

GUIDELINE FOR REGISTRATION OF AGRO-PESTICIDES

Pursuant to the Sections 6 through 13 and the Section 23 of the Control of Pesticides Act No. 33 of 1980 as amended by the Control of Pesticides (Amendment) Act No. 06 of 1994. The purpose of this document is only to provide overall guidance to the registrant on necessary steps to be followed when forwarding applications for registration of pesticide. Applicants are requested to refer to the specific details of relevant guidelines under each category when submitting their applications.

Office of the Registrar of Pesticides
Department of Agriculture

GUIDELINES FOR REGISTRATION OF AGRO-PESTICIDES

Following general procedure is adopted in dealing with the registration of agricultural pesticides;

1. Evaluate the company profile for engaging in pesticide business and bulk handling of pesticides;

If the applicant (individual or corporate institute) is new for the pesticides industry, the profile of the company/facilities and other requirements to be fulfilled before granting approval for the submission of applications for registration of a pesticide will be evaluated. The eligibility criteria and general information for this purpose are given in the following guideline.

Guideline 1: Guidelines for Accepting Individual/Corporate Institutions to Engage in Pesticide Importation, Distribution and Sale

2. Selection of registration category;

Product registration can be either **Principle Registration** or **Third-Party Registration**.

Principle Registration:

Agro Pesticides Subcommittee $^{(1)}$ is the technical body which recommends the pesticides for Principle Registration.

a) Data submission for the Agro Pesticide Subcommittee;

Following documents should be forwarded to the Registrar of Pesticides in order to proceed with the preliminary evaluation and data submission for the subcommittee.

- Duly filled **RP-02A Form**
- Material Safety Data Sheet (MSDS) of the product to be registered.
- Detail composition of the product
- Duly filled "Summary Sheet of Data submission for Agro Pesticides Subcommittee"
- b) Agro-pesticide sub-committee recommendations;
 - Each product requested to be registered will be forwarded to the agropesticide subcommittee¹ and depending on the subcommittee

recommendation, the product will either be cleared for local bio-efficacy testing or rejected registration in Sri Lanka.

- Any decision on rejection can be appealed to the subcommittee or to the Registrar of Pesticides along with reasonable justifications.
- Local bio-efficacy data have to be generated by the research stations of the Department of Agriculture or by other relevant crop research institutes, according to the mandate of crop/pest category (2). It is applicant's responsibility to get their products tested by relevant authorities.
- According to the requests made by the applicants, the pesticides are divided into different groups⁽³⁾ and depending on the experimentation chart scheduled⁽⁴⁾ conducted by the Department of Agriculture, either full scale research experiments or pilot scale experiments or both will be conducted under the recommendations of the agro-pesticide subcommittee.
- Respective research institute will submit completed bio-efficacy test reports to the Registrar of Pesticides to be forwarded to the agro-pesticide subcommittee for result evaluations.
- c) Sample Importation for testing Purposes;
 - Importation of samples for experimental purposes will be granted only for pesticides recommended by the agro-pesticides subcommittee.
 - Following documents should be forwarded to the Registrar of Pesticides in order to proceed with the sample importation for testing/trial purposes (5).
 - Duly filled **RP-02B Form**
 - Application for Import of Pesticides (in triplicate)
 - o A copy of the letter issued by the Registrar of Pesticides on subcommittee recommendation.
- d) Once the local bio-efficacy trials are completed and recommended by the subcommittee, the applicant will be informed to submit completed application with dossier and application fee for product registration.
- e) The general instructions are given in the following guideline in submitting applications for registration of pesticides.

Guideline 2: Guideline for Submission of Information for Registration of Pesticides (Form No. RP/01/GL (Rev-11/07/2012)

Third-Party Registration:

- a. Applications for third-party registrations are accepted under the following conditions;
 - The product must have a valid registration under the Control of Pesticides Act No. 33 of 1980.
 - The consent of the principle registrant must be provided with the application.
- b. Requirements to be fulfilled under the third-party registration;
 - Duly filled application for third-party registration
 - Label artworks in duplicate for each container size (Label artworks should be approved by the Registrar of Pesticides before final printing)
 - Please refer the following guideline for instructions.
 - Filling fee and the registration fee

Guideline 3: Guideline for Preparing and Up-Grading Pesticide Labels

Notes:

- (1) Agro-pesticide Subcommittee is a subcommittee appointed by the Pesticides Technical and Advisory Committee (PeTAC) based on the authority provided by the Control of Pesticides Act No. 33 of 1980 in order to support the PeTAC on issues related to agro-pesticides.
- (2) Bio-efficacy trials should be carried out at the research stations of the Department of Agriculture under the supervision of departmental officials. If the product is to be used for tea, rubber, coconut, etc. the relevant experiments will be conducted at the research institutes of respective mandates (e.g. TRI, RRI, and CRI).
- (3) The pesticides which are requested to be registered under normal registration can be divided into following groups;
 - I. New molecule
 - II. New formulation of an already registered molecule;
 - i. Registered, same formulation type and different strength
 - ii. Registered, same strength and different formulation type
 - iii. Registered, different in both strength and formulation type
 - *III.* Registered, identical formulation from a different source
 - IV. Registered, identical formulation from the same source
 - V. Registered, identical formulation from the same source with slight change in recipe

- VI. Registered, identical formulation from a different source with slight change in recipe
- VII. Pesticides made only for export;
 - i. New molecule
 - ii. Commodity molecule

(4) DOA Experimentation Schedule:

Status		Research Experiments	Pilot Scale Experiments
New molecules	Proprietary/commodity	1	1
New formulation of already	Registered, same formulation type and different strength	√	V
registered pesticide	Registered, same strength and different formulation type	٧	V
	Registered, different in both strength and formulation type	V	V
Registered Identical Formulations	Registered, identical formulation from the same source	_	V
	Registered, identical formulation from a different source	-	V
	Registered, identical formulation from the same source with slight change in recipe	-	1
	Registered, identical formulation from a different source with slight change in recipe	-	V
Pesticides made only for export	New molecule	√	V
	Commodity molecule	_	V

(5) If the amount of the experimental sample is exceeding 10 kg or 10 l, a justification from the relevant researcher should be submitted along with the other documents.