AFRICAN BIOLOGICALS ALLIANCE

For Africa. By Africa.

REGISTRATION · SOUTH AFRICA · BIOLOGICAL REMEDIES

# The data a biological remedy needs

A core pack that every biological remedy supplies, then extra requirements for the kind of organism or product you have.

| | |
|---|---|
| **19** items in the core pack | **3** successful field trials for each use |
| **2** seasons for a new active ingredient | **4** replicates at the very least |

THE CORE PACK

## What every biological remedy supplies

Section 3 of the Registrar's 2015 guideline, in seven groups.

### Identity

Where it was isolated, an accession number, a voucher sample in a recognised collection, and proof of identification. Section 3.4.

### Where it comes from

Mass release permits. For an imported organism, the country, permits and a letter from a recognised authority. For a local one, where it was collected. Sections 3.5 to 3.7.

### Safety

Toxicology and environmental studies to OECD guidelines, formulation toxicity, bee risk studies, and a safety data sheet. Sections 3.8, 3.9, 3.18, 3.19.

### Quality

Physical properties and shelf life, checked by an independent laboratory. Section 3.10.

### Does it work

Efficacy and phytotoxicity trials, mixing partner tests, and residue data. Sections 3.12 to 3.17.

### The label

The proposed label, with at least twelve elements. Section 3.11.

### The paperwork

Proof of the fee, a covering letter and the application forms with the dossier indexes. Sections 3.1 to 3.3.

> If you think a required item is unnecessary, argue it. A waiver request with a good scientific argument goes in before you run any test and before you apply.

IDENTIFY IT

# Proving what it is

The method depends on what the organism is. Dots mark the techniques the guideline names.

| Organism | Cultural | Microscopic | Morphological | Molecular sequencing | DNA barcoding | Chemical analysis |
|---|---|---|---|---|---|---|
| **Bacteria** | ● | ● | | ● | | |
| **Fungi** ITS gene region | | | ● | ● | ● | |
| **Insects** | | | ● | | ● | |
| **Nematodes** | | | ● | | ● | |
| **Viruses** | ● | ● | | ● | | |
| **Plant extracts and hormones** five batches or certificates of analysis | | | | | | ● |

01

## Isolate

Say where it was isolated: soil, larvae, water.

02

## Number it

The manufacturer gives it an accession number.

03

## Deposit it

A voucher sample goes into a recognised collection.

04

## Get their number

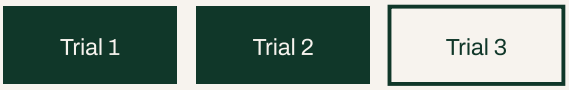
The collection issues its own accession or voucher number.

TRIALS

# How many, how long, how laid out

## How many

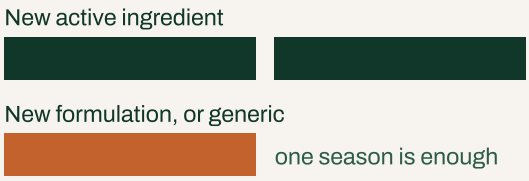
For each use (crop and pest).




At least three successful trials. Two thirds or more in Sout

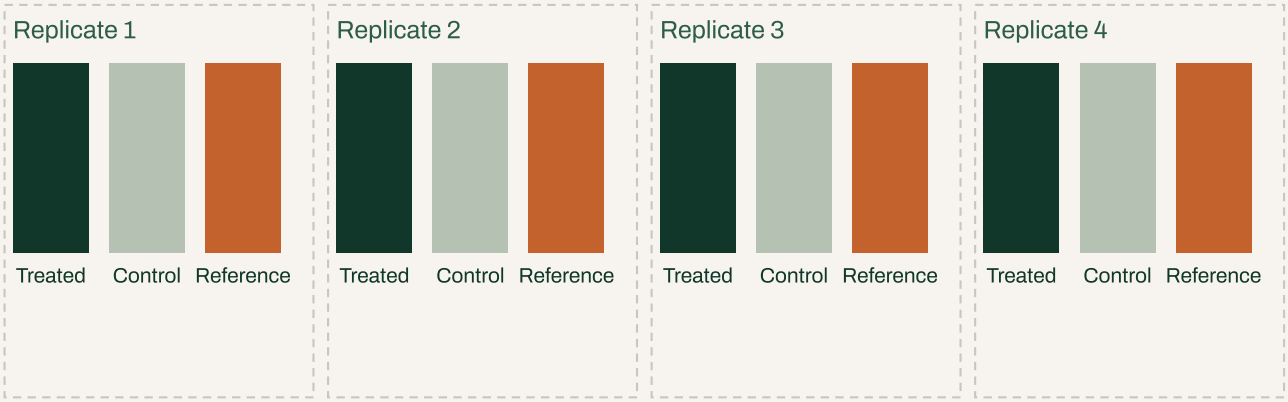
## How long

Seasons or cropping cycles.




## The layout

randomised blocks, at least four replicates, drawn to scale (2 m by 5 m)




### Untreated control

In every trial.

### A reference product

Something with a similar spectrum, or common in the crop.

### 1x and 2x

Phytotoxicity trials include a single and a double dose.

### Enough replicates

Error degrees of freedom of 12 or more. One product at two rates, plus control and reference, needs five.

Trial material must be the product to be registered and no more than two years old. Sites must be open to inspection, and trials follow Good Agricultural Practice.

THE LABEL

# Twelve things it must carry

| | |
|---|---|
| **1 Genus, species and strain** | **2 Minimum guaranteed active ingredient**<br>At expiry: spores, cfu or organisms per ml or g. |
| **3 Manufacturer**<br>Name and address. | **4 Pack size** |
| **5 Crops or pests** | **6 Shelf life** |
| **7 Storage**<br>Recommendations or restrictions. | **8 Precautions**<br>Including specificity, host range and risk of infection in humans. |
| **9 Warranty statement** | **10 Compatibility**<br>If supported by data. |
| **11 Batch code and dates**<br>Manufacture and expiry. | **12 Directions for use**<br>Rate, interval, method and frequency. |

A home-garden label too, if the product is also sold in small packs. The label must also meet the current labelling regulations: see the GHS guide.

BY ORGANISM OR PRODUCT

# What each kind adds

## Micro-organisms

Fungi, bacteria, viruses

1. Viable for at least six months.
2. Contaminants under 100,000 cfu per g or ml, or the Department of Health's limit.
3. Known metabolites reported.
4. A new strain needs new efficacy and toxicology data.

## Macro-organisms

Nematodes, insects

1. Nematodes: taxonomy, history, life cycle, mode of action, state and stage on the label.
2. Plots of 2 by 5 m with 4 replicates.
3. Highly mobile insects: 0.5 ha plots with 2 to 3 replicates.

## Semiochemicals

Pheromones and biochemicals

1. Reduced residue data may apply.
2. None if no contact with plant parts and no residue, or the Department of Health has exempted it.

## Enzymes, hormones, extracts

No additions

1. Requirements are similar to conventional pesticides.

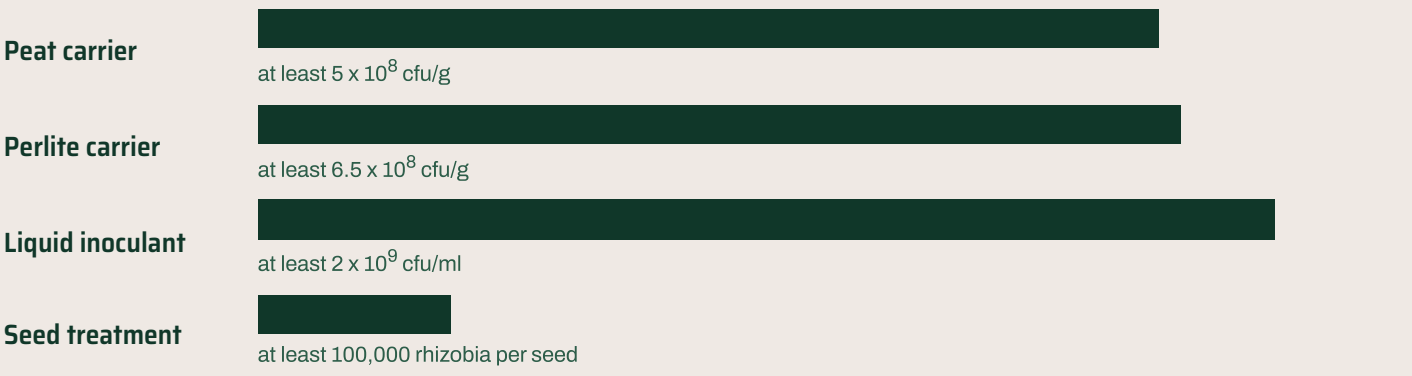
## Biostimulants and biofertilizers

Growth promoters

1. Trials in sterile pots and in non-sterile pots.
2. Tested for human pathogens such as E. coli.
3. A claim of induced resistance to disease makes it a biological remedy instead.

## Legume and other inoculants

minimum counts, drawn on a log scale




### Trial fields

Free of the legume for three years. Report nodules: number, size, position, colour.

### Tested at 1x and 2x

Against a market product, or an untreated control if none exists.

### Contaminants

Identified. Under 100,000 cfu per g or ml.

WHERE IT IS UNCLEAR

# Ask before you rely on it

| This 2015 guideline says | But |
|---|---|
| Three copies of the application form and of the label | The 2023 regulations say duplicate, and two printed label copies |
| The label follows the 2006 regulations | The 2023 regulations replace them |
| Residue data follow the 2015 residue guideline | The residue guideline is now dated July 2026 |
| Application forms from the old department's website | Get the current forms from the Registrar's office |

This guideline is from 2015. Ask the registrar's office, in writing, whether it is still the current data guideline for your product.

Information, not legal advice. Facts as of 26 October 2026, from the Registrar's Guidelines on the data required for registration of biological/biopesticides remedies in South Africa (June 2015). Later changes are not reflected. Guidelines page: https://www.nda.gov.za/index.php/publication/581-guidelines

## Sources

Prepared by the African Biologicals Alliance from these documents. They belong to the department and remain subject to its own terms.

- Guidelines on the data required for registration of biological/biopesticides remedies in South Africa. Issued by the Registrar of Act 36 of 1947, June 2015. https://www.nda.gov.za/index.php/publication/581-guidelines

## Licence

Data a biological remedy needs, version 1.0, 26 October 2026. Copyright African Biologicals Alliance.

This work is licensed under Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0). You may share it, unchanged, for non-commercial purposes only, and you must always credit the African Biologicals Alliance. Do not use it for commercial gain and do not alter it. https://creativecommons.org/licenses/by-nc-nd/4.0/

The licence covers our summary and drawings only. It does not cover the department documents listed here. Information, not legal advice.