agriculture, land reform & rural development

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

PROTOCOL FOR SUBMISSION OF APPLICATIONS FOR FAST-TRACKING OF REGISTRATIONS TO REPLACE AGRICULTURAL REMEDIES IDENTIFIED AS SUBSTANCES OF CONCERN

ISSUED BY THE REGISTRAR: ACT 36 OF 1947, PRIVATE BAG X343, PRETORIA, 0001

REPUBLIC OF SOUTH AFRICA

NOVEMBER 2023

BACKGROUND

According to the “Regulations relating to agricultural remedy” of 25 August 2023, substances of concern mean 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 fulfils the substances of concern criteria when such agricultural remedy have 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 may not grant or renew a registration after 1 June 2024 if it 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, where there is no other agricultural remedy, the Registrar may grant registration of an implicated agricultural remedy when the following conditions are met:

a) The risk to humans, animal 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 addition, regulation 7 specifies that the Registrar shall prioritize the review and registration for suitable alternative solutions for substances of concern. Therefore, in the case where applicants have agricultural remedies that could partially or entirely replace uses identified by grower associations as essential and for which no viable alternatives are currently registered, the registration holder may apply for fast-tracking of the registration of the alternative remedy, provided that:

- The remedy is not classified as a substance of concern.
- The remedy is not banned in the Republic.

PROCEDURE FOR SUBMISSION OF APPLICATIONS

Applications that are complete and that have already been submitted to Act No. 36 of 1947 for evaluation:

The following information needs to be submitted to the office of the Registrar:

1. A cover letter stating that the application is for fast-tracking to replace an agricultural remedy identified as a substance of concern for one or several of the uses regarded as essential by grower associations. The cover letter should contain the following information regarding the application:
    a. The date of submission of the application.
    b. Reference to the agricultural remedy identified as a substance of concern along with the essential use/s aimed to be replaced by the registration of the alternative remedy.
2. A copy of the submitted service request form, ensuring the date of submission is clearly legible.
3. Two copies of the updated application form indicating the GHS classification of the alternative remedy, and the status of registration of the alternative remedy in other countries.
4. An explanation letter providing as much information as possible regarding the alternative remedy being proposed for registration and how it aims to replace the remedy identified as a substance of concern for the specified uses. Include, amongst others, information on the following:
    a. Reasonable scientific explanation as to why the proposed remedy will be a suitable replacement.
    b. Resistance management. Take into consideration the resistance group of the agricultural remedy being phased out in comparison with the proposed remedy for registration, as well as any other agricultural remedies currently registered for the pest/crop combination. Resistance groups of agricultural remedies registered for the control of other pests on the same crop or the same pest on other crops grown in proximity should also be taken into account.
    c. Efficacy under adequate pest pressure in comparison with the remedy being phased out. Data comparison is not necessary, however a brief overview of the anticipated performance of the proposed remedy compared to the remedy being replaced, to the best of the applicant's knowledge. For example, if the remedy being phased out is a fungicide with curative action and the replacement remedy is a biological remedy providing only suppression or perhaps control when disease pressure is low.
    d. Indication of whether the remedy can be considered as a full replacement for the remedy being phased-out or only a partial replacement and the reasoning, taking into consideration whether products are systemic or contact, withholding periods, etc. In the example above, the biological remedy may be considered for fast-tracking as a partial replacement of the remedy being phased out, however, other remedies should also be considered for registration in conjunction with the biological remedy, or a derogation needs to be provided for the remedy being phased out for use under circumstances of high disease pressure. Partial replacement of a remedy can still reduce the number of applications and therefore, risk of use of agricultural remedies identified as substances of concern. Derogations of agricultural remedies will only be considered when conforming to the requirements laid out in regulation 8(6) of the "regulations relating to agricultural remedy" of 25 August 2023.

    e. Implications for market access taking into consideration the main regions/markets to which the implicated commodity is exported. For example, a remedy that is restricted in export regions/markets cannot be regarded as a suitable replacement remedy for use on crops which are destined for that region/market.
5. Two copies of the proposed label if the proposed label is not the same as the label included in the previously submitted dossier.
    a. If the label in the dossier is not compliant with GHS classification and labelling, a GHS label needs to be submitted along with a rationale if not previously submitted, along with the associated fee to update the label according to GHS. If the applicant already applied to update the label according to GHS, no additional payment is necessary and only a copy of the approved GHS label need to be submitted with the application as reference.
6. A declaration stating that (i) the alternative agricultural remedy does not contain active ingredients, co-formulants or biological organisms regarded as substances of concern, (ii) no new scientific evidence is available on the agricultural remedy's potential health effects for vulnerable groups, especially children and (iii) all the information provided in this application is authentic, accurate and complete.
7. A declaration stating that the proposed remedy will, to the best of the applicant's knowledge, replace the agricultural remedy being phased out as stipulated in the explanation letter submitted with the application.

With the exception of the GHS classification where applicable, there are no additional fees associated with the submission of this information to the office of the Registrar as fees were already paid with the original submission of the application.

New applications (applications that are in process and for which development work is underway but an application for registration have not yet been submitted to Act No. 36 of 1947 for evaluation):

In the case of applications for alternative remedies for which an application has not yet been submitted to Act No. 36 of 1947 for evaluation, **all the data as stipulated in the applicable guidelines need to be submitted in addition to the following requirements**:

1. A cover letter stating that the application is for fast-tracking to replace an agricultural remedy identified as a substance of concern for one or several of the uses regarded as essential by grower associations. The cover letter should contain the following information regarding the application:
    a. Reference to the agricultural remedy identified as a substance of concern along with the essential use/s aimed to be replaced by the registration of the alternative remedy.
2. Two copies of the application form indicating the GHS classification of the alternative remedy, and the status of registration of the alternative remedy in other countries.
3. An explanation letter as stipulated in point 3 above in the section regarding "applications that are complete and that have already been submitted to Act No. 36 of 1947 for evaluation".
4. Signed assessment reports for all applicable trials (efficacy, phytotoxicity and residues).
5. Two copies of the proposed label.
    a. Only claims for essential uses to replace products that are identified as substances of concern may be considered for fast-tracking and therefore included on the proposed label.
    b. If a GHS label has already been submitted for the agricultural remedy in question, a copy of the approved GHS label needs to be included in the application as reference and no additional payment for the GHS classification is required. If it's a new registration, a GHS label with a full classification rationale must be submitted with the application. There are no fees associated for a GHS classification for an application for a new registration. In the case of a label extension where the label has not previously been updated according to GHS, a full classification rationale must be submitted and the relevant tariff to update the label according to GHS must be paid.
6. A declaration stating that (i) the alternative agricultural remedy does not contain active ingredient, co-formulants or biological organisms regarded as substances of concern, (ii) no new scientific evidence is available on the agricultural remedy's potential health effects for vulnerable groups, especially children, and (iii) all the information provided in this application is authentic, accurate and complete.
7. A declaration stating that the proposed remedy will, to the best of the applicant's knowledge, replace the agricultural remedy being phased out as stipulated in the explanation letter submitted with the application.

Department of Agriculture, Land Reform, Rural Development
Private Bag X343
Pretoria
0001

[insert date]

The Registrar (Act 36 of 1947)

DECLARATION MADE BY THE COMPANY REPRESENTATIVE

The applicant hereby declares that the application for registration for the remedy [insert agricultural remedy tradename and registration number where available] conforms to the following requirements as stipulated in the "Regulations relating to agricultural remedy" of 25 August 2023:

i. The agricultural remedy does not contain active ingredients and/or co-formulants or biological organisms regarded as substances of concern.
ii. No new scientific evidence is 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 applicant
Full name of company representative	Signature
Date	Tel no.

Department of Agriculture, Land Reform, Rural Development
Private Bag X343
Pretoria
0001

[insert date]

The Registrar (Act 36 of 1947)

DECLARATION MADE BY THE COMPANY REPRESENTATIVE

The applicant hereby declares that the application for registration for the proposed alternative remedy [insert agricultural remedy tradename and registration number where available] will, to the best of the applicant's knowledge, replace the agricultural remedy being phased out as stipulated in the explanation letter submitted with the application.

_____	_____
Applicant company	Title of applicant
_____	_____
Full name of company representative	Signature
_____	_____
Date	Tel no.