GP 7/2016

GUIDELINES FOR

BIOPESTICIDE REGISTRATION

Pesticides Board
Malaysia
2016

PREFACE

The Pesticides Board in its efforts to further upgrade its services to the public, in particular companies applying for the registration of biopesticides has prepared these guidelines. These biopesticides guidelines published provide information for the registration of micro-organisms / microbials and botanicals / plant extract with minimum data requirements.

In the preparation of these guidelines references were made to some international and national guidelines such as those published by FAO and GIZ. Applicants who require further clarification on these guidelines or other matters related to registration may contact the Secretary of the Pesticides Board at the following address:

Pesticides Board
Department of Agriculture
Jalan Sultan Salahuddin
50632 Kuala Lumpur
Malaysia.

Tel. No.: (03) 20301476
Fax No.: (03) 26917551

Chairman

Pesticides Board

DATA REQUIREMENTS FOR MICROBIAL REGISTRATION

A. Biological and Chemical Characteristics

1. Systematic name

The systematic names, consisting of genus and species names, of microbial shall be given. (example: *Bacillus thuringiensis, Trichoderma harzianum*).

2. Strain or isolate of microbials

The strain or isolate of microbial shall be stated clearly.
(Example: *Bacillus thuringiensis* subsp. *kurstaki*, strain ABTS-351; *Trichoderma harzianum* UPM 29)

3. Common name

The common name of microbial shall be provided if available.

4. Source or origin, host range, and mode of action

The source or origin of microbial shall be mentioned.
The host range of microbial has to be tested on honey bee or selected flora and fauna. For Bacillus *thuringiensis aizawai*, *Bacillus thuringiensis kurstaki*, Nuclear Polyhedrosis Virus (NPV), *Steinerma* spp. (*Neoaplectana* spp.) and *Heterorhabditis* spp., of which technical information is well known to be safe to human, plant, animal and the environment, it is not required to submit host range data. Host range data for other microbial are required to be submitted. Reports from any reliable and reputable publication journal are accepted.
The mode of action of microbial should be mentioned clearly (example: non-toxic mechanisms, infection of target, competitive or antagonistic behaviour, etc).

5. Specification of the product

The specification of the product includes appearance, physical state, colour, pH, persistent foaming, solubility or suspendability, particle size, viscosity (liquids) and density. Type and test method used shall be mentioned clearly.

6. Composition of the product

Composition of active and inert in % w/w and purpose in formulation shall be clarified. Microbial active ingredient needs to be specified in relevant unit of activity. The example unit of activity for each microbial are as follows:

- Entomotoxic bacteria in endotoxin content (IU/mg or ml),
- Baculoviruses (Nuclear Polyhedrosis Virus (NPV) and Granulosis virus (GV)) in viral unit (Polyhedral Occlusion Body (POB)/capsul count/ml or mg),
- Entomopathogenic fungi and antagonistic bacteria (Colony Forming Unit (cfu)/g or ml) product.

7. Manufacturing process and quality control

The manufacturing activity shall be stated clearly;

(a) The name and address of the manufacturing plant at which the biopesticide will be produced.

(b) Flowchart of the process of manufacturing process of the biopesticide shall be submitted with the application. All raw materials used shall be stated.

8. Test procedure and criteria for identification

Test procedure and criteria for identification for each microbial shall be stated clearly. The following bioassays are preferred;

(a) Entomotoxic bacteria; immunology assays: Elisa/Dot Blot assay test or potency of product by bioassay method (LC50) on target larvae (*Trichoplusia ni*/*Helocoverpa armigera*) and potency against a reference using artificial diet or leaf disc method or in the water for mosquito larvae.

(b) Baculoviruses; biological assay for determining the LC50/LD50 of the formulation. Bioassay for Nuclear Polyhedrosis Virus (NPV) by the diet surface contamination method and Granulosis virus (GV) using bioassay against *Chilo infuscatellus*, *Plutella xylostella* or *Acheae janata*.

(c) Entomopathogenic fungi; pathogenicity test on insect and bioassay procedure for *Plutella xylostella*.

Test procedure other than above may also be used for consideration.

9. Impurities and contaminants

The formulation product should be free from biological contaminant especially human and mammalians pathogenic contaminants such as S*almonella typhi*, *Salmonella paratyphi* A, B, and C, *Salmonella sendai, Salmonella cholera-suis, Shigella dysenteriae, Escherichia coli* and *Vibrio cholerae*. Other microbial contaminants should not exceed 1 x 10^4 count/ml or g of formulation. The microbial contaminants should be determined throughout the process of production. The method used shall be mentioned and the result attached in product specification sheet.

10. Shelf life claim

Shelf life claim of biopesticide/BCA product should not less than six months. A minimum of two months storage stability data for six months claim or three months data for one year shelf life claim at ambient temperature (specify temperature and storage conditions in the study report) shall be submitted.

11. Verification report

Verification report to ensure that content of active ingredient is the same as in the composition declared. The report from own or third party independent laboratory is accepted.

B. Bioefficacy

12. Field studies

The recommended product use on local major crops (rice, oil palm, cocoa, black pepper and rubber) should obtained from local bioefficacy trials. For other crops, results obtained from trials conducted in other countries under similar climatic regimes and cultural practices may be considered. Data on phytotoxicity and data on non-target organisms (natural predators/parasites) should be included. Details on efficacy test protocol for microbial is attached in appendix I.

13. Laboratory studies

Laboratory studies reports may be accepted depending on proposed use.

C. Packaging, and Labelling

14. Packing

The type of packing material used shall be stated. The packaging should comply with Malaysian Standard (MS409:2012), code of practice for packaging and storage of pesticide or other international standard. If the packaging does not comply with the Malaysian Standard (MS409:2012), the result of a quality evaluation test shall be provided.

15. Labels and leaflets

A draft label and leaflet of the product shall be submitted for evaluation.

16. Usage and storage information

The usage and storage information of product shall be included on draft label.

D. Infectivity and Pathogenicity or Toxicity to non-target Organisms

17. Infectivity and pathogenicity or toxicity to non-target organisms data

Report on infectivity and pathogenicity or toxicity to non-target microorganism for the technical material of the microbial shall be submitted. Acute oral study and acute dermal study for formulated product shall be submitted.

E. Human Health Exposure, Environmental Fate and Effects

18. Human health exposure, environmental fate and effects data

Data on human health exposure/ environmental fate are required if any results from section A to C suggest further risk assessment. Extrapolation to human health can be done from mammalian testing if the microbial pest control agent is in any category of concern. Reports from publication journals about negative effects on human health and environmental fate are accepted. *Bacillus thuringiensis aizawai*, *Bacillus thuringiensis kurstaki*, Nuclear Polyhedrosis Virus (NPV), *Steinerma* spp. (*Neoaplectana* spp.) and *Heterorhabditis* spp., which has technical information that it is well known safe to human, plant, animal and the environment, does not require human health exposure, environmental fate and effects data.

F. Residue

19. Residue data

Residue data shall be submitted if microbes are suspected to produce any residue or metabolites of concern on food or feed items. Substances used for formulation must not produce residues of concern on food or feed items. Reports from any reliable and reputable publication journal is accepted.

DATA REQUIREMENT FOR BOTANICAL/PLANT EXTRACT

A. Biological and Chemical Characteristics

1. **Systematic name (genus and species of plant)**
   The systematic name or Latin name consist of genus and species name of the plant shall be given (example; *Pongamia glabra*, *Annona squamosa, Chrysanthemum cinerariaefolium*).

2. **Common name**
   The common name of plant shall be provided when available.

3. **Source or origin**
   The origin of the plant shall be stated included locality and growth condition.

4. **Specification of product**
   The specification of product shall conform to Malaysian Regulation, FAO or WHO requirements or FAO or WHO specifications whenever such specifications are available.

5. **Composition of the product**
   Composition of active and inert in % w/w and purpose in formulation shall be clarified. The following information is required: chemical name according to IUPAC and CAS, CAS number, structural formula and ISO name.

6. **Manufacturing process**
   The manufacturing activity shall be stated clearly and the following information must be provided;
   a. The name and address of the manufacturing plant.
   b. A description of the procedures used to assure consistency of the composition of substance produced, e.g., calibration of equipment, sampling regimens, analytical methods or other quality control methods should be stated clearly.
   c. Information on substances used in the manufacturing process (example: identity of any extraction solvent, enzymes, stabilizers such as antioxidants), and any special precautions such as control of light, humidity and temperature.
   d. Flowchart of the process of manufacturing the formulated product shall be submitted.

7. **Test procedures and criteria for identification**
   Test procedures/methods and criteria for identification of active ingredient shall be provided. Botanical or plant extract products include unpurified or partially purified extracts derived from plants including oils or other extracts. For example, natural 'pyrethrum' may consist of a chemical mixture of a number of related pyrethrins. 'Neem oil' may consist of a mixture of chemical components, some characterised and other not characterised. If the substances are identified, validated method for analysing the identified active substance shall be provided. Only identified or characterised active ingredients shall be declared on the label. If the active substances are not identified, validated method of analysis of the marker shall be provided.

8. **Impurities**

Product should be free from any impurities such as toxic metabolites apart from actives, inactive metabolites and microbial. Show in detail the process of impurities (method of removal) during manufacturing process.

9. Storage stability

Storage stability test shall be conducted in accordance with the;

a. FAO Accelerated Storage Test Procedures is performed usually at 54 ± 2 °C for 14 days or at 45 ± 2 °C for 6 weeks or at 40 ± 2 °C for 8 weeks or at 35 ± 2 °C for 12 weeks or at 30 ± 2 °C for 18 weeks when applicable.
b. Two- Year Storage Stability (Ambient testing) to demonstrate the storage stability of a formulation under true storage conditions usually over a period of 2 years. The test shall be conducted at ambient temperature or, 20 °C, 25 °C or 30 °C dependent on the final area of use.
c. The packaging used in the study shall be based upon that in which the product is sold.

10. Verification report

Verification report to ensure that content of active ingredient same as in composition declared. The report from own or third party independent laboratory is accepted.

11. Packaging and labelling

The type of packing material used shall be stated. The packaging should comply with Malaysian Standard (MS409:2012), code of practice for packaging and storage of pesticide or other international standard. If the packaging not comply with the Malaysian Standard (MS409:2012), the result of a quality evaluation test shall be provided.

B. Toxicological evaluation

12. Toxicology data

The aim of the assessment is to ensure that botanical/plant extract product do not has any harmful effects on humans or mammals. Information from studies or publications is accepted for evaluation. Toxicological data on acute oral and acute dermal are required for formulated product.

13. Environmental and ecotoxicology safety testing

Information from studies or publication on ecotoxicity is accepted for evaluation. Based on the evaluation on the available information, further ecotoxicological data may be required.

C. Efficacy

14. Field and laboratory studies

Efficacy data requirements for botanical/plant extract are similar to those for conventional agriculture products. Field study and laboratory study are accepted depend on purpose of used. Detailed on efficacy test protocol for botanical/plant extract is attached in appendix II.

D. Residue

15. Residue data

Residue studies are usually not required for botanical/plant extract. Botanical/plant extracts usually do not generate residues because they are rapidly degraded in the

environment. They are also cannot be radio-labelled for tracing purpose like synthetic pesticide. Botanical/plant extracts are also exempted from the need for maximum residue limit (MRL). The residue data will only requested on case-by-case basis if evaluation found any significant issue on toxicology, environment or non-target species.

Summary of data requirements for microbial registration

No.	Folder	A.I.	Formulation
A.	**Biological and Chemical Characteristics**		
1	Systematic name	R	
2	Strain or isolate of microbials	R	
3	Common name (if available)	R	
4	Source or origin, host range, and mode of action	R	
5	Specification of the product - physical - colour - pH - persistent foaming - suspendability - particle size - viscosity - density - test method		R
6	Composition of the product		R
7	Manufacturing process and quality control - manufacturer name and address - flowchart of manufacturing process		R
8	Test Procedure and criteria for identification	R	
9	Impurities and contaminants		R
10	Shelf life claim		R
11	Verification report		R
B.	**Bioefficacy**		
12	Field studies		R
13	Laboratory studies		R
C.	**Packaging and Labelling**		
14	Packing		R
15	Labels and leaflets		R
16	Usage and storage information		R
D.	**Infectivity and Pathogenicity or Toxicology to non-target Organisms**		
17	Infectivity and pathogenicity or toxicology to non-target organisms data - acute oral - acute dermal		R
E.	**Human Health Exposure, Environmental Fate and Effects**		
18	Human health exposure, environmental fate and effects data	CR	
F.	**Residue**		
19	Residue data	CR	

Summary of data requirements for botanical/plant extract registration

No.	Folder	A.I.	Formulation
A.	**Biological and Chemical Characteristics**		
1	Systematic name	R	
2	Common name (if available)	R	
3	Source or origin	R	
4	Specification of the product - physical - colour - pH - persistent foaming - suspendability - particle size - viscosity - density - test method		R
5	Composition of the product		R
6	Manufacturing process and quality control - manufacturer name and address - flowchart of manufacturing process		R
7	Test Procedure and criteria for identification	R	
8	Impurities		R
9	Storage stability		R
10	Verification report		R
11	Packaging and labelling		R
B.	**Toxicology Evaluation**		
12	Toxicology data - acute oral - acute dermal		R
13	Environmental and ecotoxicology safety testing		R
C.	**Efficacy**		
14	Field and laboratory study		R
D.	**Residue**		
15	Residue data	CR	

Abbreviations: R = Required CR = Conditional Required

References:

1. **FAO** (2012) Guidance for Harmonizing Pesticide Regulatory Management in Southeast Asia.

2. **GIZ** (2014) ASEAN Guidelines on the Regulation, Use, and Trade of Biological Control Agents (BCA).

Appendix I

EFFICACY TEST PROTOCOL

MICROBIAL

1.0 EXPERIMENTAL CONDITIONS

1.1 Selection of Crop and Cultivar, Test Organisms

This test protocol is concerned with the efficacy evaluation of microbial pest control agents for the control of (common name /scientific name of insect-pest/plant pathogen) in (common name /scientific name of crop).

The selection of crop, cultivar and test insects/plant pathogen must be relevant to the (proposed) label/leaflet claims. (Specify objective of the trial and basic information on the trial site like scientific name of the pest and crop, type of trial, environment of trial like field, glasshouse, etc. Any other relevant information)

1.2 Trial Conditions

Trials should be conducted only on crops with a known history of uniform high infestation/infection of the target insect-pest(s)/disease(s) (usage of chemical pesticides). Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials for the relevant pest or disease should be carried out in different locations with distinct environmental conditions over an entire growing period of the crop (e.g. about 2 trials in 2 locations or seasons). The timing, amount and method of irrigation, if applied, should be recorded.

Trials can be done under semi-field conditions (e.g. outdoor, but protected environment or cages) or involving larger scales in farmers' fields. Generally, highly mobile pests require larger scales than less mobile pests.

The relevant conditions of the plot and crop should be adequately described like sowing or planting date, row spacing, cultivation measures, crop condition and pest/diseases densities etc.

1.3 Design and Layout of the Trial

1.3.1 Treatments

Test product(s), and untreated control are to be arranged in a randomized block design or any other statistically suitable design. (Describe design and layout of the plots like type of experimental design, number, size and shape of plots. Any additional remarks)

In the case of on-farm trials, it is recommended to include a negative control, farmers'practice and the microbial product under question.

1.3.2 Plot Size and Replication

Net plot size: Use an optimum plot size (e.g. 15-20 sq.m.); however this will depend on the type of crop/ pest and disease /product under study and location of trial. Highly mobile pests might require larger plot sizes for evaluation (e.g. 60-80 sp.m. or larger).

For perennial trees: Net plot size: 2 trees/plot for big trees and 4 trees /plot for small trees.

Depending on type of the plants/cultivar used; mobility of the test organism, technique of application, type of formulation or application equipment; it may be necessary to take a larger plot size than net plot size or guard or buffer rows /strips are needed to take in to account pest dispersal and possible drift of pesticides.

Replications: should be 4 per treatment (provided the error or residual degrees of freedom are at least 12). More replications are recommended, in particular, if one wants to account for an expected higher variability of the negative control plots which might show higher pest/disease pressures and crop damage.

2.0 APPLICATION OF TREATMENTS

2.1 Test Products (s)

The product (s) under investigation should be the named formulated product(s).

2.2 Mode of Application

All Applications should comply with good experimental practices.

2.2.1 Method of Application

The method of application (e.g. spray, broadcast, soil application, etc.) will normally be specified on the (proposed) label/leaflet.

Different microbial products show different modes of action and require different environmental conditions. Accordingly, there exist specific recommendations for application. A selection of examples is listed in the Annex of this protocol.

2.2.2 Type of Equipment Used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 %. Other application techniques different to spraying also need proper description.

Precaution should be taken to avoid drift between plots where relevant by holding a screen around the plot being treated.

2.2.3 Time and Frequency of Application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. (Additional general information on factors influencing time and frequency of application like growth stage of the crop, threshold levels or development stage of pest or infestation level).

As specified in the Annex, many microbials should be used in a preventative manner rather than curative; that means these products are applied when pest/disease incidence is in the lower range and insect stages are young for instance. Different modes of action when compared with synthetic pesticides usually result in a longer reaction time between application and the observation of visible effects. Thus, proper timing of application is crucial for success.

2.2.4 Doses and Volumes Used

The product should be tested at a dose range that accommodates for environmental and target pest variability. The recommended application dose would be recommended based on the results ogf the official field testing.. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (lit/ha) should also be given. The spray volume (lit/ha) will be appropriate to the stage of the crop. (Add something on soil)

3.0 MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1 Characterization of the location

Characteristics of the location are presented here, including coordinates, elevation, climatic zone, etc.

3.2 Type, Time and Frequency of Assessment

3.2.1 Type

Type of assessment depends on the type of the insect-pest(s)/disease(s) under investigation but normally by number of insects on selected plants in the trial or by percentage of damage/percent infection (damage) per unit area of plant parts on selected plants in the trial

3.2.2 Time and Frequency

Microbial pesticides assessments are adjusted to the mode of action of the product under question, the type of pots, and the biology of the pest population. Because microbials show also long-term effects, it is recommended to observe during a whole cropping season.

3.3 Direct Effects on the Crop

The crop should be examined for presence or absence of phytotoxic effects. The type and extent of these effects should be recorded like (include major symptoms of pesticides phytotoxicity on crops as defined in FAO guidelines for phytotoxicity assessment in protocol FAO/AP/027). In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

3.4 Quantitative and /or Qualitative Recording of Yield

If the proposed label claims an effect on yield then yield should be included in the field evaluation of the product. Quantitative and/or qualitative yield should be recorded where relevant in each treatment and should preferably be converted in to kg/ha for statistical comparison.

4.0 RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions).

5.0 REFERENCES

- Lace L.A. & Kaya H.K., eds. (2007) Field Manual of Techniques in Invertebrate Pathology. Application and Evaluation of pathogens for control of insects and other invertebrate pests. Springer, Dordrecht, Netherlands
- Caldwell, B. et al. (2013) Resource Guide for Organic Insect and Disease Management. Cornell University.

ANNEX

Microbial products show different modes of action and require different environmental conditions compared with synthetic pesticides. General application guidelines that contain many practical tips and include notes on the safety and the effectiveness of various microbials can be found in Caldwell et al. 2013:

Freely available under: http://web.pppmb.cals.cornell.edu/resourceguide/pdf/resource-guide-for-organic-insect-and-disease-management.pdf

Appendix II

EFFICACY TEST PROTOCOL

BOTANICAL

1.0 EXPERIMENTAL CONDITIONS

1.1 Selection of Crop and Cultivar, Test Organisms

This test protocol is concerned with the efficacy evaluation of botanical pest control agents for the control of (common name /scientific name of insect-pest/plant pathogen) in (common name /scientific name of crop).

The selection of crop, cultivar and test insects/plant pathogen must be relevant to the (proposed) label/leaflet claims. (Specify objective of the trial and basic information on the trial site like scientific name of the pest and crop, type of trial, environment of trial like field, glasshouse, etc. Any other relevant information)

1.2 Trial Conditions

Trials should be conducted only on crops with a known history of uniform high infestation/infection of the target insect-pest(s)/disease(s) (usage of chemical pesticides). Cultural conditions (e.g. soil type and pH, fertilizers, tillage, row and plant spacing, etc.) should be uniform for all the plots of the trial and should conform to local agricultural practices. A series of trials for the relevant pest or disease should be carried out in different locations with distinct environmental conditions over an entire growing period of the crop (e.g. about 2 trials in 2 locations or seasons). The timing, amount and method of irrigation, if applied, should be recorded.

Trials can be done under semi-field conditions or involving larger scales in farmers' fields (depends on BCA under evaluation and purpose/claim of product).

The relevant conditions of the plot and crop should be adequately described like sowing or planting date, row spacing, cultivation measures, crop condition and pest/diseases densities etc.

1.3 Design and Layout of the Trial

1.3.1 Treatments

Test product(s), and untreated control are to be arranged in a randomized block design or any other statistically suitable design. (Describe design and layout of the plots like type of experimental design, number, size and shape of plots. Any additional remarks)

In the case of on-farm trials, it is recommended to include an untreated control, farmers'practice (preferred over chemical standard) and the botanical product under question. In all cases the length of the observation time should be appropriate for the botanical under consideration. Pest or disease levels should be considered together with achieving an economic benefit to the user.

1.3.2 Plot Size and Replication

Net plot size: Use an optimum plot size (e.g. 15-20 sq.m.); however this will depend on the type of crop/ pest and disease /product under study and location of trial. Highly mobile pests might require larger plot sizes for evaluation (e.g. 60-80 sp.m. or larger).

For perennial trees: Net plot size: 2 trees/plot for big trees and 4 trees /plot for small trees.

Depending on type of the plants/cultivar used; mobility of the test organism, technique of application, type of formulation or application equipment; it may be necessary to take a larger plot size than net plot size or guard or buffer rows /strips are needed to take in to account pest dispersal and possible drift of pesticides.

Replications: should be 4 per treatment (provided the error or residual degrees of freedom are at least 12). More replications are recommended, in particular, if one wants to account for an expected higher variability of the negative control plots which might show higher pest/disease pressures and crop damage.

2.0 APPLICATION OF TREATMENTS

2.1 Test Products (s)

The product (s) under investigation should be the named formulated product(s).

2.2 Mode of Application

All Applications should comply with good experimental practices.

2.2.1 Method of Application

The method of application (e.g. spray, broadcast, soil application, etc.) will normally be specified on the (proposed) label/leaflet.

Different botanical products show different modes of action and require different environmental conditions. Accordingly, there exist specific recommendations for application. A selection of examples is listed in the Annex of this protocol.

2.2.2 Type of Equipment Used

The application equipment used should be a type in current use, properly calibrated to give intended application rate and droplet spectrum in case of sprays. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10 %. Other application techniques different to spraying also need proper description. It is important to optimize volume application rates, especially when treating foliage.

Precaution should be taken to avoid drift between plots where relevant by holding a screen around the plot being treated.

2.2.3 Time and Frequency of Application

The time and frequency of application will normally be specified on the (proposed) label/leaflet. The number of applications and the date of each application should be recorded. (Additional general information on factors influencing time and frequency of application like growth stage of the crop, threshold levels or development stage of pest or infestation level).

2.2.4 Doses and Volumes Used

The product should be tested at a dose range that accommodates for environmental and target pest variability. The recommended application dose would be recommended based on the results of the official field testing.. The spray volume should be uniform for all the plots and should be used as per recommendations on the label/leaflet. For sprays, data on concentration (%) and volume (litre/ha) should also be given. The spray volume (litre/ha) will be appropriate to the stage of the crop.

3.0 MODE OF ASSESSMENT, RECORDING AND MEASUREMENTS

3.1 Characterization of the location

Characteristics of the location are presented here, including coordinates, elevation, climatic zone, etc.

3.2 Type, Time and Frequency of Assessment

3.2.1 Type

Type of assessment depends on the type of the insect-pest(s)/disease(s) under investigation but normally by number of insects on selected plants in the trial (caged?) or by percentage of damage/percent infection (damage) per unit area of plant parts on selected plants in the trial

3.2.2 Time and Frequency

Botanical pesticides assessments are adjusted to the mode of action of the product under question, the type of pots, and the biology of the pest population. Because botanicals show also long-term effects, it might be considered to observe during a whole cropping season.

3.3 Direct Effects on the Crop

The crop should be examined for presence or absence of phytotoxic effects. The type and extent of these effects should be recorded like (include major symptoms of pesticides phytotoxicity on crops as defined in FAO guidelines for phytotoxicity assessment in protocol FAO/AP/027). In addition, any positive effects (phytotonic) of test product on crop growth and yield should also be noted.

3.4 Quantitative and /or Qualitative Recording of Yield

If the proposed label claims an effect on yield then yield should be included in the field evaluation of the product. Quantitative and/or qualitative yield should be recorded where relevant in each treatment and should preferably be converted in to kg/ha for statistical comparison.

4.0 RESULTS (REPORTING)

The results should be reported in a systematic form and the report should include an analysis and evaluation. The report of the trial should include a biological dossier containing the individual efficacy trial reports or their summaries and record keeping and reporting of individual trials (field note book, trial report including objective of the trial, organizational aspects, methodology, results, discussions and conclusions).

5.0 REFERENCES

Caldwell et al. (2013) Resource guide for organic insect and disease management. Cornell University, New York.

ANNEX

Botanical pesticides show different modes of action and require different environmental conditions compared with synthetic pesticides. General application guidelines that contain many practical tips and include notes on the safety and the effectiveness of various botanicals can be found in Caldwell et al. 2013. Products like neem, pyrethrum, and rotenone are covered in depth. Additionally, useful categories for efficacy evaluation of botanicals are proposed and extensive target pest lists are presented:

Freely available under: http://web.pppmb.cals.cornell.edu/resourceguide/pdf/resource-guide-for-organic-insect-and-disease-management.pdf