PESTICIDES CONTROL BOARD

REGISTRATION

Guidelines for the submission of an application for the registration of pesticides in Belize

General

The registration applicant (manufacturer, formulator or owner of the commercial product) may consult with the PCB to obtain the current roster of persons registered with the institution as local representatives for the registration process and duly appoint one to administrate their registration processes.

Requirements for local representatives for the registration of agricultural-use pesticides and related substances:

- Professional in agricultural or natural] sciences
- Permanent resident or citizen of Belize
- Fluent in the English language

Duly authorized local representatives are responsible for ensuring that applications comply with technical requirements, criteria and submission procedures established by the PCB for the various processes such as registration, registration renewals, requests for registration modifications etc.

Using the PCB appointment template letter that is available from the website, the applicant will communicate their selection to the PCB.

The applicant should then, through its duly appointed local representative with the PCB ensure that applications for registration are submitted according to the format and conditions as specified by the PCB.

The applicant should include a full and objective summary of all data.

Any request for waivers (of data requirements) from the applicant must be submitted in writing for consideration.

The relevant general requirements for the dossier are publicly available and any other specific requirement will be made available by the PCB.

The applicant should fulfill all technical and financial requirements as specified by the PCB and is encouraged to consider submission of electronic dossiers to facilitate storage and retrieval of data.

Screening: Completeness check

The applicant, through its local representative, presents a complete dossier for a completeness check.

(The local representative may seek specific guidance on issues relevant to the specific product and the data to be presented as part of this initial step).

The PCB, then, checks whether the dossier is complete with respect to the requirements and specified data set.

Based on the completeness check and preliminary evaluation of technical data, PCB can request the applicant to supply any missing, incomplete and/or additional information to supplement the dossier.

Preparation and Submission of the Dossier by the Applicant

All applications for the registration of pesticides are to be presented by the local representative at the office of the Pesticides Control Board (PCB) in Central Farm, Cayo District, Belize or submitted electronically to the office mail [pcbinfo@pcbbelize.com]

The applicant prepares and submits the registration dossier following the requirements for content and format and making payment of a non-refundable application fee of $100.00 BZD (Household Products) and $300.00 BZD (Agricultural Products).

The following describes the general guidelines for submission of dossier copies:

- The data must be presented following the content and order in which it is detailed in the pertinent data requirements on legal or letter sized paper.
- Table of contents clearly matching page numbers with dossier contents separated by tabbed and labelled data sections and annexes.
- Clearly marked sections – administrative, data on the active ingredient with annexes, data on the formulated product with annexes and confidential section
- Consolidate in soft folders and fasten on the left-hand side
- A biological efficacy trial per crop family
- Three copies of all label presentations intended to be imported.

Administrative Actions

Payment proof of the non-refundable application fee $100.00 BZD (Household Products) and $300.00 BZD (Agricultural Products) and dossier copies are submitted by the local representative.

PCB issues a receipt and logs receipt number on the Form 1 of the original dossier.

PCB advises registration clients from time to time of the status of applications based on the institution's quarterly evaluation schedule.

Technical and Scientific Evaluation

The role of the Registration Committee of the Pesticides Control Board is to review technical and scientific data submitted for the registration of pesticides. The Committee shall make recommendations to the Pesticides Control Board pertaining to the registration and classification

of pesticides.

The registration dossier, including any data generated at the request of the PCB, is submitted to members of the Registration Committee who are qualified experts in relevant fields including efficacy, human health and environmental effects for technical evaluation of the data. Whenever possible, evaluations make use of internationally agreed methodologies and criteria. The PCB is to ensure that there is no conflict of interest with respect to the data being evaluated and that the dossier is treated confidentially.

Committee members are bound by the Committee's Code of Ethics pertaining to the protection of confidentiality of data submitted to support applications for registration.

During the evaluation of the data in the relevant fields, the PCB will, if necessary, request the applicant to submit any additional data that are deemed essential by the evaluators, specifying a time period within which these data should be submitted as well as indicating that further processing of the application for registration is postponed until receipt of these data.

When appropriate, the Registration Committee may also take note of expert opinion from other competent regulatory authorities when evaluating data.

Preparation of Summaries and Conclusions

Reviewers on the Registration Committee submit their conclusions providing a summary listing of the data and assessments that formed the basis of their conclusions.

Based on the evaluation and recommendations of the experts, the conclusions are prepared for subsequent consideration by the Board for a decision.

Risk Management and Registration Decision

The PCB will take the final decision on the registration of the pesticide, considering the review prepared by the Registration Committee.

The decision of the Board may be provisional or full registration, with or without restrictions and/or conditions, or refusal, The Board may also decide to suspend a decision and request further assessments by the Registration Committee.

Use of a pesticide is generally approved only for specific applications, e.g., for control of specific pest(s) on certain crops or specific applications for control of nuisance pests or vectors of diseases. These approved purposes are incorporated in the registration decision.

Effectiveness of the product to control specific pests, and risk of residues on the crop concerned, are among the factors that play a role in decisions to limit approval to certain crop-pest combinations.

In cases of elevated human health or environmental risk, the use of certain pesticides may be severely restricted. Such restrictions may, for instance, specify that the product can be used only by licensed applicators for very specific purposes. Monitoring and enforcement of compliance to registration restrictions is carried out by PCB Inspectors.

Restricting the use of pesticides as a form of risk management is only effective if the restrictions are adhered to and are being enforced. Aside from prohibition on the importation, sale and purchase of highly toxic and hazardous products, other control measures and marketing practices must ensure that products can be handled with acceptable risk to the user.

In case the Board concludes that a registration may be granted, it assigns a unique registration number linked to the specific registration from the specific applicant. If the registration is refused, or if the use of the pesticide is severely restricted, specific additional post-registration actions may need to be taken to protect human health or the environment.

The PCB can publish its summary and proposed registration decision and invite third parties to provide comments, ensuring that any public review period does not unreasonably delay the registration process.

Publication and Dissemination of Registration Decision

The PCB informs the applicant via its local representative of the decision of the Board by way of a formal notification. In cases where registration is granted, the applicant should proceed to comply with any final requirements and make the final payment of registration fees prior to issue of the certificate of registration and all relevant conditions linked to the registration, including labeling and marketing conditions and the registration number.

Pesticides approved for registration by the PCB are compiled in the Register of Pesticides which is available from the PCB website.

Examples of requests for registration modifications

Label Extension

A label extension is a client request to add another crop or pest onto the label of an existing registered formulation. Clients need to provide the following upon soliciting request:

- Cover letter soliciting request and explaining the reason for such request. The letter must come signed by either the Legal Representative or the Company Representative.
- Form 1 with updated intended use
- Biological Efficacy Trial(s)
- Pamphlet with new intended use(s)

Change in the use pattern or use directions

A change in the use pattern or use direction is a client request to change the mode of application, dosage, pre-harvest interval, dosage etc. Client needs to provide the following upon soliciting request:

- Cover letter soliciting request and explaining the reason for such request. The letter must come signed by either the Legal Representative or the Company Representative.
- Form 1 with updated intended use
- Biological Efficacy Trial(s)
- Pamphlet with new intended use(s)

Additional Presentations

An additional presentation is a client request to add additional presentations (product sizes) to the register of pesticides facilitating its successful importation of requested presentation sizes. Clients need to provide the following upon soliciting request:

- Cover letter soliciting request and explaining the reason for such request. The letter must come signed by either the Legal Representative or the Company Representative.
- 3 copies of additional presentation labels.

Amendment to Concentration

On very rare occasions amendments to the concentration of a formulation must be made because of weight/volume concentration or acid/salt concentration. Such changes must be informed in writing to the Registrar of Pesticides.

Addition of new formulation site

There are instances where a new formulation site for a product is acquired and as such changes must be informed in writing to the Registrar of Pesticides.

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Addition of new Origin (Manufacturer)

There are instances where a new origin for a product is acquired or the manufacturing site on occasions may change its name. Such changes must be informed in writing to the Registrar of Pesticides.

Change of Formulation site name and/or company

There are instances where a formulation site for a product is changed or the formulation site on occasions may change its name. Such changes must be informed in writing to the Registrar of Pesticides.

Change in Toxicological Color Band

Due to the new labeling regulation requirements in Central America (RTCA) and the interim approval by the Board in (year) the new toxicological classification for labelling follows Globally Harmonized System (GHS), as a result the LD_{50} values fall under different categories that directly result in the change of the color band.

Change in Registration Holder

There are instances whereby companies merge and/or disassociate and as a result the holder of the registration may change. Such a request must come in writing to the Registrar of Pesticides.

Change in Trade Name

Registration holders on occasion may decide to change the trade name of a product for commercial reasons. Such a request must come in writing to the Registrar of Pesticides.

Amendments to the approved label/pamphlet

After approval of the label-pamphlet, any changes to it must come as a request to the Registrar of Pesticides. Such changes can include but are not limited to pre-harvest interval, re-entry period, method of application, etc.

NB: All written requests and/or notifications must be notarized and signed by the legal representative or company representative. It must be accompanied with the updated Form 1 application signed by the LR, 2 copies of updated label-pamphlets (where relevant), certificates of origin and analysis (where relevant).

Correspondence and certificates (where necessary) will be prepared and issued along with an invoice for administrative costs incurred. Please wait for the invoice to be issued prior to making payment.

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Administrative fees pertinent to requests for modifications to registration details:

SCHEDULE OF REGISTRATION PROCESS FEES

AGRICULTURAL-USE PRODUCTS

[15 February 2024]

REGISTRATION FEES	
Process	**Fee**
REGISTRATION of a new pesticide	**$1000**
	$300 nonrefundable application fee.
	$700 payable once registration approval is granted.
Registration of an identical product by the same registration holder under an alternative trade name.	Same as above.
Unless cancelled by the PCB under Regulation 11 of the Registered and Restricted Pesticides (Registration) Regulations, 1995, pesticide registrations are valid for a period of 5 years.	
RENEWAL of pesticide registration	**$700**
FEES FOR AMENDING A PESTICIDE PRODUCT REGISTRATION	
AMENDMENT Type One: This type of amendment is divided into <u>two categories</u> based on whether scientific review is required for approval. The registration holder submits a request for amendment, supported by required documents to the PCB for evaluation. After the PCB approves, the pesticide product can be sold and distributed with the modified changes in the Belize market.	
1. Amendments which do not require scientific review by the Registration Committee	

These amendments include but are not limited to:
- Transfer of ownership of the registration (change in registration holder)
- A change in the name and address of the registration holder.
- Label changes e.g.
  o Change of a trade name
  o Deletion of recommended use
	$75
	Covers the administrative process ($50) and a new registration certificate ($25) or other formal approval document from the PCB.

○ Change in registered presentation sizes. ○ Change in toxicological classification where the goal is to standardize with the GHS system for pesticide labelling or to address an erroneous previous registered classification. ○ Changes in authorized importers. - Change in basic formula when the new formulation remains *substantially similar* to the original formula. [i] - *Addition/change of formulator/origin. [ii]*		
2. Amendments which require scientific review by the Registration Committee		
These amendments include but are not limited to: - Label extension - new intended use referring to use for an additional pest and/or additional crop (family) - Change in the use pattern or use directions e.g. mode of application, dosage etc. - Change of product's claims and precautions. - Substantial change in product formula.	**$125** Covers the administrative and scientific review process ($100) and a new registration certificate ($25) or other formal approval document from the PCB.	
AMENDMENT Type Two: This type of amendment is a notification submitted by the registration holder to inform the PCB of a change in its registration portfolio in Belize.		
1. Amendment by Notification		
- Change in local representative.	No fee	No fee

[i] Guide for Determining Substantially Similar

To be considered substantially similar, the applicant declares that the new product formula, when compared to the original formula:

- Contains the same active ingredient(s).

- Contains the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations.

- Contains the same or substantially similar inert ingredient(s).

- Contains the same or a substantially similar percentage of each type(s) of inert ingredient(s).

- Bears the same label language regarding signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.

- Bears the same or substantially similar method(s) of application.

- Claims to control the same or substantially similar pests or site/pest combination(s).

- Bears the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination.

Note: this list should be viewed as a guide and does not represent regulatory requirements, nor should it be considered exclusive.

[ii] Subject to change to Type One, Category 2 in line with the foreseen regulation of registered sources of active ingredient and product manufacturing process.