# GOVERNMENT NOTICES
# GOEWERMENTSKENNISGEWINGS

## DEPARTMENT OF AGRICULTURE
## DEPARTEMENT VAN LANDBOU

**No. R. 1086** **3 November *2006***

**FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT NO. 36 OF 1947)**

**REGULATIONS RELATING TO STERILIZING *PLANTS***

I, Lulama Xingwana, acting under section 23 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), made the regulations in the annexure hereto.

L. Xingwana
Minister of Agriculture

**SCHEDULE**

***DefInitions***

1. Words and phrases in these regulations shall have the meaning assigned thereto in the Act, and unless the content otherwise indicates-

**"animal by-product"** means the entire bodies or parts of animal origin not intended for human consumption;

**"animal"** means any mammal, bird, fish, reptile or amphibian which is a member of the phylum vertebrates, including the carcass of such animal;

**"application fee"** means fees that, in terms of these regulations, are payable for the registration of an animal feed and the annual renewal of such registrations;

**"veterinary inspection certificate"** means a certificate issued by State Veterinarian attesting to the effect that the hygienic standards at a sterilizing plant are in the public interest and that the practices and equipment applied or to be applied for sterilizing animal by-products are suitable and sufficiently effective to ensure that animal by-products manufactured or processed are free from pathogenic organisms, including *Baccillus* anthracis and organisms of the gasgangrene type, and ensure that putrefactive or other organisms are not present in quantities which are likely to endanger the health of animals;

**"farm animal"** means animal nourished and kept by man for commercial purposes;

**"feed ingredient"** means a product of animal origin, in its natural state, fresh or preserved; a product derived from the industrial processing thereof .Feed ingredient has the same meaning as raw material, feedstuff or any words of similar connotation;

**"good manufacturing practice or GMP"** means a system of manufacturing designed to ensure that the final products made are fit for their intended purpose and meet all agreed specifications and statutory requirements;

**"Intermediate plants"** means a processing plant where the raw animal by-products are only partially processed and not fully sterilized;

**"label"** means when used as a noun, any written, printed or graphic representation attached to an immediate container of an animal feed or produced on an immediate container in any possible manner and which states the details required in terms of these regulations for the particular animal feed;

**"labeling"** means all labels and other written, printed or graphic matter upon animal feed or any of its immediate containers or wrappers accompanying such animal feed;

**"manufacture"** means make, compound mix, formulate, process, package and label for purpose of sale. Manufacturing and manufacturing process have a similar meaning:

**"pet animal"** means an animal belonging to a specie, domesticated by man which is kept as a companion and nourished, and/or used for recreational purposes by man;

**"Plant registration number"** means the number given by the Registrar once a sterilizing plant has been registered and under which the plant may operate;

**"sealed"** means to close a container in such a visible manner with a mechanism that will break visibly the first time the container is opened;

**"registration holder"** means the legal or natural person to whom the Registrar has issued a registration number;

**"registration number"** means the number given by the Registrar once a product has been registered under which a product may be sold;

**"sterilization"** includes a heat treatment, pasteurization, irradiation and any other means whereby pathogenic organisms are destroyed;

**"Sterilizingplant"** means a facility where a process of sterilization is carried out, to render a product free from pathogenic organisms;

**"the Act"** means the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No 36 of 1947);

**"the Department"** means the Department of Agriculture;

**"trademark"** means a mark to which the holder of the registration has the right, either as the owner or a registered user thereof, to distinguish his animal feed from that of other manufacturers but excludes the registered name of an animal feed as intended in these regulations;

**"TSEs"** means all transmissible spongiform encephalopathies, except those that occur in humans;

## PART I – REGISTRATIONS

### *Application for registration*

2. (1) An application in terms of Section 3(1) of the Act for registration of a sterilizing plant must be made on a form available from the Registrar for the purpose, or a clearly legible facsimile thereof on good-quality A4 size paper of the same colour as the form supplied by the Registrar.

**Such application must-**

(a) be made by a person residing in the Republic of South Africa, or, in the case of legal person, that legal person shall have a registered office in the Republic;

(b) accompanied by the applicable fee specified in Table 1 and a veterinary inspection certificate; and

(c) be accompanied by the facilities plan and manufacturing process and or processes.

### *Period of registration*

3. (1) Apart from the provisions of Sections 4 and 4A of the Act, a sterilizing plant registration in terms of Section 3 of the Act shall be valid to 30 September of a calendar year.

**(2)** In the event that a registration is granted after 1 July in a particular calendar year, such registration shall remain valid until 30 September in the following calendar year.

***Renewal of registration***

4. (1) An application in terms of Section 3(4)(a) of the Act for renewal of registration of a sterilizing plant must be made on either a form available from the Registrar for the purpose, on good-quality A4 size paper of the same colour as the form supplied by the Registrar.

(2) Such an application must be-

(a) depending on the case, made by the person to whom the applicable registration certificate has been issued;

(b) postmarked or courier dispatched by the applicant no later than 30 September of the year in which registration lapses; and

(c) be accompanied by the applicable fee specified in Table 1 and a veterinary inspection certificate.

(3) Apart from the provisions of sub-regulation 2(b) above, an application under sub-regulation 4(1) received by the Registrar after 1 October of a particular year will not be considered as a renewal application, and an application for original registration must be made under regulation 2, with the proviso that the Registrar may at his discretion grant exemption from the requirement to submit the application form as specified in sub-regulation 2(1) in such circumstances.

(4) Anyone applying for renewal of a registration in terms of this regulation shall submit a sworn statement that the information he/she supplies with such an application for the particular sterilizing plant does not deviate in any respect at all from the comparable details that have already been registered or approved.

***Conditions for renewal of registrations***

5. A renewal of a registration for sterilizing plant, in terms of section 3 of the Act, shall be granted on condition that during the period of registration or a renewal of registration –

(1) the details of approved facilities and the facilities at the sterilizing plant are not altered;

**(2)** the approved sterilization process is not altered; and

**(3)** the particular registration may not be transferred in any manner or respect to anyone else.

***Application for amendment of certain registrations***

***6*** Such an application for amendment should be accompanied by the applicable documentation, the current registration certificate and application fee stated applicable under regulation 2(1)(b), on the proviso that the Registrar may waive the application fee should the particular change or amendment be either in the public interest, or be made at the Registrar's insistence.

***Return of registration certificate***

7. (1) A registration certificate that is returned under Section 4A(3) of the Act should reach the Registrar within 14 days of the day on which –

(a) the person to whom the particular registration certificate has been issued is informed in writing under Section 5 of the Act of the reason for withdrawal of such registration; or

(b) the registration of the sterilizing plant has expired under Section 4A(2) of the Act.

## PART II – APPEALS

***Submission of Appeals***

8. (1) An appeal under Section 6 of the Act must be lodged with the Director-General of the Department of Agriculture within 60 days after the date on which the reason on which the decision of the Registrar was based has been furnished under Section 5 of the Act.

(2) Such an appeal shall-

(a) be in the form of a written statement that has been sworn or affirmed;

(b) contain the reference number and date of the notification by which such person or applicant has been informed of that decision;

(c) indicate the grounds on which such an appeal is based;

(d) be accompanied by the documentation relating to the subject of the appeal; and

(e) be accompanied by the applicable fee as stipulated in Table 1.

**(3)** The person who appeals may be represented by a third party, in which case the appeal application shall be accompanied by a power of attorney attesting to the fact that such third party is empowered to act for him.

(4) The applicable fee within the meaning of regulation 8(2)(e) above shall be paid by cheque, postal order or money order in favour of the Director-General, Department of Agriculture, with the proviso that the fee may be paid in cash if the appeal is delivered to the Department by hand.

**(5)** An appeal within the meaning of Regulation 8(1) must -

(a) When submitted by post, be addressed to the Director-General, Department of Agriculture, Private Bag X250, Pretoria 0001; and

(b) when delivered by hand or private courier service, be delivered to the Director-General: Department of Agriculture, 20 Beatrix Street, Pretoria.

## PART III- ADVERTISEMENTS FOR STERILIZING PLANTS AND STERILIZATION PROCESSES FOR ANIMAL BY-PRODUCTS

***Publications or distribution of false or misleading advertisements***

***9.*** **(1)** No person may publish or distribute a false or misleading advertisement for a sterilizing plant or sterilization process.

**(2)** Specific scientific claims in the advertisement must be submitted for approval to the Registrar.

**(3)** Advertising shall require approval and must conform to the approved registration and the standards of the Advertising Standards Authority of South Africa.

## PART IV- INVOICES FOR ANIMAL BY PRODUCTS

10. (1) invoices must specify-

(a) the date on which the material was taken from the premises.
(b) the description of the material.
(c) the species of origin – i.e. ruminant, porcine, avian, fish or mixed, etc
(d) the quantity of the material.
(e) the name and address of the carrier.
(f) the name and address of the receiver and if applicable, its approval number.

**(2)** The invoices must be produced at least in triplicate (one original and two copies). The original must accompany consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the other copy must be kept for the Registrar's inspection.

**PART V – GENERAL REQUIREMENTS FOR THE COLLECTION AND TRANSPORT OF ANIMAL BY-PRODUCTS AND PROCESSED PRODUCTS**

11. (1) All animal by-products of different species must be identifiable and kept separate, if collected from a dedicated plant, during collection and transportation.

(2) Processed products from dedicated plants must be identifiable and kept separate during transportation.

(3) The animal by-products and processed products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles.

(4) Vehicles and reusable containers, and all reusable items of equipment or appliances that come into contact with animal by-products must be -

(a) cleaned, washed and disinfected after each use;
(b) maintained in a clean condition; and
(c) clean and dry before use

(5) Reusable containers must be dedicated to the carriage of a particular product to the extent necessary to avoid cross contamination.

**(6)** During transportation delivery notes must be produced when required by this Regulation, must accompany animal by-products and processed products.

***(7)*** The transport of unprocessed animal by-product must take place at an appropriate temperature, to avoid any risk to animal or public health.

***(8)*** Unprocessed material destined for the production of farm feed material or pet food must be transported chilled or frozen, unless processed within 24 hours of departure.

**(9)** No person shall transport raw materials from other areas to a sterilizing plant situated on the premises of an abattoir without the prior approval and permit from the Director: Veterinary Public Health.

**PART VI – IMPORTS OF ANIMAL BY-PRODUCTS FOR STERILIZATION**

***Harbors and places through which import may occur***

12. (1) Animal by-products intended for sterilization must be imported through the ports of entry referred to in Annexure 1.

**(2)** Notwithstanding the provisions of subregulation (1) the Registrar may, on written request of the person to whom the Registration Certificate for Sterilizing plant has been issued in terms of Section 3, read in conjunction with section 16(1) of the Act, for farm feed authorise the import of a particular consignment thereof through a port of entry other than a recognized port of entry.

***Conditions for importing animal by products intended for sterilization***

13. (1) animal by-products imported for sterilization must be accompanied by import permits issued under Animal Disease Act **No.** 35 of 1984 and where applicable, permit issued under Meat Safety Act No. 40 of 2000.

(2) The importer must submit copies of bill of lading and import permits to the Registrar.

**(3)** a container in which an imported animal by-product is packed must, in addition to any details that the Register may approve , be marked or labeled with the details **'NOT TO BE USED IN ANIMAL FEEDS OR FEEDING'.**

**PART VII – HYGIENE REQUIREMNTS FOR INTERMEDIATE AND STORAGE PLANTS**

14. **(1)** Intermediate plants must not engage in activities other than the importation, collection, sorting, cutting, chilling, freezing into blocks, partial processing, temporary storage and dispatch of animal by products.

**(2)** The sorting of animal by-product material must be carried out in such a way to avoid any risk of propagation of pathogens or animal diseases.

**(3)** The premises and facilities of intermediate and storage plants must meet at least the following requirements-

(a) the premises must be adequately separated from other premises such as slaughterhouses;

(b) there must be a covered space to receive animal by-products;

(c) the facilities must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the drainage of liquids;

(d) there must be adequate toilets, changing rooms and washing basins for staff

(e) there must be an appropriate pest control programme;

(f) there must be a waste water disposal system which meet hygiene requirements;

(g) where it is necessary facilities must have suitable temperature-controlled storage facilities of sufficient capacity for maintaining animal by-products at appropriate temperatures and designed to allow the monitoring of those temperatures; and

(h) the plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the vehicles in which they are transported. Adequate facilities must be provided for the disinfecting of vehicle wheels;

**PART VIII – GENERAL REQUIREMENTS OF PREMISES, HYGIENE AND FACILITIES**

15. **(1)** No person shall receive any material of animal origin into the premises of a sterilizing plant otherwise than into the unclean area.

**(2)** No person shall remove any material of animal origin from the unclean area other than through the charging apertures of the sterilizing equipment.

**(3)** Suitable cooling facilities or preservation methods shall be present in the sterilizing plant if sterilization cannot take place within **24** hours from receipt of perishable material.

(4) (a) No person shall keep or permit to remain on the premises of a sterilizing plant any animal or dog or cat or bird: Provided that the Registrar: Act No. 36 of 1947 may authorise the temporary entry of a draught animal or a police dog.

(b) All possible steps shall be taken to keep the premises of a sterilizing plant free from insects, rodents and other vermin.

**(5)** In the case of a new sterilizing plant or alteration to an existing sterilizing plant, the application for registration shall be accompanied by site and building plans. Building shall not commence before approval of the applicable plans. A hygiene management plan can be submitted to the satisfaction of the Registrar: Act No. 36/1947.

***(6)*** An application for registration of a sterilizing plant shall only be approved with the submission of a "no objection" certificate from relevant authorities in terms of applicable legislation.

***(7)*** Any establishment where an animal by-products and/ or pet food are manufactured, controlled, packed, marked or labeled, shall be duly registered under the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

***(8)*** The premises of a sterilizing plant shall be so controlled as to prevent the entry of unauthorized persons, vehicles and animals and shall include the following areas: -

(a) The unclean area, comprising the rooms or places in which material is received, stored or prepared for sterilizing. The charging apertures of the sterilizing apparatus shall be situated within the unclean area;

(i) The unclean area must have equipment to reduce the size of animal by-products and equipment for loading crushed animal by product into the processing unit, where applicable; and

**(ii)** Where heat treatment is applied, all installations must be equipped with:

a. Measuring equipment to monitor temperature against time;
b. Recording devices to record continuously the results of these measurements; and
c. An adequate safety system to prevent insufficient heating.

(b) the clean area, comprising the rooms or places in which the material is sterilized and dried, milled or otherwise prepared, packed, stored or dispatched.

(c) The plant must have its own laboratory or make use of services provided by an external laboratory. The laboratory must be equipped to carry out necessary analyses and be accredited by SANAS.

**(9)** The unclean area shall comply with the following requirements –

(a) the entire area shall be enclosed by walls and a roof, and shall be provided with floor suitably sloped and drained to allow the unimpeded run-off of water to a sewerage system;

**(b)** the floor surface shall allow easy cleaning and hygienic conditions. Joints in the floor surface shall be filled with suitable fillers to allow effective cleaning and disinfection;

(c) the entry to any sewer shall be provided with a grating to prevent the ingress of solid matter, and a fat-trap. The drainage system shall be designed to prevent the emission of offensive odours;

(d) all apertures at floor level in the wall shall be provided with raised sills to prevent the escape of effluent from the floor to any place other than the drainage system provided;

(e) walls shall be faced on the inner surface with a smooth non-absorbent light-coloured finish impervious to water and capable of being cleaned without sustaining damage;

(f) all internal angles between floors, walls, steps and other aspects shall be rounded off: provided that this aspect shall be approved by the Registrar: Act No. 36/1947 in the hygiene plan for the sterilization plant;

(g) ventilation shall be provided and may not take place from the unclean to the clean area;

(h) sufficient natural or artificial light shall be provided and the general intensity of artificial light shall be at least 220 lux;

(i) window-frames shall be constructed of metal or suitable alternatives. Window coverings shall be insect proof. Internal window-sills shall be suitably sloped to prevent collection of dust and dirt, the surfaces shall be smooth to allow easy cleaning. Insect proofing shall be fitted and maintained in front of windows that can open;

(j) hose connections shall be provided at convenient points, together with hoses, holders for hoses and a supply of hot water to the satisfaction of the Registrar: Act No. 36/1947;

(k) cloakrooms with showers, toilets and hand-wash basins shall be provided for workers in the unclean area. Toilet paper, hot and cold water, soap, disinfectant, and disposable paper towels or hot air hand driers shall be provided at all times during working hours;

(l) eating facilities shall be provided on site for all workers; and

(m) hand-washing facilities and disinfectant foot baths or boot-washing facilities for cleaning and disinfection of hands and boots shall be provided at all exits from the unclean areas. The taps of hand-wash basins shall be operated by feet or knees.

(10) The floors, walls and equipment of the unclean areas of a sterilizing plant shall be cleaned daily after the cessation of operation according to the hygiene management plan approved by the Registrar: Act No. 36/1947.

(a) Persons working in the unclean area shall -

(i) be provided with and wear distinctively marked overalls and rubber boots when on duty;

(ii) be provided with clean overalls on a daily basis;

(iii) wash their hands and disinfect their boots before leaving the unclean area; and

(iv) change from their soiled protective clothing and footwear and thoroughly clean themselves with soap and water before leaving the premises.

(b) No person who is employed in or who has entered the unclean area shall enter the clean area, unless he has cleaned and sanitized his boots and hands.

(c) The clean area shall comply with the following requirements -

(i) The entire area shall be enclosed by walls and a roof, and shall be provided with a floor suitably sloped and drained to allow the unimpeded run-off of water to a sewerage system. The floor surface shall allow easy cleaning and hygienic conditions. Joints in the floor surface shall be filled with suitable fillers to allow effective cleaning and disinfection;

(ii) the entry to any sewer shall be provided with a grating to prevent the ingress of solid matter, and a fat-trap. The drainage system shall be designed to prevent the emission of offensive odours;

(iii) all apertures at floor level in the wall shall be provided with raised sills to prevent the escape of effluent from the floor to any place other than the drainage system provided;

(iv) walls shall be faced on the inner surface with a smooth non-absorbent light-coloured finish impervious to water and capable of being cleaned without sustaining damage;

(v) all internal angles between floors, walls, steps and other aspects shall be rounded off: provided that this aspect shall be approved by the Registrar: Act No. 36/1947 in the hygiene plan for the sterilization plant;

(vi) ventilation shall be provided and may not take place from the unclean to the clean area;

(vii) sufficient natural or artificial light shall be provided and the general intensity of artificial light shall be at least 220 lux;

(viii) window-frames shall be constructed of metal or suitable alternatives. Window coverings shall be insect proof. Internal window-sills shall be suitably sloped to prevent collection of dust and dirt, the surfaces shall be smooth to allow easy cleaning. Insect proofing shall be fitted and maintained in front of windows that can open;

(ix) hose connections shall be provided at convenient points, together with hoses, holders for hoses and a supply of hot water to the satisfaction of the Registrar: Act No. 36/1947;

(x) cloakrooms with showers, toilets and hand wash basins shall be provided for workers in the clean area. Toilet paper, hot and cold water, soap, disinfectant, and disposable paper towels or hot air hand driers shall be provided at all times during working hours;

(xi) eating facilities shall be provided on site for all workers; and

(xii) hand-washing facilities and, disinfectant foot baths or boot-washing facilities for cleaning and disinfection of hands and boots shall be provided at all entrances to the clean area. The taps of hand-wash basins shall be operated by feet or knees.

(d) The floors, walls and equipment of the clean area of a sterilizing plant shall be cleaned daily after the cessation of operation according to the hygiene management plan approved by the Registrar: Act No. 36/1947.

(e) Persons working in the clean area shall -

(i) be provided with and wear distinctively marked overalls and rubber boots when on duty;

(ii) be provided with clean overalls on a daily basis;

(iii) wash their hands and disinfect their boots before entering the clean area;

(iv) change from their soiled protective clothing and footwear and thoroughly clean themselves with soap and water before leaving the premises; and

(v) protective clothing and boots shall not be removed from the premises by the workers.

(f) No person who is employed in or who has entered the clean area shall enter the unclean area, except with the permission of the person in charge of the sterilizing plant and subject to conditions set by this person.

## PART IX – STERILIZATION METHODS FOR ANIMAL BY-PRODUCTS

16. The following sterilization methods must be adhered to when sterilizing animal by- products;

***Method 1*** (compulsory *for* ruminant animal ***by*** products)

(1) where the particle size of the animal by-product to be processed is more than 50 mm, then the size must be reduced using appropriate equipment **so** that the particle size after reduction is **less** than 50 mm and conforms to the requirements.

**(2)** animal by-products must be heated to a core temperature of more than 133 "C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars by saturated steam meaning that all air is evacuated and replaced by steam in the sterilization chamber; the heat treatment may be applied as the sole process or as a pre- or post-process sterilization phase.

(3) The process may be carried out in batches or in a continuous system.

***Method 2***

(1) where the particle size of the animal by-product to be processed is more than 150 mm, then the size must be reduced using appropriate equipment **so** that the particle size after reduction is less than 150 mm and conforms to the requirements.

(2) animal by-products must be heated to a core temperature of more than 100 °C for at least 125 minutes, a core temperature greater than 110 °C for at least 120 minutes and a core temperature greater than 120 "C for at least 50 minutes without interruption.

**(3)** the process may be carried out in a batch system.

**(4)** animal by-products must be cooked in such a manner that the time-temperature requirements are achieved at the same time.

***Method 3***

(1) where the particle size of the animal by-product to be processed is more than 30 mm, then the size must be reduced using appropriate equipment **so** that the particle size after reduction is less than 30mm and conforms to the requirements.

(2) animal by-products must be heated to a core temperature of more than 100 "C for at least **95** minutes, a core temperature greater than 110 "C for at least 55 minutes and a core temperature greater than 120 °C for at least 13 minutes without interruption.

**(3)** the process may be carried out in batches or in a continuous system.

**(4)** animal by-products must be cooked in such a manner that the time-temperature requirements are achieved at the same time.

***Method 4***

(1) where the particle size of the animal by-product to be processed is more than 30 mm, then the size must be reduced using appropriate equipment **so** that the particle size after reduction is **less** than 30mm and conforms to the requirements.

(2) animal by-products must be placed in a vessel with added fat and heated to a core temperature of more than 100 °C for at least 16 minutes, a core temperature greater than 110 °C for at least 13 minutes, a core temperature greater than 120 "C for at least 8 minutes and a core temperature greater than 130 "C for at least 3 minutes without interruption.

(3) the process may be carried out in batches or in a continuous system.

(4) animal by-products must be cooked in such a manner that the time-temperature requirements are achieved at the same time.

***Method 5***

(1) where the particle size of the animal by-product to be processed is more than 20 mm, then the size must be reduced using appropriate equipment so that the particle size after reduction is less than 20 mm and conforms to the requirements.

(2) animal by-products must be heated until they coagulate and then pressured so that fat and water are removed from the proteinaceous material. The proteinaceous material must be heated to a core temperature of more than 80 °C for at least 120 minutes and a core temperature greater than 100 °C for at least 60 minutes.

**(3)** the process may be carried out in batches or in a continuous system.

(4) animal by-products must be cooked in such a manner that the time-temperature requirements are achieved at the same time.

## PART IX- INSPECTIONS

***Inspection for issuing of veterinary inspection certificate***

17. (1) the State Veterinary Official will supervise the sterilizing plants and issue a certificate which will accompany the application verifying the following-

(a) There is compliance to hygienic requirements and standards of the premises, equipment and staff ;

(b) the effectiveness of own checks conducted by plant management in accordance with plants own procedure developed to comply with the requirements of this Regulation, particularly in taking samples and examining the results;

(c) the standard of products after processing, analyses and test are carried out in accordance with scientifically recognized methods;

**(d)** availability good storage facilities and conditions; and

(e) ensure that processed animal by-products are free from pathogenic organisms.

***Routine and validation inspections***

18. An officer delegated under section 2 (2) (a) of the Act shall perform the following duties at sterilizing plants-

(1) take any samples required for laboratory analyses.

(2) take samples in terms of section 15 (1) of the Act, A certificate in terms of section 15(4)(b) of the Act relating to a sample which is forwarded to an analyst shall be in a form of Annexure 2 and a certificate in terms of section 15(4)(b) of the Act relating to the result of a test, examination or analyses of a sample shall be in the form of Annexure 3.

**(3)** make any other routine checks which might be considered necessary to ensure compliance with these regulations;

(4) make the following validation inspections;

(a) description of the sterilizing process (by a process of flow diagram);

(b) identification of critical control points (CCPs) including the material process rate for continuous systems;

(c) compliance with the following microbial standards;

(i) samples of material taken after heat treatment. for ***Clostridium perfringens*** are negative for the organism in 1g of the product.

(ii) Samples of material taken during or upon withdrawal from storage at the processing plant are negative for ***Salmonella:*** negative in ***25*** g: n =5, c = 0, m =0, **M** = **0**

(iii) Samples of material taken during or upon withdrawal from storage at the processing plant are negative for Enterobacteriaceae: negative in **1** g: n =5, c = ***2,*** m = 10, **M = 300**

where:-

n = number of samples taken

m = the threshold value for the number of bacteria; the results to be considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result to be considered unsatisfactory if the number of bacteria in one or more samples taken is **M** or more; and

C = number of samples the bacterial count of which may be between m and **M,** the sample still being considered acceptable if the bacterial count of the other sample is m or less

(d) achievement of the following requirements in the batch system-

(i) the temperature is monitored with a permanent thermocouple and it is plotted against a real-time graph;

(ii) the pressure is monitored with a permanent pressure gauge and plotted against real-time graph;

(iii) the process time is shown by time/temperature and time /pressure diagrams; and

(iv) at least once a year the thermocouple and the pressure gauge are calibrated

***Analysis Method***

**19.** In the case of a dispute only methods of analysis as recognized by the Registrar may be used.

**PART X - RECORD KEEPING**

20. **(1)** A person managing the operation at a sterilizing plant shall put in place, implement and maintain a permanent procedure developed to comply with the requirements of this regulation. They shall in particular-

(a) identify and control the critical points in the plant;

(b) establish and implement methods for monitoring and checking such critical control points;

(c) take representative samples to check compliance of each processed batch with the standards for the products established by this Regulation; and

(d) introduce a system ensuring traceability of each batch dispatched.

**(2)** where the results of a test on samples taken in relation to paragraph(c) do not comply with the provisions of this Regulation, the operator of a processing plant must-

(a) establish the cause of failures of compliance;

(b) reprocess or dispose of the contaminated batch in accordance with this regulation;

(c) ensure that no material suspected or known to be contaminated is moved from the premises before being reprocessed and re-sampled in order to comply with the standards laid down in this Regulation, unless destined for disposal;

(d) increase the frequency of sampling and testing of production;

(e) investigate animal by-product records appropriate to the finished sample; and

(f) investigate appropriate decontamination and cleaning procedures within the plant.

**(3)** The records to be kept at an establishment in terms of regulation 20, shall be preserved at the registered office of such establishment or such other place as may on application be approved by the Registrar, for at least two years.

**PART XI - GENERAL PROVISION**

21. If, because of the type of material to be sterilized or because of technological development, the construction of a plant is no longer functional as described in these regulations, another suitable construction may be approved and registered by the Registrar: -Act No. 36/1947.

**PART XII**

**GENERAL**

***Offences and Penalties***

22. Anyone who refuses or omits to comply with the provisions of these regulations shall be guilty of an offence and upon conviction in a court of law shall be liable to a fine not less than R1000 or imprisonment for a period not less than 1 year or to both the fine and imprisonment.

***Payment of fees***

23. (1) The postal charges on and the delivery costs of an application or documents submitted under these regulations as well as the postal charges and the delivery costs of anything else in connection therewith must be paid by the sender.

**(2)** Any fee payable in terms of these regulations must be paid by means of a cheque, postal order or money order in favour of the Director-General of Agriculture. If such fees are delivered by hand, they may be paid in cash in which case a receipt shall be issued.

(3) Fees which are paid in terms of these regulations shall subject to section 6 of the Act, not be refundable.

***Address for submission***

**24.** An application or item or anything connected therewith that under these Regulations has to be submitted to the Registrar, must –

(a) When sent by post, be addressed to – The Registrar: Act No. **36** of 1947, Private Bag X250, Pretoria, 0001; and

(b) When sent by rail, delivered by hand, or delivered by a private courier service, be addressed to or delivered to – The Registrar: Act No. **36** of 1947, Agricultural Building, Beatrix Street 20, Pretoria.

***Repeal of Regulations***

**25.** The following Regulations are hereby repealed in as much as they apply to sterilizing plants-

Regulations relating to sterilizing plants, Government Notice No R **1359** of **27** June 1980.
Regulations relating to the registration of fertilizers, animal feeds, Agricultural Remedies, Stock Remedies, Sterilizing Plants and Pest Control Operators, appeals, imports and Amendments to and repeal of certain regulations Government Notice No R1449 of 1 July 1983.

**TABLE 1**
**FEES PAYABLE**
**[REG. 2(1)(B)]**

| | PURPOSE | AMOUNT PAYABLE PER APPLICATION |
|---|---|---|
| A. | Application for **the** registration of: | |
| | (a) a fertilizer, farm feed or sterilizing plant | R1 **100** |
| | (b) an agricultural remedy or a stock remedy | R2 **250** |
| | (C) a pest control operator | R 480 |
| B. | Application for the renewal of the registration of: | |
| | (a) a fertilizer, farm feed or sterilizing plant | **R 600** |
| | **(b)** an agricultural remedy or a stock remedy | R1 100 |
| | *(c)* a pest control operator | R **330** |
| **C.** | Payment in addition to that specified in paragraph B, in the case of a late application for the renewal of the registration of: | |
| | (a) fertilizer, farm feed or sterilizing plant | **R 450** |
| | (b) an agricultural remedy or a stock remedy | R **800** |
| | (c) a pest control operator | **R** 145 |
| **D.** | An appeal in terms of section 6 of the Act | **R3 600** |

| | | | |
|---|---|---|---|
| **E.** | Payment for information and documentation: | | |
| | (a) | Application form and instructions | R45,00 per package |
| | (b) | Certificate of free sale | R15,00 per certificate |
| | (c) | Import permit | R10,00 per permit |
| | (d) | Documents from own product files as requested by registration holders | R45,00 per request plus 50c per page |

**ANNEXURE 1**

**PORTS OF ENTRY**

| Land boarder posts | International Airports | International harbours | Inland |
|---|---|---|---|
| Beitbridge | Cape Town | Cape Town | Johannesburg |
| Caledonspoort | Durban | Durban | Kimberly |
| Ficksburg | Gateway (Pietersburg) | East London | Pretoria |
| Golela | Johannesburg | Mossel Bay | Mmabatho |
| Groblersburg | Lanseria | Port Elizabeth | Pietermaritzburg |
| Kapfontein | Port Elizabeth | Richards Bay | Upington |
| Jeppesreef | Richards bay | Saldanha Bay | Bloemfontein |
| Lebombo | Upington | | Stellenbosch |
| Mahamba | Bloemfontein | | Germiston |
| Mananga | Mafikeng | | |
| Maseru bridge | | | |
| Nakop | | | |
| Nerston | | | |
| Oshoek | | | |
| Qachas' Nek | | | |
| Ramatlabana | | | |
| Skilpadshek | | | |
| Van Rooyenshek | | | |
| Vioolsdrif | | | |

**ANNEXURE 2**

agriculture

Department
Agriculture
REPUBLIC OF SOUTH AFRICA

Department of Agriculture
Private Bag X 250
Pretoria
0001

**CERTIFICATE IN RESPECT OF THE TAKING OF SAMPLES IN TERMS OF SECTION 15 OF ACT 36/1947**

**Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947)**

***(To* be completed in duplicate)**

I here by certify that the accompanying sample identified by the above serial number, was taken by me on ..... day.. ..... of..... .20.……
At..... in the presence of.....
*(Name of owner/person in charge of stocks/witness)
From the stock of.....
(Name and address of seller)

PARTICULARS FROM WHICH SAMPLE WAS TAKEN

1. Name of registration holder.. .....

2. Name of product†. .....

3. Registration number?..... Act 36/1947

4. Manufacturer details.. .....

5. Composition of sample†

5.1 Physical properties.. .....

.....

***6.*** Estimated quantity of a sample taken:

***7.*** Remarks.. ..... .....

.....

..... .....
Signature of witness Registrar

† Shall be particulars as indicated on the affixed label to the containers from which the sample was taken or as it is marked on such containers, or if the animal feed which is sampled, is not sold in containers, as it appears on the invoice which is supplied together with that animal feed.

‡ One copy shall accompany each of the three parts of the sample and the forth copy shall be kept by the officer who took the sample

**ANNEXURE 3**

Analyst address
.....

.....

**CERTIFICATE OF RESULTS OF ANALYSES OR TEST OF A SAMPLE BY ANALYST**
**Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947)**
**(To *be completed in duplicate)***

I (full name)_____

of _____

A duly appointed analyst in terms of section **14** of the Fertilizer, Farm Feeds, Agricultural Remedies and Stock remedies Act, **1947** (Act 36 of **1947)** do hereby make oath and state:

(a) that on_____I received a sample of *_____ from+_____

for analyses and/or test;

(b) that the sample was labelled, sealed and marked#_____
_____

(c) that I have analysed and/ or tested the said sample and as a result of the analyses and/or test I found it to be constituted as follows:

1. Microbiological composition_____

2. Physical properties_____

_____
Signature of analyst

(a) state name of farm feed as specified on label/insert name of person supplying the sample and state whether it was "by hand", "by post" or by courier.
(b) Insert distinguishing mark or number of sample.
(c) State names of particular chemical constituents and physical properties

**DECLARATION TO BE MADE IN THE PRESENCE OF JUSTICE OF PEACE/ COMMISSIONER OF OATHS.**

..... ..... **TEL NO** .....

**DATE** **INITIALS AND SURNAME**

.....

**SIGNATURE OF THE DEPONDENT**

I certify that the dependent has acknowledged that he/she know and understands the contents of this declaration which was sworn to/affirmed before me and the dependents signature/thumb print/mark was placed thereon in my presence.

.....

**JUSTICE OF PEACE/ COMMISIONER OF OATHS**

**Full first name and surname:.** .....

**(BLOCK LETTERS**

**Designation (rank):..** ..... **Ex Officio Republic of South Africa** .....

**Business address:** .....

**(street address must be stated)**

**Date:** .....

**Place** .....