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GOVERNMENT NOTICES GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF AGRICULTURE DEPARTEMENT VAN LANDBOU

No. R. 502

3 June 2005

FERTILIZER, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT No. 36 OF 1947)

PROPOSED REGULATIONS REGARDING AGRICULTURAL REMEDIES

I, Angela Thoko Didiza acting under section 23 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), hereby --

- (a) make known that I intend to make the regulation in the Schedule; and
- (b) invite interested persons to submit any objections to or representations concerning the proposed regulation in writing to the Registrar: Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies, Private Bag X343, Pretoria, 0001: e-mail address: <u>ernestmo@nda.agric.za</u>, within four weeks from the date of publication hereof.

1. Definitions

Words and phrases in these regulations shall have the meaning assigned hereto in the Act, and unless the context otherwise indicates --

"advertisement" means any written, illustrated, visual or other descriptive material or oral statement, communication, representation or reference distributed to members of the public or brought to their notice in any other manner and which is intended to promote the sale of fertilizers, farm feeds, agricultural remedies or stock remedies or encourage the use thereof or draw attention to the nature, properties, advantages or uses thereof, and "advertise" has a corresponding meaning;

"agricultural remedy" means 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 mucrobe, 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 No. 101 of 1965), or the Hazardous Substances Act, 1973 (Act No. 15 of 1973); or
- (b) as plant growth regulator, defoliant, desiccant or legume inoculant, and anything else which the Minister has by notice in the Gazette declared an agricultural remedy for the purposes of this Act;

"establishment", in relation to a fertilizer, **farm**, feed, agricultural remedy or stock feed, means the premises where such fertilizer, farm feed, agricultural remedy or stock feed is manufactured, controlled, packed, marked or labelled for the purposes of sale;

"invoice" means also an accompanying letter, delivery note or weighbridge ticket, receipt note or receipt;

"label" means any written, printed or graphic representation attached to a container of an agricultural remedy or produced on a container in any possible manner and which states the details required in **terms** of these regulations for the particular agricultural remedy and "labelled" has a similar meaning; "manufacture" means make, compound, mix, formulate, process, package and label for purpose of sale and, "manufacturing" and "manufacturing process" have a similar meaning;

"manufacturer" means an individual or undertaking that manufactures or mixes agricultural remedies;

"mark" means a mark as defined in section 1 of the Trade Marks Act, 1963 (Act No. 62 of 1963);

"Minister" means the Minister responsible for Agriculture;

"officer" means an officer as defined in section 1 of the Public Service Act, **1957** (Act No. **54** of **1957**);

"registered name" means the name approved by the registrar under which an agricultural remedy is registered and may be sold

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

"trademark" means a mark to which the holder of the registration has the right, either as owner or a registered user thereof, to distinguish **his/her** agricultural remedy from that of any other manufacturer but excludes the registered name of an agricultural remedy as intended in these regulations.

PART

REGISTRATION

Application for registration

- 2. (1) An application in terms of section 3(1) of the Act for the registration of an agricultural remedy shall be submitted to the Registrar on a form which is obtainable from Registrar's office or on a clearly legible facsimile thereof.
 - (2) Such application shall
 - (a) be made by a person who is resident in the Republic or in the case of a juristic person, who has a registered office in the Republic;
 - (b) be accompanied by the applicable application fee,
 - (c) be accompanied by three copies, in English, of a typed version of the label. Provided that such label shall be in accordance with the requirements determined under section 7(1)(c), read with section 23(1)(g), of the Act and the regulations concerned be specific;
 - (d) further be accompanied by -
 - (i) a copy of the experimental data on the biological efficacy of the agricultural remedy concerned and of the residues of the agricultural remedy concerned as determined under South African conditions; or any other data acceptable to the Registrar;
 - experimental data relating to the pharmacology and toxicology of the active ingredient/s concerned and to the toxic metabolites of such ingredientls

- (iii) the method of analysis for the determination of the active ingredient concerned in the formulation and, where applicable, the method of analysis for the active ingredient and its toxic metabolites in residues; and
- (iv) the details of the effect, which the agricultural remedy may have on the environment;

Provided that the Registrar may grant exemption from the submission of any document referred to in paragraphs (i)to (iv).

- (3) The Registrar may request any further data or sample which may enable him to evaluate the application.
- (4) An agricultural remedy of which the active ingredient and formulation, is identical to that of an agricultural remedy which is registered in **favour** of another person, further be accompanied by the written permission of such other person that the agricultural remedy be registered.

Periodofregistration

3. (1) Subject to the provisions of sections 4 and 4A of the Act and regulation (3), a registration in terms of section 3 of the Act shall be valid until 31 March in each alternate year. Provided that if a registration is granted during a particular calendar year within six months prior to the applicable expiry date it shall be valid until the expiry date concerned in the following alternate year.

Suitability and efficacy of agricultural remedies

- 4 (1) The suitability and efficacy of an agricultural remedy stated in an application for the registration thereof shall, where applicable, be proved by results of trials which were carried out therewith by the person who made such application or by a **com**petent body which is recognized for this purpose by the Registrar.
 - (2) The person or body referred to in subregulation (1) shall where applicable, prior to the commencement of a trial indicated in that subregulation, notify the Registrar of the intention to conduct such trial, and the Registrar may inspect the performance of such a trial.

Determination of toxicity and potential hazards of agricultural remedies

- 5. (1) The toxicity or potential hazards of the active or inert ingredients of an agricultural remedy shall, in accordance with the LD-50 values specified in Appendix 7.1 of the Republic of South Africa Classification Code for Agricultural and Stock Remedies and Associated Label Hazard Requirements and with due observance of additional toxicological information relating to properties such as systemic accumulation, chronic poisoning, carcinogenecity and teratogenecity of such active or inert ingredients, be determined on the oral or inhalationtoxicity to the rat or the dermal toxicity to the rabbit, as the case may be.
 - (2) When the LD-50 values of an agricultural remedy were thus determined, such agricultural remedy shall be classified as the group indicated in Appendix 7.1 of the RSA Classification Code for Agricultural and Stock Remedies and Associated Label Hazard Requirements, opposite which the applicable LD-50 values are specified in the said Appendix.
 - (3) No Group Ia and Group Ib may be sold in containers smaller than a mass of 1 kilogram or volume of I litre or as specified by the Registrar.

Dataprotection

6. In granting a registration the Registrar shall not make use of the information of another registration holder for the benefit of another applicant unless the holder has agreed with the first applicant.

Maintenance of registration

- 7. (1) An application in terms of section 3(4)(a) of the Act for the maintenance of the registration shall be submitted to the Registrar on a form which is obtainable from him/her, or on a clearly legible facsimile thereof.
 - (2) Such application shall -
 - (a) be submitted to the Registrar not later than 30 days prior to the expiry date of the registration concerned but not more than six months prior to such expiry date;
 - (b) be accompanied by the applicable application fee;
 - (3) An application made in terms of subregulation (1) which --
 - (a) is received by the Registrar after the expiry date of the registration concerned, but not more than 30 days after such expiry date, shall be considered only if it is accompanied by the applicable additional late application fee, or
 - (b) which is received by the Registrar after the days of grace referred to in paragraph (a) expired shall not be considered. A new application must be made in terms of regulation 2.
 - (4) Any person who applies in terms of this regulation for the renewal of a registration shall in an affidavit confirm that the details which helshe furnishes with such application in respect of the agricultural remedy concerned or of a label which is being used in connection therewith, do not deviate in any manner whatever from the congruent details which have already been registered or approved in relation to that agricultural remedy or label: Provided that only the original of each application need be thus sworn to or attested.

Conditions for certain registrations, amendments and maintenance of certain registrations

- 8. A registration, amendment and maintenance of an agricultural remedy under section 3 of the Act is granted on condition that during the period of registration or maintenance of the registration--
 - the formulation of the agricultural remedy concerned shall not deviate more than the permissible deviation from the formulation which is registered in respect thereof;
 - (b) the details which are approved to be indicated on a label or container used in connection with the sale of the agricultural remedy concerned, shall not be altered without the prior written approval of the Registrar: and

Application for amendment of certain registrations and approved labels

9. If any person in whose favour an agricultural remedy is registered, intends to alter the registered composition thereof or to effect any amendment to the details which are approved

to be indicated on a label or container in connection with the sale and use thereof, such application shall be accompanied by the applicable documents, application fee and shall be accompanied by the applicable certificate of registration if it will be affected by the amendment;

Provided that the Registrar may grant exemption from the payment of the application fee concerned or submission of the application form if the alteration α amendment concerned:

- (a) is in the public interest;
- (b) is effected by the Registrar;
- (c) is due to editorial changes to improve the label.

Review of registrations

- **10.** The Registrar may institute a review of existing agricultural remedies.
 - (1) When a review procedure is instituted the Registrar shall inform all applicable registration holders in writing for the reason of the review and that a review will be carried out six (6) months after notification.
 - (2) If significant data gaps are identified in order to review the remedy the Registrar can request registration holders to submit new data within two years of the request.
 - (3) The Registrar, may upon written request of the registration holder, extend the period for the submission of new data by one year.
 - (4) Upon receipt of the requested data a risk assessment will be compiled. If the agricultural remedy in question poses an unacceptable risk to humans, animals or the environment the Registrar shall initiate procedures to restrict or cancel the registration of such agricultural remedies.
 - (5) Registration holders requested to submit new data will have exclusive use of the new data.

Return of certificate of registration

- 11. A certificate of registration which is returned in terms of section **4A(3)** of the Act shall reach *the* Registrar
 - (a) within 14 days of the date on which -
 - (i) the person to whom the certificate of registration in question was issued, was notified in terms of section 5 of the **Act** in writing of the reasons for the cancellation of such registration; or
 - (ii) the registration of the agricultural remedy concerned has lapsed in terms of section **4A(2) of** the **Act**, or
 - (b) at least **30** days prior to the date on which the registration of an agricultural remedy, is to be transferred to another person: Provided that an **application** as contemplated in regulation 2 for the registration of the agricultural remedy, in question in favour of such other person shall be submitted simultaneously.

PARTII

LABELLING AND CONTAINERS

Containers of agricultural remedies

- 12. (1) Subject to the provisions of any other law relating to containers, a container in which a quantity of an agricultural remedy is packed for sale and a container in which a measured dosage of an agricultural remedy is packed (respectively referred to in these regulations as an immediate container and a sachet), shall at the time of packing
 - (a) be sound and clean;
 - (b) be dosed or sealed in the manner permitted by the agricultural remedy concerned and the immediate container or sachet concerned.
 - (2) The design of an immediate container or sachet shall-
 - (a) after the contents thereof has been used not be instrumental to the use of such empty container or sachet for any other purpose;
 - (b) in the case of a liquid agricultural remedy, prevent spillage when pouring out the contents thereof.
 - (3) An immediate container or sachet or an outer container or display container respectively referred to in regulation 13 shall not be labelled with any other marks or signs than the applicable details referred in regulation 13 on which shall appear in terms of a provision of any other law on such container or sachet, or which related to the contents of such container or sachet and which was approved by the Registrar.
 - (4) Containers and packaging material shall comply with South African National Standards **10229**.

Labelling of containers of agricultural remedies

- 13. (1) An immediate container and, where applicable, a sachet referred to in regulation 12 (1) shall, except when it contains a legume inoculant, be labelled with --
 - (a) the trade mark, if any, and the trade name which may be used by the person in whose favour the agricultural remedy concerned is registered;
 - (b) the name of the active ingredient contained in the agricultural remedy concerned, if such a name is not already included in the trade name;
 - (c) the registration number of the agricultural remedy concerned together with a reference to the Act expressed as "Reg. No.Act <u>No.</u> 36 of 1947);
 - (d) the applicable Republic of South Africa classification danger group as which the agricultural remedy concerned was classified in accordance with regulation 5;
 - (e) the type of formulation of the agricultural remedy and the purpose for which it is registered;
 - (f) the composition of the agricultural remedy concerned;
 - (g) the number of the batch from which the agricultural remedy in such container originates and the manufacturing date of that batch, provided that in the case of **an** agricultural **remedy** --

- of which the registered active ingredient contents will possibly diminish over a period of two years to below the applicable permissible deviation specified in regulation 22, the expiry date shall be indicated instead of the manufacturing date:
- (ii) which is sold in an aerosol container, the batch number and manufacturing date may be marked on the bottom of such container provided an appropriate indication to that effect appears on the main panel referred to in subregulation (2)(a);
- (h) subject to the provisions of the Trade Metrology Act, 1973 (Act No. 77 of 1973), the nett volume or mass, as the case may be, of the agricultural remedy in such container; and
- (i) the name and address of the person and where applicable, the company registration number in whose favour the agricultural remedy concerned is registered.
- (2) (a) A label shall be divided into different panels and the applicable details referred to in subregulation (1) shall, in the order set out in that subregulation, be labelled on the main panel which shall not take up more than 40 percent of the total surface of the label concerned, together with any other details or indications which are to appear on such main panel in terms of the provision of any other law provided that the Registrar may approve alternative label layouts:
 - (b) The name of an active ingredient of an agricultural remedy, shall when it is induded in the trade name or is labelled in accordance with the provisions of subregulation(1)(b), be the name as is accepted as a common name by International Organisation for Standards or be the chemical name of the common name of the active ingredient;
 - (c) The danger group to be labelled in accordance with the Guidelines for RSA Classification Code for Agricultural and Stock Remedies and Associated Label Hazard Requirements, shall in the case where the agricultural remedy concerned
 - (i) was classified as group 1 <u>a</u>, consist of the expression 'Very toxic" in letters at least half the size of the largest letter of the trade name and be in black with a red background with skull and crossbones:
 - (ii) was classified as group 1b, consist of the expression "Toxic" in letters at least half the size of the largest letter of the trade name and be in black with a red background;
 - (iii) was classified as a group II, consist of the expression "Harmful" with the Saint Andreas cross; and
 - (iv) was classified as group III, consist of the expression "Caution".
 - (d) The composition to be labelled in accordance with subregulation (1)(f) shall, with due observance of the provisions of paragraph (b)(i), consist of the common name or chemical name, as the case may be, of the active ingredient concerned and, if that ingredient has been classified in the list referred to in the said paragraph as a particular chemical group, the name of the chemical group concerned, followed by the nominal value of the contents of such active ingredient expressed--

- (i) in the case of a liquid agricultural remedy, as gram per liter at **20°C**;
- (ii) in the case of a dry agricultural remedy, as gram per kilogram, and
- (iii) in the case of an agricultural remedy contained in an aerosol container, as gram per kilogram:

provided that in the case of wood preservatives, such indication shall represent the minimum value of the active ingredient concerned.

- (e) The manufacturing date or expiry date, as the case may be, to be labelled in accordance with the provisions of subregulation (1)(g) shall be expressed separately from the batch number as a month and year provided that the requirement of subregulation (e) does not apply to remedies to be used in swimming **pools**.
- (3) (a) Warning statements and precautionary measures relating to the use of an agricultural remedy and in the case of a Group I or Group II agricultural remedy, the symptoms of poisoning, first aid and a note to the physician shall be labelled under those headings and in that sequence on a side panel of the label.
 - (b) If a withholding period is required between the last application of an agricultural remedy and the harvesting, feeding, grazing or processing of a commodity which is treated with such agricultural remedy, the period which shall thus expire shall as the first statement appear in bold type face, or be underlined, immediately below the heading "Warning Statements".
- (4) (a) Directions for use and where applicable resistance warnings, use restrictions, waiting period for follow-up crops, compatibility statements, mixing instructions in the form of a table, the actual uses of the agricultural remedy concerned after such mixing shall be labelled under those headings and in that sequence on a side panel of the label and shall be clearly distinguishable from any other details to be indicated in accordance with subregulations (1) and (3).
 - (b) If the efficacy of an agricultural remedy will be enhanced or the spectrum of use thereof will be broadened by adding to the final mixture thereof another agricultural remedy, the compatibility statement referred to in paragraph (a) shall furnish the trade name and registration number of the agricultural remedy of which it is known that it is compatible with the agricultural remedy concerned.
 - (c) Directions for use of an agricultural remedy shall --
 - (i) if applicable, state the method **of** mixing and the rate at which dilution shall be made;
 - (ii) indicate the method of application and the rate at which it shall be administered.
- (5) In the case where the immediate container or sachet referred to in regulation 13(1) is packed in an outer container in which it is sold, such outer container shall also be labelled with all the applicable details and in the manner referred to in subregulations(1), (2) (3) and (4).
- (6) (a) If such immediate or outer container is too small to be labelled with all the

applicable details and in the manner referred to in subregulations (1), (2), (3) and (4), the container concerned may be labelled with those details only referred to in subregulation (1), together with the words "For full details see attached label" or the words "For full details see included label", as the case may be.

- (b) Such attached or included label shall, in addition t any other marks or indications relating to the agricultural remedy conceived, be labelled with the applicable details and in the manner referred to in subregulations (1)(a), (b), (c), (d), (e), (f) and (i), (2), (3) and (4).
- (7) A sachet referred to in subregulation 13(1) which is too small to be labelled with all the applicable details referred to in subregulations (1), (3) and (4) may be labelled with the details only referred to in subregulation (1) (a), (b), (c), (d) (9 and (h), in which case the outer container of such sachet shall be labelled with those details and in the manner referred to in subregulation (5) or (6), as the case may be.
- (8) A label which is attached to a container in terms of subregulation (6) or in terms of that subregulation as applied at subregulation (7) shall not obliterate any details labelled in terms of those subregulations on the container concerned.
- (9) Herbicide labels must be indicated by a purple square in the top right hand corner.
- (10) A label shall in relation to a legume inoculant be labelled with --
 - (a) the applicable details and in the applicable manner referred to in subregulations (1)(a), (b), (c), (e), (g), (h) and (i), (2), (4)(a), (5), (6), (7) and (8), on the panel specified in the subregulation concerned: Provided that the expiry date of the inoculant concerned shall not be more than six months of the date of manufacture; and
 - (b) the words "**KEEP IN** A **COOL**, **DRY AND DARK PLACE**" on the main panel referred to in subregulation 2(a): provided that the word "dark" may be omitted if the container concerned is opaque.
- (11) (a) If an immediate container or sachet referred to in regulation 13(1) or an outer container referred to in subregulation (5) or (6) or in those subregulations as applied by subregulation (7) or (IO), is packed in a display container, such display container shall in addition to any other particulars, marks or signs relating to the agricultural remedy concerned, be labelled with the details referred to in subregulations (1) (b), (c), (d), (g) and (i).
 - (b) A casing in which a container or sachet referred to in paragraph (a) is packed for transport shall, in addition to any other details, marks or indications relating to the transportation of the agricultural remedy concerned, be labelled with the applicable details referred to in subregulation (1) (b), (c), (d), (g) and (i).
- (12) Unless otherwise provided for in these regulations, the applicable details referred to in subregulations (1), (3), (4), (6), (7), (10) and (11) shall be labelled with permanent ink, contrasting to the background in letters, figures and symbols of not less than one mm high.
- (13) Containers and labels, which at the commencement of these regulations, do not comply with the requirements specified in this regulation shall only be used for the labelling of the agricultural remedy concerned until 31 March 2006.

PARTIII

ADVERTISEMENTS

Details of advertisements

- 14. (1) An advertisement shall in addition to any other relevant details which the Registrar may approve to appear therein --
 - (a) when published in a newspaper, magazine or other printed matter
 - (i) furnish the trade mark, if any, and the trade name which may be used by the person in whose favour the **ag**ricultural remedy in question is registered;
 - (ii) where it is applicable furnish the toxicity group as which the agricultural remedy in question was classified and the name of the active ingredient which it contains, if such name is not already included in the trade name;
 - (iii) contain the registration number of the agricultural remedy in question together with a reference to the Act, expressed as Reg. No. ... Act No. 36 of 1947), and
 - (iv) furnish the name and address of the person in whose favour the agricultural remedy in question is registered, or
 - (b) when screened or broadcasted, at least furnish those details referred to in paragraph(a)(i), (ii), (iii) and (iv).
 - (2) Any reference in an advertisement to --
 - (a) an ingredient or active ingredient as the case may be;
 - (b) the instructions for use, application or administration; and
 - (c) the registration

of the agricultural remedy in question shall be restricted to those details which are approved to be indicated on a label or container used in connection with the sale of that agricultural remedy.

(3) All advertisements must comply to the prescriptions for advertising of the Advertising Standards Authority of South Africa.

Publication or distribution of false or misleading advertisements

- **15.** (1) No person shall publish or distribute any false or misleading advertisement relating to an agricultural remedy.
 - (2) it shall be a sufficient defence for any person, other than the person selling the agricultural remedy to which the false or misleading advertisement relates, who is charged with a contravention of sub regulation 15(1), if he/she proves to the satisfaction of the court that helshe did not know and could not reasonably be expected to have known that the advertisement was false or misleading in any respect, unless it is proved that the accused failed on demand by the registrar or a police official to furnish the name and address of the person at whose instance the advertisementwas published or distributed.

PARTIV

MANUFACTURING ESTABLISHMENT

Practices to be followed at establishments

- 16. (1) The practices in respect of the operation of the undertaking at an establishment and which relates to the manufacture, control, packing, marking or labelling of an agricultural remedy for the purpose of sale, shall be in conformance with quality documented management systems and be such that the composition and efficacy of the agricultural remedy in question comply with the details registered in respect thereof, and that it possesses all the chemical, physical and other properties thus registered.
 - (2) Raw materials used for the manufacture of an agricultural remedy, and the agricultural remedy manufactured therefrom, shall be handled and stored at the premises of an establishment in such a manner that -
 - (a) it is protected against damage, contamination and deterioration;
 - (b) access to the different raw materials and agricultural remedies can readily be obtained.
 - (3) Chemical or physical quality checks shall be made on each consignment of all raw materials used for the manufacture of an agricultural remedy and on the agricultural remedy manufactured from such raw materials by the person in whose favour an agricultural remedy is registered or by a competent body in the Republic which is recognised for this purpose by the Registrar.
 - (4) The person managing the undertaking at an establishment shall keep samples (at least 30 ml/300g) in respect of each batch of different agricultural remedies manufactured for a period of at least 2 years from the date of manufacturing.
 - (5) The names of the raw materials to be used for the manufacture of an agricultural remedy shall be marked clearly and legibly on the containers thereof provided that if such raw materials are stored in bulk, the names of such raw materials shall be shown on the containers in or the places at which they are thus stored.
 - (6) If an agricultural remedy is not packed and labelled immediately after manufacture, the name thereof shall be shown on the containers in or places at which it is stored.

Requirements for establishments

- 17. (1) An establishment where an agricultural remedy is manufactured, controlled, packed or labelled for the purpose of sale, shall be duly registered under the Factories, Machinery and Building Work Act, 1941 (Act No. 22 of 1941) and must conform to the requirements of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).
 - (2) The premises of such establishment shall be kept orderly and clean.
 - (3) The area at such establishment which is used for the performance or a particular function in connection with the manufacture, control packing or labelling of an agricultural remedy shall be adequate for the proper carrying out of that function.
 - (4) Facilities and equipment which shall ensure that an agricultural remedy shall be manufactured, packed and labelled in the manner determined in these regulations and that the Composition and efficacy of the agricultural remedy concerned complies with the requirements registered in respect thereof, and that it possessed

the chemical physical and other properties registered, shall be available at the establishment concerned.

(5) An employee at an establishment who is responsible for the manufacture, control, packing, marking or labelling of an agricultural remedy shall have the knowledge of the practices to be followed in the operation of the undertaking at such establishment and of the provisions of the Act which, in the opinion of the Registrar, is sufficient for the performance of the duty imposed upon such employee.

Maintenance and care of facilities

- 18. (1) All facilities and equipment used in the manufacture, control packing or labelling of an agriculture remedy shall be maintained in a sound condition and be cleaned at regular intervals.
 - (2) Where the same facilities and equipment are used for the manufacture, control, packing of labelling of different agricultural remedies, such facilities and equipment shall be cleaned properly before it is used in connections with another agricultural remedy.

Records at establishments

- 19. (1) A person managing the undertaking at an establishment shall, in respect of each batch of the different agricultural remedies manufactured, controlled, packed or labelled there, keep comprehensive record of --
 - (a) the results of quality checks which were made in terms of regulation 16(3) of the raw materials used for the manufacture of the agricultural remedy comprising such batch and of such agricultural remedy;
 - (b) the total quantity of the agricultural remedy comprising such batch and if packed, the number of containers in which it is packed;
 - (c) the records indicating the source of raw materials and processing;
 - (d) the names and addresses of the persons to whom the agricultural remedy was sold, and the quantity thereof which is sold to each such person;
 - (e) complaints which were received in connection with the composition or efficacy of the agricultural remedy comprising such batch, or the chemical, physical or other properties thereof.
 - (2) The records to be kept at an establishment in terms of subregulations(1) as well as the formula for formulating a batch of an agricultural remedy there, shall be preserved at such establishment or such other place as may on application be approved by the Registrar, for at least two years after the date on which the batch concerned were sold: provided that if a complaint referred to in subregulation (1)(d) was received, the records in respect of the batch in question shall not be destroyed within two years after the date of such complaint.
 - (3) The records must always be kept at an establishment and made available when required by the **authority**.

PARTV

SAMPLING AND PERMISSIBLE DEVIATIONS IN ACTIVE INGREDIENT CONTENT

Representative samples of agricultural remedies

- **20.** (1) (a) An agricultural remedy which is sold in containers shall be sampled by selecting at different places from the batch of a particular agricultural remedy the number of containers required to obtain a sufficient quantity for a sample of such agricultural remedy.
 - (b) Such containers shall be similarly labelled and the agricultural remedy therein shall originate from the same batch.
 - (c) If a sample is composed of the contents of more than one container, such sample shall be thoroughly mixed before being divided in terms of section 15(3)(c) of the Act.
 - (d) Notwithstanding the provisions of paragraph (a) at least three sealed containers in which an agricultural remedy is sold, may also be taken as the sample of such agricultural remedy and the containers comprising such sample shall without being opened, be divided in terms of section **15(3)** of the Act.
 - (2) (a) An agricultural remedy which is not sold in a container shall be sampled by taking small quantities at different places from the stock of such agricultural remedy to obtain a sufficient quantity for a sample.
 - (b) Such sample shall be thoroughly mixed before being divided in terms of section 15 (3) (c) of the Act
 - (3) The provisions of subregulation (2) shall *mutatis mutandis* apply to the sampling of an agricultural remedy referred to in subregulation (1) prior to the packing thereof in containers, and to the sampling of an active ingredient used in the manufacture of an agricultural remedy.
 - (4) A certificate which in terms of section 15(4)(b) of the Act is forwarded to the accredited laboratory together with a sample of an agricultural remedy, shall be in the form as approved by the Registrar.
 - (5) A certificate on which the result of a test, examination of analysis of a sample of an agricultural remedy is to be recorded in terms of section 15(14)(b) of the Act shall be in the form as approved by the Registrar.
 - (6) That part of a sample of an agricultural remedy which is referred to in section 15(4)(c) of the Act --
 - (a) shall, if a certificate referred to in subregulation (5) indicates that such sample does not possess the chemical, physical or other properties specified in the application for registration of the agricultural requirements referred to in these regulations, be retained until the action arising from such certificate is concluded;
 - (b) may otherwise be destroyed.

Permissible deviations in active ingredient contents

21. Notwithstanding anything to the contrary contained in these regulations, an agricultural remedy shall not be deemed to deviate in its registered active ingredient contents if a

certificate referred to in regulation 20(5) in relation to the analysis of a sample of such agricultural remedy indicates that -

- (a) when it nominally contains less than 25 g of the active ingredient concerned per kilogram or litre, it deviates with not more than 15 per cent;
- (b) when it nominally contains 25 g or more, but less than 100g of the active ingredient concerned per kilogram or litre, it deviates with not more than 10 per cent;
- (c) when it nominally contains 100 g or more, but less than 250 g of the active ingredient concerned per kilogram or litre, it deviates with not more than six per cent;
- (d) when it nominally contains 250 g or more, but less than 500 g of the active ingredient concerned per kilogram or litre, it deviates with not more than five per cent; or
- (e) when it nominally contains 500 g or more of the active ingredient concerned per kilogram or litre; it deviates with not more than 2,5 per cent.

PART VI

INVOICES

Invoices for agricultural remedies

- 22. (1) An invoice given or sent in terms of section 9 of the Act by a person who sells any agricultural remedy not in a container, shall furnish all the applicable details referred to in regulation 13 in the applicable manner specified in that regulation: provided that such details may be omitted from the invoice if a label relating to the agricultural remedy concerned is given or sent with such invoice.
 - (2) A copy of an invoice referred to in subregulation (1) shall be preserved by the seller of that agricultural remedy for at least two years after the date on which such agricultural remedy was thus sold.

PART VII

SALES

Minimum standards of a person selling agricultural remedies

- 23. (1) Any person in control of an establishment selling, supplying or making available any danger groups I and II agricultural remedies may only do so if approved by the Registrar.
 - (2) The Registrar can require suitable training for approval of persons selling danger groups I and II agricultural remedies.
 - (3) The Registrar may grant exemption for certain group II agricultural remedies if helshe is of the opinion that such agricultural remedies will not pose any undue hazard to humans, animals or the environment.
 - (4) Proof of approval should be readily available at the premises where the agricultural remedies are being sold, supplied or made available.
 - (5) Any person in control of an establishment selling, supplying or making available danger group I agricultural remedies must be licensed in terms of the regulations promulgated in terms of the Hazardous Substances Act, 1973 (Act No. 15 of

1973), comply with the conditions of sale or supply of Group I hazardous substances and keep such records as required.

Handling, storage and disposal

24. All requirements with regard to South African National Standards must be complied with.

PART XIII

IMPORTS

Harbours and places through which imports may be made

- 25. (1) Agricultural remedies may only be imported through the ports of entry mentioned or approved by the Registrar.
 - (2) A container in which an imported agricultural remedy is packed not for sale in South Africa shall be marked clearly with the wording "For export only".
 - (3) No unregistered agricultural remedy may be imported into South Africa unless such a remedy complies with the requirements as stipulated in section 16 of the Act.

PARTIX

APPEALS

Submission of appeals

- 26. (1) An appeal in terms of section 6 of the Act shall be submitted to the Director-General: Agriculture within 60 days of the date on which the reasons for the decision against which is appealed, were furnished in terms of section 5 of the Act.
 - (2) Such appeal shall
 - (a) be in the form of a written affidavit; [which is sworn to or attested
 - (b) state the reference number and date of the documents by means of which such applicant or person was given notice of that decision;
 - (c) state the grounds on which the appeal is based;
 - (d) be accompanied by the documents relating to the subject of the appeal; and
 - (e) be accompanied by the fee as published in the Gazette.
 - (3) If such appeal is submitted by a person other than the person in respect of whom the decision concerned was furnished, the appeal concerned shall be accompanied by a statement in which the person concerned discloses his interest **in** that decision or action.
 - (4) The amount referred to in subregulation (2) (e) shall be paid by cheque, postal order or money order made out in favour of the Director-General: Agriculture: Provided that if the appeal concerned is delivered by hand, such amount may be paid in cash.

Address for submission of appeals

- 27. An appeal referred to in regulation 28(1) shall --
 - (a) when forwarded by post, be addressed to the Director-General, **Department** of Agriculture, Private Bag X250, Pretoria, 0001; and
 - (b) when delivered by hand, be delivered to the Director-General, Department of Agriculture, Agriculture Building, 20 Beatrix Street, Agriculture Place, Arcadia, Pretoria.

PARTX

GENERAL

Offences and penalties

28. Any person who refuses or **fails** to comply with the provisions of these regulations shall be guilty of an offence and liable on conviction to a fine or imprisonment or to both a fine and imprisonment. The fine will be determined by the Adjustment of Fines Act, 1991 (Act No. 101 of 1991).

Payment of fees

- 29. (1) The postage on delivery costs of any application or document submitted in terms of these regulations, as well as on or of anything else pertaining thereto, shall be paid by the consignee.
 - (2) Any fee payable in terms of these regulations shall be paid by means of a cheque postal order or money order made out in favour of the Director-GeneralAgriculture: Provided that if such a fee is delivered by hand, it may be paid in cash.
 - (3) Fees which are paid in terms of these regulations shall subject to section 6 of the Act and not be refundable.

Address for submission of documents

- 30. Any application or document or anything else pertaining thereto which is required in terms of these regulations to be submitted to the Registrar shall -
 - (a) when forwarded by post be addressed to: The Registrar: Act **No.** 36 of 1947, Private Bag X343, Pretoria, 0001; and
 - (b) when forwarded by rail or delivered by hand, be addressed or delivered to: The Registrar: Act No. 36 of 1947, Agriculture Place, 20 Beatrix Street, Arcadia, Pretoria.

Amendment and repeal of certain regulations

- 31. The regulations relating to --
 - (a) Agricultural Remedies, published under Government Notice R. 2561 **d** 27 November 1981, are hereby amended --
 - (i) by the deletion of regulations 2, 3, 4, 5, 6, 17 and 21 and Table 1 thereof;
 - (ii) by the substitution for subregulation (13) of regulation 15 of the following subregulation:

- "(13) Containers and labels, which, at the commencement of these regulations, do not comply with the requirements specified in this regulation shall be used for the labelling of the agricultural remedy concerned until 31 March 1984 only," and
- (iii) by the substitution for Schedule A thereto of the Annexure hereto;
- (b) Appeal against Decisions of the Registrar, published under Government Notice R. 2296 of 11 November 1977, are hereby repealed; and
- (c) the Importation of Agricultural Remedies published under Government Notice R. 2042 of 3 October 1980, are hereby repealed.
- (d) Government Notice R. 2561 of 27 November 1981 in as much as it refers to agriculture remedies;
- (e) Government Notice R. 1449 of 1 July 1983 in as much as it refers to agriculture remedies.