GARIS PANDUAN PENDAFTARAN BIOPESTICIDES

15 OGOS 2017

RUJUKAN

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).

- Minimum data requirement
- Agriculture used

KATEGORI BIOPESTICIDES

1. MICRO-ORGANISMS / MICROBIALS
2. MACRO-ORGANISMS
3. SEMIOCHEMICALS
4. BOTANICALS / PLANT EXTRACT

KEPERLUAN DATA UNTUK PENDAFTARAN MIKROORGANISMA/MIKROBIAL

A. SIFAT-SIFAT BIOLOGI DAN KIMIA

1. **Nama saintifik:** genus and species names
2. **Strain or isolate**
3. **Nama biasa**
4. **asal, perumah dan cara tindakan**

   source/origin: country, GPS coordinate, nama dan alamat pembekal

   host range: target pest, life cycle

   cara tindakan: non-toxic mechanism, infection of target, antagonistic behaviour

   etc

5. **Spesifikasi keluaran:** appearance (physical state, colour, pH), persistent foaming, wettability, solubility or suspendability, wet sieve and dry sieve, particle size, viscosity (liquids) and density. (Product specification sheet). Type and test method in detail.

   Nyatakan mana-mana spesifikasi yang dipenuhi.

6. **Komposisi keluaran:** active and inert in % w/w, relevant unit of activity.

7. Proses pengilangan dan kawalan kualiti:

(a) name and address of the manufacturing plant, (b) Process of manufacturing and flowchart.

8. Test procedure and criteria for identification:

a) morphological characteristics, b) cultural characteristics, c) Analytical methods for identification and characterisation of microbial

9. Bendasing dan pencemaran: bebas dari pencemaran biologi terutama pathogenic kepada manusia dan mamalia. (*Salmonela typhi*, *Escherichia coli*, *Vibrio cholera*)

DATA REQUIREMENTS FOR MICROBIAL REGISTRATION

10. Shelf life claim: ujian kestabilan yang sebenar dalam pembungkusan komersil pada suhu bilik (27 – 35 degree C) atau accelerated temperature stability.

11. Verification report: report from own or third party independent laboratory. Method of analysis of active ingredient content in the formulation.

DATA REQUIREMENTS FOR MICROBIAL REGISTRATION

B. BIOEFFICACY

12. Kajian lapangan: local major crops (rice, oil palm, rubber and cocoa) obtained from local bioefficacy trials.
13. Kajian makmal: depending on proposed use.

DATA REQUIREMENTS FOR MICROBIAL REGISTRATION

C. PACKAGING, AND LABELLING

14. Packing: comply with Malaysian Standard (MS409:2012), code of practice for packaging and storage of pesticide or other international standard.

15. Labels and leaflets

16. Usage and storage information

DATA REQUIREMENTS FOR MICROBIAL REGISTRATION

D. TOXICITY TO NON-TARGET ORGANISMS

17. Acute oral study and acute dermal study for formulated product

- **Human Health Exposure, Environmental Fate and Effects**

18. Human health exposure, environmental fate and effects data: section A to C suggest further risk assessment

E. RESIDUE

19. Residue data: if suspected to produce any residue or metabolites

DATA REQUIREMENT FOR BOTANICAL/PLANT EXTRACT

A. BIOLOGICAL AND CHEMICAL CHARACTERISTICS

1. Systematic name (genus and species of plant)
2. Common name
3. Source or origin ; nama dan alamat pengilang
4. **Specification of product:** Malaysian Regulation, FAO or WHO requirements
5. **Composition of the product**: active and inert in % w/w, chemical name according to IUPAC and CAS, CAS number, structural formula and ISO name

DATA REQUIREMENT FOR BOTANICAL/PLANT EXTRACT

6. **Manufacturing process:** name and address of the manufacturing plant, Information on substances used in the manufacturing process, Flowchart of the process of manufacturing

7. Test procedures and criteria for identification: Test procedures/methods and criteria for identification of active ingredient shall be provided

8. Impurities: process of impurities

DATA REQUIREMENT FOR BOTANICAL/PLANT EXTRACT

9. Storage stability: 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

10. Verification report/ sample for verification: report from own or third party independent laboratory

11. Packaging and labelling: comply with Malaysian Standard (MS409:2012), other international standard.

DATA REQUIREMENT FOR BOTANICAL/PLANT EXTRACT

B. TOXICOLOGICAL EVALUATION

12. Toxicology data: acute oral and acute dermal.

13. Environmental and ecotoxicology safety testing

C. EFFICACY

14. Field and laboratory studies

DATA REQUIREMENT FOR BOTANICAL/PLANT EXTRACT

D. RESIDUE

Residue studies are usually not required for botanical/plant extract