**FORM: RP/2D (1st revised version 27.08.2021)**

**Checklist for Evaluation of Bio-pesticides[1] of Foreign Origin (To be filled by the proposer of the product and submitted together with a brief summary of Information/Material Data Sheet/ Proposal/ Product Brochure for evaluation)**

**Name of the company/person: ……**

**Name of the product**: ……

| CRITERIA | | SUPPORTED BY DOCUMENTARY EVIDENCE/ AVAILABLE[2] | |
|---|---|---|---|
| **1. Product authority** | | **YES** | **NO** |
| **1.1.Registration status in the country of origin** | **(i) Indigenous use** | ☐ | ☐ |
| | **(ii) Export only** | ☐ | ☐ |
| **1.2.Registration status in a foreign country** | | ☐ | ☐ |
| **1.3.Documents such as registration certificates/Certifications on organic farming** | | ☐ | ☐ |
| **1.4.Certificate of manufacturing license if issued or any other approval under any government regulation to support that applicant is a manufacturer/actual producer** | | ☐ | ☐ |
| **1.5.Certificate from manufacturer that the importer is an authorized dealer/ trader of the manufacturer** | | ☐ | ☐ |
| **2. Product parameters** | | | |
| **2.1.Process of manufacture** | | ☐ | ☐ |
| **2.2.Information about raw materials/ ingredients used** | | ☐ | ☐ |
| **2.3.Source(s) of supply raw materials/ ingredients** | | ☐ | ☐ |
| **2.4.Step-wise manufacturing process** | | ☐ | ☐ |
| **2.5.Identity of the origin and natural occurrence (in case of microbial products)** | | ☐ | ☐ |

[1] Bio-pesticides include microorganisms (including viruses), extracts from natural plant materials (i.e. botanicals), or semiochemicals as active ingredient, except pheromones (but includes repellents), but exclude genetically modified organisms and chemically-derived analogues of plant extracts (which are mimics, natural-identical synthesized molecules and biosimilars)

[2] Detailed and authenticated reports are required to be submitted at the time of application for registration.

| | | |
|---|---|---|
| **2.6.Specification of the material(s) used for manufacture of formulated product** | ☐ | ☐ |
| **3. Product identification** | | |
| **3.1.Product category: Insecticide/Fungicide/ Nematicide/Herbicide etc.** | ☐ | ☐ |
| **3.2.Intended use: Crops/Pests** | ☐ | ☐ |
| **3.3.Proposed application rate for each crop/pest with frequency of application, application interval, time of application, method(s) of application and application equipment** | ☐ | ☐ |
| **3.4.Crop residue data & Pre-harvest interval(s)** | ☐ | ☐ |
| **3.5.Chemical or biological composition (scientific name, species description, strain characterization in case of microbial products)** | ☐ | ☐ |
| **3.6.Minimum content of active ingredients/micro-organisms (e.g. gram or CFU or spores per volume or weight, etc.)** | ☐ | ☐ |
| **3.7.Chemical or biological identity of technical material** | ☐ | ☐ |
| **3.8.Physico-chemical properties of adjuvant(s)** | ☐ | ☐ |
| **3.9.Method of analysis (test procedure & criteria used for identification, e.g. DNA/RNA sequencing etc. in case of micro-organisms)** | ☐ | ☐ |
| **3.10.Five-batch analytical test report for five representative batches/practical production batches** | ☐ | ☐ |
| **3.11.Identification & quantification of identifiable impurities, additives (chemical or biological contaminants, mutants, etc.)** | ☐ | ☐ |
| **3.12.Shelf-life claim** | ☐ | ☐ |
| **3.13.Shelf-life data** | ☐ | ☐ |
| **3.14.Establishment of chemical or biological equivalence/proof of technical grade active ingredients for identical strain or isolate** | ☐ | ☐ |
| **4. Fate and behavior in the environment** | | |
| **4.1.Potential dispersal routes of the micro-organism** | ☐ | ☐ |
| **4.2.Persistence (e.g. soil, water, air, harvest, etc.) & sensitivity to environmental conditions (UV, temperature, pH, Humidity etc.)** | ☐ | ☐ |

| | | |
|---|---|---|
| **4.3.Relationship to known plant, animal or human pathogen** | ☐ | ☐ |
| **4.4.Genetic stability data** | ☐ | ☐ |
| **4.5.Harmful microbial metabolites** | ☐ | ☐ |
| **5. Effects on non-target organisms** | | |
| **5.1.Acute toxicity (oral, dermal, inhalation, eye irritation, skin irritation, skin sensitization)** | ☐ | ☐ |
| **5.2.Pathogenicity & infectivity (e.g. cell culture study)** | ☐ | ☐ |
| **5.3.Chronic/Sub-chronic toxicity (neuro-behavioural toxicity, reproductive toxicity, carcinogenicity, mutagenicity, genotoxicity, teratogenicity etc.)** | ☐ | ☐ |
| **5.4.Bee toxicity (oral, contact)** | ☐ | ☐ |
| **5.5.Earthworm toxicity** | ☐ | ☐ |
| **5.6.Fish toxicity** | ☐ | ☐ |
| **5.7.Bird toxicity** | ☐ | ☐ |
| **5.8.Silk worm toxicity** | ☐ | ☐ |
| **6. General declarations** | | |
| **6.1.Declaration that product does not contain any genetically modified organism** | ☐ | ☐ |
| **6.2.Declaration that product is totally natural origin and free from synthetic pesticides** | ☐ | ☐ |

**Applicant's declaration:**

I, the undersigned, Prof./Mr./Ms./Dr. ……., working in the company/firm ……, having office at ……(address), do hereby declare that the product status submitted in the above checklist are genuine and correct, and are based on factual documents on product development, and if any of the information are found to be false in any material particulars, the applicant shall be liable for legal & administrative consequences, in accordance with the provisions of the Control of Pesticides Act No. 33 of 1980. I hereby further declare that upon acceptance of the product for submission of the application for registration after due recommendation, I shall abide by submission of required documents/detailed reports as per the checklist for further verifications/assessments.

Name: Date:

Signature: Seal of the Company/Firm/Person

**This space for comments by sub-committee:**

Committee No. . . . . Date: . . . . . .

1.

2.

3.

**Office use only:**

Application No.: …… Date of receipt: …… Date stamp: