
- (5) The Registrar shall provide an opportunity for public notice and comment on all registration applications. To that end, before the application is submitted to the [regional pesticide registration body], the Registrar shall publish on the Ministry website, with notice in a newspaper of national distribution:
- a) the application request, removing the information deemed confidential under **section 25**; and
 - b) the instructions and time frame for the submission of comments by interested stakeholders.
- (6) If an application for a pesticide registration meets the requirements, the Registrar shall submit the application to the Registration Board for initial evaluation;

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- (7) The Registration Board will prepare a preliminary assessment including the necessary information and submit the application to the [regional pesticide registration body / CAHFSA] for evaluation of the dossier;
- (8) Upon receipt of the recommendation from the [regional pesticide registration body / CAHFSA] on the application request, the Registrar shall send the file to the Registration Board for a final decision.

This article contains basic registration requirements, with further details (forms, fees) to be stipulated by regulation. As there are works on the way to harmonize pesticide application forms/dossiers by the TWG CAHFSA, it is also suggested to define these matters by regulation so that they can be updated as the regional harmonization progresses.

It is envisioned that Registrars receive the applications, to review the conformity to prescribed requirements. If the Registrar identifies that the request is fine, it sends the application to CAHFSA for evaluation and emission of a (non-binding) recommendation, and then return to the national Registration Board for a final decision.

Special Registration procedures

17. (1) The Registration Board may approve special registration procedures, including but not only:

- (a) Registration by reference or analogy to the pesticides registered in selected jurisdictions;
- (b) Registration by equivalence;
- (c) Tiered or step-wise approaches to evaluation and data requirements;
- (d) Special registration procedures for biopesticides or low risk pesticides;
- (e) Other special registration procedures for products that present different hazards or where other circumstances so require.

(2) Special registration procedures in this section may have different data requirements than those established under **Section 16**.

Criteria for decisions on pesticide registration

18. (1) The criteria for decisions on the applications for registration or re-registration of pesticides will be stipulated by regulation under this Act, including at least the following:

- (a) the advice provided by the regional registration body;
- (b) the intended use (crop/pest) and the efficacy of the product;
- (b) occupational health hazards and risks to an operator and user at different stages of the product cycle;
- (c) hazards and risks to public health with special attention to a vulnerable group;
- (d) hazards and risks to the environment, especially to groundwater (drinking water) and aquatic organisms (marine and freshwater);
- (e) envisaged mode and conditions of use and associated risk factors;
- (f) existence of alternatives that present lower risk or is less hazardous;

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- (g) potential antimicrobial impact of the pesticide and potential to create antimicrobial resistance;
- (h) the phasing out of Highly Hazardous Pesticides in **Schedule 1**;
- (i) the status of registration of the pesticide in reference jurisdictions, to be defined by the Registration Board.

Decisions on pesticide registration

19. (1) The Registration Board shall make a final decision within 30 days of receiving the application and recommendation from the [regional pesticide authority] and either:

- a) Approve the registration, in which case it shall instruct the Registrar to:
 - (i) assign a registration number to the pesticide or, for re-registration, re-assign the same number;
 - (ii) enter the pesticide in the Register;
 - (iii) publish the registration on the Ministry website and in a newspaper with national distribution; and
 - (iv) send the certificate of registration or re-registration to the applicant; or
 - b) Refuse registration of the pesticide, notifying the applicant in writing of the reasons for that refusal, which may include, inter alia, that:
 - (i) the regional registration body provided negative advice on registration, and the reasons justifying such advice;
 - (ii) the information contained in the application is false in any material respect;
 - (iii) the quality of the pesticide is unsatisfactory;
 - (iv) the residues are too persistent or are toxic and/or bio accumulative when metabolized;
 - (v) the pesticide is not effective for its intended purpose;
 - (vi) the pesticide is too hazardous to human or animal health or the environment to permit its use or there is insufficient information on its potential short- and long-term risks;
 - (vii) there is a risk that the active substance creates antimicrobial resistance relevant for human and animal health;
 - (viii) other products or practices are available which are equally or more effective and are less hazardous; or
 - (ix) the risks outweigh the benefits under local socio-economic, climatic or other conditions.
- (2) If the decision of the Registration Board is contrary to the recommendation from the [regional pesticide registration body / CAHFSA], a notification shall be sent to [the regional pesticide registration body / CAHFSA] with a justification of the reasons for the deviation and risks/other factors that might have been uncovered during the analysis of the registration application.

These provisions have been designed to accommodate a system of regional evaluation of pesticide registration applications, while allowing countries to deviate from the regional recommendation and keep sovereignty. At the same time, it is envisioned that national authorities should justify eventual deviations, and also alert other countries and the regional authority about potential risks not identified at regional level.

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- (3) For any pesticide approved under subsection (1), the Registration Board may impose conditions or restrictions on the manufacture, storage, transport, import, packaging, repackaging, labelling, distribution, sale, use, or disposal.
- (4) Pesticide registration shall have a standard validity of [2] years. The Registration Board may establish, in accordance with criteria prescribed by regulation under this Act:
 - (a) A reduced validity period for products in view of the hazards posed to humans, animals or plants, or any other circumstance that may justify a limitation in time; or
 - (b) a longer period for products with low toxicity.

It is normally the case that applicants own an exclusive right to formulate or import a formulated product. This right can be their own or result from a contract between the importer and the pesticide company that owns the formulation data. Even for generics, the registration of a pesticide brand would grant the applicant the exclusive right to import or sale that product. The importation or sale of a different brand of the same generic product would require a separate registration, which could of course benefit from a special registration procedure (by equivalence). This is the situation in most countries.

The exclusive right of the applicant is, therefore, not based (only) on the text of the law, but on the agreements between the pesticide company and the importer, and the rationale is the need to protect the data associated to the pesticide formulation, as this data is normally protected by intellectual property rights. When the application has been made by the pesticide company directly, this may decide to engage under distribution contracts with more than one operator.

With regards to validity, the suggested criteria of 2 years can be further discussed, varying in most cases up to 5 years. Factors that can be considered include the potential toxicity of the product. If a highly hazardous product has been approved because there is no alternative, it would be useful to reconsider registration after a short time period.

Finally, another matter for discussion is related to the effects of registration or, in other words, if once a product is registered this can be imported or not by anybody. There is no one-size-fits-all model, the best model depends on the country's preference and context. In some countries the pesticide industry would only assume the costs associated to the application if granted some sort of exclusive right to import the product. In other countries they consider that once the product is registered any operator can import or produce it, as long as the use remains within the registered use. The latter makes most sense in countries where there is also potential registration at its own initiative by the Registration board.

Board Registration of New Pesticides

20. (1) The Registration Board may by its own initiative register a new pesticide in the following cases:

- (a) the Registration Board determines that the currently registered pesticides are not sufficient to enable effective control of a new or existing pest; or
- (b) the Registration Board finds that other products have become available which are more effective, less hazardous, and/or more economical.
- (c) by reference to registration procedures in analogous cases in other countries of the Caribbean, or by reference to recommendations of the [regional pesticide registration body / CAHFSA];

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(2) Decisions on registration undertaken pursuant to subsection 1 shall be based on a pesticide dossier prepared by the Registrar in accordance with the requirements under **section 16**.

These rules allow the Board to register a new pesticide without a specific request by a third party, including cases where CAHFSA has already issued a positive recommendation; and by reference to other countries in the region. This helps to streamline registration.

It should be emphasized, however, that this entails risks and should only be done in circumstances where countries have limited resources/capacities and heavy dependence on the public sector, but that this is not the case in more advanced economies. It may open the door for pressure by companies and corruption in the public sector, hence care should be taken when deciding to keep this provision.

Changes to a registered pesticide

21. (1) Any registration holder who wishes to change the formulation, trade name, active ingredient, concentration or permitted usage of the pesticide shall submit a new registration application in accordance with this Act.

c) Any registration holder who wishes to change the container, label or use of the pesticide shall submit a written request to the Registrar specifying such change(s), in the form and manner prescribed by regulation under this Act.

d) Within 30 days of receipt, the Registration Board shall approve or reject the request or inform the applicant if additional time and/or data are required to undertake an appropriate risk analysis.

e) If the change requested is approved, the Registrar shall amend the Pesticides Register accordingly, publish a notice on the Ministry website and in a newspaper of national distribution and notify any operating license and permit holders of the change.

Additional information and mandatory reporting

22. (1) The Pesticide Authority may by notice in writing require an applicant or registration holder to —

(a) compile information, conduct tests and monitor the performance of a pesticide to obtain additional information with respect to its —

(i) effects on human, animal, or plant health or the environment,

(ii) potential antimicrobial effects, and/or

(iii) efficacy or quality; and

(b) report the additional information to the Registration Board within the time and in the form specified in the notice.

Deregistration

23. (1) The Registration Board may, by its own initiative or upon request, deregister a pesticide at any time if it determines that:

(a) the registration was secured in violation of any of the provisions of this Act;

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- (b) the pesticide or relevant pesticide product has been banned under international conventions on pesticides, or regulatory action to that effect has been taken in other countries;
- (c) the Regional Registration Board has decided to deregister the product or has issued a negative recommendation;
- (d) monitoring of the pesticide's use or new scientific information indicates that:
 - (i) it is no longer effective for the intended purpose;
 - (ii) it causes unwanted health or environmental impacts, or there is high risk of such impact; or
 - (iii) the risks outweigh the benefits under local socio-economic conditions.
- (e) other registered products or practices have become available which are equally or more effective, but less hazardous;
- (f) the manufacturer has withdrawn the pesticide from the market;
- (g) any of the conditions subject to which the registration was granted have been breached;
- (h) there are new facts or changes in circumstances which, if known or existing at the time the registration application was made, would have caused its rejection;
- (i) new information becomes available that suggest that the hazardousness of the product had not been correctly evaluated or may cause severe damage to human, animal or environmental health;
- (j) following the advice of the [regional pesticide body].

(2) Before the deregistration under subsection 1(a) or (f), the registration holder shall be notified to submit, in [30] days and in writing, the reasons against such action.

(3) Deregistration under this section shall be published on the Ministry website and in a newspaper with national distribution and notified directly to all operating license holders, whose licenses shall be automatically revoked with respect to the pesticide in question, and to the relevant government authorities. The Registrar shall amend the Register accordingly and notify the [regional pesticide body].

(4) The Registration Board shall periodically review the pesticides included in the register, to assess whether any of the conditions for deregistration have occurred.

Application for renewal of registration

24. (1) An application for renewal of the registration of a pesticide must be made to the Registration Board at least [thirty] days before the expiry of the validity of the registration of the pesticide.

(2) In an application under this section the Registration Board may require the applicant to submit the information and samples the Board considers appropriate.

(3) The same requirements and procedures for registration apply to the renewal of the registration as **per section 16**.

(4) If the evaluation by the Registration Board of an application under this section demonstrates that the pesticide continues to be effective for the intended purpose and does not pose

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an unacceptable risk to human, animal, plant in the environment, the Board shall allow the renewal of the pesticide for another [2 years].

Recall of pesticides

25. (1) If the registration of a pesticide is cancelled, the Registration Board shall order a recall of the pesticide to protect human, animal or plant health or the environment.

(2) If a recall has been ordered under subsection (1) the Registrar shall publish that order of recall in the *Gazette* and in at least one local newspaper or the electronic media.

(3) Pesticide operators shall notify to the Pesticide Authority the existence of stocks of pesticides for which registration has been cancelled.

Confidential information

26. (1) The information submitted in the application for pesticide registration shall be deemed confidential, including trade secrets, and the rules for its treatment shall be prescribed by regulation under this Act, in accordance with applicable national legislation.

(2) The Registrar, staff from the Ministry and members of the Registration Board shall not disclose to any third party the confidential information they come into contact with during the course of executing their duties under this Act, except as required by law or judicial order.

PART IV

OPERATING LICENCES

This Chapter deals with operating licenses for pesticides-related activities. These licenses are different from the commercial licenses that might be required by other national licensing authorities. Licenses are an important tool for controlling the qualifications, training, skills, and facilities needed for safe and effective pesticides operations.

General Requirement

27. (1) No person shall manufacture, formulate, pack, repack, label, import, transport, export, advertise, supply, store, sell or distribute a pesticide, or carry on the business of a pest control operator in [country], unless that person has a valid operating license issued under this Act, in addition to any commercial license or authorization from the national licensing authority as may be required by Law.

(2) In addition to the requirements in subsection 1, a restricted use license shall be required for any person to use a pesticide whose use has been restricted by the Registration Board according to this Act.

(3) The Minister may establish special requirements for the issuance of operating licenses to regulate the use of specified pesticides, or specific modes of pesticide application, including aerial application and fumigation.

(4) A facility with an operating license to manufacture or formulate pesticides shall only operate with respect to the pesticide(s) specified in the operating license.

(5) Licensing requirements shall not apply to individual farmers or farmers' groups in respect of botanical or microbial pesticides with a history of safe use when applied for private, non-

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commercial purposes. The Ministry shall provide farmers and/or farmers' groups with training and awareness on the safe formulation and application of botanical or microbial pesticides.

Applications for Operating Licenses

28. (1) Licensing requirements shall be developed by the Minister by regulation under this Act, outlining the procedures for the application to obtain and renew each type of operating license under **section 27**.

(2) The licensing requirements shall take into account such factors as the necessary skills, training, facilities, equipment and other aspects of the activity in question, and in accordance with applicable national legislation.

(3) Applications for licenses shall be done to the Chief of the Pesticide Authority, in the form and accompanied by the fee as stipulated by regulation under this Act.

Decisions on License Applications

29. (1) The Chief of the Pesticide Authority shall —

- (a) issue the requested license, if the application complies with all requirements prescribed;
- (a) refuse the application, notifying the applicant in writing of the reasons for the refusal which may include inter alia, that —
 - (i) application relates to a pesticide which is not registered according to this Act,
 - (ii) the information contained in the application is incomplete or false in a material respect;
 - (iii)** the applicant is not technically competent, according to the requirements under **section 27**;
 - (iv) the premises in question are not appropriate for the intended purpose, or use of those premises will endanger human or animal health or the environment; or
 - (v) the applicant is not aware of the toxicity of the pesticide or the risks involved in using or handling it, or is not equipped to avoid or minimise those risks.;

(2) Operating licenses shall be valid for an initial period of [xx] years and are renewable for [xx]-year periods thereafter, unless otherwise provided in the license.

(3) Renewals are subject to the applicant's demonstration of compliance with the applicable requirements, which shall include compliance with this Act, and shall include proof of record keeping as provided in **section 30** and, where relevant, cooperation in inspection and enforcement actions carried out under this Act.

(4) Where an application is rejected for incompleteness, the Registrar shall notify the applicant in writing of the respect(s) in which the information is insufficient, and that the application may be supplemented within a specified time period.

(5) If the applicant does not supplement the application within 30 days, the application will lapse and a new application must be submitted.

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Record Keeping

30. (1) Every person who holds a license issued under this Act shall keep records of all quantities of pesticides so dealt with and of any other information that may be prescribed, for at least [5 years].

(2) Records kept in accordance with subsection 1 shall be made available, upon request, to any inspector, the Minister, the Registration Board or any other public authority.

Variation, suspension or revocation of licences

31. (1) The Chief of the Pesticide Authority may revoke an operating license at any time in light of new information, a material change in circumstances or a violation of any condition, any of which would have resulted in the denial of the license application.

(2) Prior to effecting a revocation under subsection 1, the Chief of the Pesticide Authority shall suspend the license and give the license holder [30 days] to submit a written justification as to why the license should not be revoked. If no justification is submitted, or if the reasons provided are considered inadequate, the license shall be revoked.

PART V

IMPORT AND EXPORT

General requirements

32. (1) No person shall import a pesticide into [country] unless:

- (a) that person holds a valid import license granted according to this Act, and any other document or certificate as required by applicable legislation;
- (b) the pesticide is presented for inspections at a designated port of entry for inspection, as required by this Act and other applicable legislation;
- (c) a notification of the imported quantity is sent to the Pesticide Authority, as required under this Act;

(2) Import and export licenses may include maximum quantities allowed for importation or exportation per year as well as a duty to report on quantities imported and /or exported each year. Such matters will be determined by regulation under this Act.

Export of pesticides

33. Any person wishing to export a pesticide shall hold a respective operating license and shall apply for an export permit demonstrating, among other requirements, that the applicable conditions of the importing country have been met. The application for the export permit will be detailed by regulation under this Act.

PART VI

PESTICIDE POST-REGISTRATION

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Packaging and labelling

34. (1) No person shall pack, repack, store, sell, import, export, transport or distribute pesticides unless —

- (a) it is in a container which is safe for storage, handling or use of the pesticide and is adequate to prevent harm to plant, human or animal health or to the environment;
 - (b) the container prominently displays a legible label that cannot easily be detached or erased and complies with the conditions of registration of the pesticide. Information to be contained in labels will be prescribed by regulation under this Act, including but not limited to:
 - i. common name of the pesticide;
 - ii. active ingredient(s);
 - iii. formulation and concentration;
 - iv. the crop and pests on which the use of the product is permitted;
 - v. the recommended mode of application and dosages;
 - vi. safety measures to protect the user and the environment, including prescription of the recommended protective gear;
 - vii. warning against reuse of the container and instructions for its safe disposal or decontamination after use;
 - viii. information on the storage stability of the pesticide;
 - ix. pre-harvest interval (PHI) if the pesticide is for agricultural activities;
 - x. warning and cautionary statements, including: signs and symptoms of poisoning; information on safety, health and first aid measures; symbols or pictograms and toxicity warnings;
 - xi. the batch number, manufacturing date and expiry date; and
 - xii. the name and address of the manufacturer or supplier.
- (2) If a pesticide is contained in more than one container, subsection (1) shall —
- (a) not apply to the inner container in contact with the pesticide, where the pesticide could not be sold if it were solely in that inner container;
 - (b) apply to the container representing the smallest unit of the pesticide that can be sold separately; and
 - (c) apply to a container containing more than one retail unit, if no bill of lading is attached and if a reasonable person would expect that container to be seen by a consumer in [country].

Storage

35. (1) No person shall store pesticides on the same premises as food products, medicines or other consumables, feedstuffs, or animals other than as prescribed by regulation.

(2) Premises in which pesticides are stored in large quantities:

- (a) Shall be located at least 1 kilometre from hospitals, schools, shops, densely populated urban areas, protected areas, waterways or the shoreline; and
- (b) Shall be surrounded by a security fence with signs clearly indicating the presence of hazardous materials and strictly prohibiting entry by all non-authorized personnel.

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(c) might be subject to the application for a special license.

(3) Further details on pesticide storage, including on obsolete pesticides, used containers and contaminated materials, will be stipulated by regulation under this Act, taking into account the characteristics of, and risks presented by the pesticide in question.

Transport

36. (1) No person shall transport pesticides, pesticide containers or materials contaminated with pesticides in the same vehicle as food products, medicines or other consumables, feedstuffs, or animals in a manner other than as prescribed by regulation.

(2) Transport of pesticides in excess of [specific amounts] in public or private vehicles may be subject to a special operating license, to be issued in accordance with section 27 of this Act and other applicable national legislation.

(3) Further details on pesticide transport will be stipulated by regulation under this Act.

Advertising

37. (1) No person shall advertise pesticides:

- (a) that are not registered according to this Act;
- (b) for a purpose or use other than as approved by registration;
- (c) with safety claims not supported by scientific evidence, or unaccompanied by a qualifying phrase such as “*when used as directed*”;
- (d) with an offer of gifts or other incentives to encourage purchases; or
- (e) in a manner that:
 - (i) is false or misleading in any material particular or is intended to deceive;
 - (ii) compares the effectiveness, risk, hazard or safety of different pesticides or pesticide products;
 - (iii) visually depicts potentially dangerous practices; or

Handling and Use

38. (1) No person shall use, require an employee to use, or recommend the use of pesticides in any manner contrary to the conditions of registration and/or of the operating license relating to that pesticide.

(2) An employer who requires or permits an employee to apply or formulate pesticides shall —

- (a) give instruction as necessary to enable that person to achieve the required standard of competence, including information on potential hazards;
- (b) provide adequate facilities and protective personal equipment required for the safe handling of the pesticide and require the employee to use such facilities and clothing;

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- (c) ensure that empty containers and left-over products are disposed of as prescribed under this Act; and
 - (d) arrange for the employee to undertake periodic medical check-ups and provide access to medical assistance in the event of adverse health effects resulting from exposure to the pesticide.
- (3) No person shall employ a [child/minor], a pregnant woman or a vulnerable person to apply or handle pesticides.
- (4) Further requirements on pesticide use, as well as measures to be taken by license holders to prevent, or minimize to the extent possible, the risk of pesticide contamination, will be stipulated by regulation under this Act.
- (5) The Minister and the [area of government responsible for safety and security at work] shall make every effort to coordinate inspections at facilities where pesticides are handled.

For discussion: regulations could make it mandatory for users to triple rinse the containers and using the rinsate as part of the spray, where possible And for manufacturer/importer/distributor/retailer to take back triple-rinsed empty containers and to be responsible for their safe recycling and/or disposal?

Inventory of Pesticides

39. (1) The Pesticide Authority shall keep an inventory of pesticides which shall include information for the purposes of adequate pesticide management in [country]. This will include, among other elements, information on —

- (a) types and quantity of pesticides produced, imported and used in [country];
- (b) obsolete pesticide in a storage facility or elsewhere in [country] including information on the reason this pesticide has become obsolete; and
- (c) a contaminated site.

Note: With the FAO Pesticides Stock Management System (PSMS), it was possible to keep records of imports, exports, uses, users and obsoletes in one database. Originally for locust control, it evolved so that all types of pesticides, quantities and users could be tracked. Even import licenses issued and ports of entry through which products were imported. This provision could serve for overall pesticide management and for reporting to FAO accurately on national annual pesticides use data.

Disposal of Pesticides and Pesticide Waste

40. (1) No person shall dispose of pesticides or pesticide waste, including pesticide containers, obsolete pesticides or pesticide leftovers, in a manner that is harmful or is likely to be harmful to human health, animal health and/or the environment.

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(2) The requirements and instructions for the disposal of pesticides shall be established by regulation under this Act, including the circumstances in which the owner shall be liable for the associated costs and those in which such costs shall be borne by the government.

(3) The Minister shall, in co-operation with the Minister with responsibility for the environment and in consultation with the Registration Board —

- (a) make every effort to prevent the accumulation of obsolete or banned pesticides and to ensure the disposal of pesticides and pesticide containers in an environmentally sound manner;
- (b) establish a system for the collection of pesticide containers as well as obsolete or banned pesticides;
- (c) identify appropriate sites for the collection or disposal of obsolete or banned pesticides or pesticide containers.
- (d) institute a system for the assessment of a levy on pesticide containers to encourage its return; and
- (e) encourage good handling practices for pesticides containers, including the triple-rinse of empty containers.

(4) Pesticide operators shall keep records of all pesticides purchased or produced, sold, used or disposed, and transmit this information to the Pesticide Authority as prescribed.

(5) Pesticide operators will be responsible to ensure they do not store unused stocks of pesticides, particularly of HHP and pesticides that are persistent organic pollutants (POPs). Pesticide operators will assume the cost of disposal for stocks of obsolete pesticides or pesticides that have been banned or for which registration has been cancelled, *[unless they have notified such stock to the Pesticide Authority as per the procedure under section 24 (3) as soon as the ban or cancellation took place]*.

This last sentence would serve to alleviate the economic burden of the operator when it is demonstrated that the operator acted in good faith and due diligence. Also, bearing the cost on pesticide operators in these cases could discourage notification.

Adulterated, Counterfeited and Substandard Pesticides

41. (1) No person shall adulterate or counterfeit pesticides, or sell pesticides that are known or reasonably believed to be adulterated, counterfeited or otherwise substandard.

(2) Any person who has reason to believe that an adulterated, counterfeited or otherwise substandard pesticide is being sold shall immediately notify the Pesticide Authority, the local government or any other law enforcement official.

PART VI

DESIGNATION OF LABORATORIES

Laboratories and analyst

42. (1) The Minister may by notice in the Gazette appoint a competent person to be a designated pesticides analyst and designate one or more suitable laboratories to be officially utilised for the analysis of a pesticide under this Act.

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(2) If necessary and due to the complexity of the analysis, a sample may be submitted to a regional or international recognised laboratory for analysis and that analysis shall be deemed official for the purposes of this Act.

Certificate of analysis

43. (1) A designated pesticides analyst shall issue a certificate of the analysis conducted under this Act.

(2) A certificate of analysis issued by a laboratory designated under this Act shall state the method of analysis used and any other information that may be prescribed.

(3) A certificate of analysis issued under this section shall be *prima facie* evidence of the facts stated therein in a court proceeding.

PART VII

ENFORCEMENT

Inspectors

44. (1) Without prejudice to the powers of the national inspections authority, the Minister shall appoint or designate qualified staff members of the Ministry, and, with the concurrence of the relevant officials, staff members of other relevant ministries, to be pesticides inspectors for the purposes of this Act, which shall be done by notice in the Gazette.

(2) The Pesticide Authority shall, in consultation and coordination with the relevant ministries and entities, develop a common framework for inspections covering the entire life cycle of pesticides, to be stipulated by regulation under this Act.

(3) An inspector shall be issued with an identification card and provided training in, *inter alia*, what to look for and how to handle pesticides during inspections, including sample taking.

(4) Inspectors shall not be held liable for the consequences of an action or omission committed in good faith in the course of his or her duties.

Powers of inspectors

45. (1) Without prejudice to the powers of the national inspections authority, and with or without the presence of any of its agents, a pesticides inspector under this Act may enter commercial or other private premises which are not used as residence, during regular business hours, for the purposes of ensuring compliance with this Act, without a warrant and on presentation of an identification card, and —

- (a) carry out periodic inspections of an establishment which imports, exports, manufactures, packs, repacks, labels, stores, sells, distributes, uses or advertises a pesticide to determine whether this Act is being complied with;
- (b) require production, inspection, examination or copying of a certificate, permit, licence, record or another document relating to the provisions of this Act;

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- (c) take samples of a substance to which this Act relates and, as may be prescribed, submit the samples for analysis; and
- (d) seize an equipment, pesticide, document, record, or other thing which the inspector believes has been used in, or which appears to be in contravention of this Act, provided that:
 - i. the inspector gives a receipt to the person from whose custody the item was taken; and
 - ii. the item is promptly returned to that person once the necessary inquiry, prosecution or administrative process has been completed, except in the case of unregistered pesticides, which, if so ordered by the Minister or the national inspections authority, shall be destroyed;
- (e) request the assistance of customs agents, police or local government authorities in the exercise of his or her duties under this Act.

Inspection of vehicles

- 46.** (1) An inspector may require a person operating a vehicle to stop for inspection.
- (2) For the purposes of carrying out an inspection under this section, an inspector may:
- (a) request that a compartment of the vehicle or a container in or on the vehicle be opened; and
 - (b) exercise the powers under **section 44.**

Offences and penalties

- 47.** (1) A person commits an offence and is liable on conviction to a fine not exceeding [XXX] or to a term of imprisonment not exceeding [XX] months or to both, if that person—
- (a) obstructs an inspector; or
 - (b) provides false information to an inspector;
 - (c) fails to comply with an order, requisition or direction made or given by an inspector;
 - (d) fails to answer a question asked by an inspector; and
 - (e) prevents or attempts to prevent another person from complying with an order, requisition or directions or from answering a question from an inspector,
- (2) A person commits an offence if that person —
- (a) imports, exports, manufactures, packs, repacks, labels, sells, stores, distributes, possesses, uses or performs any other activity related to pesticides not registered under this Act, without an operating licence as required under this Act;
 - (b) fails to comply with conditions of registration, licence or permit of any pesticides;
 - (c) sells or distributes a pesticide —
 - i. without an approved label attached to it; or
 - ii. which does not meet the specifications as stated when the product was registered;

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- (d) detaches, alters, defaces or destroys a label on the container of a pesticide product;
- (e) repacks or transfers the contents of a pesticide product in a container which is not labelled with an approved label and the operation is carried out in unlicensed premises;
- (f) advertises a pesticide which is not registered, or in a manner that is misleading or inaccurate;
- (g) supplies a pesticide which is packaged in a container which has deteriorated or has been damaged that it is dangerous in storage or transport, or when opened for use;
- (h) uses a pesticide in a manner which is not consistent with the conditions on the approved label;
- (i) transports a pesticide or pesticide containers in contravention of this Act;
- (j) stores or disposes a pesticide or pesticide waste and containers in a manner that may harm human or animal health or the environment or in a manner in contravention of this Act;
- (k) fails to keep records which are required under this Act; and
- (l) contravenes the provisions of this Act;

(3) A person who commits an offence under subsection (2) is liable on summary conviction to a fine not exceeding [XX] or to a term of imprisonment not exceeding [XXX].

(4) A person who intentionally provides false information for the purpose of registration, obtaining a licence or a permit, commits an offence and is liable on conviction to a fine not exceeding [XX] or to a term of imprisonment not exceeding [XX] or to both.

Offence by corporation

48. If an offence under this Act is committed by a body corporate, a person who at the time of the commission of the offence was a director, manager, secretary or other officer of the body corporate, or was purporting to act in any such capacity, shall be deemed to have committed that offence, unless he or she proves that the contravention took place without his or her consent or connivance and that he exercised all diligence to prevent the commission of the offence as he or she ought to have exercised having regard to the nature of his or her functions in that capacity and to all the circumstances.

Forfeiture

49. (1) If a person commits an offence under this Act, the Court may, in addition to other penalties, order that the pesticide or item in relation to which the offence was committed or the proceeds received from its disposal be forfeited to the Ministry.

(2) The pesticide or item forfeited under subsection (1) must be disposed of according to the provisions of this Act.

(3) If a person with lawful custody of a pesticide or item that is seized and detained under this Act consents to the forfeiture, that pesticide or item shall be forfeited to the Ministry and shall be disposed of according to the provisions of this Act

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Return of seized pesticide or item

50. If a pesticide, item or proceeds have been seized under this Act and no order has been made to forfeit the seized item, the seized item the proceeds must be returned to the owner or the person having the lawful possession, care and control of the pesticide or the item at the time of seizure.

Fees, charges and costs

51. The Minister may recover from a person a prescribed fee or charge and the costs incurred by the Ministry in relation to anything required or authorised under this Act including the —

- (a) cost of a laboratory analysis or report in respect of a pesticide for which an application for registration has been made under this Act;
- (b) inspection, treatment, testing, analysis of an animal, a plant or an item or the removal, disposal or return of an animal, a plant or an item required or authorised under this Act; and
- (c) seizure, detention or disposal of an item under this Act.

PART VIII

FINAL PROVISIONS

Regulations

52. (1) The Minister shall promulgate all necessary regulations to give effect to the purposes and provisions of this Act, in consultation with the Ministries in charge of health and the environment.

These provisions ensure that all necessary regulations can be made; while some are already highlighted in subsection 2, leaves space for other regulations that may also be necessary.

It should be noted, as highlighted above in the section regarding the Pesticide Authority, that in some countries the approval and amendment of regulations is not done by a Minister but by the Government (e.g. a Council of Ministers). It is, in any case important, that the regulations are developed in consultation between the authorities responsible for the areas of agriculture, environment, and health.

(2) In particular and without prejudice to the generality of subsection (1) the Regulations made under subsection (1) may prescribe all or any of the following matters —

- (a) in relation to a pesticide or a class of pesticides, the authorization, regulation, control, restriction or prohibition of the —
 - i. manufacture;
 - ii. alteration;
 - iii. decanting;
 - iv. repackaging;
 - v. import and export;
 - vi. storage;

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- vii. transportation;
 - viii. sale;
 - ix. use; and
 - x. disposal.
- (b) a ban or restriction on the import, export and use of a pesticide;
 - (c) the designation of a place as a port of entry or exit, where a pesticide may be presented for inspection or importation or exportation from [Member State];
 - (d) rules on information sharing and access to data;
 - (e) procedures and rules for the treatment of confidential information; and
 - (f) the procedure and criteria to be followed by the Pesticide Authority in considering the grant, review, variation, suspension, renewal and revocation of registration, a licence or a permit; and the period of validity of registration, a licence or permit granted or issued;
 - (g) the requirements of a pesticide container and label;
 - (h) the storage and proper disposal of a pesticide and pesticide container;
 - (i) advertising of a pesticide;
 - (j) precautions and work safety measures to be taken for protection from injury, ill-health and death of a person exposed to a pesticide during the manufacture, transportation, storage or use of a pesticide;
 - (k) the maximum residue limits in respect of crops that have been treated before or after harvesting with a pesticide or its components or derivatives, or have been gathered from plants that have been so treated;
 - (l) the form, content and manner of keeping and maintaining a register, inventory and record;
 - (m) the notification of a case suspected of poisoning, intoxication, injury, illness and death of person and animals that have been exposed to a pesticide;
 - (n) the duties and responsibilities of a person responsible for a pesticide for premises on which the pesticide is kept;
 - (o) criteria and requirements for a designated laboratory;
 - (p) the procedure to be followed for submitting a sample for analysis;
 - (q) the procedure to be followed if an equipment, a pesticide, document, record or another item is seized;
 - (r) the seizure and destruction of a pesticide manufactured, modified, imported, stored, transported or used in contravention of this Act;
 - (s) the payment of fees for an application for registration, issuance of a permit and licence, for analysis of a sample and any other fees referred to under this Act;
 - (t) compliance with the implementation of [Member States] under bilateral and multilateral treaties, conventions or agreements.
 - (u) penalties for contravention of Regulations, Rules or any conditions attached to a registration, license or permit issued; and

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Repeal

53. (The Pesticides Act/Pesticides and Toxic Chemicals Act), [] is repealed.

Entry into force

54. This Act shall enter into force in accordance with XX rules of [country].

TRANSITIONAL CLAUSES

To be drafted according to legal traditions of the country. Notably, the following issues should be considered:

- *from the moment of approval of this Act no new pesticides can be registered under the old system. This shall apply also to applications submitted before the entry into force of the law but not yet registered.*
- *The Registration Board, in its first session, will prepare a calendar for the revision of all pesticides which are authorized to be placed on the market. The order for the revision of the pesticides will take into consideration their potential hazard and risks associated. The calendar for the revision of pesticides authorized to be placed on the market will be published and applicants will be notified in writing.*

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SCHEDULES (e.g. highly hazardous pesticides, others that might be decided)