Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette No. 8239 *Regulasiekoerant*

Vol. 480 Pretoria, 3 June / Junie 2005 **No. 27615**

AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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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: ernestmo@nda.agric.za, 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 I

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;

(ii) experimental data relating to the pharmacology and toxicology of the active ingredient/s concerned and to the toxic metabolites of such ingredient/s

(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.

Period of registration

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 competent 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 inhalation toxicity 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.

Data protection

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 he/she 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 --

(a) 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 or 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.

PART II

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 closed 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 No. 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 --

(i) 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 included 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 a, 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 to any other marks or indications relating to the agricultural remedy concerned, 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) (f) 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 (10), 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.

PART III

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 agricultural 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 he/she 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 advertisement was published or distributed.

PART IV

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.

PART V

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 he/she 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.

PART IX

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.

PART X

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-General Agriculture: 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 of 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.

No. R. 503 **3 June 2005**

DEPARTMENT OF AGRICULTURE

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

PROPOSED REGULATIONS REGARDING STOCK 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: ernestmo@nda.agric.za, within four weeks from the date of publication hereof.

1. ***Definitions***

In these regulations, unless inconsistent with the context -

"certified translator" means a translator approved by the courts of South Africa;

"label" means any written, printed or graphic representation attached or included in the container of a stock remedy;

"over the counter" means any stock remedy which has no restrictions with regards to its use or sale thereof;

"maintenance" of a registration means renewal of registration;

"SANS" means South African National Standards;

and any other word or expression shall have the meaning assigned thereto in the Act.

PART I

REGISTRATION

Application for registration

2 (1) An application in terms of section 3(1) of the Act, for the registration of a stock remedy, must be submitted in triplicate to the Registrar on a form which is obtainable from the Registrar"s office for this purpose or on a clearly legible facsimile thereof;

(2) An application must only 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.

(3) An application shall be accompanied by -

(a) the applicable application fee as published in the Government Gazette;

(b) a draft typed label in triplicate, in English and any other official language. The label may also be submitted in any other official languages and be accompanied by an affidavit from a certified translator declaring the label to be a true reflection/translation of the English label. Such a label shall be in accordance with the requirements determined under section 7(1)(c), read with section 23(1)(g), of the Act and regulation 16 and 17;

(c) a copy of the experimental data on the biological efficacy and of the residues of the stock remedy concerned as determined under South African conditions; or any other data acceptable to the Registrar;

(d) experimental data relating to the pharmacology and toxicology of the active ingredient of the stock remedy concerned and to the metabolites of such ingredient;

(e) the method of analysis for the determination of the active ingredient in the stock remedy concerned and, where applicable, the method of analysis for the active ingredient and its toxic metabolites in residues;

(f) the details of the effect which the stock remedy concerned may have on the environment, where relevant;

(g) a copy of the stability data of the product in the containers as indicated on the application form;

(h) details relating to the suitability of the source of the active ingredient/s;

(i) details relating to the suitability of the manufacturer of the product.

The Registrar may grant exemption from the submission of any document referred to in paragraphs (c) to (i);

(4) In the case of a stock remedy of which the active ingredient and formulation is identical to that of a stock remedy which is registered in favour of another registration holder, further be accompanied by the written permission by such other registration holder that the stock remedy in respect of which the application for registration is made may be registered in favour of the applicant concerned.

(5) the Registrar may request any further data or sample which may enable him to evaluate the application.

Period of registration

3. Subject to the provisions of sections 3(4)(a) and 4A of the Act a registration will be valid for one year from the date of registration.

Suitability and efficacy of stock remedies

4 (1) The suitability and efficacy of a stock remedy shall be proved by results of trials which were carried out in the Republic, by the applicant or by a competent body which is recognized for this purpose;

(2) The person or body referred to in sub-regulation (1) shall, prior to the commencement of a trial, request approval from the Registrar in writing of the intention to conduct such a trial, and the Registrar may inspect the performance of such trial;

(3) The Registrar may permit the use of an unregistered stock remedy for the purpose indicated in sub-regulation (1);

(4) The Registrar may permit the import of an unregistered stock remedy for the purpose indicated in sub-regulation (1);

(5) The Registrar may permit the use of a registered stock remedy contrary to label indications for the purpose indicated in sub-regulation (1).

Determination of toxicity and potential hazard of stock remedies

5. (1) The toxicity or potential hazards of the active or inert ingredients of a stock remedy shall, where applicable, be in accordance with the LD-50 values specified in Appendix 7.1 of the RSA Classification Code for Agricultural and Stock Remedies and Associated Label Hazard Requirements as it may be amended from time to time.

(2) When the LD-50 values of a stock remedy are thus determined, such stock 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 7.1.

Data protection

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 in writing 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 a registration of a stock remedy, shall be submitted to the Registrar on a form which is obtainable from the Registrar for this purpose, or on a clearly legible facsimile thereof.

(2) Such application shall:

(a) be made by the applicant;
(b) be submitted to the Registrar on or before the expiry date of the registration concerned but not more than three months prior to such expiry date;
(c) be accompanied by the applicable maintenance fee as published in the Gazette;

(3) An application made in terms of sub-regulation (1) which:

(a) is received by the Registrar after the expiry date, but not more than 30 days after such expiry date, shall be considered only if it is accompanied by the applicable maintenance fee for a late maintenance referred to in the Gazette;
(b) which is received by the Registrar after the days of grace referred to in paragraph (a) expired, will 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 maintenance of a registration shall confirm that the details which he furnishes with such application in respect of the stock remedy concerned or of a label which is being used in connection therewith, do not deviate in any manner whatsoever from the congruent details which have already been registered or approved in relation to that stock remedy or label.

Conditions for registrations, amendments and maintenance of registrations

8. A registration and the maintenance of a registration of a stock remedy under section 3 of the Act is granted on condition that during the period of registration or maintenance of the registration:

(a) the formulation of the stock 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 stock remedy concerned, shall not be altered without the prior written approval of the Registrar;
(c) that the details of the manufacturer of the active ingredient/s and the manufactured product shall not differ from the approved details; and
(d) all conditions determined by the Registrar are met.

Application for amendment of certain registrations and approved labels

9. (1) If any person in whose favour a stock remedy is registered, intends to-

(a) alter the registered composition thereof;
(b) amend any detail relating to the registration on the label or package insert thereof;

he shall apply for an amendment to the registration on a form obtainable from the Registrar or on a clearly legible facsimile thereof.

(2) An application for an amendment shall-

(a) be made by the current applicant;
(b) be accompanied by the applicable application fee as published in the Government Gazette;
(c) be accompanied by a typed label in triplicate in English and any other official language, if the amendment will affect any change to the label;
(d) be accompanied by the current certificate of registration if the amendment will affect any changes to the certificate;
(e) be accompanied by the relevant data as stipulated in regulation 2(3)(c) – (g) if the data has not previously been submitted to the Registrar.

Provided that the Registrar may grant exemption from the payment of the application fee concerned if the alteration or amendment concerned -

(a) is in the public interest; or
(b) is effected by the Registrar.

(3) If any person in whose favour a stock remedy is registered, intends to:

(a) amend the details of the manufacturer of the active ingredient;
(b) amend the details of the manufacturer of the product,
(c) amend the details of the containers of the product; or
(d) amend the details of the shelf-life of the product;

shall apply to the Registrar for approval of the amendment. The application shall be accompanied by relevant data to support the amendment requested.

Review of registrations

10. The Registrar may institute a review of existing stock remedies.

(1) When a review procedure is instituted the Registrar shall inform all applicable registration holders in writing of the reason of the review and such review will be carried out 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 stock 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 stock remedy.

(5) Registration holders requested to submit new data will have exclusive use of the new data as described in regulation on data protection (section 6).

Application for transfer of a registration

11 If any person in whose favour a stock remedy is registered intends to transfer a registration to another person, such application shall be submitted to the Registrar on a form which is obtainable from the Registrar for this purpose or on a clearly legible facsimile thereof.

(1) Such application shall 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.

(2) Such application shall be accompanied by:

(a) the applicable application/registration fee as published in the Government Gazette;

(b) the current registration certificate of the stock remedy to be transferred, if it has not already been submitted;

(c) written consent from the current registration holder of the stock remedy to be transferred for the transfer;

(d) an affidavit from the applicant that the label will remain identical to the approved label, except for the details of the registration holder.

Return of certificate of registration

12. 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 stock remedy, concerned has lapsed in terms of section 4A(2) of the Act, as the case may be; or

(b) at least 30 days prior to the date on which the registration of stock remedy is to be transferred to another person: Provided that an application as contemplated in regulation 2 for the registration of the stock remedy in question in favour of such other person shall be submitted simultaneously.

PART II

LABELLING AND CONTAINERS

Containers of stock remedies

13. (1) Subject to the provisions of any other law relating to containers, a container in which a quantity of a stock remedy is packed for sale and a container in which a measured dosage of stock 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 closed or sealed in the manner permitted by the stock 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 stock remedy, prevent spillage when pouring out the contents thereof.

(3) An immediate container or sachet or an outer container or display container referred to in regulation 17 shall not be labelled with any other marks or signs than the applicable details referred in regulation 17 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 .

Labelling of containers

14. (1) No person may sell any stock remedy without an approved label. The label and package insert will indicate the following information in the sequence approved by the Registrar:

(a) contain the words "For animal use only" or a similar statement;

(b) the registration number and trade name;

(c) the composition on a mass/mass and/or mass/volume basis in accordance with the directions of the Registrar: provided that, unless the Registrar otherwise directs, only the active ingredients shall be indicated and such a percentage shall be in terms of the pure chemical and not of the technical product;

(d) a statement in a form approved by the Registrar, specifying the properties claimed for such remedy;

(e) the nett mass of the remedy in the container, or in the case of a remedy in liquid form the nett volume, or in the case of a remedy which is a dehydrated vaccine the number of doses in the container;

(f) the batch number and expiry date;

(g) the name and the business address of the registration holder;

(h) full directions for use, indicating the dilution or doses, the number of treatments required to be effective, the intervals between treatments and the method of application;

(i) if required the hazard statement and markings as required in the South Africa Bureau of Standards Code 0304-02;

(j) any other information which the Registrar may require.

(2) In cases where the container in which the stock remedy is packed, or the label which is affixed thereto, is too small to accommodate all the details stipulated in paragraphs (a) to (j) of sub regulation (1) the Registrar may grant exemption from the details provided that, the details required by sub regulation (1) are given on a package insert which is attached to or enclosed in the container in which the stock remedy is packed.

(3) In addition to the foregoing the requirements of any other Act relating to labeling must be adhered to.

(4) Despite sub regulations (1), (2), (3) and (5) and subject to the provisions of any other law, no words or marks may appear on the container in which a registered stock remedy is sold, or on a label and/or pamphlet affixed thereto without prior approval of the Registrar.

(5) Only recognized chemical, analytical and pharmaceutical expressions or terms or those expressions or terms which, for reasons of clarity, have been approved by the Registrar, may be marked or printed on a container in which a registered stock remedy is sold, or on a label affixed thereto, for the purpose of explaining the composition of such remedy.

PART III

ADVERTISEMENTS

Publication or distribution of false or misleading advertisements

15. No person shall publish or distribute any false or misleading advertisement relating to a stock remedy.

Details of advertisements

16. (1) An advertisement shall when published in a newspaper, magazine or other printed matter --

(a) furnish the trade mark, if any, and the trade name of the stock remedy;

(b) where it is applicable furnish the hazard statement;

(c) indicate the name of the active ingredient which it contains;

((d) contain the registration number of the stock remedy in question together with a reference to the Act, expressed as "Reg. No. ..... Act 36/1947"; and

(e) furnish the name and address of the registration holder.

(2) An advertisement shall, when screened or broadcast, at least furnish those details referred to in sub-regulation (1)(a) and (f).

(3) Any reference in an advertisement to --

(a) an active ingredient;

(b) the instructions for use, claims, application or administration; and

(c) the registration, of the stock remedy in question

shall be restricted to those details approved on the label of the stock remedy.

(4) Any statements made in an advertisement must be scientifically validated and on request of the Registrar such validation must be provided to the Registrar.

PART IV

MANUFACTURING ESTABLISHMENTS

Manufacturing Facilities

17. (1) The practices in respect of the operation of the undertaking at an establishment and which relates to the manufacture, control, packing, marking or labeling of a stock remedy for the purpose of sale, shall be in conformance with Good Manufacturing Practice guidelines as published in the government gazette and be such that the composition and efficacy of the stock remedy in question complies 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 a stock remedy, and the stock remedy manufactured there from, shall be handled and stored at the premises of an establishment in such manner that-

(a) it is protected against damage, contamination and deterioration; and

(b) access to the different raw materials and stock 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 a stock remedy and on the stock remedy manufactured from such raw materials by the person in whose favour a stock remedy is registered or by a competent body which is recognized for this purpose;

(4) An employee at an establishment who is responsible for the manufacture, control, packing, marking or labeling of a stock remedy shall have the knowledge of the practices to be followed in the operation of the undertaking of 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.

(5) The names of the raw materials to be used for the manufacture of a stock 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 a stock remedy is not packed and labeled immediately after manufacture, the name thereof shall be shown on the containers in or places at which it is stored.

Requirements for establishments

18. (1) An establishment where a stock remedy is manufactured, controlled, packed or labeled for the purpose of sale, shall be 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 labeling of a stock remedy shall be adequate for the proper carrying out of that function.

(4) Facilities and equipment which shall ensure that a stock remedy shall be manufactured, packed and labeled in the manner determined in these regulations and that the composition and efficacy of the stock remedy concerned complies with the requirements registered in respect thereof, and that it possesses the chemical, physical and other properties thus registered, shall be available at the establishment concerned;

(5) The Registrar may publish additional guidelines for the requirements of establishments in t he Government Gazette that must be adhered to.

Records at establishments

19. (1) A person managing the undertaking at an establishment shall, in respect of each batch of the different stock remedies manufactured, controlled, packed or labeled there, keep comprehensive records of -

(a) the results of quality checks which were made in terms of regulation 18(3) of the raw materials used for the manufacture of the stock remedy, comprising such batch, and of such stock remedy;

(b) the total quantity of the stock remedy comprising such batch and if packed, the number of containers in which it is packed;

(c) the names and addresses of the persons to whom the stock remedy was sold, and the quantity thereof which is sold to each such person;

(d) complaints which were received in connection with the composition or efficacy of the stock remedy comprising such batch, or the chemical, physical or other properties thereof.

(2) The records to be kept at an establishment in terms of sub-regulation (1) as well as the formula for formulating a batch of a stock remedy there shall be preserved at such establishment and for at least five years after the date on which the batch concerned was manufactured. In the case of raw materials after the date of first receipt provided that if a complaint referred to in sub-regulation (1)(d) was received, the records in respect of the batch in question shall not be destroyed within two years from the date of such complaint. Records must always be available at an establishment for inspection by the authority.

PART V

SAMPLING AND PERMISSIBLE DEVIATIONS

Sampling of stock remedies

20. (1) A stock remedy which is sold in containers shall be sampled by selecting at different places from the stock of a particular stock remedy the number of containers required to obtain a statistically significant quantity for a sample of such a stock remedy:

(a) Such containers shall be similarly labeled and the stock remedy therein shall originate from the same batch.

(b) If a sample is composed of the contents of more than one container, such a sample shall be thoroughly mixed before being divided in terms of section 15(3)(c) of the Act.

(c) Despite the provisions of subregulation (1)(a), at least three sealed containers in which a stock remedy is sold, may also be taken as the sample of such stock remedy and the containers comprising such sample shall, without being opened, be divided in terms of section 15(3)(c) of the Act.

(2) A stock remedy which is not sold in a container shall be sampled by taking small quantities at different places from the stock of such stock remedy to obtain a sufficient quantity for a sample. Such a sample shall be thoroughly mixed before being divided in terms of section 15(3)(c) of the Act.

(3) The provisions of sub regulation (2) shall *mutatis mutandis* apply to the sampling of a stock remedy referred to in sub regulation (1) prior to the packing thereof in containers, and the sampling of an active ingredient used in the manufacture of a stock remedy.

(4) Where a stock remedy in a container is of a perishable nature, or where for any reason the opening of the container would interfere with the analysis of the remedy unless such analysis were effected at the time of opening or immediately thereafter, at least three containers, similarly labeled and purporting to contain a similar stock remedy, shall be procured. The containers thus procured shall be split up into three groups, each of which shall contain one or more unopened containers and which shall further be dealt with as prescribed by section 15(2) of the Act.

(5) A certificate which in terms of section 15(4)(b) of the Act is forwarded to an analyst t ogether with a sample of the stock remedy, shall be in the form as approved by the Registrar.

(6) A certificate on which the result of a test, examination or analysis of a sample of a stock remedy is to be recorded in terms of section 15(4)(b) of the Act, shall be in a form as approved by the Registrar.

(7) That part of a sample of a stock remedy which is referred to in section 15(4)(c) of the Act-

(a) shall, if a certificate referred to in sub regulation (5) indicates that such sample does not possess the chemical, physical or other properties specified in the application for registration of the stock remedy concerned, or does not comply with any requirements referred to in these regulations, be retained until the action arising from such certificate is concluded. The registration holder must be notified of the results of the test, examination or analysis within 7 days;

(b) may otherwise be destroyed.

Permissible deviations in active ingredient contents

21. Despite anything to the contrary contained in these regulations, a stock remedy shall not be deemed to deviate in its registered active ingredient contents if a certificate referred to in regulation 18(5) in relation to the analysis of a sample of such a stock remedy indicates that the active ingredient concentration is within 10 % of the registered label claim, when the product is within its shelf life, and stored as instructed.

PART VI

SALES

Minimum standards of a person selling stock remedies

22. (1) Any person in control of an establishment selling, supplying or making available any danger groups I and II stock remedies may only do so if approved by the Registrar.

(2) The Registrar can recognize suitable accredited training courses for registration of persons selling danger groups I and II stock remedies.

(3) The Registrar may grant exemption for certain group II stock remedies if he is of the opinion that such stock remedies will not pose any undue hazard to humans, animals or the environment.

(4) Any person in control of an establishment selling, supplying or making available danger group I stock 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

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

PART VII

IMPORTS

Importation of Stock Remedies

24. No person shall import a stock remedy into the Republic unless such remedy is registered: Provided that the Registrar may permit, in writing, the importations into the Republic of a specified quantity of a stock remedy which is not registered for purposes of experimentation or for some purpose other than the sale of such remedy.

Harbors and places through which imports may be made

25. Stock remedies may only be imported through the ports of entry approved by the Registrar.

PART VIII

APPEALS

Appeals

26. (1) Whenever an application for registration is rejected, or a registration is made subject to conditions in terms of the provisions of section 3(3) of the Act, or is cancelled in terms of the provisions of section 4 of the Act, the Registrar shall notify the applicant, in writing, of such rejection, imposition of conditions or cancellation, and the applicant may within 60 days of being notified of such rejection, imposition of conditions or cancellation appeal to the Minister, in writing, against such decision.

(2) The provisions of regulation 27(2)(a) shall apply *mutatis mutandis* in respect of any decision by the Minister in connection with an appeal lodged with in terms of paragraph 27(2)(b) of the regulations.

Submission of appeals

27. (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 statement which is sworn to or attested;

(b) state the reference number and date of the document 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 interest in that decision or action.

4) The amount referred to in sub regulation (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

28. An appeal referred to in regulation 28(1) shall:

(1) when forwarded by post, be addressed to the Director-General, Department of Agriculture, Private Bag X250, Pretoria, 0001; and

(2) when delivered by hand, be delivered to the Director-General, Department of Agriculture, Agriculture Building, Beatrix Street, Pretoria.

PART IX – GENERAL

Offences and penalties

29. 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

30. (1) The postage on and 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 consigner.

(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-General: Agriculture: Provided that if such 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, not be refundable.

Address for submission of documents

31. Any application or document or anything else pertaining thereto, which is required in terms of these regulations to be submitted to the Registrar shall --

(1) when forwarded by post, be addressed to;
The Registrar: Act No. 36 of 1947, Private Bag X343, Pretoria, 0001; and

(2) when forwarded by rail or delivered by hand, be addressed or delivered to :
The Registrar: Act No. 36 of 1947, Agriculture Building, 20 Beatrix Street, Pretoria.

Amendment and repeal of certain regulations

32. The Regulations relating to Stock Remedies published under Government Gazette Notice No. R857 of 28 May 1971 are hereby repealed. The Regulations relating to Stock Remedies published under Government Notice No. R1449 of 1 July 1983 are repealed in so far as they pertain to stock remedies.

No. R. 511 **3 June 2005**

PLANT BREEDERS' RIGHTS ACT, 1976 (ACT No. 15 OF 1976)

REGULATIONS RELATING TO PLANT BREEDERS' RIGHTS: AMENDMENT

The Minister of Agriculture, acting under section 44 of the Plant Breeders' Rights Act, 1976 (Act No. 15 of 1976), has made the regulations in the Schedule.

SCHEDULE

Definition

1. In this Schedule "the Regulations" means the Regulations published by Government Notice No. R. 1186 of 12 September 1997, as amended by Government Notices Nos. R. 1582 of 28 November 1997, R. 867 of 3 July 1998, R. 1285 of 16 October 1998, R. 323 of 19 March 1999, R. 604 of 14 May 1999, R. 1271 of 29 October 1999, R. 392 of 20 April 2000, R. 690 of 14 July 2000, R. 1078 of 3 November 2000, R. 387 of 18 May 2001, R. 667 of 27 July 2001, R. 548 of 10 May 2002 and R. 409 of 28 March 2003 and R. 465 of 8 April 2004.

Substitution of Table 2 of the Regulations

2. The following table is hereby substituted for Table 2 of the Regulations with effect from 1 April 2005:

No. R. 511 **3 Junie 2005**

WET OP PLANTTELERSREGTE, 1976 (WET No. 15 VAN 1976)

REGULASIES BETREFFENDE PLANTTELERSREGTE: WYSIGING

Die Minister van Landbou, handelende kragtens artikel 44 van die Wet op Planttelersregte, 1976 (Wet No. 15 van 1976), het die regulasies in die Bylae uitgevaardig.

BYLAE

Woordomskrywing

1. In hierdie Bylae beteken "die Regulasies" die Regulasies gepubliseer by Goewermentskennisgewing No. R. 1186 van 12 September 1997, soos gewysig deur Goewermentskennisgewings Nos. R. 1582 van 28 November 1997, R. 867 van 3 Julie 1998, R. 1285 van 16 Oktober 1998, R. 323 van 19 Maart 1999, R. 604 van 14 Mei 1999, R. 1271 van 29 Oktober 1999, R. 392 van 20 April 2000, R. 690 van 14 Julie 2000, R. 1078 van 3 November 2000, R. 387 van 18 Mei 2001, R. 667 van 27 Julie 2001, R. 548 van 10 Mei 2002 en R. 409 van 28 Maart 2003 en R. 465 van 8 April 2004.

Vervanging van Tabel 2 van die Regulasies

2. Tabel 2 van die Regulasies word met ingang 1 April 2005 deur die volgende tabel vervang:

"TABLE 2/TABEL 2

FEES PAYABLE/GELDE BETAALBAAR

No.	Purpose/Doel	Amount/Bedrag
1.	An application for the grant of a plant breeder's right/ 'n Aansoek om die toestaan van 'n planttelersreg [Reg. 3(2)(f)]	R1000,00 each/elk
2.	A claim to give priority in terms of section 8(2) of the Act to an application for the grant of a plant breeder's right/ 'n Aansoek om ingevolge artikel 8(2) van die Wet voorrang te verleen aan 'n aansoek om die toestaan van 'n planttelersreg [Reg. 4(2)(c)]	R600,00 each/elk
3.	An objection to the grant of a plant breeder's right/ 'n Beswaar teen die toestaan van 'n planttelersreg [Reg. 8(1)(e)]	R4 000,00 each/elk
4.	Examination fee for a plant breeder's right: Category A (agronomic, vegetable and pasture crops and annual ornamentals)/ Ondersoekgeld vir 'n planttelersreg: Kategorie A (akkerbou-, groente- en weidingsgewasse en eenjarige sierplante) [Reg. 3(2)(g) and/en (9)(1)]	R1 700, 00 each/elk
5.	Examination fee for a plant breeder's right: Category B (fruit, vines, citrus and perennial ornamentals)/ Ondersoekgeld vir 'n planttelersreg: Kategorie B (vrugte, rankplante, sitrus en meerjarige sierplante) [Reg. 3(2)(g) and/en 9(1)]	R2 200,00 each/elk
6.	Provision of results of tests and trials undertaken by the registrar, to the appropriate authority in a convention country or an agreement country/ Voorsiening van resultate van toetse en proewe deur die registrateur onderneem aan die toepaslike gesag in 'n konvensieland of 'n ooreenkomsland [Reg. 9(3)]	Tariff to fluctuate with exchange rate.
7.	Annual fee for a plant breeder's right/ Jaargeld vir 'n planttelersreg [Reg.10(1)]	R200,00 each/elk
8.	An application for the issue of a compulsory licence in respect of a plant breeder's right/ 'n Aansoek om die uitreiking van 'n verpligte lisensie ten opsigte van 'n planttelersreg [Reg. 13(1)(d)]	R3 500,00 each/elk
9.	Notice of the transfer of a plant breeder's right/ Kennisgewing van die oordrag van 'n planttelersreg [Reg. 14(2)(b)]	R600,00 each/elk
10.	An application for the alteration or supplementation of the denomination approved for a variety/ 'n Aansoek om die wysiging of aanvulling van die benaming goedgekeur vir 'n variëteit [Reg. 15(1)(b)]	R1 200,00 each/elk

No.	Purpose/Doel	Amount/Bedrag
11.	An objection against the intended approval of an alteration or supplementation of the denomination approved for a variety/ 'n Beswaar teen die beoogde goedkeuring van 'n wysiging of aanvulling van die benaming goedgekeur vir 'n variëteit [Reg. 15(3)(e)]	R600,00 each/elk
12.	An objection against the intended termination of a plant breeder's right/ 'n Beswaar teen die voorgenome beëindiging van 'n planttelersreg [Reg.16(1)(f)]	R600,00 each/elk
13.	A notice of the voluntary surrender of a plant breeder's right/ 'n Kennisgewing van die vrywillige afstanddoening van 'n planttelersreg [Reg. 17(1)(b)(i)]	Free/Gratis
14.	Inspection of the register of plant breeders' rights/ Insae in die register van planttelersregte [Reg.20(2)]	Free/Gratis
15.	Inspection of a document submitted to the registrar in connection with an application for the grant of a plant breeder's right/ Insae in 'n dokument by die registrateur ingedien in verband met 'n aansoek om die toestaan van 'n planttelersreg [Reg. 21(2)]	R300,00 per occasion/ Geleentheid
16.	A certificate of any particulars in the register or of any document in connection with an application for the grant of a plant breeder's right/ 'n Sertifikaat van enige besonderhede in die register of van enige dokument in verband met 'n aansoek om die toestaan van 'n planttelersreg [Reg. 21(2)].	R300,00 per certificate/sertifikaat
17.	A copy of any particulars in the register or of a document submitted to the registrar in connection with an application for the grant of a plant breeder's right/ 'n Afskrif van enige besonderhede in die register of van 'n dokument by die registrateur ingedien in verband met 'n aansoek om die toestaan van 'n planttelersreg [Reg. 21(2)]	R8,00 per application plus R0,95c per photocopy / R8,00 per aansoek plus R0,95c per fotokopie
18.	Submission of appeal against any decision or action taken by the registrar in terms of the Act/ Voorlegging van appèl teen enige beslissing van of stappe gedoen deur die registrateur ingevolge die Wet [Reg. 22(1)(d)]	R3 500,00 each/elk".

No. R. 512 **3 June 2005**

PLANT BREEDERS' RIGHTS ACT, 1976
(ACT No. 15 OF 1976)

REGULATIONS RELATING TO PLANT BREEDERS' RIGHTS: AMENDMENT

The Minister of Agriculture, acting under section 44 of the Plant Breeders' Rights Act, 1976 (Act No. 15 of 1976), has made the regulations set out in the Schedule.

SCHEDULE

Definition

1. In this schedule 'the regulations' mean the regulations published by Government Notice No. R.1186 of 12 September 1997, as amended by Government Notices Nos. R.1582 of 28 November 1997, R.867 of 3 July 1998, R.1285 of 16 October 1998, R.323 of 19 March 1999, R.604 of 14 May 1999, R.1271 of 29 October 1999, R.392 of 20 April 2000, R.690 of 14 July 2000, R.1078 of 3 November 2000, R.387 of 18 May 2001 and R.667 of 27 July 2001.

Amendment of Table 1 of the Regulations

2. Table 1 of the Regulations is hereby amended by the insertion of the entry in Annexure A in the alphabetically correct position.

No. R. 512 **3 Junie 2005**

WET OP PLANTTELERSREGTE, 1976
(WET NO. 15 VAN 1976)

REGULASIES BETREFFENDE PLANTTELERSREGTE; WYSIGING

Die Minister van Landbou, handelende kragtens artikel 44 van die Wet op Planttelersregte, 1976 (Wet No. 15 van 1976), het die regulasies in die Bylae uitgevaardig.

BYLAE

Woordomskrywing

1. In hierdie Bylae beteken 'die Regulasies' gepubliseer by Goewermentskennisgewing No. R.1186 van 12 September 1997, soos gewysig deur Goewermentskennisgewing Nos. R.1582 van 28 November 1997, R.867 van 3 Julie1998, R.1285 van 16 Oktober 1998, R.323 van 19 Maart 1999, R.604 van 14 Mei 1999, R.1271 van 29 Oktober 1999, R.392 van 20 April 2000, R.690 van 14 Julie 2000, R.1078 van 3 November 2000, R.387 van 18 Mei 2001 en R.667 van 27 Julie 2001.

Wysiging van Tabel 1 van die Regulasies

2. Tabel 1 van die Regulasies word hierby gewysig deur die inskrywing in Aanhangsel A in die alfabeties korrekte posisie in te voeg.

ANNEXURE A/AANHANGSEL A

TABLE 1/TABEL 1
KINDS OF PLANTS AND PERIOD OF RIGHTS
SOORTE PLANTE EN TERMYNE VAN REGTE
[Reg. 11; 11(A)]

1		2	3	4
Kind of Plant Soort Plant		Category Kategorie	Period of Plant Breeders' Right (years) Termyn van Planttelelersreg (jare)	Period of sole Right (years) Termyn van Alleenreg (jare)
Botanical Name Botaniese Naam	Common Naam Gewone Naam			
Agathosma spp	Agathosma	A	20	5
Angelonia spp	Angelonia	A	20	5
Adenanthos Labill.	Adenanthos	A	20	5
Ajuga L.	Bugleweed	A	20	5
Bouvardia Salisb.	Bouvardia	A	20	5
Brunfelsia latifolia (Pohl) Benth.	Brunfelsia	A	25	5
Ceanothus dentatus Torr. & A. Gray	Red Root	A	20	5
Chlorophytum Ker-Gawl.	St Bernard's Lily	A	20	5
Cuphea hyssopifolia HBK	False Heather	A	20	5
Dianella spp	Dianella	A	20	5
Eriocephalus	Eriocephalus	A	20	5
Iris L.	Iris	A	20	5
Lespedeza cuneata (Dum. Cours.) G. Don	Lespedeza	A	20	5
Limonium Mill.	Statice	A	20	5
Merwilla Speta	Merwilla	A	20	5
Murraya paniculatum (L.) Jack	Orange JasminE	A	20	5
Sambucus L.	Elderberry	A	20	5
Stenotaphrum secundatum (Walt.) O.Kunze	Buffalo Grass	A	20	5
Symphoricarpos albus (L.) S.F.Blake	Waxberry, Snowberry	A	20	5
Watsonia Mill.	Bugle Lily	A	20	5
Weinmannia L.	Weinmannia	A	20	5
Zizyphus jujube Mill.	Jujube	A	20	5

DEPARTMENT OF TRADE AND INDUSTRY
DEPARTEMENT VAN HANDEL EN NYWERHEID

No. R. 518 **3 June 2005** **No. R. 518** **3 Junie 2005**

INTERNATIONAL TRADE ADMINISTRATION COMMISSION OF SOUTH AFRICA

IMPORT CONTROL

I, Mandisi Mpahlwa, in my capacity as Minister of Trade and Industry, acting under the powers vested in me by section 6 of the International Trade Administration Act (Act 71 of 2002) hereby amend Government Notice No 3 of 2 January 2004 by-

the addition of the following paragraph after paragraph (n)

" (o) goods imported in terms of rebate item 405.04 of Schedule 4 to the Customs and Excise Act, 91 of 1964."

M. MPAHLWA, MP
MINISTER OF TRADE AND INDUSTRY.

INTERNASIONALE HANDELSADMINISTRASIE KOMMISSIE VAN SUID AFRIKA

INVOERBEHEER

Ek, Mandisi Mpahlwa, in my hoedanigheid as Minister van Handel en Nywerheid, en handelende kragtens die bevoegdheid my verleen deur artikel 6 van die Wet op Internasionale Handelsadministrasie, (Wet 71 van 2002) wysig hierby Goewermentkennisgewing No.3 van 2 Januarie 2004 deur-

die byvoeging van die volgende paragraaf na paragraaf (n)

" (o) goedere ingevoer ingevolge kortingitem 405.04 van Bylae 4 tot die Doane en Aksynswet, 91 van 1964."

M. MPAHLWA, LP
MINISTER VAN HANDEL EN NYWERHEID.

DEPARTMENT OF LABOUR
DEPARTEMENT VAN ARBEID

No. R. 501 **3 June 2005**

LABOUR RELATIONS ACT, 1995

CORRECTION NOTICE

METAL AND ENGINEERING INDUSTRIES BARGAINING COUNCIL: RE-ENACTMENT, AMENDMENT AND EXTENSION OF COLLECTIVE BARGAINING LEVY COLLECTIVE AGREEMENT TO NON-PARTIES

The following printing correction to Government Notice No. R. 355 appearing in **Government Gazette** No. 27464 of 15 April 2005, is hereby published for general information:

Please insert the date of "24 November 2004" in the last sentence on top of the signatures to read as follows: "Thus singed at Johannesburg, for and on behalf of the parties, this 24 November 2004".

DEPARTMENT OF MINERALS AND ENERGY
DEPARTEMENT VAN MINERALE EN ENERGIE

No. R. 520 **3 June 2005**

MINES AND WORKS ACT, 1956 (ACT No. 27 OF 1956)

DECLARATIONS OF WORK IN NATIONAL INTEREST

Under section 9 (1) (f) of the Mines and Works Act, 1956 (Act No. 27 of 1956), I, Phumzile Mlambo-Ngcuka, Minister of Minerals and Energy, hereby declare that, in my opinion the conducting of normal mining operations on Sundays at G & W Base and Industrial Minerals (Pty) Ltd: Koppies Bentonite Mines and Plant situated in the Magisterial District of Koppies in the Free State Province, is necessary in the National Interest for a period of one year from 7 August 2005.

P. MLAMBO-NGCUKA
Minister: Minerals and Energy

No. R. 500 **3 June 2005**

MINES AND WORKS ACT, 1956 (ACT No. 27 OF 1956)

DECLARATIONS OF WORK IN NATIONAL INTEREST

Under section 9 (1) (f) of the Mines and Works Act, 1956 (Act No. 27 of 1956), I, Phumzile Mlambo-Ngcuka, Minister of Minerals and Energy, hereby declare that, in my opinion the conducting of normal mining operations on Sundays at Masimong 4 and 5 Shafts, situated in the Magisterial District of Hennenman in the Free State Province, is necessary in the National Interest for a period of seven weeks ending 26 June 2005.

P. MLAMBO-NGCUKA
Minister: Minerals and Energy

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
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