agriculture

Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

# GUIDELINES ON THE DATA AND DOCUMENTS REQUIRED FOR THE REGISTRATION OF MACROBIAL REMEDIES IN SOUTH AFRICA

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## 1. INTRODUCTION

The National Department of Agriculture (NDA) regulates agricultural remedies through Act No. 36 of 1947, the “Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947” [(1)].

An 'agricultural remedy' is defined in the Act as “…any chemical substance or biological remedy, or any mixture or combination of any substance or remedy intended or offered to be used-

(a) for the destruction, control, repelling, attraction or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof, but excluding any chemical substance, biological remedy or other remedy in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), or the Hazardous Substances Act, 1973 (Act 15 of 1973); or

(b) as plant growth regulator, defoliant, desiccant or legume inoculant,

and anything else which the Minister has by notice in the Gazette declared an agricultural remedy for the purposes of this Act” [(2)].

In terms of section 3(1) of Act 36 of 1947 an application to register or amend agricultural remedies must be submitted to the Registrar of Act 36 of 1947. The information to accompany the application are set out in the Regulations Relating to Agricultural Remedies [(3)].

The purpose of this document is to outline and provide guidance on the information to accompany applications of macro-organisms or “macrobial” type agricultural remedies, defined as living, multi-celled structures which are larger than 0.1mm in size. In terms of biological control, these organisms typically belong to the classes Insecta, Nematoda or Arachnida (e.g. Mites) and are useful components of IPM. These are agricultural remedies otherwise known as invertebrate biological control agents (IBCAs) [(5)] and exclude micro-organisms defined as living or non-living structures which are made up of single or multiple cells that are smaller than 0.1mm in size (e.g. virus, bacteria, protozoa, algae and fungi).

This guideline is intended to be complementary and does not replace Act 36 of 1947, or the regulations promulgated thereunder. The latest regulations and any applicable published guidelines should be consulted, as they become available, for any changes or other information which may be required by the Registrar of Act 36 of 1947 [(3)].

This guideline replaces the general and specific registration requirements in the “Guidelines on the data required for registration of biological/biopesticides remedies in South Africa”, June 2015, under Section 3 for macro-organisms only, and section 4.2 (Macro-organisms) [(4)].

This document is effective as from the date of publication on the NDA website.

## 2. DEFINITIONS

**"Augmentative releases"** means either inundative or seasonal inoculative releases, i.e. those forms of biological control where mass-produced, biological control agents are released to reduce a pest population without necessarily leading to continuing impact or establishment of the IBCAs.

"**Biological remedy**", "**bioproducts**", "**biological products**" and "**biopesticides**" means any biological remedy, or any mixture or combination of any substance or remedy intended or offered to be used for the destruction, control, repelling, attraction or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof, but excluding any biological remedy in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), or the Hazardous Substances Act, 1973 (Act 15 of 1973) (Agricultural remedy as defined in Act 36 of 1947).

**"Biological control (biocontrol)"** in the context of this document means a pest management strategy making use of living natural enemies, pathogens, antagonists or competitors and other self-replicating biotic entities.

**"Bioprospecting"** means the exploration of biodiversity for commercially valuable genetic resources and biochemicals, as regulated under the National Environmental Management: Biodiversity Act (Act No. 10 of 2004) and the Bioprospecting, Access and Benefit Sharing Regulations of 2008.

"**Globally Harmonized System (GHS)**" means the Globally Harmonized System of classification and labelling of chemicals, a guidance document developed by the United Nations for standardising and harmonising the classification and labelling of chemicals globally, as may be updated from time to time, commonly known as the UN Purple Book.

"**Integrated Pest Management (IPM)**" means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keeps agricultural remedies and other interventions to levels that are economically justified and reduce or minimise risks to human and animal health and/or the environment.

**"Inundative release"** means the release of very large numbers of a mass-produced biological control agent with the expectation of achieving a rapid reduction of a pest population without necessarily achieving continuing impact or establishment of the IBCA.

**"Invertebrate Biological Control Agents (IBCAs)"** are macro-organisms used for the purpose of Biological Control.

"**Macro-organisms**", "macrobials" and/or "macrobes" are living, multi-celled structures which are larger than 0.1mm in size. In terms of biological control, these organisms typically belong to the classes Insecta, Nematoda or Arachnida (e.g. Mites).

"**Macrobial pest control**" refers to the method of controlling pest organisms through the augmentative and inundative release of beneficial macro-organisms and/or sterile insects

(used SIT) in or around an agriculture production area in order to suppress pest populations, reduce damages to crops and improve crop yields.

**“Macrobial product”** refers to the offered agricultural remedy which contains the macro-organism active, plus any co-formulants, as presented in its final packaging.

**“Mass release”** is the single and/or repeated release (e.g. augmentative) of large numbers of macro-organisms for the purpose of pest management.

**“Naturalised”** means organisms that have become established in an area outside of their native range.

“**Pest Risk Analysis (PRA)**” is conducted by the regulatory Directorate Plant Health authority to identify the appropriate phytosanitary measures required to protect plant resources from new or emerging pests and regulated plants or plant products. Specifically, pest risk analysis is defined in the Plant Health (Phytosanitary) Act (Act No. 35 of 2004) as “the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated, and the strength and phytosanitary measures to be taken against it”.

“**Plant pest**” or “**Pest**”, in a phytosanitary context refers to any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products and includes plant pathogenic bacteria, fungi, fungus-like organisms, virus type organisms, as well as insects, mites, nematodes and weeds.

**“Rearing”** refers to the production of macro-organisms.

**“Sterile Insect Technique (SIT)”** refers to the management of a pest insect population by mass releases of sterilised individuals of the same species as that of the pest. Sterilisation can be achieved by Gamma Irradiation, X-ray technology or other methods.

## 3. REQUIREMENTS FOR THE REGISTRATION OF MACROBIAL PRODUCTS

An application shall be accompanied by:

3.1. Proof of payment of the applicable prescribed application fee.

3.2. Completed service request form.

3.3. Checklist demonstrating that the dossier provided is complete.

3.4. A cover letter outlining the purpose of the application.

3.5. "Application for the Registration of an Agricultural Remedy" form, obtainable from the NDA website nda.gov.za, fully completed.

- The Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II) where relevant. However, all information relevant to a macro-organism, as listed under point 3.7, must be provided in the dossier, along with an index to where in the dossier this information can be obtained.

3.6. Letter of access and supply for the macro-organism from the manufacturer (e.g. such as from a rearing facility or insectary) and for the macrobial product from the formulator (e.g. may be the same facility as the manufacturer) to the applicant.

3.7. Biological properties related to the macro-organisms including: i) class, ii) genus and species name, iii) common name(s), iv) geographic distribution, v) origin or source of organisms (where it was originally collected from), vi) confirmation of identity according to latest and scientifically sound techniques **such as** morphological and/or molecular vii) description of the mode of action, site of infection and entry into host if applicable, viii) any known metabolites i.e. primary/secondary and ix) registration status or exemption of registration requirements of organisms (e.g. in other countries).

- Should there be a reclassification of the species name of a registered macrobial product, the new identification should be communicated to Act 36 through an Administrative Minor Change as defined in the regulations relating to agricultural remedies with supporting scientific information such as a formal taxonomic reports or peer reviewed publication(s).

3.8. A document showing proof of deposition of the macro-organism with a South African national collection with voucher/specimen number.

- In the case of entomopathogenic nematodes (EPNs), if no local deposition within a national collection is possible due to lack of infrastructure, an international deposition voucher number or university deposition will suffice.

3.9. Information on the production or rearing process as well as quality control procedures to ensure product purity is maintained and contamination prevented. (IOBC Guidelines "Quality control and production of biological controls" are available for certain species).

3.10. Information on any genetic modification apart from traditional breeding. (See Annexure 1 for the decision flowchart covering points 3.7, 3.8 and 3.10.)

3.11. History of the organism and its uses/pest(s) against which it will be released (target). (See Annexure 5 for the history-of-use and efficacy decision flowchart, which also covers points 3.14 and 3.15.)

3.12. Bioprospecting permits from Department of Forestry, Fisheries and the Environment (DFFE), and import and/or mass release permits issued by the Directorate Plant Health, where relevant. (See Annexure 2 for the permits decision tree and Annexure 3 for the bioprospecting and Nagoya Protocol compliance flowchart. Both cover point 3.12.)

- Proof of adherence to relevant bioprospecting legislation and the Nagoya protocol. If the organism is to be sourced from another country, the country of origin must be declared. All valid permits must be submitted; this could include import documentation including customs and excise documents and import permits for trials from Plant Heath Directorate.
- Macro-organisms that are indigenous to, or considered naturalised in South Africa and are reared within the borders of South Africa do not require import permits or mass release permits.
- Macro-organisms that are indigenous to, or considered naturalised in South Africa and reared outside of the borders of South Africa require import permits but are exempt from mass release permits.
- Macro-organisms that are not considered naturalised and non-indigenous to South Africa;

  - when reared within the borders of South Africa require manufacture permits (if applicable) and mass release permits (which may require a PRA by Directorate Plant Health)
  - when reared outside of South Africa require import permits and mass release permits.

3.13. Risk assessment report in the format of a literature review signed off by a SACNASP registered individual. The literature review should include relevant aspects on the known environmental effects and non-target effects (including bees and other pollinators) must accompany the application. This may be substantiated with scientific peer reviewed literature. Any known scientific published information or reports to show that the product is not harmful to humans and the environment must be submitted. Any known risks to non-target organisms must be submitted. Risk assessment should also extend to the production methodology used during rearing or manufacture.

- In the absence of published data, expert opinion or extrapolation from related species may be submitted with justification (See Annexure 4 for the risk assessment decision checklist covering point 3.13.).

3.14. Macro-organism type products including SIT will require no specific efficacy data when claims are made within the known scientific scope of the organism's abilities from scientific peer reviewed literature. A detailed summary of the scientific peer reviewed literature supporting each claim (thus, each crop group and/or target pest scenario) must be submitted with full copies of the cited literature included and indexed in an appropriate

manner (See Annexure 5 for the history-of-use and efficacy decision flowchart, which also covers points 3.14 and 3.15.).

- If claims outside of this scientific scope are to be made, efficacy data will be required and must adhere to efficacy data requirements as specified in the "Guidelines on the data required for registration of biological/biopesticides remedies in South Africa" [(4)]. Efficacy studies should be considered according to Codex Commodity Crop Groupings and conducted according to GEP [(3)].

3.15. Macro-organisms will not be required to generate residue data, propose a Maximum Residue Limit (MRL) or present phytotoxicity data (as they do not produce residues nor cause phytotoxic symptoms). Refer to the latest regulations and "Guidelines on requirements for residues arising from the use of biological remedies in South Africa".

3.16. 5-Batch Analysis must be from five distinct production batches and signed off by a suitable qualified SACNASP registered individual. It is not required to conduct the 5-batch Analysis for macro-organisms under OECD GLP accreditation. However, the minimum parameters should be determined as per the table below and meet the evaluation targets/specifications as outlined in information provided to address point 3.9. The results of the 5-batch can be presented as a certificate(s) of analysis.

| **Minimum parameters evaluated per production batch** | **Description** | **Unit/Method** | **Evaluation target** |
|---|---|---|---|
| **1. Viability** | Proportion of live individuals post-packaging | % live organisms | As per production and quality details provided in point 3.9 |
| **2. Morphological integrity** | Percent of individuals free from deformities | Visual inspection / % intact bodies | |
| **3. Developmental stage uniformity** | Consistency of instar/age or maturity stage | % in target stage | |
| **4. Contaminant presence (for EPNs only)** | Presence of biotic contaminants (such as bacteria) | Microscopy / presence-absence & Total Plate Count (TPC) of colony forming units (CFUs)* | |
| **5. Longevity of Macro-organism** | Survival rate after standard storage duration | % survival after X days | |

* The formulation should not exceed contaminants ≥ 100,000 cfu/g or ml/or not exceed limits set by the Department of Health.

3.17. Shelf-life study of the macrobial product signed off by a suitable qualified SACNASP registered individual. The Shelf-life study does not need to be conducted under OECD GLP accreditation. The shelf-life should be determined using the representative product container or packaging including co-formulants and correlate with any label claims being made. Any material or structural design changes of the container or packaging (e.g. changing from a foil pouch to a plastic bottle) will require a new set of storage life data. The method used to determine shelf life must be described in detail in the test report.

- Should an applicant wish to apply for an extended shelf life for a product, this must be accompanied by supporting data. For EPNs, the formulation should not exceed contaminants ≥ 100,000 cfu/g or ml/or not exceed limits set by the Department of Health at the final time point of the proposed shelf life.

3.18. If co-formulants are part of the macrobial product, they should be described by providing the name of each co-formulant, CAS registry number (if available), content, and purpose in the macrobial product.

3.19. Label of the product which conform to the latest "Regulations relating to Agricultural Remedies" and complies with any published label guidance documents under Act 36 of 1947. Notable stipulations are provided below for macrobial products.

The main panel of agricultural remedy shall show the following information:

- If the active ingredient of the product is a macro-organism, it must be identified by genus and species (and if appropriate, also by subspecies and/or isolate/strain).

- Content must be expressed as macrobial units per container as indicated in the table below per macrobial type:

| **Macrobial type** | **Macrobial unit** |
|---|---|
| Entomopathogenic nematodes | Infective juveniles (IJs) |
| Parasitoid wasps | Parasitised eggs or mummies |
| Predatory mites | Adults/larvae |
| Predatory insects | Adults/larvae |

- If product label indicates aerial application, include an aerial risk assessment report in line with the latest regulations and guidelines referring to agricultural remedies.

3.20. Formulation toxicity calculated according to GHS and a signed declaration that the GHS calculations have been done by a qualified individual and that the applicant agrees to amend the classifications or safety information if it is found to be inaccurate. If there no chemicals in the formulation but only insects, the GHS classification is not a requirement and the product, or insects cannot be classified.

3.21. A compliant safety data sheet (SDS) for the macrobial product, including the full contact details of the manufacturer. (See Annexure 10 for the labelling compliance checklist covering points 3.19–3.21.)

3.22. Signed declaration that the agricultural remedy does not contain active ingredient(s) and/or co-formulant(s) or biological organisms regarded as substances of concern and that no new scientific evidence is available on the agricultural remedy's potential health effects for vulnerable groups, especially children.

## 4. REFERENCES AND LIST OF REGULATORY DOCUMENTS


(1) Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947). Department of Agriculture, Land Reform and Rural Development, South Africa. 1947 (Gov. Gazette, 18 June 1947, No. 3834).

(2) Fertilizers, farm feeds, agricultural remedies and stock remedies amendment act. 1977 (Gov. Gazette, 23 March 1977, No. 5461).

(3) Regulations relating to agricultural remedies. 2023 (Gov. Gazette, 25 August 2023, No. 49189).

(4) Guidelines on the data required for registration of biological/biopesticides remedies in South Africa. June 2015 (Registrar, Act No. 36 of 1947).

(5) OECD (2004), Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs), Series on Pesticides and Biocides, OECD Publishing, Paris.

(6) Plant Health (Phytosanitary) Act, 2024 (Act No. 35 of 2024). Department of Agriculture, Land Reform and Rural Development, South Africa. 2024 (Gov. Gazette, 20 December 2024, No. 51806).

## 5. IMPORT REQUIREMENTS OF UNREGISTERED MACROBIAL PRODUCTS

This import permit under Act 36 of 1947, is issued for the import of unregistered biological remedies or biological fertilizers for use in efficacy/residue trials for registration, laboratory work or export.

The following information should accompany the request for an import permit for agricultural remedies submitted to the:

1. Cover letter

2. Protocol.

3. The description of the macrobial product. This should include the macrobial species identification and the intended use of it.

4. Specify the quantity of macrobial product imported and the origin of desired imported macrobial product. Indicate the port of entry and/or exit.

5. Copy of the safety data sheet.

6. If the consignment is to be re-exported, attach documentation e.g. registration status of the macrobial product in the destination country if required.

7. If the macrobial product is imported for trial purposes, attach the trial protocol. In the case of laboratory tests, the name and address of the laboratory concerned.

8. A Permit from Directorate Plant Health, NDA will be required.

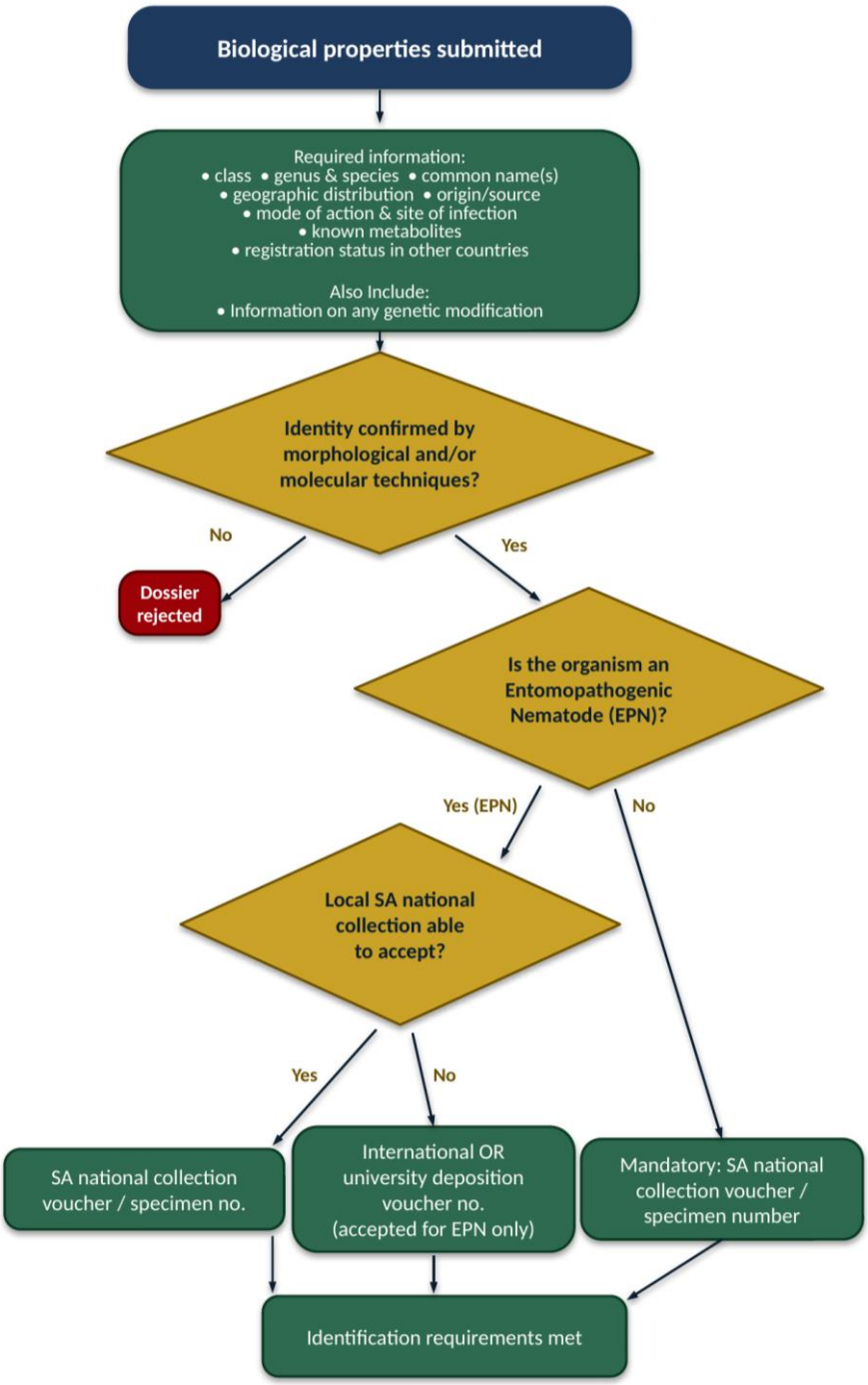
9. Proof of payment of the application fee.

**ANNEXURES: DECISION FLOWCHARTS**

*The following annexures contain the decision flowcharts that accompany Section 3 of this guideline. Each flowchart is a companion tool to the requirements described in the corresponding Point(s) of Section 3. They are provided to help regulators evaluate whether a dossier meets the stated requirements, and to help applicants decide what data, permits, studies or declarations must accompany their submission.*

## Annexure 1: Identification, Taxonomy & Voucher Deposition

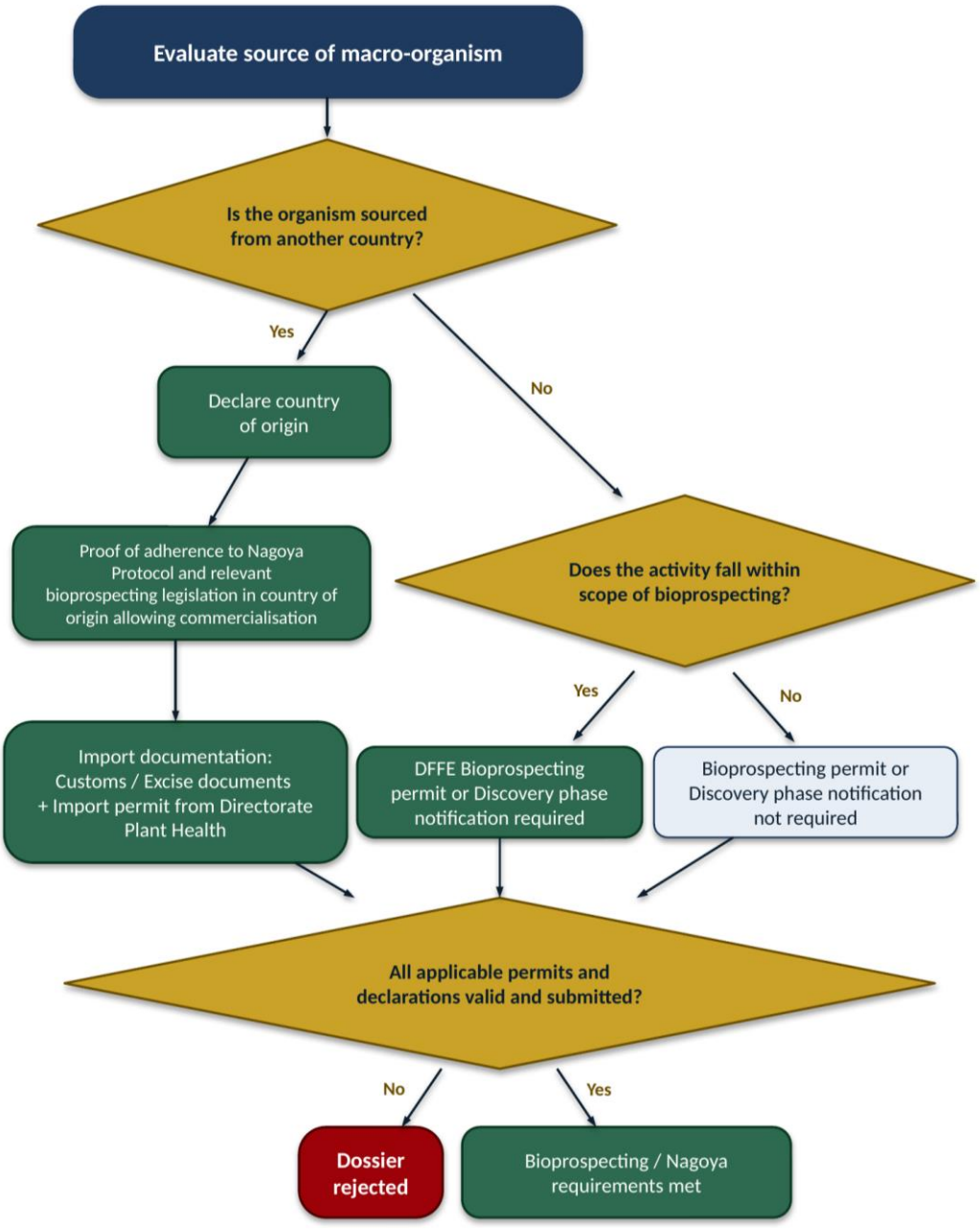
*Covers Section 3, Points 3.7, 3.8 and 3.10*



**Annexure 2: Permits Decision Tree**
*Covers Section 3, Point 3.12*

## Annexure 3: Bioprospecting & Nagoya Protocol Compliance

*Covers Section 3, Point 3.12*



**Annexure 4: Risk Assessment Checklist (Literature Review)**

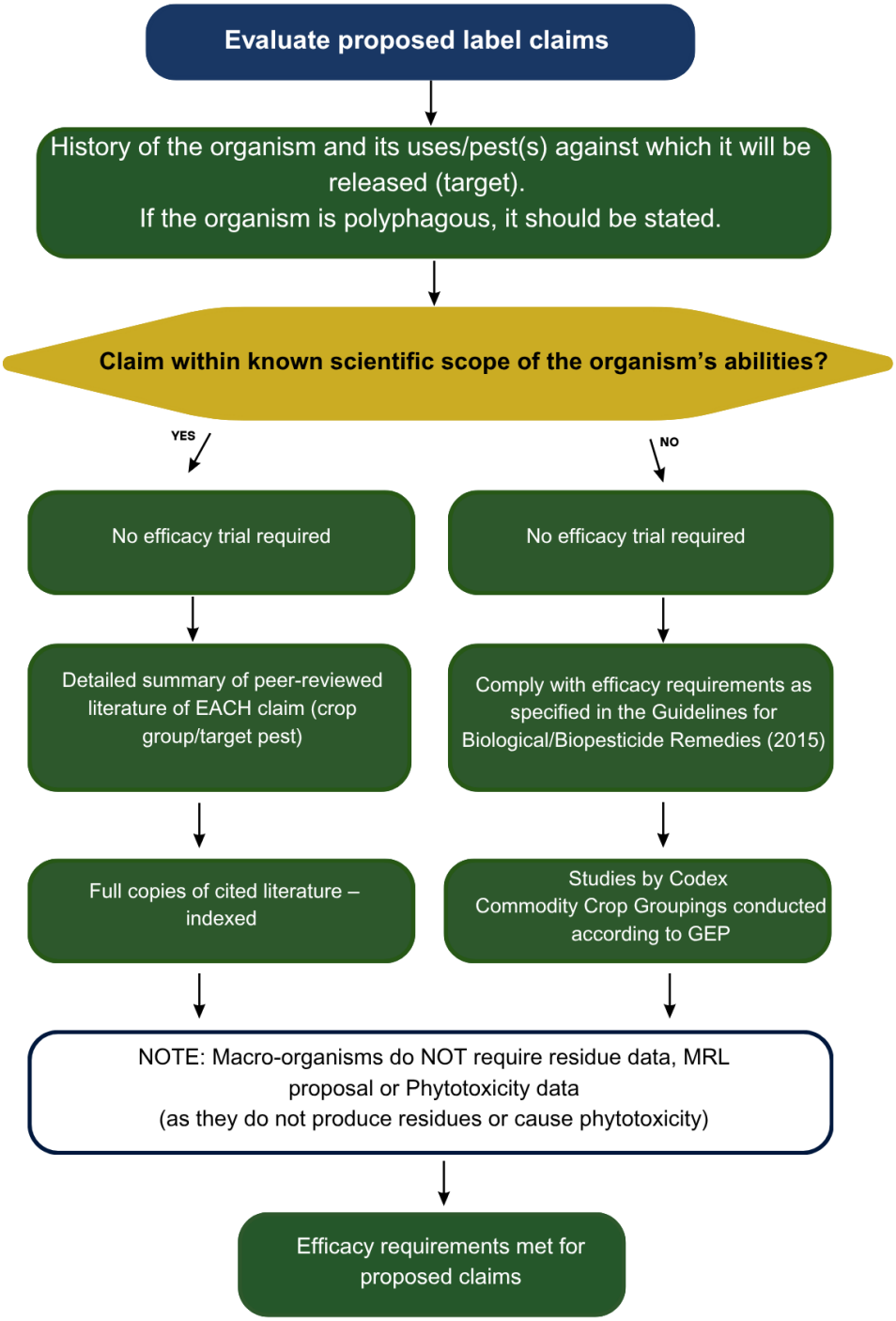
*Covers Section 3, Point 3.13*

A risk assessment report must be drafted that contains:

| **Types of information accepted:** | |
|---|---|
| 1. Toxicity data, if available. |  |
| 2. Toxicological assessment conducted by overseas regulatory bodies if available |  |
| 3. If point 1 and/or 2 are not available, a full literature review is required and supporting scientific articles must be included (i.e. not just a reference) |  |
| 4. Where points 1, 2 and 3 are not available. Expert opinion or extrapolation from a related species is required with written justification |  |
| 5. Signed off by a SACNASP-registered individual? |  |
| **Targets to be addressed:** | |
| Effects on humans i.e. consumers and operators |  |
| Effects on plant species |  |
| Environmental & non-target effects |  |
| Non-target effects on bees and other pollinators |  |
| Effects on other beneficial organisms |  |
| Assessment of rearing/ production methodology |  |
| Biodegradability and persistence in the environment |  |

## Annexure 5: History of Use & Efficacy Data Decision

*Covers Section 3, Points 3.11, 3.14–3.15*



**Annexure 10: Labelling Compliance Checklist**

*Covers Section 3, Points 3.19–3.21*

All labels should conform to latest Regulations relating to Agricultural Remedies & Label Guidance published under Act 36 of 1947. These should contain:

| | |
|---|---|
| Registration number: Reg No. L xxxx of Act 36 of 1947<br>For initial applications list L-pending or Lxxx |  |
| Product name and Trademark (where applicable) |  |
| Active ingredients identified by genus + species (and where appropriate subspecies/strain) |  |
| Type of agricultural remedy with a short description of its general purpose |  |
| Formulation type |  |
| Instructions to users:<br>- "READ THE LABEL BEFORE USE"<br>- "KEEP OUT OF REACH OF CHILDREN AND ANIKMALS"<br>- Storage, disposal and recycling instructions |  |
| Content expressed in correct macrobial unit per container<br>**Macrobial units reference:**<br>- EPN: infective juveniles(IJs)<br>- Parasitoid wasps: parasitized eggs/mummies<br>- Predatory Mites: adults/ larvae<br>- Predatory insects: adult/larvae |  |
| FRAC/IRAC or HRAC code listed if applicable |  |
| GHS pictograms, hazard statements, precautionary phrases and first aid advice.<br>If not classified as hazardous according to GHS, this should be stated. |  |
| UN number<br>If not applicable mention that product is not regulated under UN transport requirements |  |
| Batch details:<br>- Batch number<br>- Manufacturing Date<br>- Expiry date |  |
| Registration holder contact details:<br>- Name<br>- Company registration number<br>- Physical Address<br>- Contact information |  |
| Contact numbers in case of an emergency or spill |  |

| | |
|---|---|
| Label indicates AERIAL application if applicable with required aerial directions<br>(Aerial risk assessment report required) |  |
| Indemnity statements: “NOTICE TO THE USER” as described in the Regulations Regarding Agricultural Remedies of 2023 |  |
| Application recommendations/Directions for use:<br>- Pest targeted<br>- Dose<br>- Application interval<br>- Maximum number of applications per season<br>- Method of application<br>- Disposal considerations |  |