



agriculture, land reform & rural development

Department:
Agriculture, Land Reform and Rural Development
REPUBLIC OF SOUTH AFRICA

GUIDELINE FOR THE APPLICATION FOR A DEROGATION FOR AN AGRICULTURAL REMEDY IDENTIFIED AS A SUBSTANCE OF CONCERN

**ISSUED BY THE REGISTRAR: ACT NO 36 OF 1947, PRIVATE BAG
X343, PRETORIA, 0001**

REPUBLIC OF SOUTH AFRICA

APRIL 2024

1 BACKGROUND

According to the “Regulations relating to agricultural remedies” of 25 August 2023, a substance of concern means any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in an agricultural remedy in sufficient concentration to present risks of such an effect. Agricultural remedy active ingredients and their formulations fulfil the substances of concern criteria when such agricultural remedy has one or more of the following characteristics –

- (i) Criterion 1: agricultural remedy active ingredients and their formulations that meet the criteria of carcinogenicity categories 1A or 1B of the GHS, or
- (ii) Criterion 2: agricultural remedy active ingredients and their formulations that meet the criteria of mutagenicity categories 1A or 1B of the GHS, or
- (iii) Criterion 3: agricultural remedy active ingredients and their formulations that meet the criteria of reproductive toxicity categories 1A or 1B of the GHS, or
- (iv) Criterion 4: agricultural remedy active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention except for dichloro diphenyl trichloroethane (DDT) used for malaria vector control by the Department of Health; and
- (v) Criterion 5: agricultural remedy active ingredients listed under the Montreal Protocol.

According to regulation 8(1)(d) and 10(3)(e) respectively, the Registrar (Act 36 of 1947) may not grant a new registration or renew an existing registration after 1 June 2024 if the product contains substances of concern, or any other agricultural remedy banned in the Republic of South Africa.

However, according to regulation 8(6), notwithstanding regulation 8(1)(d), in exceptional circumstances, the Registrar may grant or renew a registration of an implicated agricultural remedy when the following conditions are met:

- a) The risk to humans, animals or the environment from exposure to the active substance in an agricultural remedy, under realistic worst-case conditions of use, is negligible or
- b) There is evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or
- c) Not approving the active substance would have a disproportionate negative impact on society when compared to the risk to human health, animal health or the environment arising from the use of the substance.

In these cases, approval of an agricultural remedy may be granted for a specific period, and for restricted uses, following publication of the risk assessment report for public comment by the applicant.

2 PROCEDURE FOR DEROGATION

2.1 NOTIFYING THE REGISTRAR OF THE INTENT TO APPLY FOR A DEROGATION

Before commencing an application for derogation of an agricultural remedy, the applicant must conduct a risk assessment to evaluate the risks associated with the use of the remedy according to the proposed uses for which a derogation is sought and determine whether the associated risks can be sufficiently mitigated. The applicant needs to inform the Registrar of their intent to apply for a derogation before publishing the risk assessment report for public comment, or before 1 June 2024, whichever occurs first. The following information needs to be provided to the Registrar:

- a) The name, active ingredient and registration number of the agricultural remedy for which the risk assessment has been or is being conducted.
- b) The final hazard classification of the remedy according to GHS, or other classification resulting in the remedy being considered as a “substance of concern”.
- c) The intended use(s) for which a derogation is sought.
- d) A copy of the risk assessment report that will be published for public comment and where this report will be made available. If the risk assessment report is not yet finalised at the time, proof that the study has been initiated must be submitted (i.e., confirmation from the specialist conducting the assessment that the study is in progress or in line to be conducted with an estimated timeframe for completion). Both a hard copy and electronic copy of the final report must be shared with the Registrar as soon as it is finalized.

The notification to the Registrar will be in the form of a formal letter which may be submitted to the Registrar via email. The Registrar will acknowledge receipt of the notification of intent to apply for a derogation within 14 days. If no objections are raised by the Registrar, the applicant may go ahead and publish the risk assessment report and notifications as proposed. This procedure may only commence once a hard copy of the risk assessment report has been delivered to the office of the Registrar (Act no. 36 of 1947), where the report will be made available for public inspection.

2.2 PUBLIC COMMENT NOTIFICATION

2.2.1 Minimum requirements according to the “Regulations on Fair Administrative Procedures” of 2002 promulgated under the Promotion of Administrative Justice Act (Act no. 3 of 2000)

When administrative action is taken by an organ of state that has the potential to materially and adversely affect the right of the public as envisaged in section 4(1) of the Promotion of Administrative Justice Act (Act no. 3 of 2000) and the administrator decides in terms of section 4(1) of the Act to follow a notice and comment procedure contemplated in section 4(1)(b) of the Act, the procedure provided in chapter 2 of the “Regulations on Fair Administrative procedures” of 2002 must be considered.

Because the envisaged administrative action affects the right of the public throughout the Republic, information concerning the administrative action must be published by way of notice in the Government Gazette, and a newspaper which is distributed, or in newspapers which collectively are distributed, throughout the Republic.

Such a notice must include:

- a) An invitation to members of the public to submit comments in connection with the proposed administrative action to the administrator concerned on or before a date specified in the notice, which date may not be earlier than 30 days from the date of publication of the notice.
- b) A caution that comments received after the closing date may be disregarded.
- c) The name and official title of the person to whom any comments must be sent or delivered. This should include the work, postal and street address and, if available, also an electronic mail address, work telephone number, and fax number.
- d) Sufficient information about the proposed administrative action to enable members of the public to submit meaningful comments.
- e) Details on the place or places where, and the hours within which, further information concerning the proposed administrative action will be available for public scrutiny.

A notice published in a newspaper may, notwithstanding the above, only contain –

- i. A concise statement of the proposed administrative action.
- ii. The name, official title, contact telephone number and physical address of the person from whom further information on the proposed administrative action and the administrative procedure can be obtained.
- iii. A note that a more detailed notice concerning the proposed administrative action appears in the Government Gazette, as the case may be.

If a notice specifies a place or places where further information about the proposed administrative action will be available for public scrutiny, access to that information must be allowed from the date on which the notice is published until the closing date for comment, with the exclusion of Saturdays, Sundays and public holidays.

The notice must be in at least two of the official languages.

2.2.2 Case-specific considerations when applying for a derogation according to the “Regulations relating to agricultural remedies” of 25 August 2023

A notification must be published by the applicant to inform the public of the application for derogation that is being sought in terms of regulation 8(7) of the “Regulations relating to agricultural remedies” of August 2023 and invite the public to comment on the relevant risk assessment report. The derogation application must be product specific and will only be granted for a specific period and for restricted uses.

Notwithstanding the minimum requirements as per the "Regulations on Fair Administrative Procedures" presented above, the following case-specific considerations for the derogation procedure must be included on the notice:

- Full name of the applicant
- Objective of the application, referencing the applicable legislation
- A full description of agricultural remedy and its proposed uses, the hazard classification of the remedy and why a derogation and consequent public comment is being sought, along with a short summary of the outcome of the risk assessment report (i.e., whether the risks associated with using the remedy are considered manageable).
- Request for interested parties to submit comments in connection with the application, to the Registrar (Act no. 36 of 1947), within 30 days of the date of publication:

Mr. Maluta Mudzunga

The Registrar: Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies, 1947 (Act no. 36 of 1947)

Department of Agriculture, Land Reform and Rural Development

Private Bag X343, Pretoria, 0001

30 Hamilton Street, Harvest House Building, Office 417, Arcadia, Pretoria, 0002

Tel no: 012 319 6530

Email to MalutaM@dalrrd.gov.za

- The contact details of the administration at the office of the Registrar where more information on the proposed application and administrative procedure can be obtained:

Mr. David Motloi
Head of Administration: Fertilizer, Farm Feeds, Agricultural Remedies and
Stock Remedies, 1947 (Act no. 36 of 1947)
Department of Agriculture, Land Reform and Rural Development
Private Bag X343, Pretoria, 0001
20 Steve Biko Street, Agriculture Building, Arcadia, Pretoria, 0002
Tel no: 012 319 6889
Email: DavidM@Dalrrd.gov.za

- The location at which the full risk assessment can be accessed, both online and in a hard copy. A hard copy of the risk assessment report must be submitted to the office of the Registrar before the notice is published, to allow access to the public to the relevant report. Access will be allowed during normal business hours, Monday to Friday from 08:00 to 16:00, excluding public holidays.
- A caution that comments received after the closing date may be disregarded.

An example of a public notification is included in Appendix A.

Proof that the notification was published as per the current guideline needs to be submitted to the Registrar on the same day of publication. This may be done via email.

2.2.3 Public comment period

The Registrar must accept comments for 30 days from the date of the last publication of the notification unless a longer period was provided in the notice. In the event of an individual/ entity wishing to comment after the 30-day comment period has expired, the individual/ entity must obtain written authorisation from the applicant to submit comments at a later stage. Approval from the applicant must be attached to the inputs provided to the Registrar.

The Registrar must acknowledge receipt of all comments received from individuals/ entities who submitted comments. The Registrar must forward all comments received to the applicant to formulate a response which in turn will be sent to the individual/ entity who raised the comment.

- The Registrar must send the comments received by any interested party to the applicant within 7 days of their receipt and, on the same day, the Registrar must acknowledge receipt of the comment to the relevant party.
- The applicant has 14 days to formulate a response and send it to the Registrar for conveyance to the relevant party. The Registrar will send the response to the relevant party on the same day that he acknowledges receipt of the response from the applicant, which may not exceed 7 days from the date on which the response from the applicant was sent to the Registrar.

After receipt of all comments and corresponding responses, the applicant may submit an application for derogation to the Registrar for his consideration.

2.3 APPLICATION

An application for derogation needs to be submitted to the office of the Registrar for evaluation within 30 days of conclusion of the public participation process. The public participation process will be considered concluded on the last day on which comments can be received

from the public, or on the last day that the applicant/ Registrar may respond to the comments received, whichever occurs last. The application must contain the following information:

1. Proof of payment of tariff related to “technical/ data evaluation in case of application for an exemption”.
2. A cover letter stating that the application is for a derogation for an agricultural remedy identified as a substance of concern for continued use after 1 June 2024. The cover letter should contain a summary of the uses for which the applicant is applying for derogation, why a derogation is considered necessary, and a short summary of the outcome of the risk assessment report for the applicable uses.
3. Service Request form.
4. Two copies of the application form, excluding List I and List II if these have previously been submitted.
5. A copy of the risk assessment report. If a hard copy of the risk assessment report was already submitted to the Registrar during the public comment period, the applicant does not need to resubmit a hard copy of the report.
6. A copy of the notifications that were published in the Government Gazette and national newspapers for public comment.
7. Copies of all comments received in response to the notification for public comment, as well as any responses sent to the public in response.
8. Two copies of the proposed label containing only the claims for which derogation is sought, as well as any risk mitigation measures identified by the risk assessment report.
9. Declaration (as per Appendix B)

2.4 DEROGATION APPROVAL

If the Registrar is satisfied that the risk assessment addresses the material concerns associated with the use of the remedy, and public comments did not reveal any additional, unmanageable risks or concerns, the Registrar may approve the use of the agricultural remedy. If the remedy no longer complies with the conditions provided in regulation 8(6), the Registrar will provide a reasonable phase-out period to deplete stock before cancelling the registration.

Appendix A – Example of a public notification

Example of a Notification in the Government Gazette

PUBLIC NOTICE

Application for derogation for the restricted use of agricultural remedies identified as substances of concern

This notice is to inform the public of administrative action being taken in relation to the approval of agricultural remedies under the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act no. 36 of 1947).

[Company trade name] hereby informs the public of its intention to submit an application for derogation for the registered agricultural remedy **[tradenname, registration number]** containing **[active ingredient and active load]**, identified as a substance of concern due to its classification as a **[mutagen/ carcinogen/ reproductive toxin category 1A or 1B according to the Globally Harmonized System of Classification and Labelling of Chemicals; or other]**, for the following use in South Africa: **[summarised list of restricted uses for which a derogation is sought, for example: a herbicide used for broadleaf weeds in agriculture / a rodenticide used in public health]**.

As per the requirements of the “Regulations relating to agricultural remedies” of August 2023, a risk assessment was conducted for the proposed end uses and the public is hereby invited to review the risk assessment report and submit comments in relation to the proposed application. This report can be accessed online via the following website: _____ or in hard copy at the Department of Agriculture, Land Reform and Rural Development (20 Steve Biko Street, Agriculture Building, Arcadia, Pretoria, 0002) during office hours (08:00 to 16:00 on Mondays to Fridays, excluding public holidays). Interested parties must submit comments or objections in connection with the proposed application in writing to:

Mr. Maluta Mudzunga

The Registrar: Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies, 1947 (Act no. 36 of 1947)

Department of Agriculture, Land Reform and Rural Development

Private Bag X343, Pretoria, 0001

30 Hamilton Street, Harvest House Building, Office 417, Arcadia, Pretoria, 0002

Tel no: 012 319 6530

Email to MalutaM@dalrrd.gov.za

Interested parties must submit comments or objections in relation to this application within 30 days of the publication of this notice. Comments received after this date need not be considered.

Example of a notification in a newspaper when referring to the Government Gazette

PUBLIC NOTICE

Application for derogation for the restricted use of agricultural remedies identified as substances of concern

This notice is to inform the public of administrative action being taken in relation to the approval of agricultural remedies under the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act no. 36 of 1947).

[Company trade name] hereby informs the public of its intention to submit an application for derogation for the registered agricultural remedy **[tradenname, registration number]** containing **[active ingredient and active load]**, identified as a substance of concern due to its classification as a **[mutagen/ carcinogen/ reproductive toxin category 1A or 1B according to the Globally Harmonized System of Classification and Labelling of Chemicals; or other]**, for the following use in South Africa: **[summarised list of restricted uses for which a derogation is sought, for example: a herbicide used for broadleaf weeds in agriculture / a rodenticide used in public health]**.

More information on the proposed application and administrative procedure can be obtained from Government Gazette Notice ____ or by contacting:

Mr. David Motloi

Head of Administration: Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies, 1947 (Act no. 36 of 1947)

Department of Agriculture, Land Reform and Rural Development

Private Bag X343, Pretoria, 0001

20 Steve Biko Street, Agriculture Building, Arcadia, Pretoria, 0002

Tel no: 012 319 6889

Email: DavidM@Dalrrd.gov.za

Interested parties must submit comments or objections in relation to this application within 30 days of the publication of this notice. Comments received after this date need not be considered.

Appendix B – Declaration

Directorate Agricultural Inputs Control (Act No. 36 of 1947)
Department of Agriculture, Land Reform and Rural Development
Private Bag X343
Pretoria
0001

[insert date]

The Registrar

DECLARATION MADE BY THE COMPANY REPRESENTATIVE

The applicant hereby declares that the application for derogation of the remedy **[insert agricultural remedy tradename and registration number]** conforms to the following requirements as stipulated in the “Regulations relating to agricultural remedies” of 25 August 2023:

- i. The agricultural remedy contains active ingredients and/ or co-formulants or biological organisms regarded as substances of concern;
- ii. No new scientific evidence is known to be available on the agricultural remedy’s potential health effects for vulnerable groups, especially children, other than what has already been disclosed;
- iii. All the information provided in this application is authentic, accurate and complete.

Applicant company

Title of company representative

Full name of company representative

Signature

Date

Tel No.