

29;

product or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide;

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;

labeled, registered,
and promoted by the person granted registration of the pesticide under this Law.

CHAPTER II ADMINISTRATION

Article 3 Implementing Authority

1. The primary responsibility for the administration and implementation of this Law lies with the Ministry.
2. The Ministry department responsible for pesticide management (hereinafter functions related to pesticides management as provided in this Law and implementing instruments.
3. The Pesticide Unit shall monitor the implementation of this Law and report the results to the Pesticides Registration Board as prescribed.
4. The Minister shall designate a Registrar from among Pesticide Unit staff to be responsible for handling registration applications and keeping the Pesticides Register.
5. The Minister may call upon other government units or officials as he or she deems appropriate to assist in the implementation of this Law.

Article 4 Pesticides Registration Board

1. A Pesticides Registration Board is hereby created as an inter-ministerial body under the coordination of the Ministry for the registration of all pesticides in Timor-Leste.
2. The Board shall carry out the following functions:
 - (a) evaluate and decide on applications to register pesticides in accordance with article 8;
 - (b) consider, advise on, and propose the content of regulations to be issued pursuant to article 33;

- (a) common name (scientific name of the active ingredient);
 - (b) formulation;
 - (c) concentration;
 - (d) trade name;
 - (e) country of origin;
 - (f) purpose(s) and use(s) for which the pesticide is approved (crop/animal pest or disease vector); and
 - (g) any conditions or restrictions on registration, including a reduction in duration imposed under article 9.6, or on the manufacture, storage, transport, import, packaging, repackaging, labeling, distribution, sale, use, or disposal imposed under article 9.3.
4. Each pesticide in the Pesticides Register shall have an accompanying product file containing the supporting materials prescribed pursuant to article 8.

Article 8 Applications for Registration

1. Any person wishing to register a pesticide in Timor-Leste shall apply to the Pesticide Unit in the manner and form, and with such supporting materials, as shall be prescribed by regulation.
2. Applications for registration shall be received by the Registrar, who shall ensure they are complete, and prepare the pesticide dossier for the consideration of the Pesticides Registration Board.
3. The Pesticides Unit shall provide an opportunity for public notice and comment on all registration applications. To that end, at least [xx] weeks before the meeting of the Board in which an application is scheduled for consideration, the Registrar shall publish on the Ministry website, with notice in a newspaper of national distribution: (i) the application, redacted to remove the information deemed confidential under article 14.1; and (ii) the instructions and time frame for submitting comments.

Article 9 Decisions on Registration Applications

1. In evaluating an application for the registration of a pesticide, the Pesticides Registration Board shall apply the criteria set forth by regulation, which shall include at least the following:
 - (a) characteristics of the pesticide:
 - (i) hazards to human and animal health, both acute and chronic;

- (ii) environmental factors, including the effect on beneficial organisms and other non-targeted species and the toxicity to fish and the marine environment;
 - (iii) social factors, including potential application by, or exposure to, vulnerable groups, including women and children, potential need for personal protective equipment and the availability and likelihood that the such gear is used appropriately in the local conditions;
 - (iv) ability to move through soil and potential to contaminate *ground water*;
 - (v) efficacy in relation to pest control needs and risk for causing pest resurgence and resistance;
 - (vi) relative level of hazard in relation to other products on the List or that are available;
 - (vii) product persistence in the soil or water and subsequent risk of pesticide residues on or in food crops above established Maximum Residue Level values;
 - (viii) product volatility and potential for drift;
 - (ix) potential uses as antimicrobials, with special attention to antimicrobial residues and antimicrobials of critical use for human health purposes;
 - (x) status on the lists of Rotterdam and Stockholm Conventions and other relevant international agreements pertaining to pesticides;
 - (xi) compliance with relevant international standards; and
 - (xii) status of registration in selected countries with reliable registration schemes from a list approved by the Pesticides Registration Board at the proposal of the Pesticide Unit.
- (b) proposed container (description, photograph or exemplar);
 - (c) proposed label, which shall:
 - (i) be written in, or include a full translation into, Tetum,
 - (ii) include pictograms, and
 - (iii) otherwise comply with the Globally Harmonized System of Classification and Labelling of Chemicals; and
 - (d) extent to which the concentration, formulation, and package size reduce risks to the user.

2. Within the time period specified by regulation, the Board shall complete its evaluation under paragraph 1 and take one of the following actions:
- (a) approve the application, in which case it shall:
 - (i) assign a registration number to the pesticide or, for re-registration, re-assign the same number;
 - (ii) instruct the Registrar to 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) request for additional information, if the application is incomplete or further information is required, in which case it shall:
 - (i) communicate the applicant in writing the additional information required; and
 - (ii) provide a deadline for submission of the additional information, after which the application will be rejected; or
 - (c) reject the application and notify the applicant in writing of the reason(s), which may include, *inter alia*, that:
 - (i) the pesticide is included in the List of Banned Pesticides, the List of Severely Restricted pesticides or the list of chemicals in Annex A of the Stockholm Convention;
 - (ii) the information contained in the application is false in any material respect;
 - (iii) the residues are too persistent or are toxic and/or bioaccumulative when metabolized;
 - (iv) the pesticide is not effective for its intended purpose;
 - (v) 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;
 - (vi) the product is overly prone to drift or volatilisation;
 - (vii) other products or practices are available which are equally or more effective and are less hazardous; or
 - (viii) the risks outweigh the benefits under local socio-economic, climatic or other conditions.

3. The 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;

3. If the change requested in paragraph 2 is approved, the Registrar shall amend the Pesticides Register accordingly, publish notice on the Ministry website and in a newspaper of national distribution and notify any operating license and permit holders of the change.

Article 12
Board Registration of New Pesticides

1. The Board may on its own initiative register a new pesticide that meets the prescribed criteria if it determines that:
 - (a) the currently registered pesticides are not sufficient to enable effective control of a new or existing pest; or
 - (b) other products have become available which are more effective, less hazardous, and/or more economical.
2. Decisions on registration undertaken pursuant to paragraph 1 shall be based on a pesticide dossier prepared by the Pesticide Unit in accordance with the requirements established under Article 8.
3. Pesticides registered by the Board shall not have a named registrant, and the permit requirement in Article 10 shall not apply.

Article 13
Deregistration of Pesticides

1. The Pesticides Registration Board may, at its own initiative or that of any person, deregister a pesticide at any time if it determines that:
 - (a) the registration was secured in violation of any of the provisions of this Law;
 - (b)
 - (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.
 - (c) other products or practices have become available which are equally or more effective, but less hazardous, and the Board has proceeded to register such product under article 12;
 - (d) 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;
 - (e) the manufacturer has withdrawn the pesticide from the market;
 - (f) any of the conditions subject to which the registration was granted have been breached; or

- (g) 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.
2. Before effecting any deregistration under paragraph 2.1(a) or (f), the Pesticide Unit shall give the registrant [30] days to submit in writing the reasons against such action *provided, however*, that the Pesticide Unit may suspend and order the immediate withdrawal from the market of pesticide products at any time, in case of new information 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.
 3. Deregistration under this section shall be (i) published on the Ministry website and in a newspaper with national distribution and (ii) 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, and the Registrar shall amend the Register accordingly.
 4. The Pesticides Registration Board shall periodically review the List of Permitted Pesticides to assess whether any of the conditions for deregistration have occurred.

Article 14

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CHAPTER V
PESTICIDES LIFE CYCLE

Article 20
Import and Export

1. Any person wishing to import a pesticide into Timor-Leste shall obtain an import permit issued by the Pesticide Unit based on requirements prescribed by regulation.
2. Applications for import permits shall be made to the Pesticide Unit in the prescribed manner and form, and shall be accompanied by the prescribed documentation and fee.
3. The Pesticide Unit shall either:
 - (a) issue the permit if:
 - (i) the pesticide is on the List of Permitted Pesticides in the Pesticides Register, or has received a temporary permit pursuant to article 14 of this Law;
 - (ii) the applicant holds a valid operating license to import pesticides issued under article 17; and
 - (iii) any additional requirements issued under paragraph 4 are met; or
 - (b) deny the application and notify the applicant in writing of the reasons, which may include:
 - (i) the conditions in paragraph 3(a) are not met;
 - (ii) the information contained in the application is incomplete or false in a material aspect;
 - (iii) the importation of such pesticide is planned for or in the process of deregistration under article 13;
 - (iv) the presence in the country of sufficient or excessive quantities of the pesticide; or
 - (v) such other reason as the d shall be under a

5. Any person wishing to export a pesticide manufactured or formulated in Timor-Leste shall hold the requisite operating license and shall apply for an export permit demonstrating, among such other requirements as may be established by regulation, that the applicable requirements of the importing country have been met.

Article 21
Manufacture and Formulation

1. No person shall manufacture, formulate or repackage a pesticide unless such person holds an operating license duly issued by the Ministry under article 17 of this Law, except as provided under article 15.3.
2. 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.
3. The Ministry shall provide farmers and/ awareness on the safe formulation of botanical or microbial pesticides undertaken pursuant to article 15.3.

Article 22
Handling and Use

1. No person shall use, require an employee to use, or recommend the use of a pesticide in any manner other than as prescribed, or contrary to any conditions attached to the issuance of the registration and/or operating license relating to that pesticide.
2. The prohibition on unauthorized uses in paragraph 1 expressly includes the use of pesticides to catch fish by adding any amount, in any concentration, to a pond, lake, stream, river, estuary, or other body of water.
3. Every employer who requires or permits an employee to apply or formulate pesticides during the course of employment shall provide the employee with such:
 - (a) instruction as is necessary to enable that person to achieve the required standard of competence, including information on potential hazards;
 - (b) appropriate personal protective equipment and access to hand washing and other facilities;
 - (c) periodic medical check-ups; and
 - (d) access to medical assistance in the event of adverse health effects resulting from exposure to the pesticide;

as may be prescribed in the relevant operating license requirements issued under article 16.2 of this Law.

2. Any facility or other premises in which pesticides are stored in excess of prescribed quantities:
 - (a) must be located at least 1 kilometer 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.
3. Pesticides, obsolete pesticides, used containers and contaminated materials shall be stored in accordance with the requirements set forth in regulations prescribed under this Law and other applicable legislation. The specifications under such regulations shall take into account the characteristics of, and risks presented by, the pesticide in question.

Article 25
Transport

1. No person shall transport any pesticide, pesticide container or material 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. No person shall transport pesticides in excess of such maximum amounts as shall be prescribed in any public or private vehicle without a valid operating license issued in accordance with article 17 of this Law and other applicable national legislation.

Article 26
Advertising

It shall be prohibited for any person to advertise any pesticide:

- (a) that is not included in the List of Permitted Pesticides;
- (b) for a purpose or use other than as approved;
- (c) with safety claims not supported by scientific evidence, or unaccompanied by a *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
- (iv) is contrary to the conditions of registration of the pesticide.

Article 27

Adulterated, Counterfeited and Substandard Pesticides

1. It shall be prohibited for any person to adulterate or counterfeit a pesticide, or to sell a pesticide that is 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 a Ministry, local government or law enforcement official.

Article 28

Disposal of Pesticides and Pesticide [

1. It shall be prohibited for any person to dispose of any pesticide or pesticide waste, including pesticide containers, obsolete pesticides or pesticide leftovers, in a manner that may harm human or animal health or the environment, or in a manner other than prescribed.
2. The applicable requirements and instructions for the disposal of pesticides shall be established by regulation, including the circumstances in which the owner shall be liable for the 2E.68 resociated costs and those in which such costs shall be borne by the government.

CHAPTER VI

INSPECTIONS, OFFENSES AND PENALTIES

Article 29

Appointment of Inspectors

1. Without prejudice to the powers of the national inspections authority, the Minister shall appoint or designate from time to time 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 Law.
2. The Pesticide Unit shall, in consultation and coordination with the national inspections authority and relevant ministries, develop a common framework for inspections covering the entire life cycle of pesticides, to be set forth in regulations.
3. All pesticides inspectors shall be issued official identification certificates and provided training in, *inter alia*, what to look for and how to handle pesticides during inspections, including sample taking.

Article 30
Powers and Duties of Inspectors

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 Law may, during regular business hours, without a warrant and upon production of his or her identification certificate:
 - (a) carry out periodic inspections of all establishments which import, manufacture, pack, repack, label, store, sell, distribute, use commercially, dispose of, or advertise pesticides, to determine whether the provisions of this Law and its accompanying regulations are being complied with;
 - (b) require the production of, inspect, examine, and copy certificates, licenses, records, or other documents under this Law;
 - (c) take samples of any substances to which this Law relates and submit such samples for analysis;
 - (d) seize any equipment, pesticide, document, record, or other item which the inspector believes has been used in, or which appears to provide evidence of, a contravention of this Law, provided that:
 - (i) the inspector gives a receipt in the prescribed form 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 in the prescribed manner;
 - (e) request the assistance of customs agents, police or local government authorities in the exercise of his or her duties under this Law.
2. Pesticides inspectors shall report all violations of this Law to the Ministry and the national inspections authority.
3. The national inspections authority shall be responsible for investigating reported violations and for imposing the applicable fines and any accompanying sanctions as provided under article 32.
4. The Minister shall designate one or more official laboratories for analyzing pesticide samples under this Law, including by contracting public or private third-party laboratories in Timor-Leste or abroad, and shall establish basic sample-taking facilities at the ports of entry where consignments of pesticides are imported.

Article 31

(m)

Article 33 Regulations

The Minister and, where appropriate, the Government shall promulgate one or more such regulations as may be necessary to give effect to the purposes and provisions of this Law, including on the following matters:

- (a) pesticide registration, including the application procedure, exceptions and forms, decision-making criteria, period of validity and renewal requirements;
- (b) temporary permits for unregistered pesticides under article 6, including the criteria, conditions, permitted amounts or applicable guidelines for determining such amounts, and other requirements;
- (c) operating licenses, including the application procedure and forms, decision-making criteria, period of validity, and renewal requirements;
- (d) form and content of the Pesticides Register;
- (e) type of information to be deemed confidential under this Law and the applicable rules for handling and storing such information;
- (f) establishing a common framework for the inspections conducted under this Law; including the procedures to be followed where any equipment, pesticide, document, record, or other thing is seized under this Law;
- (g) monitoring the implementation of this Law by the Pesticide Unit under article 4, including the matters, indicators and modalities, and the reporting requirements;
- (h) the fees to be assessed under this Law;
- (i) the form and manner of request where any change under article 11 is proposed after a pesticide has been registered under this Law;
- (j) the duties of employers whose employees are required or permitted to use pesticides in the course of their employment as provided in article 22;
- (k) the procedures to be followed for taking and submitting samples for analysis and for analyzing samples under this Law;
- (l) the rules for advertising pesticides in accordance with the requirements in article 26;
- (m) the essential requirements for pesticide containers and labels;
- (n) the prescribed quantities and/or types of pesticides for the application of the storage and transport requirements in articles 24 and 25;

- (p) the requirements and instructions for the disposal of pesticides under article 28;
- (q) the criteria and procedures for determining and applying the penalties under article 32; and
- (r) the dates on which different elements of the registration, licensing, and permit schemes of this Law shall come into force in Timor-Leste.

Article 34
Transitional Provisions

1. Notwithstanding any other provision of this Law, the Minister may, after this Law