



Pesticides Act 1974

GUIDELINES ON PESTICIDES REGISTRATION

Secretariat
Pesticides Board
Department of Agriculture
Ministry of Agriculture and Food Security Malaysia

2021

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PREFACE

The Purpose of these of these guidelines is to provide guidance to all potential applicants on the legal requirements to register pesticides before they are allowed to be imported or manufactured for sale and use in the country as provided for under the Pesticides Act 1974.

These Guidelines replace the 'Guidelines on Registration and Labelling of Pesticides' issued by the Pesticides Board in 1991 (4th Edition). The present registration guidelines were revised to accommodate the changes brought about by the amendment to the Pesticides Act 1974 which was passed by the Parliament in 2004. There are a number of new or amended provisions in the Act that affects the registration processes and procedures. These include the requirement for applicants to pay an application fee and a registration fee as well as the extension of the registration period from 3 years to 5 years.

These guidelines provide information on the application procedures to guide the applicants on how submissions for pesticides registration can be made to the Pesticides Board. It also provided an explanation on the requirements to register commodity and proprietary pesticides as well as new registration and re-registration procedures.

It is important to note that, these guidelines should be read together with other guidelines and related circulars produced by the Pesticides Board, in particular guidelines on data requirements namely on physical and chemical properties, toxicology and eco-toxicology, residue, bio-efficacy and environmental fate.



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1.0 INTRODUCTION

This Pesticides Registration Guideline is intended as a resource for companies and organizations who want to have their pesticide products registered for sale in Malaysia. Detailed information for pesticide registrants (the company or organization applying to register a pesticide) concerning a procedure is included in this guideline.

Sections 7-13 of the Pesticides Act 1974 provides for the control of importation and manufacture of pesticides. The objective of pesticide registration is aimed at ensuring that pesticides offered for sale in the country are of good quality, effective for their intended use and at the same time would not cause unacceptable adverse effects to man and the environment.

Registration of pesticides is implemented through the Pesticides (Registration) Rules 2005 which was gazette on 18 August 2005 to replace the Pesticides (Registration) Rules 1976. These new Rules describe how pesticide registration approval can be obtained from the Pesticides Board.

2.0 TERMS AND DEFINITIONS

2.1 Pesticide

The term 'pesticide' under the Pesticides Act 1974 is defined as 'any substance that contains an active ingredient' or 'any preparation, mixture or material that contains any one or more of the active ingredients as one of its constituents', while the term 'active ingredient' means an ingredient, as listed in the First Schedule of the Pesticides Act 1974.

Generally pesticides includes, but are not limited to, herbicides, insecticides, fungicides, acaricides, nematocides, rodenticides, molluscicides, bactericides, fumigants, soil fumigants, miticides, preservatives, repellants and termiticides.

Applicants are required to refer to the First Schedule of the Pesticides Act 1974, in order to ascertain whether their product contains any of the listed active ingredients, thus requiring registration. As the First Schedule is updated from time to time to include new active ingredients, it is necessary for the applicant to refer to the Pesticides Board for the updated listing.

2.2 Commodity and Proprietary Pesticide

For the purpose of registration, pesticides are divided into two (2) categories namely commodity and proprietary.

"Commodity pesticides" are pesticides containing active ingredients that have been registered in Malaysia more than 10 years.

“Proprietary pesticides” are pesticides that are not classified as commodity pesticides as defined above and have been registered in Malaysia less than 10 years. In case of a pesticide mixture containing commodity and proprietary active ingredients, the pesticide shall be considered as a proprietary pesticide.

2.3 Manufacture

The term manufacture as defined by the Act means to prepare, compound, formulate, mix, make, pack, re-pack or label a pesticide or otherwise treat the pesticide with a view to its sale.

2.4 Registration

Registration is a process of evaluation and approval by the Pesticides Board before a pesticide is allowed to be imported, manufactured, sold and used in the country. Only those pesticides that are of good quality, effective for the intended purposes and do not cause unacceptable adverse effect on human beings, animals, plants, fruits or property would be registered in the country.

In order for the evaluation to be carried out, the Pesticides Board requires the applicant to submit relevant data when applying for the registration. The data requirements for pesticide registration under these rules are adapted from the Food and Agriculture Organisation of the United Nations (FAO) and other international organizations. The details of information required for evaluation are given in the application form.

A separate application is required if the pesticide is different from another pesticide. A pesticide is considered different from another pesticide, if:

- a) the active ingredient of that pesticide is different from that of the other pesticide;
- b) the trade name or trade mark of that pesticide is different from that of the other pesticide;
- c) the ingredients of that pesticide are different from those of the other pesticide in type, number, proportion, concentration, or in other respects; e.g. glyphosate isopropylamine 13.6% w/w soluble concentrate (SL) and glyphosate isopropylamine 41.0% w/w soluble concentrate (SL) must be registered separately under each concentration;
- d) the pesticide is differently formulated from the other pesticide, e.g. if alpa-cypermethrin is formulated as an emulsifiable concentrate (EC) and also as suspension concentrate (SC), it must be registered separately under each formulation;
- e) the pesticide is manufactured by a manufacturer other than the manufacturer of the other pesticide; e.g. if dimefluthrin is manufactured by two companies, the products from both companies must be registered separately even if the products are identical; or

- f) that pesticide is different in quality, nature, characteristics or efficacy from the other pesticide; e.g. if one azadirachtin product is different in quality, nature, characteristics or efficacy from another product it must be registered separately from the other.

A separate application is also required if the category of usage is different e.g. insecticide for agriculture use and insecticide for public health.

3.0 APPLICATION PROCEDURES

3.1 Application For Registration

Application to register and re-register a pesticide **must** be made using Application Form, Form A [Subrule 2(1)] (Application for Registration/Re-registration of A Pesticide)] and only local registered companies may apply. All applications must be submitted to the following address:

Secretary
Pesticides Board
Pesticides Control and Fertilizers Division
Department of Agriculture
4th – 7th Floor Wisma Tani
Jalan Sultan Salahuddin
50632 Kuala Lumpur

Tel. : +603-2030 1400

Fax : +603-2691 7551

Application forms are obtainable from the above-mentioned address. Submissions should be made well in advance of the desired registration date.

Applicants should indicate in the standard cover-letter of the application (See Annex I) whether the product is a commodity pesticide or a proprietary pesticide. The onus is on the applicant to provide evidence that a product is a commodity pesticide. For commodity pesticides, some registration requirements have been waived but the Pesticides Board reserves the right to still request for them if necessary.

Only one (1) pesticide source (manufacturer) are allowed for registration³.

The period of registration of a pesticide is five (5) years, effective from the date of registration unless it is terminated by the registrant or cancelled by the Pesticides Board. Under the Pesticides (Registration) Rules 2005, two (2) types of fee will be imposed on an application to register and re-register a pesticide. The fee for an application is **RM 1,500.00 (One thousand five hundred ringgit)** payable at the time the application is submitted. This fee is not refundable.

Upon approval, a registration/re-registration fee will be imposed for each product payable prior to the issuance of the Registration Certificate. The amount¹ imposed for registration varies according to class as follows:-

Class Ia per approval	RM 3,500.00 (Three thousand five hundred ringgit)
Class Ib per approval	RM 3,500.00 (Three thousand five hundred ringgit)
Class II per approval	RM 2,000.00 (Two thousand ringgit)
Class III per approval	RM 1,000.00 (One thousand ringgit)
Class IV per approval	RM 500.00 (Five hundred ringgit)

3.2 New Registration²

Applicants must apply via online for new registration by login to MyPesticide System (<http://mypesticide.doa.gov.my>). The following are the requirements for an application for registration of a new pesticide:

- Six (6) sets softcopy dossier must saved in cd/pendrive of application forms and supporting information.
- One (1) original hardcopy dossier. Please refer Part E: Particulars on Data Requirements of the Application Form for the information to be submitted.
- Administrative Document²
- All information must be on A4 size paper, properly filed in A4 size folders and accompanied by a standard cover-letter. (See Annex I).
- The source(s) of a pesticide must be declared in the cover letter. In addition, a letter from the source(s) confirming that they are the suppliers of the pesticide should also be submitted. Only one (1) source (manufacturer) are allowed for new registration³.
- Letter authorizing the use of data from the owners of the data.
- The application should be accompanied by the draft label for each packsize. Four (4) additional draft labels are to be attached to the administrative file²

- h) A pesticide sample from each of the sources must be submitted, suitably packed and clearly labeled with the following information i.e trade name, applicant name, active ingredient, concentration, type of formulation and the source name. The quantities required are as follows:

Technical material	- 50 g or 50 ml
Formulated material	- 100 g or 100 ml
Aerosol	- 4 x 100 ml cans or more
Mosquito coil	- 4 x 10 pieces
Mosquito mat	- 2 x 30 pieces
Others	- refer to Pesticides Board

The registration sample must not be submitted in plastic bags in order to avoid spillage and contamination. Dust/powder or liquid formulations should be placed in either plastic or glass bottles. For dust or powder formulations, wide-mouthed bottles fitted with stoppers or seals should be used. All imported samples must be accompanied with an Import Permit endorsed by the Malaysian Customs.

- i) Analytical standard must be submitted for each active ingredient listed in the application. Analytical standard samples must be accompanied by an Import Permit (endorsed by the Royal Malaysia Customs Department), Certificate of Analysis, and information on the date of expiry of the standard must be provided (date of expiry must not be less than 1 year from date of submission). Some active ingredients are exempted from submission of analytical standard¹.
- j) Sample and analytical standard must be labelled and submitted together with dossier during the submission of new registration². Submission by postage or courier service are not allowed.
- k) Each application must be submitted with a copy of the current Certificate of Registration of the company (ROC/ROB).
- l) Banker's draft/money order of **RM 1,500.00 (One thousand five hundred ringgit)** per application, made payable to the Director General of Agriculture, as the payment for the application.

Please refer to these circulars for details:

- 1* as per circular B.81/05.20/Jld.V(25) dated 12th December 2008
- 2* as per circular JP/KRP/207/12/656/2/Jld.VI(74) dated 22nd January 2019
- 3* as per circular JP/KRP/207/12/656/2/Jld.VI(42) dated 26th February 2013

3.3 Re-registration¹

The validity period of a registration is five (5) years. Before the end of the validity period, the registrant may make an application to re-register the pesticide, and the application must be submitted not earlier than 12 months **BUT not later than six (6) months** before expiry.

Late submissions to re-register may not be accepted and may necessitate the pesticide be submitted as a new application.

The following are the requirements for an application for re- registration:

- a) One (1)* set of application form.
- b) Four (4) copies of the amended draft label.
- c) A copy of the current Registration Certificate.
- d) The source(s) of a pesticide as approved by the Pesticide Board must be declared in the cover letter. In addition, a recent letter of undertaking (not more than one (1) year from the date of application for re-registration) from the source(s) confirming that they will continue to be the suppliers of the pesticide should also be submitted. The maximum sources allowed for the pesticides are three (3) per product (e.g. manufacturer; invoicing; shipping agent; or exporter agent). Any change of source(s) or manufacturing process during the validity period of registration must be approved by the Pesticides Board, and such evidence must be submitted at re-registration.
- e) A copy of the current Certificate of Registration of the company (ROC/ROB).
- f) A copy of the MYDATA Certificated which contains the corporate information.
- g) A copy of N-PS.1 form.
- h) All information must be on A4 size paper and accompanied by a standard cover letter. (See Annex I).
- i) Banker's draft/money order of **RM 1,500.00 (One thousand five hundred ringgit)** per application made payable to the Director General of Agriculture as payment for the application.

Please refer to this circular for details:

1* as per circular JP/KRP/207/12/656/2/Jld.VI(88) dated 16th July 2020

3.4 How To Complete The Application Form

The Application Form, Form A [Subrule 2(1)] (Application for Registration/Re-registration of A Pesticide) is divided into seven (7) parts i.e. A, B, C, D, E, F and G and all parts must be completed.

For Part E, however, depending on the general use pattern of the pesticide (whether proprietary or commodity) some studies or information/data may be waived. To assist the applicant in providing the right data/information to support the application to register or re-register a pesticide, Annex II provides a summary of data requirements for different types of pesticides.

In addition to the above, the applicant should also refer to the following guidelines for detailed information on how such data/studies should be generated and compiled:

- a) Guidelines on Product Chemistry Data Requirements for Pesticide Registration (GP1)
- b) Guidelines on Toxicological Data Requirements for Pesticide Registration (GP2)
- c) Guidelines on Efficacy Data Requirements for Pesticide Registration (GP3)
- d) Guidelines on Residue Data Requirements for Pesticide Registration (GP4)
- e) Guidelines on Biopesticide Registration (GP7)

4.0 LABELLING REQUIREMENTS

The label represents an important source of information to the user of a pesticide. A label is the written, printed or graphic material firmly attached to a product container.

Among others, the label should contain the identity of the pesticide and instructions on use, precautions to be taken and other relevant information. This is to ensure that the pesticide is used properly and effectively. Under the Pesticides Act 1974, a pesticide shall not be sold unless it is registered and labelled with an approved label.

To ensure proper labelling of pesticides sold in the country, the Pesticides (Labelling) Regulations 1984 have been gazetted and should be used. As part of the process of approving an application for registration, the proposed label of a pesticide is evaluated to ensure that it complies with the requirements of these regulations. To comply with the labelling requirement, therefore refer to the Pesticides (Labelling) Regulations 1984. For guidance, the applicant is advised to refer to *Garis Panduan Pelabelan Produk Racun Makhluq Perosak* which provides layout examples that meet the requirement of the Pesticides Board.

The applicant should also refer to the latest edition of *Garis Panduan Untuk Nama Dagangan Racun Perosak* in order to ensure trade name given to the pesticide is acceptable to the Pesticides Board.

5.0 MANUFACTURING FOR EXPORT PURPOSES

*(Still in the implementation stage)**

Registration approval under the Pesticides (Registration) Rules 2005 is only meant for all activities to import and manufacture pesticides intended for local market and sale. If the pesticide is solely manufactured for export, registration approval also required, but still under implementation stage by the Board.

6.0 IMPORTATION OF AN UNREGISTERED PESTICIDE

An unregistered pesticide may only be imported in a limited quantity for educational or research purposes, or as a registration sample or in the form of analytical standard by means of an import permit as provided for under the Pesticides (Importation for Educational and Research Purposes) Rules 1981.

The following are the requirements for an application for import permit for research purposes:

- a) One (1) set of application form (Form A, Subrule 3) with cover letter
- b) Safety Data Sheet (SDS)
- c) Trial Protocol
- d) Supporting letter from other Government Department/University/other Government Agency (if applicable)
- e) Permission letter/Consent letter from the farmer/owner to use crop area as a trial plot
- f) Fee : RM10

The following are the requirements for an application for import permit for registration sample or analytical standard purposes:

- a) One (1) set of application form (Form A, Subrule 3) with cover letter
- b) Fee : RM10

7.0 PENALTIES

It is illegal under the Pesticide Act 1974, to import and/or manufacture pesticides without any valid registration approval from the Pesticides Board. Any person, if found guilty of importing or manufacturing any pesticide without valid registration approval, is liable on a first conviction, to imprisonment for five (5) years or to a fine of RM50,000 and, on a second or subsequent conviction, to imprisonment for 10 years or to a fine of RM100,000 or both.



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