AFRICAN BIOLOGICALS ALLIANCE

For Africa. By Africa.

REGISTRATION · SOUTH AFRICA · SUBSTANCES OF CONCERN

Fast-tracking a replacement remedy

Since 1 June 2024 the registrar may not grant or renew a registration that contains a substance of concern. The registrar prioritises suitable replacements. This protocol is the way in.

1 June 2024 the cut-off for substances of concern	**2** routes: already submitted, or not yet
2 signed declarations either way	**0** decision time frame in the protocol

WHO CAN APPLY

Three tests

TEST 1

It could replace an essential use

Fully or partly. Grower associations have named the use as essential, and no viable alternative is registered.

TEST 2

It is not a substance of concern

Your own remedy must pass the same criteria.

TEST 3

It is not banned

Not banned in South Africa.

WHAT COUNTS AS A SUBSTANCE OF CONCERN

Five criteria

An active ingredient or its formulation that meets any one of these.

1A, 1B

Carcinogenicity, GHS categories.

1A, 1B

Mutagenicity, GHS categories.

1A, 1B

Reproductive toxicity, GHS categories.

Stockholm

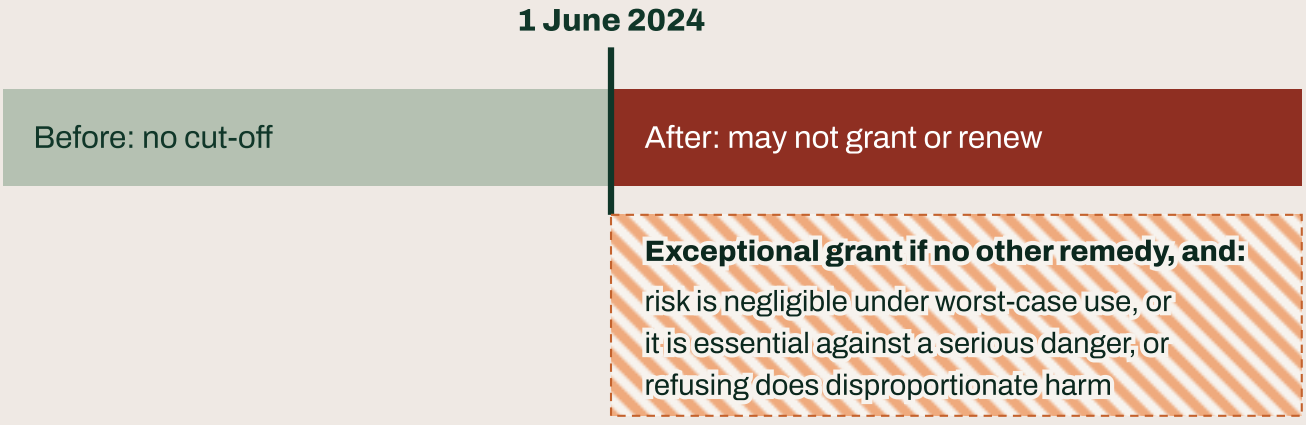
Annexes A and B, or all Annex D criteria. DDT for malaria control by the Department of Health is excepted.

Montreal

Listed under the Montreal Protocol.

THE RULE AND ITS EXCEPTION

Before and after 1 June 2024



Such a registration may be for a specified period and restricted uses. The protocol does not say the same exception applies to renewal.

WHAT TO SEND

Two routes

Pick the one that matches where your application is. The letter is the same whichever you choose.

Already with the registrar

A complete application that is already under evaluation.

1. **Covering letter**
   Says fast-tracking. Gives the submission date, the remedy being replaced and the essential uses.
2. **Copy of your service request form**
   Submission date legible.
3. **Updated application form, two copies**
   Shows the GHS classification and registration status in other countries.
4. **Explanation letter**
5. **Proposed label, two copies, if it differs**
   If the dossier label is not in GHS, send a GHS label with rationale and pay the update fee.
6. **Declaration one**
   Signed by the company representative.
7. **Declaration two**

Not yet submitted

All the usual data, plus a separate list.

1. **Covering letter**
   Says fast-tracking. Names the remedy being replaced and the essential uses.
2. **Application form, two copies**
   Shows the GHS classification and registration status in other countries.
3. **Explanation letter**
4. **Signed assessment reports**
   For all applicable trials: efficacy, phytotoxicity, residues.
5. **Proposed label, two copies**
   Essential-use claims only. Send a GHS label with a full rationale.
6. **Declaration one**
7. **Declaration two**

THE LETTER AND THE DECLARATIONS

What you explain, and what you sign

A

Why suitable

A reasonable scientific explanation.

B

Resistance

Resistance groups against other remedies for the pest and crop, other pests on the crop, and nearby crops.

C

Performance

A brief overview of expected efficacy against the remedy being replaced. No data comparison needed.

D

Full or partial

And why: systemic or contact, withholding periods.

E

Market access

A remedy restricted in an export market cannot replace one for crops going there.

Declaration one

Signed by the company representative.

1. No active ingredient, co-formulant or biological organism regarded as a substance of concern.
2. No new scientific evidence on health effects for vulnerable groups, especially children.
3. All information is authentic, accurate and complete.

Declaration two

Separate document.

1. The proposed remedy will, to the best of your knowledge, replace the remedy being phased out, as set out in your explanation letter.

WHAT IT COSTS

Which fee applies?

No extra fee	GHS update fee	No GHS fee	R13,956
Route one: fees were paid with the original application.	Route one, if the label is not yet in GHS and you have not applied. If you already applied, nothing more.	Route two, a new registration. A GHS label and full rationale are still needed.	Route two: the registration fee still applies, per application or product, from 1 April 2026. Check the current tariff.

WHERE IT IS UNCLEAR

Ask the registrar's office

Not in the protocol	So ask
A decision time frame	How long a fast-tracked decision takes.
A list of current substances of concern	Whether the remedy you replace is classed as one now. The protocol's examples do not prove it for any ingredient.
A list of essential uses	Which uses growers have named as essential.
Declaration wording in the text	The template adds "other than what has already been disclosed" to the health-evidence point. Ask which wording to sign.
Route two says the explanation letter is "point 3"	It is point 4 of the first list. Follow point 4.

Information, not legal advice. Facts as of 26 October 2026, from the Registrar's Protocol for submission of applications for fast-tracking of registrations to replace agricultural remedies identified as substances of concern (November 2023), the Regulations relating to agricultural remedies (25 August 2023) and Government Gazette 54123 (13 February 2026). Whether a particular ingredient is a substance of concern now, and later changes, 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.

- Protocol for submission of applications for fast-tracking of registrations to replace agricultural remedies identified as substances of concern. Issued by the Registrar of Act 36 of 1947, November 2023. https://www.nda.gov.za/index.php/publication/581-guidelines
- Regulations relating to agricultural remedies. Government Gazette 49189, 25 August 2023.
- Regulations relating to tariffs. Government Gazette 54123, 13 February 2026.

Licence

Fast-tracking a replacement remedy, 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.