AFRICAN BIOLOGICALS ALLIANCE

For Africa. By Africa.

REGISTRATION · SOUTH AFRICA · BIOLOGICAL REMEDIES

Do you need residue trials?

Many biological remedies need none. Each type has its own conditions, and the registrar expects a written rationale either way.

8 types of remedy, each with its own rule	**7 + 7** cases for bacteria and fungi: no trials, and trials
1 rationale in the dossier, whichever way it goes	**0** time frame or fee stated in the guideline

HOW IT WORKS

From type to rationale

01

Name your type

Virus, bacterium or fungus, macro-organism, semiochemical, hormone, enzyme or extract.

02

Check both lists

The cases with no trials, and the cases that need them. A good example never cancels a trigger.

03

Write the rationale

Toxicology and environment, numbered references, reviews from other countries.

04

File it

Put it in the dossier. If trials are needed, run them to the residue guideline.

WHAT EACH TYPE NEEDS

Trials, or no trials

Green is the route to no residue trials. Orange is what brings trials or more data back in.

Insect viruses

baculoviruses

NO RESIDUE DATA IF

Identified, and mode of action shown in the literature. The virus must be highly specific and not cause human disease.

OTHERWISE

Without these, this exemption does not apply.

Bacteriophages

viruses of bacteria

NO RESIDUE DATA IF

The phage and its production bacterium are identified, the bacterium is not known to make metabolites of concern, and mode of action is shown.

TRIALS ROUTE IF

The bacterium is known to make metabolites of concern: the bacteria rules apply.

Bacteria and fungi

including inoculants

NO TRIALS IN 7 CASES

No harmful metabolites known. No gene for them. Low or acceptable exposure. Listed on the European QPS or US GRAS list, or low risk in the EU.

TRIALS IN 7 CASES

Conflicting evidence. A gene for a harmful metabolite. A close relation to a mammalian pathogen. High exposure. A metabolite overproduced.

Macro-organisms

beneficial insects

NO RESIDUE DATA IF

The life cycle shows nothing that could leave residues.

DATA REQUIRED IF

There is any reason to suspect residues.

Semiochemicals pheromones	**NO DATA IF** No contact with plant parts and no residue (a trap or dispenser). Or contact only with non-edible parts, not systemic. Or an exemption from the Department of Health.	**DATA REQUIRED IF** It touches edible parts and there is a toxicological concern.
Plant hormones plant-derived	**USUALLY NO STUDIES** Request an exemption from a maximum residue limit and give a reasoned scientific argument. Decided case by case.	**DIFFERENT ROUTES** Hormones from insects and other sources have their own route. Synthetic growth regulators are not covered.
Enzymes toxins are not enzymes	**NO RESIDUE ANALYSIS IF** From non-pathogenic, non-toxin-producing organisms grown on raw materials with no hazardous components, and the dossier proves it.	**DATA SHOULD BE GENERATED IF** A condition is not met, for example hazardous production materials.
Extracts food, feed and others	**USUALLY WAIVED IF** Documented use in food or feed at similar concentrations. Show it is the same material and meets food law. Assess known allergens.	**CHEMICAL DATA RULES IF** No comprehensive history, or use well above normal exposure. Justified deviations are allowed.

> Whatever the type, the guideline also asks you to consider the co-formulants and carriers in the product, not only the active ingredient.

THE RATIONALE

What it has to show

The guideline's annex gives the structure.

PROVE
No risk to people
toxicology category

AND PROVE
No risk to the environment
environmental toxicology category

USING
- Published literature
- Your own studies and analysis
- Data on a similar product, explained
- Reviews from other countries

Numbered references in order of mention, full list

TWO CAUTIONS

Before you rely on an exemption

Your strain

Bacteria and fungi

1. Evidence has to be about your own strain.
2. One strain that makes no harmful compound does not clear the whole species.
3. Genetic equivalence between strains can support a bridge.

Your market

Exports

1. An exemption in South Africa does not settle the importing country's limits.
2. Check the importing market with the importer or agent.

WHERE IT IS UNCLEAR

Ask before you build the dossier

One document says	Another says
Macrobial guideline: macro-organisms need no residue data	Residue guideline: data is needed if residues are suspected
A rationale should be submitted in all cases (bacteria and fungi)	Plant hormone exemptions are decided case by case
Fee for the residue assessment: not stated	Time frame: not stated

If your product sits between two types, ask the registrar's office before you build the dossier.

Information, not legal advice. Facts as of 26 October 2026, from the Registrar's Guidelines on requirements for residues arising from the use of biological remedies in South Africa (July 2026) and the macrobial guideline. Later changes are not reflected. The foreign QPS and GRAS lists and the separate residue-trial guideline are not covered. 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 requirements for residues arising from the use of biological remedies in South Africa. Issued by the Registrar of Act 36 of 1947, July 2026. https://www.nda.gov.za/index.php/publication/581-guidelines
- Guideline on requirements for macrobial remedies (section 3.15). Issued by the Registrar of Act 36 of 1947, July 2026. https://www.nda.gov.za/index.php/publication/581-guidelines

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