
agriculture,
forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

# GUIDELINES ON THE REGISTRATION REQUIREMENTS FOR STERILIZING PLANTS IN SOUTH AFRICA

**Issued by the Registrar: Act No. 36 of 1947**
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**2015**

**Doc. Ref:** SP/Reg. Req. Guideline 01

**Version Nr.** 01

**Date Modified:** September 2015

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## SECTION A: REGISTRATION PROCESS

### 1. INTRODUCTION

The Department of Agriculture, Forestry and Fisheries (DAFF) through the Directorate of Agriculture Inputs Control (DAIC) under the authority of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), regulates the importation, manufacture, acquisition, distribution, sales, use, advertisement and disposal of farm feeds.

Sterilizing plant is defined in the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act No. 36 of 1947), as a plant used for sterilizing of bones or other substances derived from cattle, members of the horse family, sheep, goats, pigs, poultry or ostriches, of any age, or from any vertebrate specified by the Minister from time to time by notice in the Gazette.
Rendering plant has the same meaning.

Persons who wish to operate and advertise sterilizing plants in South Africa must submit detailed information for assessment to the Registrar of Act No. 36 of 1947. Section 3 of Act No. 36 of 1947 requires that applicants must submit information to assess whether a sterilizing plant is suitable and sufficiently effective for the purpose of which it is intended and that it is not contrary to the public interest.

### 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 of a sterilizing plant. The ultimate goal is to ensure that the submission management process is efficient, effective and predictable for applicants, registration holders and the DAIC registration officers.

### 3. TYPES OF SERVICES THAT MAY BE APPLIED FOR

This document pertains to all applications for:

- New registrations
- Renewal of registration
- Amendments
  - Transfer of registration
  - Re-instatement of registration
  - Cancellation of registration
  - Amendment of the manufacturing facility
- Advertisement

## 4. WHO CAN APPLY TO REGISTER A STERILIZING PLANT

The applicant may be an individual or a registered company. It must be a person residing in the Republic of South Africa, or in the case of a juristic person, it must be a person who has a registered company in the Republic of South Africa.

### 4.1. APPLICANT AND REGISTRATION HOLDER

The applicant is the individual or company who/which will become the registration holder of the approved or registered sterilizing plant should the 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. If the applicant is an individual, a copy of an Identity Document must be provided. If the applicant is a registered company, a copy of the company registration certificate from the Registrar of companies must be provided. The company must nominate an authorized/approved contact person.

### 4.2 APPROVED CONTACT PERSON

An approved person is an 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:

- giving consent to the Registrar to alter the application form.
- providing extra information or changing information previously given to the Registrar.
- giving the Registrar 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). When an applicant wishes to make use of a third party representative, they must send a letter of authority to the Registrar. 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 separate letters to the Registrar for each different approved person. The individual signing the application form must be qualified to do so and authorized by the company.

An applicant can withdraw the appointment of an approved person at any time by writing to the Registrar. An applicant may also vary the authority or responsibilities of an approved person. Should

an applicant wish to change aspects relating to the approved person, these changes must be submitted to the Registrar in writing, clearly detailing the required changes.

## 5. WHAT TO INCLUDE IN A STERILIZING PLANT REGISTRATION APPLICATION

### 5.1. COVER LETTER

It is important to include a cover letter clearly outlining the intent of the submission, including the intended purpose of the sterilizing plant.

### 5.2. APPLICATION FORM

Applicants seeking registration must submit a duly completed application form. Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms); they can also be obtained from the Registrar's office. Please ensure that the form is duly completed and signed by the Commissioner of Oaths. The application form must be submitted in **triplicate**. Accompanying documents must be enclosed as per technical requirements. The technical information requirements are outlined in the technical requirements section.

### 5.3. CONTACT DETAILS FORM

The Contact Details form (Form C) (Contact details form Ref: FF/Contact_01) should be completed by new applicants, when applying for renewal of registrations and when the contact details of the company have changed. It is available for download on the Department of Agriculture Forestry and Fisheries website (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms); and can also be obtained from the Registrar's office.

### 5.4. PROOF OF PAYMENT

The tariffs are published in the government gazette at the beginning of each financial year and are available on the Department of Agriculture Forestry and Fisheries website (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Agriculture-Input-Control-Notices). DAFF accepts payments in a form of a cheque, cash deposits into the bank account, cash payment at Finance Division of DAFF and Electronic Funds Transfers (EFT). Payment should be made to the Director-General: Department of Agriculture, Forestry and Fisheries into the following bank account:

| | |
|---|---|
| Account name: | NDA-Act 36 of 1947 |
| Account number: | 011203102 |
| Reference: | SP1 and Name of Company/Name of applicant |
| Branch code: | 010845 |
| Branch name: | Arcadia |
| Bank name: | Standard Bank |

## 6. HOW TO ALTER AN APPLICATION

An approved person may request the Registrar to alter aspects of their application or give the Registrar additional or different information, by submitting a written request and authorization in this regard. The request will be processed, provided that the technical screening and assessment process of the applicable application has not yet been completed. If the request for alteration is received after the application has been finalized, the applicant will be notified that their request was unsuccessful and that an application for amendment needs to be submitted.

## 7. HOW TO WITHDRAW AN APPLICATION

At any stage of the registration process, an applicant or approved person may request the Registrar to withdraw their application by sending written authorization. When an applicant voluntarily withdraws an application before the assessment process has commenced, the Registrar may refund the full amount to the applicant. If the application has passed technical screening and technical assessment has commenced, withdrawal of application will be regarded as a rejection of the application and thus processing of the application will be finalised and a rejection letter will be issued to the applicant. No refunds will be made.

## 8. FORMAT OF AN APPLICATION

### 8.1. LANGUAGE

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

### 8.2. CONFIDENTIAL BUSINESS INFORMATION OR TRADE SECRETS

The officials of DAFF are required to handle Confidential Business Information (CBI) submitted by applicants. Data that falls under CBI is protected for an unlimited time period. Confidential Business Information relating to an application for a new or existing farm feeds registration or as a constituent of a farm feed refers to:

- facility design plans;
- description of manufacturing process;
- other specific documents which are commercially sensitive; for example: market share information, names and addresses of suppliers and customers.

### 8.3. PHOTOCOPIES AND GRAPHIC IMAGES

Applicants must ensure that all photocopies are legible with adequate margins on both edges of the page. The Registrar will return any unreadable, unclear or incomplete copies and ask the applicant to replace them. All graphic images (including photos) must be of high quality that will enable replication.

Original prints are preferred. Photocopies of photographs will only be accepted if they are of good quality and clearly illustrate the subject.

### 8.4. REFERENCES AND TESTIMONIALS

If specific references are cited in an application, applicants must include a legible copy of the whole article with the application. Applicants must indicate which part of the reference is applicable to the application. For generally accepted scientific information, full references will not usually be required. However, in some instances the DAIC may require a copy of a reference. Testimonials and other forms of anecdotal evidence are generally not acceptable, and will be disregarded.

### 8.5. PRESENTATION, BINDING AND PAGINATION

All documents submitted must be legible and printed on A4 paper. Applicants may print pages on both sides if legibility is not affected. Margins must be wide enough to enable the material to be read when bound and/or placed on file. The material must be presented in a systematic order. If the entire application submission contains more than 10 pages of information, applicants must separate the different documents (e.g. manufacturing process, veterinary certificate, sales records and so forth) using a separator slide with a section title on it. If a section comprises a series of documents, a concise summary (abstract) must be provided at the front of each section.

The application submission must be bound and the pages on the submission file must be numbered and cross-referenced to the table of contents. Lever arch files are preferred for large applications. The use of plastic or paper folders should be limited to smaller applications. The cover page for bound applications must contain a list of contents to enable assessors to easily identify and access documents. If the application is more than one volume, applicants must label the cover of each volume. The following information must be clearly identified on the cover page:

- name of the applicant
- company name
- registration number (if registered)
- type of application or category
- volume numbers and total number of volumes in the application
- date of application.

Pages must be numbered systematically so that assessors can easily and accurately locate documents. Pages may be sequentially numbered from start to finish or, if an application is in several volumes, sequentially numbered within each volume, for example; Volume 1: Pages 1.1, 1.2, 1.3 and so on, and Volume 2: Pages 2.1, 2.2, 2.3 and so on. Any system for numbering the pages of an application may be used, if it is consistent throughout the application and is accurately reflected in the table of contents. Applicants do not need to erase page numbers on copies of other documents included in an application unless those page numbers could be confused with the page numbers of the application form.

## 9. THE REGISTRATION PROCESS

The following section provides a step-by-step description of the submission review process which can be divided into 4 categories; verification, technical screening, assessment and approval.

### 9.1. ADMINISTRATIVE SCREENING (VERIFICATION)

Administrative screening of applications take place within 14 calendar days of receipt of the documents to ensure that non-data elements including the cover letter, the appropriate application form and the proof of payment have been provided. Applications that meet all the administrative requirements are then accepted and sent for technical screening and assessment. Applicants are then provided with a letter acknowledging receipt of the application and also indicating the estimated time for completion of the registration process.

If an application fails the administrative screening, the Registrar will inform the applicant (via an e-mail or facsimile), outlining the deficiency and indicating a timeframe of 30 calendar days within which the deficiency must be rectified and re-submitted. Once the deficiency has been rectified and re-submitted the application will progress to technical advisors for technical screening and assessment.

### 9.2. TECHNICAL SCREENING

In the technical section, the data submitted are screened against the data requirements outlined in this guideline. Deficiencies are communicated to the applicant and should be rectified within 30 calendar days. If the requested information is not supplied within the specified period, the application will be rejected.

### 9.3. ASSESSMENT

Once an application passes the screening process, it is allocated for scientific assessment. During the process of assessment, 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.

### 9.4. APPROVAL

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.

## 10. APPEAL PROCESS

If the application for registration has been rejected or has been approved with conditions that the applicant is not satisfied with, section 6 of the Act provides for an appeal to the Minister against the decision of the Registrar. The Minister will then follow the process available to him/her.

## 11. REGISTRATION/APPROVAL TIME FRAMES

Applications are reviewed according to the date of submission. Depending on the type of application, the registration process timeframes vary between 14 to 120 calendar days. Please note that the time during which an application is waiting for outstanding information is not included in the 14 to 120 calendar days. The time frames for specific processes and categories can be summarized as follows:

**Table1: Timeframes according to type of applications and registration processes**

| Type of application | Registration Period |
|---|---|
| New applications | 4 months |
| Renewal of registration | 4 months |
| Re-instatement of registration | 3 months |
| Cancellation of registration | 2 months |
| Amendment of manufacturing facility | 2 months |
| Transfer of registration | 2 months |
| Advertisement | 2 weeks |

## 12. REGISTRATION PERIOD

Sterilizing plant registrations are valid for three years and expire on 31 March, three years after the date of registration. An application for renewal of a sterilizing plant can be made to the Registrar of Act No. 36 of 1947 before the expiry date is reached.

## 13. WHERE TO SEND AN APPLICATION

All applications must be submitted in hard copy and delivered to:
The Registrar: Act No. 36 of 1947
Directorate Agriculture Inputs Control
Agriculture Place, Room number LB-FF-09 or LB-FF-10,
20 Steve Biko Road, Arcadia
Pretoria, 0002
Appointments must be made prior to the delivery of any applications. Appointments can be made through AICHelpdesk@daff.gov.za or Tel. 012 – 319 7847 / 7103

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

## 15. ENQUIRIES

All enquiries must be directed to the DAIC Help Desk.
Telephone No.: 012 – 319 7847 / 7103
Facsimile No.: 012 – 319 7179
Email: AICHelpdesk@daff.gov.za

## SECTION B: TECHNICAL INFORMATION REQUIREMENTS

### 1. APPLICATION FOR REGISTRATION

1.1. A sterilizing plant as defined in Act No. 36 of 1947 is registered it terms of section 3(1) of the said Act. Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms); and can also be obtained from the Registrar's office.

1.2. An application to register a sterilizing plant shall be accompanied by:

a) Cover letter
b) Application form for registration of Sterilizing Plant **in triplicate** – (Application Form Ref: SP/Registration_01)
c) Contact details form should be completed by new applicants. Form C (Contact details) – (Application Form Ref: FF/Contact_01);
d) Veterinary inspection report.
e) Facility design plans and description of manufacturing process(es) flow.
f) Proof of approval of the Environmental Impact Assessment from the Department of Environmental Affairs and Tourism (not applicable to pet food manufacturing facilities).
g) Proof of payment.

1.3. An inspection report by inspectors from Act 36/1947 will be obtained by the DAIC assessor from the DAIC inspection services.

### 2. IMPORT PERMITS

2.1. Import permits are issued for animal by-products that are imported for sterilization. The animal by-product must be registered in terms of Act No. 36/1947. A container in which an imported animal by-product which is intended for sterilizing is packed must, in addition to any details that the Registrar may approve, be marked with the details **"NOT TO BE USED IN ANIMAL FEEDS OR FEEDING"**.

2.1.1. Application must be accompanied by:

a) An application letter must be submitted stating:
    (i) The reason for the importation.
    (ii) Type of product(s).
    (iii) Quantities of the product(s).
    (iv) The country of origin of the products.
    (v) Port of entry into the Republic of South Africa.
b) Imports of permit issued under Animal Diseases Act No. 35 of 1984 and where applicable, permit issued under Meat Safety Act No. 40 of 2000.
c) Copies of bill of landing or entry invoices.
d) Product specification sheet.
e) Proof of payment.

Note: The permit is valid for only one (1) consignment per product.

## 3. ADVERTISEMENTS

3.1. Advertising of a sterilizing plant or sterilizing process requires approval by the Registrar. The advertisement must conform to the standards of the Advertising Standards Authority of South Africa. Specific scientific claims in the advertisement must be substantiated. The application must be made by the registration holder.

3.1.1 The following documents must be submitted:

a) A cover letter
b) A copy of the advertisement
c) Proof of payment

Note: The approval is valid for one year and it is renewable.

## 4. REGISTRATION RENEWAL

4.1. Application to renew a registration can only be lodged by the registration holder. No amendments to a sterilizing plant or details thereof will be accepted at the time of its renewal. Applicants must lodge applications for approval of amendments prior to or after registration renewals or re-instatement.

4.2. The office of the Registrar sends reminders for renewals three (3) months before the end of March each year to registration holders whose registrations are about to expire. It is advisable not to wait for the reminders and apply to renew registrations at least three (3) months prior to the expiry date to ensure continuous registration. Applications for registration renewals must be submitted to the office of the Registrar not later than the 31$^{st}$ of March. Applications submitted after this date but before the 30$^{th}$ of April are liable for a late renewal penalty fee that is payable in addition to the renewal fee. The registration of a sterilizing plant whose application is submitted after the 30$^{th}$ of April in the year of its expiry is considered to have lapsed and must be re-instated.

4.3. The following documents must be submitted:

a) Renewal form for Sterilizing Plant – (Application Form Ref: SP/Renew_01) listing names and registration numbers of sterilizing plants whose registrations need to be renewed.
b) Veterinary inspection report.
c) Purchase and sales records for animal by-products sterilized and sold during registration period (not applicable to pet food manufacturing facilities).
d) Proof of payment.

4.4. An inspection report by inspectors from Act 36/1947 will be obtained by the DAIC assessor from the DAIC inspection services.

4.5. Certificates of Analyses of sterilized by-products will be obtained by the DAIC assessor from the DAIC inspection services.

## 5. AMENDMENT OF REGISTERED STERILIZING PLANTS

An application to amend a registration can only be lodged by the registration holder. An application to re-instate a registration can only be lodged by the former registration holder. An application for amendment can only be processed, reviewed and approved if the registration is still valid.

### 5.1. TRANSFER OF REGISTRATION

This application is lodged when a company changes ownership (e.g. the company being sold to another company) or when the name of the company changes. The application must be made by the current registration holder. The Registrar must be notified in writing within two months of the changes. A request to retain the current registration number must be included in the cover letter.

5.1.1. The following documents must be submitted:

a) A cover letter.
b) Sworn affidavit that serves as an agreement between two companies stating the registrations to be transferred from Company A to Company B (when company changes ownership).
c) Copy of registration certificate of the new company (issued by the Registrar of Companies).
d) Original registration certificates from the current registration holder.
e) Proof of payment.

5.1.2. The new registration holder (company B) shall keep the registration numbers that were allocated to the previous registration holder.

### 5.2. RE-INSTATEMENT OF REGISTRATION

The application must be made by the former registration holder of the sterilizing plant. The registration of a sterilizing plant can be re-instated if its registration had been cancelled or the registration has lapsed. No amendments to a sterilizing plant will be accepted at the time of its re-instatement.

5.2.1. The following documents must be submitted:

a) A cover letter.
b) Application form for sterilizing plant registration – (Application Form Ref: SP/Registration_01).
c) Veterinary inspection report.
d) Invoices for animal by-products sterilized and sold during registration period (for lapsed registrations) (not applicable to pet food manufacturing facilities).
e) An inspection report by inspectors from Act 36/1947 will be obtained from the DAIC inspection services.
f) Certificate of Analysis of sterilized by-products will be obtained from the DAIC inspection services (for lapsed registrations).
g) Proof of payment.

### 5.3. CANCELLATION OF A REGISTRATION

The registration of a sterilizing plant can be cancelled by the registration holder. In some instances, it can be cancelled by the Registrar in terms of section 4 of Act No. 36 of 1947. The registration holder must return the original registration certificate to the Registrar within 14 calendar days of the registration cancellation.

5.3.1. The following documents must be submitted to cancel a registration:

a) Sterilizing plant Form B (Cancellation) – (Application Form Ref: SP/Cancel_01) listing names of sterilizing plants and registration numbers whose registrations should be cancelled.

### 5.4. AMENDMENT OF MANUFACTURING FACILITY

This application is lodged if the manufacturing site changes/relocates, manufacturing process changes or the manufacturing facility is modified. Such application can also be lodged when a storage facility not located on the same premises as the sterilizing plant is added to the registration information.

5.4.1. The following documents must be submitted:

a) A cover letter.
b) Application form for sterilizing plant registration – (Application Form Ref: SP/Registration_01).
c) Facilities design plans and description of manufacturing process flow.
d) Proof of payment.

5.4.2. An inspection report by inspectors from Act 36/1947 will be obtained by the DAIC assessor from the DAIC inspection services.

## 6. REFERENCES


1. Fertilizers, farm feeds, agricultural remedies and stock Remedies Act 36 of 1947. Department of Agriculture, Forestry and Fisheries. South Africa. www.daff.gov.za/agricultural production, health & food safety branch/feeds, stock remedies, pesticides and fertilizers.

2. Regulations Relating to Sterilizing Plants No. R. 1086. www.daff.gov.za/agricultural production, health & food safety branch/feeds, stock remedies, pesticides and fertilizers.

## ANNEXURE 1

**Application Forms for the registration of Sterilizing plants**

The following application forms are available for the respective registration applications. The forms can be downloaded from the DAFF website at: (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms). They can also be obtained from the Registrar's office.

- Application form for sterilizing plant registration – (Application Form Ref: SP/Registration_01).
- Renewal form for Sterilizing Plants (Renewals) – (Application Form Ref: SP/Renew_01)
- Cancellation form for registration of Sterilizing Plant. Form B (Cancellation) – (Application Form Ref: SP/Cancel_01)
- Contact details form. Form C (Contact details) – (Application Form Ref: FF/Contact_01)