REQUIREMENTS AND GUIDELINES FOR EFFICACY EVALUATION TRIAL REPORTS SUBMITTED AS A PARTIAL REQUIREMENT FOR PESTICIDE REGISTRATION

1. INTRODUCTION & PURPOSE OF THIS DOCUMENT

The mandate of the Pesticides Control Board (PCB) is to ensure that pesticides placed on the market in Belize are effective for their intended purpose and do not pose unacceptable risk to human or animal healtSh or the environment.

Pesticides can only be sold or used in Belize if they are duly registered with the PCB. To register a pesticide, the agent must submit a registration dossier in compliance with data requirements. This dossier must include a report of a trial or trials that demonstrates the efficacy of the product in similar (or the same) environment, conditions and intended application as in Belize. This document provides guidelines as to what needs to be included in these efficacy trial reports.

2. WHY CONDUCT EFFICACY TRIALS?

The efficacy of a pesticide is defined as the effective control achieved from the use of the product against a target pest to fulfil the claims made for it. It includes extent of the control of the pests and considers any adverse effects on the host i.e., toxicity to animals and phytotoxicity to plants. The efficacy trial needs to provide data that demonstrates the pesticide fulfils the claims made on the proposed label and advertising materials.

3. EFFICACY TRIAL REPORT OBJECTIVES

The efficacy trial report needs to achieve the following six objectives:

3.1. Demonstrate, based on sound scientific research procedures, that the plant protection product is effective at the recommended dose, against the target pest(s), under the proposed conditions of use, in Belize.

3.2. Validate use recommendations and claims presented on the product label.

3.3. Provide evidence of a clear benefit to the user.

3.4. Support any peripheral claims such as rainfastness, compatibility when used in mixtures, safety to beneficial insects and other non-target organisms.

3.5. Establish the absence of adverse effects on treated crops or the production system (e.g., phytotoxicity to the target (or adjacent) crops, yield reduction, negative effects on succeeding crops, adverse effects on pollinators or natural enemies of crop pests or adverse environmental impacts).

3.6. If the product is a mixture of pesticide active ingredients (a.i.), the trial needs to demonstrate the complementary effectiveness, or benefits, from the mixture's effectiveness. This may include synergy, different modes of action against the target pest

(protectant and systemic), different times of action (pre-emergent and post- emergent), different biochemical modes of action, and the multiple pest scenario. The efficacy trial should evaluate formulations containing each a.i. separately (at their standard dosage) and against the mixture.

4. POINTS TO CONSIDER

In presenting the report the following points should be noted:

4.1. In the registration process, evidence of biological efficacy is a prerequisite for further assessment of human health and environmental risks of products submitted for registration approval.

4.2. The trials must be conducted within the last five (5) years in the crop(s) proposed for intended use.

4.3. The trial report must be accompanied by proof of validation from a recognized research institution in the region and/or by the relevant government department of the country in which the trial was carried out.

4.3.1. A non-exhaustive list of recognized research institutions in the region is annexed to this document (Annex 1). Others may be proposed by the registration applicant.

4.4. The report should present statistically supported evidence of the biological efficacy of the product in one or several specific host/pest combinations for which its use is being recommended.

4.5. Data submitted in support of biological efficacy may be derived from local trials or trials conducted in other countries, providing the data is obtained in conditions like those of the intended use in Belize. Cropping techniques, target pests, pest pressure, biology, and climatic conditions need to be comparable and relevant to those in Belize. Justification must be provided. Reference controls need to be the same or comparable with a product habitually used in Belize to control the pest in the proposed crop of intended use.

4.6. The implementation of the efficacy trials, data analysis, presentation of results, and conclusions drawn must be conducted and presented using internationally recognized methods.

4.7. The PCB may consider requests for the extrapolation of efficacy data from one closely related crop or pest to another, provided that the following conditions are satisfied:

4.7 (a) That a close relationship to taxonomy of the target crop / pest in Belize, is clearly demonstrated.

4.7. (b) That there is a demonstrated similarity to the biology of the crop and the behaviour and biology of the target organism.

4.8. The application could be strengthened further by the applicant providing data that demonstrates lower health & environmental risk than what is currently being used in Belize.

4.9. Data showing impact of pesticide on pest status over time should be clearly presented, where relevant.

4.10. In instances where the trial report is in a language other than English, a certified translation in English must be provided with a copy of the original trial report in the original language.

4.11. List of references to relevant publications / articles should be included at the end of the report.

5. EFFICACY TRIAL REPORTS SHOULD CONTAIN THE FOLLOWING:

5.1. Section I: Cover Information

5.1. (a) Title of the efficacy trial report.

5.1. (b) Author(s**)** of the efficacy trial report, their position and institution to which they are associated.

5.1. (c) Names and qualifications and contact information of persons conducting and responsible for the trial (if different from (b)). To establish confidence in the results, efficacy trials are to be managed in a structured and transparent manner, by persons who are scientifically qualified and responsible for implementing the trial.

5.1. (d) Date of report and date(s) of trial.

5.1. (e) Trial and report certifying body.

5.1. (f) Abstract / Summary. Summary / abstract which will include a brief objective, pest and crop, current problems with control of the pest, why a new pesticide is needed, and the results or the trial.

5.2. Section II: Introduction

5.2. (a) Brief literature review of other work to control the pest or use the product.

5.2 (b) If the data / report has been published in a publication / journal, relevant references.

5.2 (c) Trial Objective. The objective(s) of the trial needs to be clearly stated to indicate what the trial aims to achieve. The objective statement should include:

- The common and scientific name of the crop and/or produce which will be protected.

- The common and scientific name of the pest(s) against which the crop and/or produce is to be protected.
- Environment or setting in which the trial was conducted (e.g., field, storage facility).
- Type of protection that is intended (e.g., activity against certain stages or in certain periods of the season).
- Type of trial (e.g., efficacy, selectivity or crop tolerance, effects on succeeding crops).
- Where the test product is a formulation containing two or more active ingredients, the registration applicant is to demonstrate the agronomic benefits of the mixture over the use of each active ingredient separately.

5.2. (d) Criteria by which the trial and the performance of the pesticide has been assessed.

5.2. (e) Brief description of the target pest and its importance / impact on farmer's capacity to produce quality, high yielding crops. This should be an explanation of why the pest is of concern to Belize, how much of a problem it is to Belize's agriculture and should include a brief description of the biological cycle and population dynamics (in Belize) of the species to be controlled as well as its spatial distribution in Belize. The selected cultivar needs to be susceptible to the pest in question.

5.3. Section III: Materials and Methods

5.3. (a) Basic information on the trial site

The trial must be conducted in an area on where the pest is endemic and where the environmental conditions are demonstrated to be present for its normal appearance and development.

The following information must be included:

- Address, geographical coordinates and map of the trial or plot location(s).
- Details of the trial site (e.g., slope, soil type, exposure, agronomic history, altitude).
- Climate description of trial site area (temperature, rainfall and humidity patterns) (and justification for using trial results if environmental conditions different to Belize. Weather patterns during trial period (as relevant to target crop, target pest and pesticide)

5.3. (b) Trial conditions

The agronomic conditions of the crop must be uniform for all the plots and in accordance with local cultivation practices.

A description of the following information should be included:

- Sowing or planting date, density and row spacing of the crop, etc. (annual crops).
- Row spacing or arrangement, rootstock, canopy height, plant age, whether in production, etc. (perennial crops).
- Arrangement within compartments or on benches or beds.
- Size and type of storage compartment (for storage treatments).
- Preceding crops (where relevant).
- Plant protection products applied in preceding season(s) (where relevant).
- Cultivation measures (tillage, fertilizer, and irrigation regimes, etc.).
- Crop condition (growth normal or under stress, presence of other pests, etc.).

5.3. (c) Trial design and layout

The design of the trial should allow for appropriate statistical analysis of the data. Treatments are to include the test chemical evaluated at incremental dosages, the reference product and absolute control. As a rule of thumb, a trial shall include at least four replicates per treatment.

The following information should be included:

- Type of experimental design.
- Design and layout of the plots (number size and shape).
- Diagram of the trial layout should be included indicating the location of each treatment and the direction of slope (if any) of the land.
- Measures implemented, during the trial, to ensure pesticide applications did not drift from their designated treatment plot to other treatment plots, which may compromise the evaluated parameters of the trial.
- Photos of the trial site should be included were helpful.
- Arrangement of gross and net plots (protection zones between plots).
- Assignment of plots to blocks and treatments.
- Type, arrangement, and description of absolute control.
- Description and justification for choice of reference control.

5.3. (d) Trial Protocols and Standard Operating Procedures.

The trial should use well elaborated trial protocols and standard operating procedures (SOPs). The report must include:

- References to protocols and SOPs that are being followed.
- Indications and justification for any deviations from standard protocols, SOPs or Good Experimental Practice (GEP).

5.3. (e) Test and Reference Products

For the reference product, select a registered product that functions satisfactorily in practice and is normally used in Belize (a product registered for the same use and containing the same or closely related active ingredient or, if not an available, a product that is currently and normally used to control the pest). Generally, the type, formulation and mode of action must be closest to the test product, depending on the trial objective.

For the test and reference product, the following information should be included:

- Common name of active ingredient(s) (ISO)
- Exact name of formulated product(s) (including formulation and concentration codes)
- Batch number
- Recommended/proposed dose (as formulated product and as active ingredient)
- Diluent and dilution ratio (where applicable)
- Recommended application intervals (where relevant)
- For the reference product, registration, or authorization number in country where trial is being conducted

For test products containing one or more active ingredients, registered reference products containing the individual active ingredients are to be used in the efficacy trial, in addition to a similar registered formulated product, where applicable, and an untreated control (e.g., if the product contains three active ingredients, each active ingredient requires one control).

5.3. (f) Mode of Application

The pesticide application must be in accordance with proposed label/pamphlet instructions and any additional advertisement material related to the test chemical.

The following information should be described:

- Application method and equipment used (e.g., sprayer type, nozzle/atomizer type)
- Number of applications and date of each application.

- System for timing applications (e.g., calendar, stage of crop, threshold levels of pest, external warning system).
- Growth stage of the crop at application.
- Development stage of pest or infestation level at application.
- Application details (e.g., actual speed of sprayer, track spacing, flow rate, spray pressure, nozzle/atomizer settings, droplet spectrum).
- Actual surface area(s) sprayed per plot.
- Actual volume applied per plot.
- Actual dose (as kg or g of active ingredient per ha).

5.3. (g) Weather Conditions at the trial site - Meteorological data

A summary of relevant weather information occurring at least ten (10) days prior to application and during the trial must be recorded and provided in the trial report, with the recorded observations presented as an annex. This data may be taken from the site as well as from the nearest meteorological station.

The following information should be included:

- Location of weather station relative to the trial plot(s).
- Observations at application (relative humidity, temperature, rainfall, wind speed and direction).
- Daily observations throughout the trial (relative humidity (if relevant), temperature, rainfall (particularly time of first rain after treatment), unusual weather incidents). Minimum and maximum readings should be included for each variable.

5.3. (h) Soil and Irrigation Data

The following soil information must be recorded primarily for products applied to the soil:

- Soil type, including texture and structure
- Trial site topography.
- Soil conditions (pH, organic matter content, soil humidity).
- Seed bed quality (where relevant).
- Fertilizer regime.
- Irrigation regime.
- Type of (artificial) substrate and its components.

5.3. (i) Data Collected to Determine Biological Efficacy of Pesticide

Depending on the crop and the pest being studied, variables may include density or incidence of the pest, infestation and infection levels, percentage mortality or control, severity of symptoms or damage to the crop, crop yield, quality of the product etc.

The report should include a description of the following:

- A statistical assessment of the pest population in the trial plot before pesticide application, to ensure that the pest is present and evenly distributed at a threshold that merits action.
- Variables observed and measured.
- Type of assessment, including detailed description of method(s) used.
- Frequency and date(s) of assessment, including crop growth stage(s).
- Standards or protocols followed (where relevant). References to these standards or protocols should be included at the end of the report.
- Where relevant and helpful supporting photographs should be included to illustrate the data collection methods used.

5.3. (j) Other Observations should be made during an Efficacy Trial.

These could include:

- Crop tolerance with the researcher reporting on any observed adverse effects on crops, at emergence, during growth and at harvest.
- Effects on non-target organisms. The researcher is expected to report:
    - Observations of mortality or effects on pollinators or natural enemies of pests.
    - Observations of effects on adjacent crops and other plant species, example: ornamentals, hedges, and forests.
    - Methods used to evaluate effects on non-target organisms.

5.3. (k) Statistical analysis

The principal objective of the analysis is to estimate the magnitude of the differences between the various treatments and to provide a measure of variability of those estimates. That is, to determine whether any differences in pest control or crop yield, between the treatments, occurred due to chance or if it could be confidently stated that it was a result of the pesticide application. To achieve this, the treatment data should be compared using an appropriate statistical test.

The methods of statistical analysis should be described. The statistical comparisons made, or contrasts analyzed should be clearly indicated. Any transformations, if used, should be reported as well as the reasons for using them.

5.4.Section IV: Results

All results obtained from the above observations and measurement should be presented in a clear and systematic manner, with particular attention given to data that support claims on the label and in advertisements for the test product. Graphical, tabulated data and statistical summaries should be included and supported by photographic evidence where relevant. Unusual results should be reported and explained.

Raw data (i.e.) the results of assessments done in individual plots or samples within plots do not have to be reported but should be available on request (preferably in electronic format).

5.5.Section V: Discussion and Conclusions

The discussion should treat at least five issues:

- The validity of the trial, with particular attention to comparing the results of the test product with the untreated control and the reference plots. Trials having reduced validity (e.g., because pest levels were low, inappropriate statistical analysis or the issues covered in section 3) will not be accepted.
- If the trials can be considered valid, the efficacy of the test product(s) needs to be appraised in relation to the reference product, to the untreated control and to other parameters of the trial (e.g., dose, application time and frequency). Any data specifically supporting label claims should be discussed.
- Agronomic side-effects (e.g., phytotoxicity, changes in population dynamics of other pests, impact on non-target organisms – such as pollinators and beneficial insects/biological control agents)
- Positive impacts (e.g., yield increase) of using the product, if any, should be assessed.
- Final recommendations must include the recommended dosage or range, application intervals (if necessary), any special conditions of application required to control the pest.

5.6.Section VI: List of Relevant References, methodologies, standard operating procedures, publications, and articles, referred to in the text.

Annex 1

Country	**Institution**
Belize	Research, Development, and Innovation - Ministry of Agriculture
Belize	Sugar Industry Research and Development Institute
Belize	Citrus Research and Education Institute (CREI)
Belize	Banana Growers Association (BGA)
CARICOM	Caribbean Agricultural Research and Development Institute (CARDI)
Costa Rica	Instituto Nacional de Tecnología Agropecuaria (INTA)

Costa Rica	Centro Agronómico Tropical de Investigación y Enseñanza (CATIE)
Costa Rica	Centro de Investigaciones en Café
Costa Rica	Consejo Nacional para Investigaciones Científicas y Tecnológicas (CONICIT)
Costa Rica	Comisión Nacional de Investigación Agraria y Transferencia de Tecnología (CONITTA)
Costa Rica	Corporación Bananera Nacional S.A. (CORBANA)
Dominican Republic	Instituto Dominicano de Investigaciones Agropecuarias y Forestales (IDIAF)
El Salvador	Centro Nacional de Tecnología Agropecuaria y Forestal (CENTA)
Guatemala	Centro Guatemalteco de Investigación y Capacitación de la Caña de Azúcar (CENGICAÑA)
Guatemala	Consejo Nacional de Ciencia y Tecnología (CONCYT)
Guatemala	Instituto de Ciencia y Tecnologia Agricola (ICTA)
Honduras	Direccion de Ciencia y Tecnología Agropecuaria (DICTA)
Honduras	Consejo Hondureño de Ciencia y Tecnología (COHCIT)
Honduras	Consejo Nacional de Tecnología Agrícola (CONACTA)
Mexico	Centro Internacional de Mejoramiento de Maíz y Trigo (CIMMYT)
Nicaragua	Instituto Nicaragüense de Tecnología Agropecuaria (INTA)
Panama	Comisión Nacional de Ciencia, Tecnología e Innovación (CONCYT)
Panamá	Instituto de Investigaciones Agropecuarias de Panamá (IDIAP)
Peru	Centro Internacional de la Papa (CIP)
Regional LAC	Centro Internacional de Agricultura Tropical (CIAT)