GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT

NO. R. 541 **18 June 2021**

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

REGULATIONS RELATING TO THE DRAFT AGRICULTURAL REMEDY

I, Thoko Didiza, Minister of Agriculture, Land Reform and Rural Development acting under section 23 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947 (Act no.36 of 1947) hereby publish a notice to invite public comments on draft agricultural remedy.

Comments must be submitted in writing within 60 days of publication of this notice to:

Name:	Jonathan Mudzunga
Designation:	Registrar: Act 36 Of 1947
Postal Address:	Private Bag X 343, PRETORIA, 0001
Physical Address:	20 Steve Biko Street, Arcadia, PRETORIA
	Agriculture Place, Room LA-GF-09
Fax:	(012) 319 7179
Email:	MalutaM@dalrrd.gov.za

MRS A.T. DIDIZA, MP
MINISTER FOR AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT

DEPARTMENT OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT

No. R.

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

REGULATIONS REGARDING AGRICULTURAL REMEDY

I, Angela Thokozile Didiza, acting under section 23 of the Fertilizer, Farm Feeds, Agricultural remedy and Stock Remedy Act, 1947 (Act No. 36 of 1947), intend to make the regulations in the Annexure hereto.

A.T. Didiza
Minister of Agriculture, Land Reform and Rural Development.

INDEX

PART 1

SCHEDULE

Definitions

1. Words and phrases in these regulations shall have the meaning assigned hereto and any other word or expression in the Act, and unless the context otherwise indicates -

"active ingredient (technical grade/living organisms)" means any part of the product that provides the mode of action of the agricultural remedy;

''APVMA" Australian Pesticides and Veterinary Medicine Authority;

"administrative minor change" means applications that involve changes in registration holder details; changes in product brand names, artwork changes, addition of any warning or voluntary restrictions on the label; removal of claims on the label; GHS related changes; adding or changing of distributor and registration details and inclusion of foreign languages, changes in packaging specifications not impacting the type of material and pack size;

"applicant" means the person who is a resident in South Africa in whose name an application for the registration of an agricultural remedy has been filed;

"bonded warehouse" means a customs and excise warehouse licensed in terms of section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964);

"CAS registry number" means Chemical Abstract Service Number;

"co-formulant" means a non-active component of a formulated product;

"colour band" means a band printed at the bottom part of the label of a colour indicating the GHS acute toxicity hazard of the pesticide product;

"container" means any object used to hold an agricultural remedy product;

"date of manufacture" means the date on which the agricultural remedy is packed into the packaging defined in the registration application;

"**declaration"** means a sworn statement (affidavit) by an individual representing him or herself, or such person acting as designated authority of a legal person (company);

"emergency registration" means a registration for an agricultural remedy that is granted in special circumstances due to an immediate demand that arises for such a product to be registered due to unforeseen invasion or emergence of any pest, disease or weed for which no agricultural remedy are registered;

"expiry date" means the date up to which an agricultural remedy has been shown to retain the strength and other properties stated on the label and after which the agricultural remedy shall not be sold or used unless extended by the Registrar on the presentation of evidence that the chemical and physical parameters and/or biological viability of the product remain within the registered specification;

"EU" means European Union;

"FAO" means Food and Agricultural Organization of the United Nations;

"formulation" means the combination of various ingredients designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application;

"FRAC" means Fungicide Resistance Action Committee;

"GAP (Good Agricultural Practice)" means collection of principles to apply for on-farm production and post-production processes, resulting in sale and healthy food and no-food agriculture products, while taking account economic, social and environmental sustainability;

"**Globally Harmonized System"** means the Globally Harmonized System of classification and labelling of chemicals, a guidance document developed by the United Nations for standardising and harmonising the classification and labelling of chemicals globally, as may be updated from time to time, commonly known as the United Nations Purple Book;

"GEP (Good Experimental Practice)" means a practice in accordance with the provisions of European and Mediterranean Plant Protection Organisation (EPPO) Guidelines 181 and 152;

"hazard" means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property);

"hazard statement" means a statement assigned to a hazard class and category that describes the nature of the hazards of a pesticide, including, where appropriate, the degree of hazard.

"highly hazardous agricultural remedy" means a agricultural remedy that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as WHO or GHS or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous. Highly Hazardous agricultural remedy should be defined as having one or more of the following characteristics:

- **Criterion 1**: agricultural remedy formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard or;
- **Criterion 2**: Agricultural Remedy active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or;
- **Criterion 3**: Agricultural Remedy active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A and 1B of the GHS or;
- **Criterion 4**: Agricultural Remedy active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A and 1B GHS or;
- **Criterion 5**: Agricultural Remedy active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention or;
- **Criterion 6**: Agricultural Remedy active ingredients and formulations listed by the Rotterdam Convention in its Annex III or;
- **Criterion 7**: Agricultural Remedy listed under the Montreal Protocol or;

- **Criterion 8**: Pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.

"HRAC" means Herbicide Resistance Action Committee;

"IPM (Integrated Pest Management)" means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keeps agricultural remedy and other interventions to levels that are economically justified and reduce or minimise risks to human and animal health and/or the environment. Integrated Pest Management (IPM) emphasizes the growth of healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms;

"IVM (Integrated Vector Management)" means the rational decision-making process for the optimal use of the sources for disease vector control. It aims to improve efficacy, cost-effectiveness, ecological soundness, sustainability for the control of vector-borne diseases;

"IRAC" means Insecticide Resistance Action Committee;

"label" means any written, printed or graphic representation attached to or included in a container of an agricultural remedy;

"letter of access and supply" means original document by which the owner of data agrees to the use of such data under the specific terms and conditions imposed by the Registrar for purpose of granting a registration of agricultural remedy for the benefit of another applicant and undertakes to supply that applicant with the active ingredient should the registration be granted;

''Minor use'' means use of chemical pesticides or-non chemical means of crop protection where the potential use is on a scale not sufficiently large to justify registration of that use from applicant's perspective alone;

"OECD" means Organization for Economic Cooperation and Development;

"OECD GLP" means the OECD Principles of Good Laboratory Practice;

"person" means a natural person or juristic person (company);

"pesticide" means an agricultural remedy as defined in Section I of the Fertilizers, Farm Feeds, Agricultural remedy and Stock Remedies Act, 1947 (Act No. 36 of 1947) that is used for the suppression and/or control of any type of disease or pest that are harmful to plants or animals;

"pictogram" means a graphical composition that may include a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information;

"precautionary statement" means a phrase (and/or pictogram) that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a pesticide, or improper storage or handling of a pesticide;

"product (or **agricultural remedy product** or **pesticide product**)" means the formulated product (agricultural remedy active ingredient(s) and co- formulants), in the form in which it is packaged and sold;

"registration" means the process whereby the Registrar approves the sale and use of an agricultural remedy following the evaluation of scientific data aimed at demonstrating that the

product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment;

"registration holder" means the person or legal entity to whom a certificate of registration in respect of a particular agricultural remedy has been issued;

'"relevant impurity" means those by-products of the manufacture or storage of an agricultural remedy which, compared with the active ingredient, are toxicologically significant to health or the environment, are phytotoxic to treated plants, cause taint in food crops, affect the stability of the pesticide, or cause any other adverse effect;

"risk" is the probability and severity of an adverse health or environmental effect occurring as a function of a hazard and the likelihood and the extent of exposure to an agricultural remedy;

"SACNASP" means South African Council for Natural Scientific Professions established in terms of the Natural Scientific Professions Act, 2003 (Act No.27 of 2003, as amended);

"signal word" means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label;

"standards" means those specifications established by the FAO/WHO, WHOPES, APVMA, EU, and USEPA to determe equivalence for active ingredients;

"substances of concern" means any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect. Such substances have one or more of the following characteristics:

- **Criterion 1**: agricultural remedy active ingredients and their formulations that meet the criteria of carcinogenicity Category 1A of the GHS; or
- **Criterion 2:** agricultural remedy active ingredients and their formulations that meet the criteria of mutagenicity Category 1A of the GHS; or
- **Criterion 3**: agricultural remedy active ingredients and their formulations that meet the criteria of reproductive toxicity Category 1A of the GHS; or
- **Criterion 4**: agricultural remedy active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention except for dichlorodiphenyltrichloroethane (DDT) used for malaria vector control by the Department of Health;

"suitably qualified person" means a person registered with SACNASP

"sworn translator" means a person admitted and enrolled by any division of the Supreme Court (High Court) in terms of Rule 59 of the Rules of Superior Court Practice;

"symbol" means graphical element intended to succinctly convey information;

"toxicity" means a physiological or biological property which determines the capacity of a chemical to do harm or produce injury to a living organism by other than mechanical means;

"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;

"USEPA" means United States Environmental Protection Agency
"WHO" means World Health Organization;

"WHOPES" means World Health Organization Evaluation Scheme.

"withholding period" means minimum permissible time allowed between the last application of an agricultural remedy and harvesting of an edible commodity for human consumption or grazing by livestock.

PART I

PRODUCT CLASSES

Designation

2. (1) The following are the classes of agricultural remedy:

(a) **"household"**, if the agricultural remedy is to be distributed primarily to the public for personal use in or around their homes;

(b) **"commercial"**, if the agricultural remedy is to be distributed for use in commercial activities that are specified on the label;

(c) **"restricted"**, if the agricultural remedy is one for which the Registrar, out of concern for its health or environmental risks, has set out additional information to be shown on the label concerning essential conditions respecting the display, distribution or limitations on use of, or qualifications of persons who may use the product. These will amongst others include highly hazardous agricultural remedy.

PART II

REGISTRATION

Application for registration

3. (1) An application in terms of section 3(1) of the Act, for the registration of an agricultural remedy or the amendment of an existing agricultural remedy registration shall be submitted to the Registrar in duplicate using the appropriate form obtainable from the Registrar's office.

(2) An application may only be made by a person who is a resident in the Republic, or, in the case of a juristic person, who has a registered office in the Republic.

(3) Toxicological, residues and five batch studies for purpose of supporting application for registration of agricultural remedy based on chemical active ingredients shall be generated in accordance with OECD GLP, where applicable..

(4) Residue, efficacy and phytotoxicity trials shall be carried out by a suitably qualified person and in accordance with GEP.

Information with the application

4. (1) An application shall be accompanied by –

(a) applicant's name, business address, e-mail address, telephone number and signature or if the application is made by a representative on behalf of the applicant, both the representative's and the applicant's name and address business address, e-mail address, telephone number and the representatives' signature;

(b) where relevant, all necessary scientific information as indicated on the application form;

(c) the prescribed applicable fee;

(d) letter of access and supply, where relevant;

(e) two printed copies of a typed label, in English. If any other language is used such label shall be submitted in duplicate with an affidavit from the sworn translator declaring the label to be a true translation of the English label, where relevant;

(f) in the case where an applicant intends to introduce genetically modified organisms and living modified organisms as the active ingredient shall provide to the Registrar proof of compliance with any other existing laws governing such organisms;

(g) in the case where an applicant intends to introduce biological products with living organisms, whether microbial or macrobial, the applicant shall provide to the Registrar proof of compliance with any other existing laws governing such organisms.

(h) where relevant, in addition to information required by regulation 4, all scientific documentation required to demonstrate the safety, quality and efficacy of the product in respect of any of the following as set out in the guidelines issued by the Registrar Office:

(i) chemical name, common chemical name and CAS registry number of the active ingredient(s), its percentage of the total weight of the product in which it is contained, the name of each impurity that it contains, the percentage of total weight of each impurity; and the name and address of the manufacturer(s);
(ii) in case of an agricultural remedy that contains one or more co-formulants, the name of each co-formulant, its CAS registry number, the concentration expressed in gram per kilogram of the total weight of the product and the purpose of each co-formulants in the product;
(iii) other physical and chemical properties of the agricultural remedy and its active ingredient, or the species or strain and biological properties;
(iv) the size, type and packaging material of the container in which the agricultural remedy is to be distributed;
(v) validated methods of analysis for determining the active ingredient, metabolites, impurities and contaminants;
(vi) five batch analysis studies;
(vii) toxicological, metabolism and exposure data of the active ingredient and formulated agricultural remedy;;

(viii) ecotoxicological data on wildlife, aquatic organisms and non-target organisms of the active ingredient;
(ix) the environmental fate of the agricultural remedy, including data relating to the degree of persistence, retention, movement, bio-accumulation and metabolic breakdown of its active ingredient(s) in the environment;
(x) chemistry of the residue of the agricultural remedy and its active ingredient on the crop or feed and the methods of extraction, detection and analysis of such residue;
(xi) proposed Maximum Residue Limit(s) and withholding periods;
(xii) efficacy and phytotoxicity data;
(xiii) data on the effect on bees and other pollinators;
(xiv) detailed and critical expert report(s) for each study that has been signed by a suitably qualified person;
(xv) in the case where the agricultural remedy has been registered or approved (however described) for use in any foreign country -
(a) the name of the foreign country;
(b) proof of such registration or approval in the form of a registration certificate or approval certificate;
(c) the limitations, if any, imposed in the foreign country on the use of the agricultural remedy;
and if refused, reasons for such decision.

(xvi) any other information as may be required by the Registrar.

(2) The applicant shall sign, under oath, the declaration, included in the application form, that the information is authentic, accurate and complete to the best of their knowledge.

Samples to be given for analysis

5. The applicant may be requested by the Registrar, at his own cost, to provide samples for the purposes of verifying the information provided, as requred in regulation 3 and 8 or where necessary, in manner as directed to provide a sample of –

(1) a formulated agricultural remedy;

(2) technical grade of its active ingredient; or samples of micro-biological or macro-biological organisms; and

(3) laboratory standard(s) of the active ingredient(s) and any associated impurities in the case of chemical agricultural remedy or taxonomic reference samples of micro-biological or macro-biological organisms and associated organism that may be present as impurities.

Registration certificate

6. (1) Upon receipt of an application, duly made under section 3 of the Act, the Registrar, if satisfied that-
(a) all criteria for the safety, efficacy, quality and label of an agricultural remedy have been met;
(b) all the matters contained in and submitted with the application are complete and true in all material particulars;
(c) any risk associated with the agricultural remedy is manageable;
(d) the agricultural remedy complies with the established standards for the active ingredient and formulation;
(e) the agricultural remedy does not contain substances of concern;

(f) the agricultural remedy is effective for the purpose claimed, when used according to the label direction;
(g) the establishment where the agricultural remedy is manufactured is suitable; and
(h) the agricultural remedy complies with the Act and this regulation;
shall register the agricultural remedy and issue a certificate in term of Section 3(3) of the Act. The certificate for an agricultural remedy shall bear the product class, the trade name, the active ingredient(s), the registration number, the manufacturing sites, the period of validity and any conditions placed on the registration of that agricultural remedy.

(2) Notwithstanding the provisions of sub-regulations (3) and (4), the Registrar may accept an application for the emergency registration or minor use wherein –
(a) the Registrar may waive certain data requirements; and
(b) impose certain conditions upon such registration or minor

(3) An applicant may, with the permission of the registration holder, use data that had been submitted in support of an existing registered agricultural remedy to support of their registration application. The Registrar may approve the registration application on the same conditions as those imposed on the existing registration, assign a registration number thereto, and issue a registration certificate to the applicant.

(4) If the holder of a registered product notifies the Registrar of an administrative minor change, the Registrar may grant approval for such change without considering any information, provided the application is accompanied by a declaration confirming no other changes in the registration details.

Refusal to Register

7. The Registrar may refuse to register an agricultural remedy, if, in the opinion of the Registrar -

(a) the application does not comply with the provision of the Act and/or these Regulation;

(b) the information provided to the Registrar by the applicant is insufficient to enable the application to be assessed or evaluated;

(c) the product is not sufficiently effective for the purpose claimed when used according to the label direction;

(d) the establishment where the agricultural remedy is to be manufactured is not suitable;

(e) contains active ingredient(s) and/or co-formulant(s) regarded as substance(s) of concern;

(f) the product does not comply with the established standards for the active ingredient;

(g) the use of the agricultural remedy according to the label instructions will be detrimental to human, animal, plants and/or the environment.

PART III

PERIOD OF VALIDITY AND RENEWAL

Application for renewal

8. (1) A certificate of registration issued under section 3 of the Act, unless cancelled in terms of section 4 of the Act, shall be valid for a period of three years from the date of issue and may thereafter be renewed in terms of section 3(4) of the Act for an additional periods of three years.

(2) The registration holder shall apply for the renewal of registration of the agricultural remedy at least three months (90 days) before the expiry date;

(3) An application referred in sub-regulation 8(2) shall be accompanied by—

(i) prescribed renewal fee;

(ii) a certified copy of the registration certificate required by sub-regulation 6(1);

(iii) signed and dated letter of access and supply from the manufacturing source of the active ingredient(s) issued not earlier than 12 months prior to the submission of the renewal application;

(iv) In the case of a registration certificate that was issued in the circumstances described in sub-regulation 6(2), where relevant, a copy of the valid letter of access and supply from the manufacturing source of the active ingredient(s) issued within six months of renewal submission;

(v) a declaration confirming that the details furnished 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 whatsoever from the congruent details which have already been registered or approved in relation to that agricultural remedy or label.

(4) Notwithstanding sub-regulation 8(3), the Registrar may accept an application for the re-instatement of a registration if such application is submitted within 30 days after the expiry date of the registration certificate.

Request for labels

9. The Registration holder shall, if requested by the Registrar, provide the Registrar with an electronic copy of the approved label and printed or electronic copies of the commercial label.

Approval to renew an application

10. (1) If the Registrar is satisfied that an application for the renewal of a registration meets the application requirements, the Registrar shall renew the registration and issue the registration certificate and set out the conditions of renewal.

(2) In the event that the new registration certificate cannot be issued before the expiry date of the previous registration certificate, the Registrar shall, on request, provide the registration holder with a letter acknowledging receipt of a valid registration renewal application and confirming the extended validity of the current registration for a period of 90 calendar days.

Refusal of an application for renewal

11. The Registrar may refuse the renewal application if —

(a) all conditions as determined by the Registrar are not met;

(b) the agricultural remedy contains active ingredient(s) and/or co-formulant(s) or biological organisms regarded as a substance(s) of concern; or

(c) the application or product does not comply with these regulations.

Return of registration certificate

12. (1) The registration certificate issued in terms of section 3(3) of the Act, shall be returned in terms of section 4A(3) of the Act by the registration holder to the Registrar—

(a) within fourteen days of the date on which:

(i) a person to whom the certificate of registration in question had been issued, was notified in terms of section 5 of the Act in writing of the reasons for the cancellation of such registration; or
(ii) registration of the agricultural remedy concerned has lapsed in terms of section 4A (2) of the Act,

(b) at least 30 days prior to the date on which the registration of an agricultural remedy, is to be transferred to another person or

(c) on cancellation or withdrawal of the registration by the registration holder.

(2) If the original certificate of registration is lost, an affidavit shall be submitted to the Registrar's office confirming that the registration certificate is lost within fourteen day of the discovery of its loss.

PART IV

LABELLING AND CONTAINER

Approval by the Registrar

13. (1) No agricultural remedy shall be distributed or sold without the orginal label.

(2) No labels, including package leaflets, shall be used in connection with an agricultural remedy unless it has been approved by the Registrar.

(3) In the case of the notification of minor administrative amendments in terms of sub-regulation 6(3) which results in changes to the label, the registration holder shall submit with that notification a suitably revised version of the of the approved label. If the notification of such amendment is approved by the Registrar, as provided for in terms of sub-regulation 6(3), the Registrar shall provide the registration holder with formal approval of the revised label.

Languages

14. All labels and package leaflets shall be in English but may contain other languages provided that the information given is identical in all the languages.

Label presentation

15. (1) All information on the label that is required to be shown on a label shall appear in a manner that is clearly legible and indelible.

(2) Any written, printed or graphic matter on the label of an agricultural remedy shall not detract from or obscure the required information.

(3) The label of a registered agricultural remedy shall consist of a main panel and a number of secondary panels.

(4) The label layout shall be in terms of the guideline issued by the Registrar's office.

Main display panel

16. The main panel of agricultural remedy shall show the following information:
- (a) product name of the agricultural remedy, which may include distinctive brand or trademark and the common name of its active ingredient;
- (b) registration number of the agricultural remedy concerned together with a reference to the Act expressed as "Reg. No ...Act No. 36 of 1947', which shall appear below the trademark or trade name;
- (c) the product type of the agricultural remedy, which shall be descriptive of its general purpose;
- (d) the product class category as set out in regulation 2;
- (e) GHS hazard colour band indicating the acute toxicity of the formulated product—
  - (i) Red for GHS category 1 and 2, consisting of expression 'DANGER' and appropriate pictogram;
  - (ii) Yellow for GHS category 3, consisting of expression 'DANGER' and appropriate pictogram;
  - (iii) Blue for GHS category 4 and 5, consisting of expression 'WARNING' and appropriate pictogram;
  - (iv) Green for GHS category unclassified;

  at the bottom of the panel;
- (f) the instruction to the user to read the label which statement shall be in capital letters in the following form—"READ THE LABEL BEFORE USE" at the top of the panel;
- (h) the statement, as follows:
  - (i) the word "ACTIVE INGREDIENT:" or ACTIVE INGREDIENTS:" as the case may be;
  - (ii) the common chemical name of the active ingredient(s) as is accepted by ISO or locally used or, in the absence of either, the chemical designation according to IUPAC;
  - (iii) If the active ingredient is a micro biological organism or macro biological organism, it is best identified by genus and species (and if appropriate, also by subspecies and/or isolate/strain number);
  - (iv) active ingredient content expressed as "contains X g a.i./kg" (for solids, mosquito coils, viscous liquids, aerosols or volatile liquids) or "contains X g a.i. /litre" at 20 degrees Celsius (for other liquids) or "contains X g a.i./mat" (for vaporising mats);
  - (v) If the active ingredient is a micro-biological organism (microbial agent) or macro-biological organism, content may be expressed as International Toxic Units (ITU) per mg product or as the number of viable units (spores, cells, colony forming units (cfu), etc.) per unit mass or volume of product and microbials insects unit per container at 20 degrees Celsius;
- (j) the registration holder's name and, where applicable company registration number, expressed as "Registration Holder: ..... (Company Registration Number)" above the GHS hazard colour band;
- (k) appropriate indication as to where information on the date of manufacture, batch number, and, for products with a shelf-life of less than 2 years from the release date, the expiry date;
- (l) a purple square in the top right-hand corner in the case of herbicides.

Sub-regulations 16(1)(c), 16(1)(k) from first draft of the regulations have been deleted since they are believed to provide no value to the user.

Sub-regulations 16(1)(g), 16(1)(i), 16(1)(m), 16(1)(o), 16(1)(p), 16(1)(q), 16(1)(r) from first draft of the regulations have been moved to the side panels.

Secondary display panels

17. The secondary panels of the registered agricultural remedy shall show all the following information:

(a) the instruction to the user on storage shall be in capital letters in the following form—" KEEP OUT OF REACH OF CHILDREN AND ANIMALS" at the top of the panel;

(b) under the heading "WARNING", any information that identifies any significant risk associated with the handling, storage, display, distribution, use and disposal of the agricultural remedy not required in terms of sub-regulation (c), and instructions on procedures to reduce those risks;

(c) under the heading "PRECAUTIONS", any information that identifies any significant risk to human health, environment health or anything in connection with the agricultural remedy is to be used, and instructions on procedures to reduce those risks;

(c) under the heading "SAFETY INFORMATION", the applicable GHS pictogram(s), signal word, hazard statement(s) and precautionary statement(s), the phrase "In case of poisoning, call the following number" followed by contact details of a national or provincial poison information centre and the phrase "Emergency number" followed by the number of the registration holder's own disaster management centre of its contracted disaster management service provider.

The name/identity and concentration of any inert (or perhaps excipient?) ingredients classified as hazardous in terms of GHS in the formulation that contribute to the GHS classification of the formulated product shall be listed in this section together with their GHS classifications.

The accuracy of the GHS classification on the label of an agricultural remedy shall be the responsibility of the applicant. Should there be any reason to question the GHS classification of the agricultural remedy, the Registrar shall require a review of the classification by a qualified expert at the cost of the applicant. In the event that such a classification is found to be incorrect, the Registrar shall require the correction of the label and, if the Registrar deems it appropriate, the withdrawal of product with the incorrect label.

(d) under the heading "FIRST AID", instructions that:

(i) set out the practical measures to be taken in the event of poisoning or injury caused by the agricultural remedy;
(ii) include the statement "Provide medical personnel with the container label, product name or safety data sheet (SDS) when seeking medical attention;

(e) where applicable, under the heading "TOXICOLOGICAL INFORMATION", any information that is essential to the treatment of persons who are

poisoned or injured by the agricultural remedy that includes all the following:

(i) antidotes and remedial measures or if no specific antidote or remedial measures exists, the statement "Treat symptomatically";
(ii) a description of the symptoms of poisoning;
(iii) list of the components of the product, excluding the active ingredient(s), that may affect the treatment.

(f) under the heading "DIRECTIONS FOR USE", and where applicable resistance warning statement and symbols as per the mode of actions described in IRAC, FRAC and HRAC, IPM/IVM advice, 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 indicated under those headings.

(g) include NOTICE TO THE USER: "This agricultural remedy is to be used only in accordance with the instructions on the label. It is an offence under the Act to use this product in a manner contrary with the directions on the label".

(h) where applicable, reference to the relevant and applicable phrases of the latest edition of the SA National Standard for the aerial application of pesticides SANS 10118 if the agricultural remedy is registered for aerial application.

(i) where applicable, the statement 'READ ATTACHED PACKAGE LEAFLEFT BEFORE USING';

(j) where applicable, the UN number in accordance with the National Road Traffic Act, 1996 (Act No. 93 of 1996) and the latest editions of SA National Standards, SANS 10228;

(k) the registration holder's name, physical address and telephone number;

(p) distributor name or marketing partner, where relevant;

(q)) a declaration of quantity of the product contained in the package in accordance with Legal Metrology Act, 2014 (Act No. 9 of 2014), the nett volume or mass, as the case may be.

Restricted class notice

18. If the main panel reflects the product class designation "RESTRICTED", the notice that is required by sub-regulation 2(1)(c) shall appear prominently at the top of the secondary display panel, followed by the heading "RESTRICTED USES", followed by the directions for use, the application rates, the timing and frequency of application and the limitations on the use of the agricultural remedy to which the restriction relates. All the foregoing shall be separated circumscribed by a line to set the information apart from all other information that is required to be shown on the secondary display panel.

Small packs

19. Where the information required by regulation 16 and 17 cannot fit on the package, the container may be labelled with details referred to in sub-regulations the information referred to

in sub-regulations 16 (1)(a), (b), (c), (d), (e), (f) ,(g), (h),(j), (k) (l), (m); (n); (o), (p) and (q) and regulation 17 (1)(a), (b), (e) and (f), while the rest shall be presented in a brochure/leaflet attached to the package of the agricultural remedy product.

Outer Packaging

20. A casing in which an agricultural remedy is packed for transport shall, in addition to any labelling or markings required in terms of the National Road Traffic Act, 1996 (Act No. 93 of 1996), be labelled with the applicable details as required by sub-regulations, 16(a), (b), (j), (l) and (m).

Units of measurements

21. All units of measure shown on every label shall be expressed in accordance to the Legal Metrology Act, 2014 (Act No. 9 of 2014).

Container

22. (1) Every container for an agricultural remedy shall be approved by the Registrar.

(2) Every container for agricultural remedy shall be—

(a) sufficiently durable, be designed and manufactured to contain the agricultural remedy safely under normal conditions of storage, display and distribution and conform to the standards as described in the latest edition of the SA National Standard for the Transport of dangerous goods – Packaging and large packaging for road and rail transport. Part 1: Packaging SANS 10229-1, where applicable.

(b) closed or sealed in the manner that permit the content of an agricultural remedy to be safe to the user;

(c) constructed to minimize the degradation or change of its contents resulting from any interactions; and

(d) designed and manufactured to minimise spillage when pouring out the contents of a liquid agricultural remedy.

PART V

IMPORTATION OF AN AGRICULTURAL REMEDY INTO THE REPUBLIC

General

23 (1) No person shall import an agricultural remedy into South Africa unless that person is in possession of registration certificate or import permit issued under these Regulations.

(2) No person shall import any agricultural remedy into South Africa for commercial and manufacturing purpose unless such agricultural remedy is registered, packed and labelled according to these regulations excepting when the agricultural remedy is intended only for export to a destination where it is registered.

(3) Analytical standards of agricultural remedy are exempted from the import permit requirements, provided that such standards shall not exceed 5 g or 5 ml in mass or volume.

Application for import permit

24. An application for permit referred in sub-regulation 23(1) shall contain at least the following:

(a) applicable fees;

(b) trade name of the product if available or code name of the product if applicable of the product;

(c) common chemical or other name of the active ingredient of the agricultural remedy and the amount of it contained in the product or in the case of a micro-biological or macro-biological organism, the scientific name and concentration or number of units contained in such remedy;

(d) details of the manufacturer of the active ingredient;

(e) the total amount of the agricultural remedy product being imported;

(f) name and address (postal and physical) of the applicant;

(g) designation of the person representing the applicant;

(h) contact details (telephone and email address);

(i) where relevant, registration number of the agricultural remedy in the country of destination;

(j) batch number, where applicable;

(k) expiry date of the agricultural remedy;

(l) purpose of the importation; i.e. research; export to other countries

(m) in case of import for manufacturing, copy of proof of approval by the relevant authority that such agricultural remedy can be manufactured in South Africa;

(n) details of the bonded warehouse, if intended for subsequent export;

(o) copy of foreign registration document if imported for re-export; and

(p) copy of the research plan approved by a suitably qualified person, where applicable.

Decision on the permit application

25. (1) The Registrar may approve an application made under sub-regulation 23(1) if the Registrar is satisfied that—

(a) the application contains all the information as required sub-regulation 24(1);

(b) the agricultural remedy does not contains active ingredient(s) and/or co-formulant(s) regarded as a substance(s) of concern or products banned in the Republic;

(c) the application or product complies with regulations 23 and 24;

(2) Otherwise the Registrar may refuse the application.

Harbours and places through which imports may be made

26. (1) No person shall import any agricultural remedy in terms of section 16 of the Act, into the Republic, unless the Registrar directs otherwise except through one of the following ports of entry:

(a) Cape Town International Airport or Cape Town harbour;

(b) Port Elizabeth International Airport or Port Elizabeth harbour or COEGA harbour

(c) King Shaka International Airport or Durban harbour;

(d) Richards Bay harbour;

(e) O.R. Tambo International Airport.

(2) Agricultural remedy imported for export shall be stored in a bonded warehouse while in the Republic, unless it is transmitted through the Republic, during which it shall be contained in a bonded containers.

PART VI

MANUFACTURING ESTABLISHMENTS

Requirements for establishments

27. (1) An establishment within the borders of South Africa where an agricultural remedy is manufactured, controlled, packed or labelled for the purpose of sale shall conform to the following requirements:

(a) current licence in terms of the Hazardous Substances Act, 1973 (Act No. 15 of 1973), if applicable;

(b) have in place a system of Quality Assurance and Quality Control.

(d) conform to Factories, Machinery and Building Work Act, 1941 (Act No. 22 of 1941) and the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), the National Environmental Management: Waste Act (Act 59 of 2008) and the relevant municipal by-laws and other building requirements.

(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.

Practice to be followed at the establishment

28. (1) The Registration holder shall ensure that—

(a) the agricultural remedy is manufactured in accordance with the processes and in facilities that were approved for registration;

(b) each production batch is fully tested, including a full qualitative analysis, a quantitative analysis of all active ingredient(s) and all the tests or controls necessary to ensure the quality of an agricultural remedy product is in accordance with the data filed and accepted by the Registrar in support of the application for registration of the agricultural remedy;

(c) representative samples of each production batch are kept under controlled storage conditions for the approved period of the shelf life;

(d) comprehensive records of the source of the active ingredient(s), details of the raw material(s) used and results of quality controls tests conducted are kept and shall—

(i) be maintained for five years from the time it is made; and

(ii) be made available to the Registrar at such times and in such manner as the Registrar may require.

PART VII

ADVERTISING OF AN AGRICULTURAL REMEDY

General

29 (1) An agricultural remedy designated as household or commercial may be advertised to the public.

(2) An agricultural remedy designated as restricted for use by registered Pest Control Operators shall not be publicly advertised other than through media platforms catering for such registered Pest Control Operators, and an agricultural remedy that is designated as restricted for acquisition and use only by state departments for control of agricultural pests declared in the Agricultural Pests Act, 1983 (Act No. 36 of 1983), or human and animal disease vectors, may not be advertised.

(3) No advertisement for an agricultural remedy may contain a statement, which deviates from, conflicts with or goes beyond the scope of the approved label or data filed in support of the application for registration of the agricultural remedy being advertised that has been accepted by the Registrar.

(4) No person shall advertise any agricultural remedy product that has not been duly registered.

(5) No advertisement for an agricultural remedy may contain pictures of children under 16 years.

(6) No person shall publish or distribute any false or misleading advertisement relating to an agricultural remedy

(7) An advertisement shall be deemed false or misleading if it contains one or more of the following or any graphic representation which is likely to be deceiving or misleading:

(a) a statement concerning the effectiveness of the product as an agricultural remedy, unless this can be substantiated by data that has been approved by the Registrar;

(b) comparison with other agricultural remedy;

(c) statement likely to create misunderstanding about the effectiveness and safety of the product;

(d) unwarranted claims as to the safety of the agricultural remedy or its ingredients, including such statements as "Safe", "Non-poisonous", "Non-toxic", "Non-injurious", "Contains no chemicals", "Chemical free" or "Harmless" with or without such qualifying phrase as "When used as directed";

(e) any statement directly or indirectly implying that a specific brand of an agricultural remedy is recommended or endorsed by Government or any entity thereof.

Details of advertisements

30. (An advertisement for an agricultural remedy referred in regulation 29 shall contain —

(a) registered name of the agricultural remedy;

(b) applicable GHS hazard signal and statement;
(c) name and amount(s) of the active ingredient(s) which it contains;
(d) registration number of the agricultural remedy in question together with a reference to the Act as "Reg. No. Act 36/1947"; and
(e) name, contact details and address of the registration holder.

PART VII

SALE OF AGRICULTURAL REMEDY

General

31. (1) Any person in control of an establishment selling, supplying or making available agricultural remedy shall comply with the requirements in terms of the Hazardous Substances Act, 1973 (Act No. 15 of 1973), where applicable.

(2) Notwithstanding the provisions of the Hazardous Substances Act, 1973 (Act No. 15 of 1973), an agricultural remedy shall be distributed only in accordance with any condition of registration

(3) A person shall not supply a restricted agricultural remedy, or allow or permit a restricted agricultural remedy to be supplied, to a person who is not authorised to use the product under these regulations.

(4) No person may promote, advertise, recommend or sell an agricultural remedy for any purpose or for any manner of application other than those stated on the label of such agricultural remedy.

(5) No GHS acute toxicity category 1 and 2 agricultural remedy excepting rodenticides may be sold in containers smaller than 1 kilogram in mass or 1 litre in volume or as specified by the Registrar.

PART VIII

DISPOSAL OF AGRICULTURAL REMEDY

General

32. (1) No person shall dispose of any agricultural remedy or their containers in a manner that may be detrimental to humans health or the environmental health.

(2) An agricultural remedy or its container shall only be disposed of by a waste treatment facility authorised to destroy waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008) and the relevant waste management regulations.

(3) No agricultural remedy product shall be disposed of into municipal sewerage systems, open water bodies or buried underground.

PART VIII

RETURNS TO BE FURNISHED

Agricultural remedy Sales Information Reporting

33. (1) For the purpose of interpreting these Regulations, a quantity of agricultural remedy sold by the registration holder includes any quantity that the registration holder provides to a distributor for sale on the registration holder's behalf.

(2) The registration holder of an agricultural remedy shall submit a sales volume information report annually and include all the following information:

(a) the registration holder's name, postal address and telephone number;
(b) the date of the report;

(c) the calendar year covered by the report;

(d) the name and registration number of the agricultural remedy; and

(e) the quantity of agricultural remedy sold in the Republic, expressed in the unit of measurement identified in the declaration of net quantity in accordance to the Legal Metrology Act, 2014 (Act No. 9 of 2014).

(3) A report referred in sub-regulation (2) is for a period of one calendar year and shall be submitted on or before 31st of May the year following the calendar year covered by the report.

(4) The person who makes a report referred to sub-regulation 33(2) shall attach to it a signed declaration certifying that the information in the report is true and complete to the best of their knowledge and belief and is provided in good faith.

Records

34. The registration holder shall keep all original records and supporting data that relate to the sales information included in a report under sub-regulation 33(2) for five years after the day on which the report is submitted to the Registrar, and shall provide the records and data to the Registrar on request for verification and auditing purposes.

Audited sale records

35. If the Registrar believes on reasonable grounds, on the basis of any information available to the Registrar that the sales information submitted in respect of an agricultural remedy is inaccurate or incomplete, the Registrar shall require the registration holder to submit the sales information for that product in a report prepared by an independent auditor.

PART IX

SAMPLING AND PERMISSIBLE DEVIATIONS

Sampling of agricultural remedy

36. (1) An agricultural remedy that is sold in containers shall be sampled in the presence of the owner or a person duly authorized by selecting at different places from stock of the

particular agricultural remedy the number of containers required to obtain a significant quantity for a sample of such agricultural remedy, subject to the following conditions:
(a) Such containers shall be similarly labelled, and the agricultural remedy therein shall originate from the same batch;
(b) Where a sample is composed of the contents of more than one container, such a sample shall be thoroughly mixed before being divided;
(c) Notwithstanding the provisions sub-regulation 36(1)(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)(c) of the Act.

(2) An agricultural remedy, which is not in an approved container, shall be sampled by taking small quantities at different places from the bulk stock of such agricultural 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. Samples shall be stored at the correct temperature and in containers similar to containers that have been approved by the Registrar for the agricultural remedy, in accordance with registered storage conditions, until delivered to the analyst.

(3) The provisions of sub-regulation 36(2) shall mutatis mutandis apply to the sampling of an agricultural remedy referred to in sub-regulation 36(1) prior to the packing thereof in containers, and the sampling of an active ingredient used in the manufacture of an agricultural remedy.

(4) Where an agricultural 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 labelled and purporting to contain a similar agricultural 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(3) of the Act.

(5) A sample shall be forwarded to an analyst together with a certificate (Annexure 2) referred in terms of section 15(4)(b) of the Act within 14 days of sampling.

(6) A certificate on which the result of a test, examination or analysis of a sample of an agricultural remedy shall be recorded as set out in Annexure 2.

(7) That part of a sample of an agricultural remedy shall--

(a) if a certificate referred to in sub-regulation 36(5) indicates that such sample does not possess the chemical, physical or other properties specified in the application for registration of the agricultural 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; or

(b) otherwise be disposed of according the conditions contemplated in the National Environmental Management: Waste Act, 2008 (Act no. 59 of 2008) and applicable regulations.

Cost of examination or analysis

37. The state may, in the case of any investigation of a registration holder's conduct, result in a summons to appear in a court law, apply to the presiding magistrate or judge for a cost

order against the registration holder for the examination and analysis if such registration holder is found guilty.

Permissible deviations in active ingredient contents

38. Notwithstanding anything to the contrary of requirements contained in these regulations, a formulated chemical agricultural remedy shall not be deemed to deviate in its registered active ingredient contents if a certificate referred to in regulation 36(5) in relation to the analysis of a sample of such agricultural remedy indicates that it nominally contains:

Declared content in g/kg or g/L at 20°C ± 2°C	**Tolerance**
Up to 25	±15% of the declared content for —homogeneous formulations (EC, SC, SL, etc.), **or** ±25% for —heterogeneous formulations (GR, WG, etc.)
Above 25 to 100	±10% of the declared content
Above 100 to 250	±6% of the declared content
Above 250 to 500	±5% of the declared content
Above 500	±25g/kg or g/L
Note. In each range the upper limit is included.	

PART X

APPEAL AGAINST THE DECISION OF THE REGISTRAR

General

39 (1) An appeal in terms of section 6 of the Act shall be submitted to the Minister 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;

(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 prescribed in the regulation.

(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.

Address for submission of appeals

40. (1) An appeal referred to in regulation 39(1) shall:
(a) when forwarded by post, be addressed to the Director-General, Department of Agriculture, Land Reform and Rural Development, Private Bag X250, Pretoria, 0001; and
(b) when delivered by hand, be delivered to the Director-General, Department of Agriculture, Land Affairs, Rural and Development, Agriculture Building, 20 Steve Biko Road, Agriculture Place, Arcadia, Pretoria.

PART XI

GENERAL

Offences and penalties

41. 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 as contemplated in Section 18 of the Act.

Payment of fees

42. (1) The postage and delivery costs of any application or document submitted in terms of these regulations shall be paid by the sender.

(2) Fees payable in terms of these regulations shall be paid by cash or electronic payment.

(3) Monies paid in terms of these regulations, except in terms of Section 6 of the Act, are not refundable.

Address for submission of documents

43. (1) Any application or document or anything else pertaining thereto, which is required in terms of these regulations to be submitted to the Registrar shall:

(2) When forwarded by post, be addressed to: The Registrar: Act No. 36 of 1947, Private Bag X 343, Pretoria, 0001; and / or

(3) When forwarded by rail or delivered by hand, be addressed or delivered to: The Registrar: Act No. 36 of 1947, Agriculture Building, 20 Steve Biko Street, Pretoria.

Amendment and repeal of certain regulations

44. The following regulations are hereby repealed:
(a) Government Gazette R. 935 of 22 September 2006

(b) Government Gazette R.1449 of 1 July 1983.

Coming into force

45 (1) These Regulations shall come into force for new agricultural remedy registration applications six months after the date of publication of this regulation However, new

registration applications submitted prior to that date in terms of these Regulations shall be accepted.

(2) Notwithstanding regulation 45(1), these Regulations shall come into force for existing registered agricultural remedy only at the date of renewal of those registrations.

(3) Notwithstanding regulation 44(1), any agricultural remedy manufactured prior the date on which these regulations come into force shall be deemed to be compliant with these regulations.

27

PART XII

ANNEXURE 1

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

TEL NO.....

DATE ..... INITIALS AND SURNAME .....

.....
SIGNATURE OF THE DEPONENT

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

.....
JUSTICE OF PEACE/ COMMISSIONER OF OATHS

Full first name and surname:.....
(BLOCK LETTERS

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

Business address:.....
(street address shall be stated)

Date:.....

Place.....

Notes

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

28

ANNEXURE 2

Analyst address

.....

CERTIFICATE OF RESULTS OF ANALYSES OR TEST OF A SAMPLE OF AGRICULTURAL REMEDY BY ANALYST

Fertilizer, Farm Feeds, Agricultural remedy and Stock remedy Act, 1947 (Act No. 36 of 1947)

(To be completed in duplicate)

I (full name) _____

of _____

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

(a) *that on* _____ *I received a sample of* [a] _____

from _____ *by* _____ [b] *for analyses and/or test;*

(b) *that the sample was labelled, sealed and marked* [c] _____

_____

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

Pure active ingredient [d]

	g/kg
(a) _____	_____ | _____
(b) _____	_____ | _____
(c) _____	_____ | _____

Other ingredients (if required)

(a) _____	_____ | _____
(b) _____	_____ | _____
(c) _____	_____ | _____

Remarks _____

_____

_____

Signature of analyst

_____

ANNEXURE B