agriculture,
forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINE OF THE REGISTRATION PROCESS FOR AGRICULTURAL REMEDIES.

Issued by the Registrar: Act No. 36 of 1947, Private Bag X343, Pretoria 0001

Republic of South Africa

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1. INTRODUCTION

The Department of Agriculture, Forestry and Fisheries (DAFF) through the Directorate Agricultural Inputs Control (DAIC), regulates the manufacturing, distribution, sales, use and advertisement of agricultural remedies through Act No 36 of 1947 “Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies” (1). An 'Agricultural remedy' is defined in this act as “any chemical substance or biological remedy, or any mixture or combination of any substance or remedy intended or offered to be used-

(a) for the destruction, control, repelling, attraction or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof, but excluding any chemical substance, biological remedy or other remedy in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), or the Hazardous Substances Act, 1973 (Act 15 of 1973); or

(b) as plant growth regulator, defoliant, desiccant or legume inoculant,

(c) and anything else which the Minister has by notice in the Gazette declared an agricultural remedy for the purposes of this Act:”

Applicants who wish to manufacture, import, sell and advertise agricultural remedies in South Africa must submit detailed information and data for evaluation to the Registrar of Act No. 36 of 1947, DAIC.

Section 3 of Act 36 of 1947 requires that applicants must submit data generated from scientific studies for evaluation of safety, efficacy and quality of products. Data must be generated from studies carried out according to prescribed standards
All applicants must refer to “Guideline on the data and documents required for registration of agricultural remedies in South Africa” document of 2015 for specific data requirements (2).

It should be noted that the DAIC does not conduct its own tests when evaluating agricultural or stock remedies, but conducts a scientific review of the data submitted by the applicants.

The DAIC performs a full evaluation and does not consider approval by another regulatory authority as criteria for registration. DAIC has the responsibility to ensure that agricultural remedies registered for use in South Africa are:

- safe to the host, the user, the general public and the environment
- efficacious- that is, they do the job they supposed to do
- suitably formulated and properly labeled
- not unduly prejudicial to trade when used according to instructions

DAIC achieved these outcomes by:

- evaluating active constituents, products and their labels
- reviewing existing chemicals where potential risks to safety or performance have been identified
- issuing permits for emergency uses, minor uses or for research purposes
- with assistance from the states and territories, conducting a national program of compliance and surveillance up to and including the point of retail sale.

The different categories covered under the agricultural remedy definition can be summarized as follows:

- household and home garden pest control
- industrial pest control
- disease vector control, e.g., malaria

- control of unwanted trees, shrubs and invasive plant species
- control of fungi or fungal spore
- biopesticides
- inoculants
- plant growth regulators
- seed treatment products
- adjuvants
- minor uses of agricultural remedies
- swimming pool remedies

Separate guidelines exist for most of the above types of registration, or are being developed. This document must be read in conjunction with all other relevant guidelines related to pesticide registration requirements under Act No 36 of 1947.

2. AIM

The purpose of this document is to outline the procedures for applying to the Registrar of Act No. 36 of 1947 (DAIC) for registration or approval of agricultural remedies. The goal is to ensure that the submission management process is efficient, effective and predictable for applicants and the DAIC registration officers. Detailed guidance on the category under which an application must be made, and data requirements for an application are set out in Guideline on the data and documents required for registration of agricultural remedies in South Africa" document of 2015.

3. SCOPE

This document pertains to all applications for:

- New active ingredient
- New formulation type
- Generic active ingredient
- Change or addition of source of active ingredient
- Major amendment to a registered formulation
- Minor amendment to a registered formulation
- Label extension
- Administrative amendment
- Parallel and daughter registrations
- Transfer of a registration
- Trade name change
- Change or addition of a formulator
- Change or addition of packaging size and/or packing material
- Advertisements
- Import permits
- Certificate of Free Sale
- Re-instatements
- Renewals of registration
- Certificate of origin or cancellation of registration

4. APPLICANTS and APPROVED PERSONS

4.1. Applicant and registration holder

The applicant is the individual or company who / which will become the registration holder, should be application be successful. In the case where the application is for any changes to be made to an approved current registration, the applicant will be the registration holder.

All individual representative applicants must reside in South Africa or in the case of a company, the company must have a registered office in South Africa. The application form must contain the applicant's full name, street, postal address and contact details. If the applicant is a company then proof of registration in South Africa must be provided. In all cases, the applicant must nominate approved person and their position and title, with whom DAIC can correspond and who will take responsibility for the application.

4.2. Approved person

The approved person is the individual, company representative or third party representative who is resident in South Africa and who will take responsibility for the application. In relation to an application, generally the approved person is responsible for:

- signing the application form
- giving consent to the DAIC to alter the application form
- giving extra information or changing information previously given to the DAIC
- giving the DAIC written notice to withdraw the application.

An applicant may appoint a third party (a company or an individual outside their company but residing in South Africa). A representative from this third party may be appointed as the approved person. for the purposes of the application.

When an applicant wishes to make use of a third party representative, they must send a letter of authority to DAIC. The letter of authority must specify:
i) which of the regulatory matters the approved person is authorised to conduct, i.e. all aspects of the application or only specified functions.
ii) the duration of the agreements, i.e. The same person will also be responsible for only the application process or if they will also be responsible for the post-registration matters.

If an applicant appoints a different approved person for any one or more of the regulatory matters, they must send DAIC a separate letters for each different approved person.

If the approved person is a company representative, the individual signing the application form must be authorized to do so by the company. Authorisation of an individual to sign on behalf of a company must be in writing and legally binding to the company.

An applicant can withdraw the appointment of an approved person at any time by writing to DAIC. An applicant may also vary the authority or responsibilities of an approved person. Should an applicant wish to change aspect relating to the approved person, these changes must be submitted to Registrar in writing, clearly detailing the required change.

5. BASIC APPLICATION REQUIREMENTS

An application can range from only a completed application form to a multi-volume application containing detailed scientific reports and scientifically-based arguments. As a minimum, an application must include the following documents and information:

A complete application must:

- include the appropriate and fully completed application form signed by an approved person including all relevant information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II).
- information that application requires. See Guideline on the data and documents required for registration of agricultural remedies in South Africa" document of 2015.
- be accompanied by appropriate fee (See document for tariffs adjusted every financial year)

An application will not be accepted by the DAIC and proceed to a full evaluation unless it is complete.

5.1. Application form and cover letter

The application form (including the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II)) must be completed fully and comprehensively. The Application Form and cover letter must contain the signature of the approved person. Any whiteout or corrections must be initialed. All applications require a cover letter. In the cover letter, an applicant must clearly state what they are applying for. They can also list the data (and number of files) they have submitted to support their application. The application form is available on DAFF website **www.daff.gov.za** (1)

5.2. Supporting data

All applicants must refer to "Guideline on the data and documents required for registration of agricultural remedies in South Africa" document of 2015 for specific data requirements.

5.3. Application fees

Proof of payment of the application fee must be submitted with the application. The amount is determined by the application category. The tariffs are published through government gazette at the beginning of each financial year. An application cannot proceed to evaluation until the applicant has paid the application fee in full. If an applicant has submitted an excess amount, the applicant should use the excess amount when making future applications. No refunds will be made to the applicant. The DAIC is able to accept proof of payment for payments made via Electronic Transfers, Cash Deposits or receipts from payments made at Finance Division of DAFF only. No cash will be accepted by DAIC. Banking details for DAFF can be requested from the office of Registrar (Act 36).

5.4. Labels

Applicants must provide 3 hard copies of the a proposed label in hard copy. Further details may be found in Guideline on the data and documents required for registration of agricultural remedies in South Africa" document of 2015.

5.5. Application submission

All applications must be submitted in hard copy and either mailed to:

The Registrar: Act No. 36 of 1947
Directorate Agriculture Inputs Control
Department of Agriculture, Forestry and Fisheries
Private Bag X343
Pretoria
0001

or hand-delivered to:

The Registrar: Act No. 36 of 1947
Directorate Agriculture Inputs Control
Agriculture Place, Room number LB-GF-10, 20 Steve Biko Road, Arcadia
Pretoria, 0002

Appointments must be made prior to the delivery of any applications. All correspondence between the DAIC and an approved person must be dated and should include the product name or the proposed product name and the registration number (if known).

5.6. Application alterations

An applicant may request the DAIC to alter aspects of their application or give the DAIC additional or different information at any time after they have submitted an application, provided that the scientific screening and evaluation process has not commenced.

5.7. Application withdrawal

At any stage an applicant may withdraw an application by notifying the DAIC in writing. When an applicant withdraws an application before the evaluation process has commenced, the DAIC will refund the full amount to the applicant in a form of credit for future application(s). If the application has passed screening and evaluation has commenced, withdrawal of application will be regarded as a rejection of the application and thus final processing of the application and rejection letter will be issued to the applicant. No refunds will be made.

5.8. Application format

Language

All applications and accompanying data submitted to the Registrar of Act No. 36 of 1947, DAIC, must be in English. If an applicant wishes to submit material in another language, they must supply an authorised English translation, and clearly identify it as such. The DAIC may request the original foreign language document.

Presentation

In order to assist an evaluator, and to make the assessment of an application go more smoothly, it is recommended that applications conform to the following:

- If more than one file / volume is submitted, each volume must be clearly marked
- Each volume of an application has a table of contents
- All material submitted must be legible and printed on A4 paper.
- Applicants must ensure that all photocopies or photographs are clear or legible, Original documents are preferred,
- File dividers should be used to separate different section of an application
- If specific references are cited in an application, applicants must include a legible copy of the whole article with the application, with the relevant section highlighted.
- Lever arch files are preferred.
- Toxicology studies and 5-batch reports can be submitted using Compatible Discs (CDs) or DVDs.

5.9. Confidential Business Information or trade secrets

DAIC staff are required to handle Confidential Business Information (CBI) submitted by applicants. CBI in relation to an agricultural remedy is defined in the CropLife International (3) as:

- technical and formulation specifications, including confidential statement on formula, certificate of composition documents, and 5-batch analysis reports
- process of chemistry and the route of manufacture, including manufacturing description reports
- analytical methods on “non-relevant” impurities of the manufacturing process and
- other specific documents which are commercially sensitive; for example: market share information, names and addresses of scientists.

Data that falls under CBI is forever protected and not time-limited, However, this does not exempt an applicant from provided CBI documents, when required.

6. PROCESS FLOW OF THE APPLICATIONS

The following section provides a step-by-step description of the submission review process which can be divided into 3 categories; verification, scientific screening and evaluation. The DAIC will first screen the application (preliminary assessment) to assess whether it is complete. If the DAIC discovers at screening that there is missing information in the application, the DAIC will notify the applicant requesting that information. If the information is not supplied by the applicant within the specified period, the application will be rejected. For application timeframes, please refer to table 1

6.1. The screening process

The screening process is divided into two steps:

- administrative verification
- technical screening

Administrative verification

Administrative screen of applications take place within 14 calendar days after receipt to ensure that non-data elements have been provided.. During administrative screening, the following are verified:

- cover letters
- applicant details
- approved person details
- product registration number (if available) and if still valid
- application forms in triplicate, fully filled and signed
- legibility of the information and initialization of any corrections made by the applicant
- fees paid
- three copies of the labels, and
- other data specified on the cover letter

If the DAIC administrative section discovers that there is missing information.in the application, the DAIC will notify the applicant, requesting that information. If the information is not supplied by the applicant within the specified period, the application will be rejected.

Scientific screening

Once an application passes the administration verification process, it is allocated to be scientific screened The data submitted are scientifically screened against the data requirements outline in the Guideline on the data and documents required for registration of agricultural remedies in South Africa" document of 2015.

If the DAIC discovers that there is missing information.in the application, the DAIC will notify the applicant, requesting that information. If the information is not supplied by the applicant within the specified period, the application will be rejected.

6.2. Evaluation stage

Once an application passes the screening process, it is allocated for scientific evaluation. During the process of evaluation, the applicant may be contacted for clarity or if data is missing If the information is not supplied by the applicant within the specified period, the application will be rejected.

6.3. Decisions

Once the product evaluation process has been completed, the technical advisor submits an evaluation report and recommendations to the registrar. Registration officers prepare documents on the application for submission to Registrar. The applicant is informed in writing about the decision of the Registrar, and issued with the relevant documentation. A registration is valid for a term of three years and is subject to renewal.

6.4. Appeal process

If the applicant is not satisfied with a decision made by the Registrar, section 6 of the Act provides for an appeal to the Minister against this decision. The Minister will then follow the process available to him/her.

6.5. Time frames

Applications are reviewed according to the dates of submissions and categories of the different applications groups. However, under certain circumstances, an expedited review may be considered

if there is a specific critical need identified by the Registrar. The time frames for specific processes and categories can be summarized as followings:

Table1: Estimated time frames for various applications in number of calendar days for major and minor registration applications of agricultural remedies*

Category	Performance Standards in days				
Major registration applications					
	Verifications	**Screening**	**Evaluation**	**Decision**	**Total No. Days**
New molecule	14	30	569	14	627
Generic	14	30	360	14	418
New formulation or major amendment to a registered formulation	14	30	360	14	418
Label extension	14	30	360	14	418
Minor registration applications					
	Verifications	**Screening**	**Evaluation**	**Decision**	**Total No. Days**
New source of active ingredients	14	-	180	14	208
Minor amendment to a registered formulation	14	-	90	14	118
Admin amendments to the application form or label	14	-	90	14	118
Trade name change	14	-	90	14	118
Parallel registrations/daughter registrations and transfers	14	-	90	14	118
Addition or change of formulator	14	-	180	14	208
Addition or change of packaging material	14	-	90	14	118
Re-instatement	14	-	90	14	118
Advertisements	7	-	21	7	35
Import permits	3	-	8	3	14
Renewals of registrations	90	-	-	-	90
Certificate of Free Sale, or Registration cancellation	7	-	-	-	7

***Please note these time frames maybe extended, if there is a delayed response from the applicant to a DAIC communication

7. ENQUIRIES

General enquires related registration processes, should be directed to Registrations Administrators. Please refer to www.nda.gov.za for the latest contact details.

8. REFERENCES

1. Fertilizers, farm feeds, agricultural remedies and stock Remedies act 36 of 1947. Department of Agriculture, Forestry and Fisheries. South Africa. Available on internet at http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control

2. Guidelines on the data and documents required for registration of agricultural remedies in South Africa. 2013. Registrar: Act No. 36 of 1947, Agriculture, Forestry and Fisheries. South Africa. Available on internet at http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control

3. Principles of regulation. CropLife International. www.croplife.org.