

**GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS**

**DEPARTMENT OF AGRICULTURE
DEPARTEMENT VAN LANDBOU**

No. R. 548

23 May 2008

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

**REGULATIONS RELATING TO STERILIZING PLANTS, APPEALS AND IMPORTS:
PROPOSED AMENDMENT**

I, Lulama Xingwana, Minister of Agriculture, acting under Section 23 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), hereby-

- i. make known that I intend to make regulation in the schedule; and
- ii. invite interested persons to submit any objections to or representations concerning the proposed regulation in writing to the Registrar: Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies, Private bag X 343, Pretoria, 0001, within four weeks from date of publication hereof.

L. Xingwana
Minister of Agriculture

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

STERILIZING PLANTS REGULATIONS: AMENDMENT

The Minister of Agriculture has 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 Schedule.

SCHEDULE

In this Schedule "the Regulations" means regulations published by Government Notice No. R.1086 of 3 November 2006 as corrected by Government Notice No 1108 of 3 November 2006.

Amendment of regulation 1

1. Regulation 1 is hereby amended –

(a) by the substitution for the definition of "application fee" of the following definition:

"application fee" means fees that, in terms of these regulations, are payable for the registration of a Sterilizing plant and the renewal of such registration;

(b) by the insertion after the definition of "intermediate plants" of the following definition:

"inspection fee" means fees payable by the applicant or registration holder for establishment inspection;

(c) by the insertion after the definition of "registration number" of the following definitions:

"ruminant animal by-product" means the entire body or parts of ruminant animal origin whether mixed or not mixed with other animal species, which are not intended for human consumption;

"returns" means records to be kept and the returns to be rendered from those records by registered Sterilizing plant to the Registrar;

"SANAS" means South African National Accreditation System;

Amendment of regulation 2

2. Regulation 2 is hereby amended -

(a) by the substitution for regulation 2 of the following regulation:

(1) An application in terms of Section 3(1) of the Act for registration of a Sterilizing plant must be made on a form made available by the Registrar for this purpose.

(2) The application mentioned in sub – regulation (1) above must be-

(a) 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 following:

(i) applicable fee as specified in Table 1;

(ii) veterinary inspection certificate or report;

(iii) facilities plan and manufacturing process (es); and

(iv) proof of approval of the Environmental Impact Assessment from the Department of Environmental Affairs and Tourism.

Amendment of regulation 3

3. Regulation 3 is hereby amended -

(a) by the substitution for regulation 3 of the following regulation:

(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 up to 31 March of a three year registration cycle.

(2) In the event that a registration is granted after 1 January in a particular calendar year, such registration shall remain valid until the last 31 March of a three year registration cycle.

Amendment of regulation 4

4. Regulation 4 is hereby amended -

(a) by the substitution for regulation 4 of the following regulation:

(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 a form made available by the Registrar for this purpose.

(2) Such an application must be -

(a) postmarked or courier dispatched by the applicant no later than 31 March of the last year on which the three year registration cycle lapses;

(b) be accompanied by the prescribed fee and a veterinary inspection certificate; and

(c) at the request of the Registrar, be accompanied by an inspection certificate and report from a SANAS accredited inspection body, for inspecting Sterilizing plants.

(3) Apart from the provisions of sub-regulation 2(b) above, an application under sub-regulation 4(1) received by the Registrar after 1 May of the last year in a particular three year registration cycle will not be considered as a renewal application, and an application for original registration must be made under regulation 2.

(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.

Amendment of regulation 10

5. Regulation 10 is hereby amended -

(a) by the substitution for sub-regulation (3) of the following sub-regulation:

(3) The invoices for animal by-products of ruminant origin 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 sent to the Registrar: Act No. 36 of 1947 within 45 days after delivery.

Amendment of regulation 11

6. Regulation 11 is hereby amended -

(a) by the substitution for sub-regulation (8) of the following sub-regulation:

(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 or, in the case of purpose caught fish material, within 30 hours of catching.

Amendment of regulation 13

7 Regulation 13 is hereby amended -

(a) by the substitution for regulation 13 of the following regulation:

13. No person shall import any animal by product into the Republic unless-

(1) Such an animal by product is registered in terms of the Act;

(2) Imported animal by-products 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.

(3) The importer of animal by products of ruminant origin must submit copies of bill of lading/entry, invoices and import permits to the Registrar.

(4) A container in which an imported animal by-product which is intended for sterilization 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'**.

Amendment of regulation 16

8 Regulation 16 is hereby amended -

(a) by the insertion after "method 5" of the following method:

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

Method 6 (Only for fish and fish by-products)

(1) where material to be processed consist of whole fish, fish by-products or fish off-cuts, it must be heated in a continuous cooking process to coagulate the protein for at least 20 minutes with an exit temperature of not less than 85 degrees Celsius;

(2) the size must be reduced to 10 mm or less after cooking and pressing or decanting;

(3) further heat treatment of the material shall, in a direct drying process, consist of retention in a continuous dryer for a period of not less than 20 minutes and, in an indirect drying process, consist of retention for a period of not less than 30 minutes, the exit temperature in both cases must at all times a minimum of 80 degrees Celsius. Where the material is dried in two stages, the exit temperature from the pre-dryer shall at all times be a minimum of 80 degrees Celsius.

Amendment of regulation 17

9. Regulation 17 is hereby amended -

(a) by the substitution for regulation 17 of the following regulation:

17. (1) the State Veterinary Official will inspect the Sterilizing plant(s) and issue a certificate which will accompany the application for registration of such Sterilizing plant(s) verifying the following-

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

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

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

- (e) absence of pathogenic organisms in processed animal by-products.

Amendment of regulation 18

10 Regulation 18 is hereby amended -

- (a) by the substitution for sub-regulations (1), (2) and (3) of the following sub-regulations:

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. Such samples must be forwarded to an analyst together with a certificate prescribed in Annexure 2. The results of a test, examination or analyses of a sample shall be in the form prescribed in Annexure 3.

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

Amendment of regulation 19

11 Regulation 18 is hereby amended -

- (a) by the insertion after "sub-regulation (3)" of the following regulation:

Compliance and validation inspections

18A. An officer delegated under section 2 (2) (a) of the Act or an inspector from a SANAS accredited inspection body shall perform the following duties at Sterilizing plants-

- (1) make the validation inspections regarding following;
- (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* must 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

- (iv) samples of material taken during or upon withdrawal from storage at the processing plant are negative for *Escherichia Coli*: negative in 25 g: n =5, c = 0, m = 0, M = 0
- (v) samples of material taken during or upon withdrawal from storage at the processing plant are negative for *Coliform*: negative in 25 g: n =5, c = 0, m = 0, M = 0
- (d) achievement of the following requirements in the batch system-
 - (i) the temperature is monitored with a permanent thermometer 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 thermometer and the pressure gauge are calibrated

(2) make any other checks which might be considered necessary to ensure compliance with these regulations.

Amendment of regulation 20

12 Regulation 20 is hereby amended -

(a) by the substitution for regulation 20 of the following regulation:

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 these regulations. 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) Any person who has in his possession or under his control animal by products of ruminant origin or animal by products mixed with animal by products of ruminant origin shall keep records and render returns to the Registrar: Act No. 36 of 1947;

(4) Such returns shall specify-

- (a) the date on which the material was received;
- (b) the description of the material;
- (c) the species of origin –i.e. ruminant or mixed;
- (d) the quantity of the material;
- (e) the name and address of the carrier;
- (f) the name and address of the supplier and if applicable, material registration number; and
- (g) the country and place of origin if the material is imported.

(5) The records to be kept at an establishment in terms of this regulation, 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 and in a case where animal by products of ruminant origin are handled for at least 7 years.

Amendment of regulation 23

13 Regulation 23 is hereby amended -

(a) by the substitution for regulation 23 of the following regulation:

(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, money order in favour of the Director-General: Agriculture, Reference: Sterilizing Plants; if such payment is delivered by hand, they may be paid in cash in which case a receipt shall be issued, and if such fees are paid electronically through an Electronic Transfer Account payment must be made as follows:

Account name: NDA-ACT36 of 1947
Account number: 11203102
Reference: 13SP
Branch code: 010845
Branch name: Arcadia
Bank name: Standard Bank

(3) Where applicable, an inspection fee shall be paid directly to a SANAS accredited inspection body performing such inspection.

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