

# Proposed Zero draft Pesticides Decree-Law for Timor-Leste

## CHAPTER I PRELIMINARY

### Article 1 Purpose

The purpose of this Decree-Law is to regulate pesticides at all stages 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 Timor-Leste.

### Article 2 Definitions

In this Decree-Law, unless the context otherwise requires:

“active ingredient” means the part of the product that provides the pesticidal action;

“adulterate” as applied to a pesticide, means:

- (a) any constituent has in whole or in part been omitted or abstracted;
- (b) damage or inferiority has been concealed in any manner;
- (c) any substance has been substituted wholly or in part;
- (d) 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;
- (e) any constituent exceeds the amount stated on the label or permitted in the regulations; or
- (g) its nature, substance or quality has been injuriously affected.

“advertising” means the promotion of the sale and use of pesticides by printed and electronic media, signs, displays, gifts, demonstration or word of mouth;

*Comment: “gift” and “word of mouth” are included because shopkeepers, particularly in rural areas, may informally promote pesticides in these ways.*

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

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

“Decree-Law” means this Pesticides Decree-Law, including all regulations, decrees, orders, and any other instrument issued under it;

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

“inspector” means any person appointed or designated as an inspector under article 33;

“label” means the written, printed, or graphic matter on, or attached to, a pesticide product or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide;

“Minister” means the minister responsible for agriculture and “Ministry” shall have the corresponding meaning;

“Ministerial Recommendation” means the document issued under article 22 authorizing the issuance of licenses for pesticides-related businesses;

“packaging” means the container together with the protective wrapping used to carry pesticide products;

“person” means a natural or legal person;

“pest” means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products, materials or environments and includes vectors of parasites or pathogens of human and animal disease and animals causing 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.

“Pesticides Board” or “Board” means the body established under article 5;

“Pesticides Register” means the register established under this Decree-Law;

“product” (or pesticide product) means the formulated product (pesticide active ingredient(s) and co-formulants), in the form in which it is packaged and sold;

“quality” means the degree of conformity to established standards;

“Registrar” means the Registrar of Pesticides appointed under this Decree-Law;

“registration” means the process whereby the Pesticides Board established under this Decree-Law 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 conditions of use in the country;

“regulation” means, generically, any secondary instrument issued to implement this Decree-Law including, but not limited to, regulations, government decrees and ministerial orders;

“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;

“sell” means to offer or expose for sale or to have in possession for sale;

“store” means to keep [in any quantity] for distribution, sale or use;

“trade name” means the name under which a pesticide product is labelled, registered, and promoted by the person granted registration of the pesticide under this Decree-Law.

*Article 2 lists the definitions of terms used in the Decree-Law, with technical terms drawn from the most recent version of the International Code of Conduct on the Distribution and Use of Pesticides.*

## **CHAPTER II ADMINISTRATION**

### **Article 3 Implementing Authority**

1. The primary responsibility for the administration and implementation of this Decree-Law lies with the Minister.
2. The Minister shall designate a Unit/Department within the relevant division of the Ministry to act as Pesticides Unit to execute the Ministry’s functions related to pesticides management as provided in this Decree-Law and implementing instruments.
3. The Minister may call upon other agencies and/or delegate specific powers under this Decree-Law to other government units or officials as he or she deems appropriate.

*A Pesticides Unit will support the Minister in executing the functions associated with implementing the Pesticides Decree-Law. Details on its establishment, composition, functions, etc. may be provided in an implementing instrument.*

### **Article 4 Registrar**

1. The Minister shall appoint a Registrar of Pesticides who shall be a staff member of the Ministry.
2. The Registrar shall keep a Pesticides Register in accordance with article 12 and shall perform such other duties as provided under this Decree-Law.

### **Article 5 Pesticides Board**

The Minister shall establish a Pesticides Board for the registration, control, and management of all pesticides in Timor-Leste and which shall perform all other functions assigned to it under this Decree-Law.

*Decisions concerning whether a pesticide is registered or not should be taken by the Board instead of the Registrar, for several reasons:*

- *It allows for representation of the different sectors involved in pesticide management, including–agriculture (crop cultivation and veterinary medicine), environment, and public health (see notes to article 6 below).*
- *The Registrar is usually subject to very powerful pressure on the part of applicants. This pressure might prevent the person responsible for registration from dealing objectively with applications, whereas such pressure is harder to exercise on a group;*
- *A joint decision confers joint responsibility. The members of the Board will therefore feel a greater sense of responsibility in the performance of their functions;*
- *Since the Board has real powers the members will feel more committed to their work.*

*The Board will need to be convened when the Pesticides Decree-Law has been passed. In the interim, it would be useful to establish a working group, the composition of which could be similar to, if not identical with, that of the proposed Board.*

### **Article 6 Composition of the Pesticides Board**

1. The Board shall have the following composition:
  - (a) Ministry staff, to be appointed by the Minister:
    - (i) one from the department responsible for crop protection;

- (ii) one from the department responsible for veterinary medicine;
    - (iii) one from the department responsible for quarantine;
    - (iv) one from the department responsible for extension services;
  - (b) staff of other ministries or authorities, to be appointed by the head of the institution:
    - (i) one with responsibilities for vector control from the ministry responsible for health;
    - (ii) one with responsibilities for chemical contaminants and/or hazardous waste management from the ministry responsible for the environment;
    - (iii) one with responsibilities for pesticides residues appointed by the authority responsible for food safety.
2. Appointed members of the Board shall serve for a term of [three] years, and shall be eligible for reappointment [for a maximum of \_\_\_\_\_ terms].
  3. An appointed member of the Board may resign at any time by notice in writing to the Minister.
  4. The 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.
  5. The Board shall regulate its own proceedings in accordance with the requirements set forth by regulation, which shall include:
    - (a) decision making processes, including for the functions set forth in article 7;
    - (b) conflict of interest definition, disclosure requirements and disqualification rules for internal members and external experts;
    - (c) procedure for selecting the chairman;
    - (d) rules on information sharing, and
    - (e) rules on access to data and confidentiality.

*Because pesticides use raises environmental and public health concerns in addition to agricultural considerations, it is important for these interests to be represented on the decision making body with a view to arriving at a balanced consensus position. Members from MAP should include plant protection, veterinary medicine and quarantine as the three units that use pesticides on crops and livestock. In addition to agriculture, the key interests that should be represented are:*

- *Health: pesticides are relevant to public health both as a means of controlling vectors for diseases such as malaria and as toxic substances with the potential to harm human health, directly or through food or environmental contamination.*
- *Environment: monitoring and reporting of environmental effects of pesticides essential to knowing when practices should be modified or pesticides should be banned or severely restricted;*

*It is recommended that the Board have a limited number of members to facilitate decision making and keep the focus on the key interests.*

### **Article 7 Functions of the Pesticides Board**

The Pesticides Board shall carry out the following functions:

- (a) evaluate and decide on applications to register pesticides in accordance with article 14;
- (b) determine the criteria for granting, authorizing, renewing, suspending, or revoking any registration, license, or permit granted or authorized under this Decree-Law;
- (c) consider, advise on, and propose the content of regulations to be issued by the Minister pursuant to article 39; and
- (d) advise the Minister in connection with all matters relating to pesticide management in Timor-Leste.

*The Pesticides Board is the main body for determining or advising the Minister on how pesticides will be regulated in Timor-Leste, within the parameters of the Decree-Law. It should have the final decision on matters such as registration of pesticides to ensure that all of the main interests involved in pesticides management are taken into account. Ministerial endorsement of certain Board decisions, for example to grant registration or issue permits, may be required to give them legal effect; to be determined and the draft may be modified accordingly.*

### **Article 8 Confidential Information**

The Pesticides Board shall establish procedures and rules regarding which information shall be considered confidential, how confidential records shall be maintained and stored, and who shall have access to them.

*The type of information to be deemed confidential should be clearly stated in regulations and may include information regarding manufacturing processes, formulation details and special quality control programs.*

## **Article 9 Liability**

No member of the Pesticides Board shall be held liable for harm caused by any good faith act or failure to act in carrying out his or her duties under this Decree-Law.

## **Article 10 Advisory Committees**

1. The Pesticides Board may appoint technical advisory committees consisting of government or non-governmental representatives with expertise in agriculture (crops and animal production), human health, environmental protection, labour law and worker safety, including vulnerable groups, pesticides and the pesticides industry, to advise the Board on matters relating to the exercise of its functions.
2. Every committee appointed under this article shall be subject in all respects to the control of the Board and may at any time be discharged, altered, or reconstituted by the Board.

*Advisory committees should have a broad range of stakeholders such as industry representatives, experts on specific matters (toxicology, chemistry, environmental impacts, efficacy, labor experts) and/or interested groups (sellers, users, environmentalists, consumers) so the views of all sectors dealing with or affected by pesticide management issues are taken into account. Care must be taken to ensure that such advisory committees are not responsible for deciding on matters such as registration, as this may lead to conflicts of interest and may also result in a breach of confidentiality [or trade secrets] regarding applications for pesticide registration.*

## **CHAPTER III REGISTRATION**

### **Article 11 Registration Requirement**

No person may import, export, re-export, manufacture, formulate, keep, store, sell, distribute, apply, possess, or use a pesticide in Timor-Leste unless:

- (a) it is listed [as a permitted pesticide] in the Pesticides Register; or
- (b) a temporary exemption has been granted under article 19 of this Decree-Law.

*The purpose of the registration requirement is to ensure that only pesticides that are effective, efficient and safe for the intended use, as well as properly packaged and labelled, may be brought into in Timor-Leste.*

### **Article 12**

## **Pesticides Register**

1. The Minister shall establish a Pesticides Register to be kept by the Registrar.
2. The Pesticides Register shall comprise a List of Permitted Pesticides and a List of Banned Pesticides. The Board may approve other lists, including but not only, a List of Severely Restricted Pesticides.
3. Each entry in the Pesticides Register shall include the name and address of the registrant and at least the following information:
  - (a) common name (scientific name of the active ingredient);
  - (b) formulation;
  - (c) concentration; and
  - (d) purpose(s) and use(s) for which the pesticide is approved (crop/animal pest or disease vector);
3. Each entry in the Pesticides Register shall have an accompanying product file containing the supporting documentation that is prescribed pursuant to article 13, which shall be made available to any person upon request.

## **Article 13 Applications for Registration**

1. Any person wishing to register a pesticide in Timor-Leste shall apply to the Minister in the manner and form, and submit such supporting material, as the Minister shall prescribe.
2. Applications for registration will be received by the Pesticide Registrar, who will prepare the pesticide dossier for consideration of the Pesticide Board.
2. The Minister shall treat any information submitted to it in connection with an application as proprietary information of the applicant for [15] years.

*It is recommended that registration applications include the information specified in the FAO Guidelines for the Registration and Control of Pesticides. This information, which should be specified by regulation or other secondary instrument to facilitate amendment at a later date, should include the following:*

- *toxicological data on the active ingredients and the formulation;*
- *Material Safety Data Sheet;*
- *reports of efficacy trials to support the proposed uses, where available;*
- *reports of residue trials following the proposed use on crops intended for human or animal consumption, and the methods of analysis;*

- *reports of environmental effects following the use of the proposed formulation at the proposed rates, where available;*
- *the information to be included in the label or the information leaflet to be released with the product in the national market, including the required language(s), in accordance with article 14(c);*
- *information on the proper storage, transport, handling and use of the pesticide, including specific precautions;*
- *information on the storage and disposal methods for the used container and any surplus pesticide;*
- *exemplar of the proposed label.*

The Registrar shall review applications for registration, make sure they are complete and prepare the pesticide dossiers for the consideration of the Pesticide Board.

#### **Article 14**

#### **Decisions on Registration Applications**

1. In evaluating an application for the registration of a pesticide, the Pesticides Board shall apply the criteria set forth in regulations issued by the Minister, 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 insects and other non-targeted species, toxicity to fish and the marine environment;
    - (iii) social factors, including potential application by vulnerable groups, including women and children, potential need of protective gear and the availability and likelihood that the protective 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;
    - (vi) relative level of hazard in relation to other products on the list or that are available;
    - (vii) product persistence and subsequent risk of pesticide residues on food crops above established Maximum Residue Level values;
    - (viii) potential uses as antimicrobials, with special attention to antimicrobials of critical use for human health purposes;

- (ix) the status of the product on the lists of Rotterdam and Stockholm Conventions and other relevant international agreements pertaining to pesticides;
  - (x) compliance with relevant international standards and the status of registration in other countries.
- (b) proposed container (description, photograph or exemplar)
  - (c) proposed label, which shall:
    - (i) be written in, or include a full translation into, Tetun,
    - (ii) include pictograms, and
    - (iii) otherwise comply with the Globally Harmonized System of Classification and Labelling of Chemicals;
  - (d) extent to which the concentration, formulation, and package size reduce risks to the user.
2. Following review of an application for the registration [or re-registration] of a pesticide, the Board shall either:
- (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 in the Gazette; and
    - (iv) send the certification of registration or re-registration to the applicant; or
  - (b) reject the application and notify the applicant in writing of the reason(s), which may include, *inter alia*, that:
    - (i) the application is incomplete or provides insufficient information;
    - (ii) the information contained in the application is false in any material respect;
    - (iii) the residues are too persistent or are toxic 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) other products are available which are equally or more effective and are less hazardous;
  - (vii) another country with a reputable registration scheme has refused registration of the pesticide; or
  - (viii) the risks outweigh the benefits under local socio-economic, climatic or other conditions.
3. Where an application is rejected under number 2(b)(i), the Registrar shall notify the applicant in writing, specifying the additional information needed and advising that the application may be supplemented within [xx months] [a period of time as shall be determined in advance by the Board]. If an applicant does not supplement the application within the time specified, the rejection will become final.
  4. An applicant whose application was rejected for any reason may submit a new application with new information or data that responds to the reason(s) for the rejection.

*This article provides the registration criteria that the Board must take into consideration when deciding whether to approve or reject an application to register a pesticide. They essentially involve weighing the various benefits and risks of the pesticide.*

*Determining the acceptable level of risk when considering which pesticides should be allowed into Timor-Leste should take a realistic view in light of the country's circumstances, for example the limited availability, high cost, and low likelihood of use (given the hot climate) of personal protective equipment.*

*Where the Board denies an application, it must notify the applicant of the reasons for that refusal. In addition to providing transparency in decision making, this will permit the applicant to lodge an appeal as outlined in article 35 (Appeals). Applications refused for incompleteness of information may be supplemented in the prescribed fashion.*

## **Article 15**

### **Permit Required for Non-Registrants**

Where any person other than the registrant intends to import, manufacture, distribute pack, repack, or label a pesticide, he or she shall apply to the Minister for a permit from the registrant on such terms as may be [agreed][established by regulation] prior to seeking the applicable commercial license.

*The rationale for this provision is that, because the registration holder invested resources in obtaining the registration, other persons should be required to remunerate not be able*

*benefit from the fruit of that effort without remunerating him or her. The duration of the permit and amount of (or formula for calculating) the fee to be paid to the registration holder may be prescribed by regulation.*

## **Article 16**

### **Changes to Registered Pesticides**

1. Any registration holder who wishes to change the formulation, trade name, active ingredient, or concentration of the pesticide shall submit a new registration application in accordance with article 13.
2. Any registration holder who wishes to change the container, label or use of the pesticide shall submit a written request to the Board specifying such change(s), in the manner prescribed by regulation. Within 30 days of receipt, the 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.
3. If the change requested in paragraph 2 is approved, the Registrar shall amend the Pesticides Register accordingly and shall publish notice in the Official Gazette and notify any license and permit holders of the change.

*Where there is a change in the essential characteristics of a pesticide as approved, a new registration application must be made. Changes to other elements such as containers and labels require Board approval and subsequent publication and notice.*

## **Article 17**

### **Board Registration of New Pesticides**

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 equally or more effective, equally or less hazardous, and/or more economic.

Decisions on registration shall be based on a Pesticide dossier to be prepared by the Pesticide Unit at the request of the Pesticide Board.

## **Article 18**

### **Deregistration of Pesticides**

1. The Pesticides 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 Decree-Law;
  - (b) 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.
  - (c) other products have become available which are equally or more effective, but less hazardous, and the Board has proceeded to register such product under article 17;
  - (d) the product/pesticide 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 conditions subject to which the registration was granted have been breached; or
  - (g) the Board has become aware of 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, the Board shall give the registrant 60 days to submit in writing the reasons against deregistration.
  3. De-registration under this section shall be notified in the Official Gazette, and the Registrar shall amend the Register accordingly.

*The Board may deregister a pesticide for any of the enumerated reasons, provided that it gives the applicant notice and the opportunity to submit a written justification as to why the cancellation should not go forward.*

*The Board is encouraged to periodically review the list of registered pesticides and phase out (deregister, deny new or renewed registration) those where a less toxic equivalent is available at reasonably similar cost and accessibility.*

### **Article 19**

#### **Temporary Permits for Unregistered Pesticides**

1. Notwithstanding the registration requirement in article 11, the Minister, upon consultation with the Pesticides Board, may grant a temporary permit for the import and use of an unregistered pesticide:
  - (a) to a research or academic institution for specific research purposes; or

- (b) for a specific emergency purpose, to deal with a new pest or resolve temporary problems of availability or affordability of products in the market.
- 2. Each temporary permit shall specify the grantee, specific research or emergency purpose, permitted amount, period of validity and any conditions the Board may apply.
- 3. The Minister may at any time, by written notice to the holder:
  - (a) revoke any research or emergency permit; or
  - (b) change the conditions to which the permit is subject.

## **CHAPTER IV LICENSING**

### **Article 20 License Requirement**

- 1. No person may, in respect of any pesticide:
  - (a) manufacture, formulate, pack or repack;
  - (b) distribute, sell, transport or store;
  - (c) import, including storage upon arrival, export or re-export; or
  - (d) apply for profit as a pest control operator;unless such person holds a license that is duly issued by the national licensing authority, as authorized by the Minister in accordance with article 22 of this Decree-Law.
- 2. 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.

*Licensing is an important tool for controlling the qualifications and facilities of the actors involved in pesticides management activities. Commercial licenses are currently issued by the national authority, SERVE, which, where notified by the Minister, will require applicants to submit a Ministerial Recommendation as a condition for issuing the license. The draft uses the generic phrase “national licensing authority” in the event SERVE is replaced (or renamed) as the licensing authority.*

*The license requirement for pest control operators is designed to ensure the safety of applicators and their clients, generate awareness of the inherent risks of indiscriminate use and misuse of pesticides, and to enable early recognition of pesticide poisoning. (The inclusion of “for profit” ensures that farmers applying pesticides on their own land do not fall within this rule.)*

### **Article 21**

## **Licensing Criteria**

1. The Board shall develop criteria for each type of commercial license, taking into account such factors as the necessary skills, training, facilities, equipment, and other aspects of the activity in question.
2. The licensing criteria established under paragraph 1 of this article shall be set forth in regulations issued by the Minister.
3. The Minister shall inform the national licensing authority that a Ministerial Recommendation required to issue a commercial license to any person whose business activity involves any of the pesticides-related activities listed in paragraph 1 of article 20.
4. The Board may at any time change the requirements for new licenses or for renewals of previously issued licenses based on new information or changed circumstances.

## **Article 22** **License [Authorization] Applications**

1. Any person wishing to obtain or renew a commercial license to engage in any of the activities listed in paragraph 1 of article 20 shall apply for a Ministerial Recommendation in the prescribed manner and form and accompanied by the prescribed fee.
2. The Minister shall evaluate each application for a Ministerial Recommendation according to the criteria issued pursuant to article 21 and either:
  - (a) approve the application and transmit the Ministerial Recommendation to the licensing authority; or
  - (b) deny the application, notifying the applicant in writing of the reasons for that refusal, which may include, *inter alia*, that the Board has reason to believe:
    - (i) the application relates to a pesticide which is not currently registered under the Decree-Law;
    - (ii) the information contained in the application is incomplete or false in a material respect;
    - (iii) the applicant does not meet the prescribed criteria; or
    - (iv) the premises in question are not appropriate for the intended purpose, or use of those premises presents a likely hazard human or animal health or the environment.

3. Renewals are subject to the applicant's demonstration of compliance with the applicable criteria and requirements at the time of application, and shall include proof of record keeping as provided in article 23 and, where relevant, cooperation in inspection and enforcement actions carried out under this Decree-Law.
4. Where an application is rejected for incompleteness as outlined in paragraph 2 (b)(ii), the Board shall notify the applicant in writing of the respects in which the information is insufficient, and that the application may be supplemented within a specified time period.
5. If an applicant does not supplement the application within the time period specified under paragraph 3, the application will lapse and a new application must be submitted.

### **Article 23 Record Keeping**

1. Every person who holds a license for any of the activities listed in article 20 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 paragraph 1 shall be made available, upon request, to an inspector, the Registrar, the Pesticides Board, or the Minister.

*Persons dealing with pesticides must keep records for a specific period and their books and records must be available for inspection during regular business hours. Records of pesticides allow for specific amounts and types of pesticides to be inventoried and tracked as they move through their life cycle. This information will provide guidance for inspectors on who, what and where to focus inspections; help avoiding over-stocking/stockpiling; and promote the traceability of adulterated or substandard that must be quickly recalled.*

### **Article 24 Revocation of Licenses**

1. The Minister may revoke an existing license at any time in light of new information, unforeseen changes in circumstances or a violation of any condition on which the license authorization was granted.
2. Prior to effecting any revocation under paragraph 1, the Minister shall give the party to whom the license was issued 60 days to submit a written justification as to why the license should not be revoked.

## **CHAPTER V PESTICIDES LIFE CYCLE**

## **Article 25**

### **Importation**

1. The importation of any pesticide into Timor-Leste shall require an import permit issued by the Minister.
2. Applications for import permits shall be made to the Minister in the prescribed manner and form, and shall be accompanied by the prescribed documentation and fee.
3. The Minister shall either:
  - (a) issue the permit if:
    - (i) the pesticide is listed as a permitted pesticide in the Pesticides Register;
    - (ii) the applicant holds a valid commercial license to import pesticides;
    - (iii) any additional requirements 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 18;
    - (iv) the presence in the country of sufficient or excessive quantities of the pesticide; or
    - (v) such other reason as the Minister may determine [in accordance with criteria established by regulation].
4. The Minister may establish additional requirements to the import of pesticides, including limits on quantities.

## **Article 26**

### **Use**

1. No person shall use, require an employee to use, or recommend the use a pesticide in any manner other than that prescribed or contrary to any conditions attached to the issuance of the registration or license relating to that pesticide.

2. Every employer who requires or permits an employee to use a pesticide shall provide the facilities, equipment and protective clothing required for safe handling of the pesticide and require the employee to use them.
3. Every employer who requires or permits an employee to work with pesticides during the course of that employment must provide that employee with:
  - (a) such instruction as is necessary to enable that person to achieve the required standard of competence;
  - (b) appropriate protective gear; and
  - (c) such periodic medical check-ups;as may be prescribed by the Board and/or the Minister.

*These provisions outline the requirements for the use of pesticides, including that employers who require or permit employees to work with pesticides must follow certain procedures and provide the necessary facilities, equipment and protective clothing for safe use.*

#### **Article 27 Presentation**

1. No person shall pack, repack, store, sell, or distribute any pesticide unless it is in a container which:
  - (a) is safe for storage, handling, or use and is adequate to prevent harm to human or animal health and to the environment;
  - (b) prominently displays a legible label which has been approved by the Board and which cannot easily be detached; and
  - (c) otherwise meets the standards prescribed by the Board or by regulation.
2. Where a pesticide [product] is held in more than one container, the requirements of paragraph 1(b):
  - (a) shall not apply to the container in contact with the pesticide, where the pesticide could not be sold if it were solely contained in that inner container;
  - (b) shall apply to the container which represents the smallest unit of the pesticide which can be sold separately; and
  - (c) shall apply to a container containing more than one retail unit, where no bill of lading is attached and where a reasonable person would expect such a container to be seen by consumers in Timor-Leste.

3. It shall be prohibited to sell any pesticide in different packaging or repackaging than the form(s) approved for registration.

*Safe packaging and standardized, informative labelling help to inform and protect the end user as well as persons involved in shipping, handling, distribution, stocking etc.*

### **Article 28 Storage**

1. It shall be prohibited for any person to store pesticides on the same premises as food products or consumables, feedstuffs, or animals.
2. Facilities in which pesticides are stored in excess of prescribed quantities shall not be located within [ ] kilometers of hospitals, schools, shops, densely populated urban areas, protected areas or the shoreline.
3. Pesticides, obsolete pesticides, used containers and contaminated materials shall be stored in accordance with the requirements set forth by this Decree-Law.

### **Article 29 Transport**

No person shall transport any pesticide, pesticide container or material contaminated with pesticides in the same vehicle as food, feedstuffs, or animals in a manner other than prescribed by regulation.

No person shall transport pesticides in excess of such maximum amounts as the Minister may prescribe unless he/she holds a valid license issued in accordance with article 22 of this Decree-Law.

### **Article 30 Advertising**

It is prohibited for any person to advertise any pesticide:

- (a) that is not registered in the Pesticides Register;
- (b) for a purpose or use other than as approved;
- (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, unless expressly authorized by the Minister; or
- (e) in a manner that:

- (h) 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.

*Any claims made in the advertising of a pesticide should not be in conflict or at variance with those accepted by the Board. Only registered pesticides may be advertised. The International Code of Conduct for the Distribution and Use of Pesticides sets out certain standards for advertising; these should be reflected in the regulations or other secondary instrument.*

### **Article 31**

#### **Adulterated, Counterfeit and Substandard Pesticides**

1. It is prohibited for any person to adulterate or counterfeit a pesticide, or to sell a pesticide that is known or reasonably believed to be adulterated, counterfeit or otherwise substandard in any way.
2. Any person who has reason to believe that an adulterated, counterfeit or otherwise substandard pesticide is being sold shall immediately notify a Ministry or law enforcement official.

### **Article 32**

#### **Disposal of Pesticides**

1. It is 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 Minister, upon consultation with the Pesticides Board, shall approve, by regulation, appropriate policies, requirements, and instructions for the disposal of pesticides.

*Safe pesticide disposal is not only a matter of good environmental stewardship, but is required under Timor-Leste's national legislation and international obligations on the environment.*

## **CHAPTER VI INSPECTIONS AND APPEALS**

### **Article 33**

#### **Appointment of Inspectors**

1. The Minister shall, upon consultation with the Pesticides Board, appoint or designate from time to time qualified staff members of the Ministry, or, with the concurrence of the relevant authority, staff members of another public institution, to be inspectors for the purposes of this Decree-Law.
2. The Minister shall consult with the members of the Board and coordinate with the relevant ministries to set up a framework for inspections for the full life cycle of pesticides.
3. All 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.

*Inspectors could include DNQB agents, who are already stationed at ports of entry to inspect consignments of animals and plants and related products, and MS and MCIA staff with relevant functions. AIFAESA inspectors may also be called upon to conduct pesticides inspections, whether as official inspectors or as collaborating partners. A framework for inspections will help to coordinate and standardize inspections carried out at different stages of the pesticides life cycle by inspectors from different ministries or authorities. Training of inspectors is important because of the risks associated with handling pesticides and because there is limited awareness and understanding of this new area of regulation in Timor-Leste.*

### **Article 34**

#### **Powers of Inspectors**

1. An inspector 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 Decree-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 Decree-Law;
  - (c) take samples of any substances to which this Decree-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 Decree-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 and/or prosecution has been completed, except for unregistered pesticides, which, if so ordered by the Board, shall be destroyed in the manner prescribed by the Board and/or by regulation.
- (e) request the assistance of Customs, Police or local government authorities in the exercise of his or her duties under this Decree-Law.
2. Inspectors and Quarantine Agents shall be responsible for reporting violations of this Decree-Law to the Board.
3. The decision of any court in a legal proceeding instituted under this Decree-Law shall prevail over that of any inspector, in regard to the disposition of any item seized under paragraph 1(d).

*Inspectors are needed to verify compliance with the law and to enable enforcement actions that may be necessary. To do so, they should carry out regular inspections.*

*The powers given to inspectors must be clearly specified in the law and should cover such actions as entering onto premises, taking samples for analysis, confiscating products, inspecting records, and levying fines. Sampling protocols should be detailed in regulations to ensure the results will be valid in a court of law in the event of prosecution.*

*Cooperation from Customs is required as they forward consignments of pesticides to DNQB for controls at the ports of entry. DNQB agents are required to report violations of the Decree-Law regardless of whether they are appointed as inspectors under this provision.*

*Finally, the Decree-Law allows inspectors to call on police and local government authorities for assistance in carrying out their duties.*

### **Article 35 Appeals**

1. Any person aggrieved by a decision of an inspector under this Decree-Law may appeal to the Pesticides Board as prescribed by regulation.
2. Any person aggrieved by a decision of the Board may appeal to the Minister in the prescribed form and manner.
3. Any decision of the Minister under this article shall be final.

*The Decree-Law provides the right to appeal decisions taken by the Board, for example denial of a pesticide registration application, or by inspectors, such as the levying of a fine.*

**CHAPTER VII**  
**OFFENCES AND PENALTIES**

**Article 36**  
**Offences**

Any person who:

- (a) without the authority in writing by the Minister, discloses to any other person, any information relating to:
  - (i) the contents of any application or other document under this Decree-Law;
  - (ii) the business or activities of any other person;where that information was acquired by him or her in the performance of official duties under this Decree-Law;
- (b) gives false information on, alters, defaces, or destroys any application, certificate, or other document under this Decree-Law;
- (c) obstructs an inspector or other officer exercising his or her duties under this Decree-Law;
- (d) imports, manufactures, packs, repacks, labels, sells, stores, distributes, possesses, or uses a pesticide in Timor-Leste which has not been registered in accordance with this Decree-Law, except as provided in article 19;
- (e) imports, manufactures, packs, repacks, labels, sells, stores, or distributes a pesticide in Timor-Leste without a license issued under article 22 of this Decree-Law;
- (f) carries on the business for profit of applying pesticides without a Pest Control Operator's license issued under this Decree-Law;
- (g) uses or requires an employee to use a pesticide in anything other than the prescribed manner or contrary to any conditions imposed in connection with the grant of a registration or license;
- (h) fails to take the required actions *vis-à-vis* his or her employees under article 26;
- (i) disposes of any pesticide or pesticide waste in a manner that may harm human or animal health or the environment, or in a manner other than prescribed;

- (k) advertises any pesticide contrary to the provisions of article 30;
- (l) does not keep records as required under article 23 of this Decree-Law; or
- (m) adulterates a pesticide, or sells or stores a pesticide which he has reason to believe may be adulterated;

commits an offense.

### **Article 37 Penalties**

1. Any person convicted of an offense under paragraph \_\_\_\_ - \_\_\_\_ of article \_\_\_\_ this Decree-Law shall be liable:
  - (a) on a first conviction to a fine not to exceed \_\_\_\_\_ or to imprisonment for a period not to exceed [1 year], or both;
  - (b) on a second conviction to a fine not to exceed \_\_\_\_\_ or to imprisonment for a period not to exceed [2 years], or both.
2. Any person convicted of an offense under paragraphs \_\_\_\_ - \_\_\_\_ of article \_\_\_\_ of this Decree-Law shall be liable:
  - (a) on a first conviction to a fine not to exceed \_\_\_\_\_ or to imprisonment for a period not to exceed \_\_\_\_, or both;
  - (b) on a second conviction to a fine not to exceed \_\_\_\_\_ or to imprisonment for a period not to exceed \_\_\_\_\_, or both.

*Additional level(s) of penalties may be included.*

3. A court convicting a person of an offence under this Decree-Law may, in addition to any other penalty imposed:
  - (a) order that any thing used in the perpetration of the offence or the proceeds of sale thereof, be forfeited to the state;
  - (b) suspend or revoke the relevant license(s);
  - (c) order the closure of the shop, storage facility or other premises used for pesticides-related purposes; and/or
  - (d) order the payment of compensation to any person who has suffered damage as a result of the offence, taking into account factors such as:

- (i) extent of loss or injury to a person or his or her dependants;
  - (ii) seriousness of the offence and the frequency of its occurrence; and
  - (ii) pecuniary gains on the part of the offender.
3. A court shall, notwithstanding any provisions to the contrary in any law, be competent to impose any penalty or to make any order provided for in this section.

*The Decree-Law provides for fines and any other penalties for specific violations, Specific fine amounts should be provided in secondary legislation to make it easier to change with inflation or changes in income levels. Specific penalties have not been established since they are left up to the Government to decide. However, it is recommended that a range of penalties be established according to the seriousness of the offence.*

## **PART VIII MISCELLANEOUS**

### **Article 38 Delegation of Authority**

The Minister may provide any staff member of the Ministry, or, with the concurrence of another ministry, any staff member of that ministry, with a written delegation of authority to exercise any duty or function under this Decree-Law.

### **Article 39 Regulations**

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

- (a) the application procedures and requirements for the issuance of pesticide registrations, permits, and Ministerial Recommendations under this Decree-Law;
- (b) the decision making criteria for any application or request submitted under this Decree-Law;
- (c) establishing a common framework for the inspections conducted under this Decree-Law;
- (c) the procedures to be followed where any equipment, pesticide, document, record, or other thing is seized under this Decree-Law;
- (d) the form and contents of applications, registers, certificates, licenses, permits, receipts, or other documents under this Decree-Law;

- (e) the period of validity of registrations, Ministerial Recommendations, and permits granted or issued under this Decree-Law;
- (f) pesticides which are exempted from the registration requirements of this Decree-Law;
- (g) the fees to be assessed under this Decree-Law;
- (h) the form and manner of request to the Board where any change proposed under article 16 is proposed after a pesticide has been registered under this Decree-Law;
- (i) the duties of employers whose employees are required or permitted to use pesticides in the course of their employment;
- (j) the procedures to be followed for taking and submitting samples for analysis [and for analysing samples] under this Decree-Law;
- (k) the rules for advertising pesticides;
- (l) the requirements for pesticide containers and labels;
- (m) the manner of filing appeals under article 15 of this Decree-Law; and
- (n) the dates on which different elements of the registration, licensing, and permit schemes of this Decree-Law shall come into force in Timor-Leste.

*This article provides a non-exhaustive list of regulations and other secondary instruments (such as decrees and orders) necessary to implement the Decree-Law to be issued by the Minister and in some cases by the Government].*

#### **Article 40** **Transitional Provisions**

1. Notwithstanding any other provision of this Decree-Law, the Minister, acting on the advice of the Board, may, after this Decree-Law has come into force, publish a notice in the Gazette specifying a period of time within which:
  - (a) listed pesticides already in Timor-Leste shall be deemed to be registered pesticides for the purposes of this Decree-Law, *provided that* no further import of those pesticides shall be permitted; and
  - (b) listed persons shall be deemed to be licensed for the purposes of this Decree-Law.
2. Any registration or license so deemed shall lapse at the end of the time period specified in the notice unless and until a new application is submitted under this

Decree-Law, or, if during the transition period, such provisional procedure as the Minister may prescribe, and the registration is approved or the license granted.

*This article establishes a transition period for phasing in the new system so that existing pesticides in Timor-Leste will not become illegal overnight when the Decree-Law comes into effect. It will allow for pesticides currently in the country to be registered (or not) under the new system, and for existing stocks to be used up in the meantime. It also allows time for persons with pesticides-related businesses to obtain the appropriate license.*

*Applications to register existing pesticides should be given the same level of scrutiny as applications for a new pesticide; there should be no automatic or fast-track registration just because a pesticide is already in the country.*

DRAFT