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DEPARTMENT OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT

NO. 5399 11 October 2024

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

AMENDED REGULATIONS RELATING TO AGRICULTURAL REMEDIES

I, John Steenhuisen, the Minister for Agriculture acting under section 23 of the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), intends to make the regulations in the Schedule.

Interested persons are invited to send written comments on the proposed regulations within 30 days from the date of publication of this notice, to the following address:

Registrar: Act No. 36 of 1947
Department of Agriculture, Land Reform and Rural Development
Private Bag X343, Pretoria, 0001
20 Steve Biko Road, Agriculture Place, Arcadia, Pretoria
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text

MR JH STEENHUISEN, MP
MINISTER FOR AGRICULTURE

SCHEDULE

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SCHEDULE

1. Definitions

"active ingredient" means any part of the agricultural remedy that provides the mode of action of the agricultural remedy;

"advertising" means the promotion of the sale and use of an agricultural remedy by printed and electronic media, signs, displays, gifts, demonstrations or word of mouth;

"APVMA" means the Australian Pesticides and Veterinary Medicines Authority;

"administrative minor change" means applications that involve changes in the registration holder's details; adding or changing emergency numbers, changes in agricultural remedy brand names, artwork changes, addition of any warning or voluntary restrictions on the label; removal of claims on the label; adding or changing resistance codes, adding or changing of distributor and inclusion of foreign languages, changes in packaging specifications not impacting the type of material and pack size, or any other change that the Registrar may define as an administrative minor change.

"adverse reaction" means an unintended or unexpected effect on animals, people or the environment;

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

"approved label" means a label that meets the conditions of registration and authorised by the Registrar;

"banned agricultural remedy" means an agricultural remedy of which all uses have been prohibited by final regulatory action, in order to protect human health or the environment;

"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 Abstracts Service Number;

"certificate of registration" means a certificate issued by the Registrar under regulation 8;

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

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

"date of manufacture" means the date on which the remedy was formulated from its individual components;

"daughter registration" means a registration based on details of an agricultural remedy registered by another registration holder with the authorization of the principal registration holder, where the registration has its own registration number, but no changes may be made to the dossier without authorization from the principal registration holder, and the remedy may only be sourced from the principal registration holder;

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

"disposal" means any operation to recycle, neutralize, destroy or isolate agricultural remedy waste, used containers and contaminated materials;

"emergency registration" means a registration of an agricultural remedy that is granted under special circumstances for limited and controlled use, where such a registration is necessary because of urgency or a danger that cannot be contained by any other reasonable means;

"environment" means the surroundings within which humans exist and that are made up of—

(a) water, lithosphere and atmosphere of the earth;

(b) all Kingdoms of living organisms, including micro-organisms, macro-organisms, plant and animal life;

(c) any part or combination of (a) and (b) and the interrelationships among and between them; and

(d) the physical, chemical, aesthetic and cultural properties and conditions of the foregoing that influence human health and well-being;

"expiry date" in the context of the agricultural remedy formulation 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 the shelf life has been extended by the Registrar on presentation of evidence that the chemical and physical parameters and/or biological viability of the product remain within the registered specification;

"expiry date" in the context of the registration certificate of the agricultural remedy is the date on which the approval of the registration of the remedy in the Republic lapses;

"EU" means the European Union;

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

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

"FRAC" means the Fungicide Resistance Action Committee;

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

"Globally Harmonized System" or "GHS" 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 UN Purple Book;

"GHS hazard classification" means the GHS hazard classes and hazard categories assigned to an agricultural remedy;

"guideline" means a document that outline the registration process and requirements for the registration of an agricultural remedy;

"hazard" means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences;

"hazard category" means a division of criteria within a GHS hazard class based on hazard severity;

"hazard class" means the nature of a physical, health or environmental hazard under the GHS;

"hazard pictogram" means a graphical representation, including a symbol plus other graphical elements such as a border, background pattern or colour that is intended to convey specific information, that is assigned in the GHS to a hazard class and category;

"hazard statement" means a statement assigned in the GHS to a hazard class and hazard category describing the nature of the hazards of an agricultural remedy including, if appropriate, the degree of hazard;

"hazardous waste" means any waste that contains organic or inorganic elements or compounds that may, owing to the inherent physical, chemical or toxicological characteristics of that waste, have a detrimental impact on human health or the environment;

"household agricultural remedy" means an agricultural remedy, which is packed or repacked primarily in a manner and quantity for use by a household consumer or for use in an office;

"HRAC" means the Herbicide Resistance Action Committee;

"Integrated Pest Management (IPM)" means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep agricultural remedies and other interventions to levels that are economically justified and reduce or minimise risks to human and animal health and/or the environment;

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

"IRAC" means the Insecticide Resistance Action Committee;

"ISO" means the International Standards Organization;

"IUPAC" means the International Union of Pure and Applied Chemistry which is an international federation of National Adhering Organizations that represents chemists;

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

"low-risk agricultural remedy" means a substance that has been evaluated as having a low risk. Such substances meet the criteria as set out in Annexure A;

"minor use" means the use for which the demand originates with a grower or a group of growers for an agricultural remedy that is intended to be used on a particular pest in connection with a particular host organism, in all of the following circumstances:

(a) the use is for an agricultural purpose;

(b) government supports the use; and

(c) where relevant, the use is supported by crop residue data and efficacy data as directed by the Registrar;

"OECD" means the Organization for Economic Cooperation and Development;

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

"packaging" means the container together with the protective wrapping used to carry an agricultural remedy via wholesale or retail distribution channels to users;

"parallel registration" means a registration based on the details of a registered agricultural remedy by the same registration holder or registration holders within the same holding entity, where the registration has its own registration number, but no changes may be made to the dossier without authorization from the principal registration holder, and the remedy may only be sourced from the principal registration holder;

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

"pictogram" means a graphical representation 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 prescribed by the GHS that describes recommended measures that should be taken to minimise or prevent the—

(a) adverse effects resulting from exposure to an agricultural remedy; or

(b) improper storage or handling of an agricultural remedy;

"product" means the formulated 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 manufacturing, packaging, sale and use of an agricultural remedy following an evaluation of scientific data aimed at demonstrating that the agricultural remedy is effective for its intended purpose and does not pose an unacceptable risk to human or animal health or the environment;

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

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

"restricted agricultural remedy" means an agricultural remedy for which the Registrar, out of concern for its human health or environmental risks, has set out additional information to be shown on the label concerning essential conditions in respect of the display, distribution or limitations on use of, or qualifications of persons who may use the agricultural remedy, and such remedy shall comply with the criteria as set out in annexure A;

"recycle" means separation of waste from a waste stream for further use and processing of that separated material;

"SACNASP" means South African Council for Natural Scientific Professions Act, 2003 (Act No.27 of 2003);

"Shelf life" means the period of time for which the supplier guarantees the viability of the remedy for at least 2 years unless stated otherwise, under actual conditions of storage in the area where the technical grade active ingredient or formulation is to be marketed;

"signal word" means the word "danger" or "warning" used on a GHS-aligned label to indicate to the reader a potential hazard, as well as the relative severity level of such hazard;

"small pack" means a pack that is not large enough for all the information required by Regulations 18 and 19 to be presented in legible print;

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

"substances" means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

"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 an agricultural remedy in sufficient concentration to present risks of such an effect. Such substances shall comply with the criteria as set out in Annexure A;

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

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

"toxicity" means a physiological or biological property that 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.

"UN IMO International Maritime Dangerous Goods Code" means the International Maritime Organization's (IMO's) International Maritime Dangerous Goods (IMDG) Code, which was developed as an international code by the IMO, an agency of the United Nations, for the maritime transport of dangerous goods in packaged and bulk form, with particular reference to the segregation of incompatible substances, as may be updated from time to time;

"UN number" means the four-digit identification number assigned to an agricultural remedy in the UN Transport of Dangerous Goods.

"UN proper shipping name" means the proper shipping name of an agricultural remedy as specified in the UN Transport of Dangerous Goods: Model Regulations, most accurately describing the goods, as may be updated from time to time;

"WHO" means World Health Organization;

"withholding period" means the minimum permissible time allowed between the last application of an agricultural remedy and harvesting or consumption of an edible commodity by humans or animals. Also commonly referred to as the pre-harvest interval.

PART I

APPLICATION FOR REGISTRATION

Application for registration

2. (1) An application in terms of section 3(1) of the Act to register an agricultural remedy or amend the registration, shall be submitted to the Registrar on Annexure B form.

(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.

Information to accompany the application

3. 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 names and business addresses, e-mail addresses, telephone numbers and signatures;

(b) the name and physical address of the place of manufacture of the agricultural remedy;

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

(d) proof of payment of the prescribed application fee;

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

(f) GHS-compliant safety data sheet and information presented in accordance with sub-regulation 14A(3) of the Regulations for Hazardous Chemical Agents, 2021, as published in Government Notice No. R. 280 of 29 March 2021;

(g) copies of the typed GHS label in accordance with the latest edition of the UN Purple Book and the Regulations for Harzadous Chemicals Agents, 2021 promulgated in terms of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993);

(h) where relevant, all scientific documentation required to demonstrate the safety, quality and efficacy of the agricultural remedy in respect of any of the following as set out in the guidelines issued by the Registrar's Office:

(i) chemical name, common chemical name and CAS registry number of the active ingredient(s), its quantity in proportion to the total mass or volume of the agricultural remedy in which it is contained, the name and concentration of each impurity that it contains; name and physical address of the supplier(s);

(ii) in the case of an agricultural remedy that contains one or more co-formulants, the name of each formulant, its CAS registry number, expressed in gram per litre or gram per kilogram of the total volume or mass of the agricultural remedy, or any other applicable unit of measurement, and purpose of each co-formulant in the agricultural remedy;

(iii) other physical and chemical properties of the agricultural remedy and its active ingredient(s), or the species or strain and biological properties;

(iv) the size, type and design parameters of the container in which the agricultural remedy is to be distributed;

(v) validated methods of analysis for determining the active ingredient(s), metabolites and impurities;

(vi) results of five batch analysis studies, generated in accordance with OECD GLP as per the OECD guidance documents for pesticide registration (http://www.oecd.org/chemicalsafety/agriculturalpesticidesandbiocides/oecdguidancedocumentsforpesticideregistration.htm);

(vii) toxicological, metabolism and exposure data of the active ingredient and agricultural remedy generated in accordance with OECD GLP;

(viii) exposure assessment for children;

(ix) ecotoxicological data of the active ingredient on wildlife, aquatic organisms and non-target organisms, generated in accordance with OECD GLP;

(x) 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 generated in accordance with OECD GLP;

(xi) data on the chemistry of the residue of the agricultural remedy and its active ingredient on the crop or feed and the methods of the field phase (application,

sampling) and laboratory phase (extraction, detection and analysis) of such residue, generated in accordance with OECD GLP;

(xii) proposed Maximum Residue Limit(s) and withholding periods in accordance with the Foodstuffs, Cosmetics and Disinfectants Act (FCDA), 1972 (Act No. 54 of 1972) and the Regulations governing the maximum limits for pesticide residues that may be present in foodstuff as amended, 2024, as published in Government Notice No. R. 4388 of 16 February 2024;

(xiii) efficacy and phytotoxicity data, which in the case of local trials need to be generated under the supervision of a person registered as a professional scientist with SACNASP;

(xiv) data on the effect on bees and other pollinators, which in the case of local trials need to be generated under the supervision of a person registered as a professional scientist with SACNASP;

(xv) assessment report(s) for each study, signed by a person registered as a professional scientist with SACNASP;

(xvi) efficacy and phytotoxicity data must be generated according to GEP;

(xvii) in the case of aerial application, a risk assessment report to demonstrate clear advantages in terms of reduced impacts on human health and the environment in comparison with other spraying methods, or an explanation as to why aerial application is essential in a specific scenario;

(xviii) where applicable, proof of compliance with the waste management measures in accordance with the Extended Producer Responsibility Scheme for the Pesticide Sector regulation, 2023, as published in Government Notice No. R. 3177 of 23 March 2023;

(xix) In cases where the agricultural remedy has been registered or refused approval 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;

(d) if refused, reasons for such decision; and

(e) if banned, reasons for such decision.

(xx) checklist demonstrating that the dossier provided is complete; and

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

(i) The applicant shall sign the declaration that the agricultural remedy does or does not contain active ingredient(s) and/or co-formulant(s) or biological organisms regarded as a substance of concern, and no new scientific evidence is available, to the best of the applicant's knowledge, on the agricultural remedy's potential health effects for vulnerable groups, especially children. However, in the case where such data is available, this should be stated in the declaration and the relevant data must be included in the application.

(j) The applicant shall sign the declaration that all the information provided is authentic, accurate and complete.

Samples on request

4. On application to register an agricultural remedy or amend the registration, the applicant must, if requested by the Registrar, provide the Registrar with a sample of—

(a) the agricultural remedy;

(b) the technical grade of its active ingredient; and

(c) the laboratory standard of its active ingredient.

Minor use registration

5. The Registrar may, within a period of six months, expedite the review of any application for minor use in respect of an agricultural remedy registration.

Low-risk agricultural remedy

6. The Registrar may, within a period of six months, expedite the review of any application for registration of a low-risk agricultural remedy.

Prioritisation of suitable alternative products

7. The Registrar shall prioritize the review and registration of suitable alternative solutions for substances of concern.

Approval of registration

8. (1) The Registrar must grant the registration if satisfied with the following:

(a) all the information contained and submitted with the application is complete and true in all material particulars;

(b) the agricultural remedy will perform its intended function, and when used in accordance with widespread and commonly recognized practice, the agricultural remedy will not cause unreasonable adverse effects on the environment and human health;

(c) active ingredient complies with the specifications;

(d) the agricultural remedy does not contain a substance of concern or active ingredient banned in the Republic of South Africa;

(e) the agricultural remedy is effective for the purpose claimed when used according to the label instructions, and its labelling and packaging comply with the applicable requirements of this regulation;

(f) If the proposed labelling bears directions for use on food crops, or if the intended use of the agricultural remedy results, or may reasonably be expected to result, directly or indirectly, in agricultural remedy residues (including residues of any active or inert ingredient(s) of the agricultural remedy, or any metabolite or degradation product thereof) in or on food, that such residues are in accordance with the Foodstuffs, Cosmetics and Disinfectants Act (FCDA), 1972 (Act No. 54 of 1972) and the Regulations governing the maximum limits for pesticide residues that may be present in foodstuff as amended, 2024, as published in Government Notice No. R. 4388 of 16 February 2024; and

(g) the agricultural remedy complies with the requirements of the Act and these regulations, the Registrar shall register the agricultural remedy and issue a certificate in terms of Section 3(3) of the Act.

(2) The certificate of registration shall contain the following information relating to the agricultural remedy:

(a) details of the registration holder;

(b) trade name

(c) active ingredient(s);

(d) registration number;

(e) period of validity of registration; and

(f) any conditions of registration the Registrar may have determined.

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

(b) The Registrar may approve a parallel application that uses data submitted in support of an existing registered agricultural remedy for the initial registration of the remedy, with the permission of the holder of that registration, assign a registration number thereto, and issue a registration certificate to the applicant.

(4) If the holder of an agricultural remedy registration notifies the Registrar of an administrative minor change and provides a declaration confirming that no other changes in the registration details have been made, the Registrar shall advise the registration holder that approval for such change has been granted.

(5) In exceptional circumstances, where there is no other viable agricultural remedy registered for the intended use, the Registrar may grant an emergency registration for emergency use for a period not exceeding 24 months.

(6) Notwithstanding subregulations (1)(d) and (5), in exceptional circumstances, the Registrar may grant registration or renewal of an agricultural remedy classified as a substance of concern when the following conditions are met:

(a) the risk to humans, animals or the environment from exposure to the agricultural remedy, under realistic worst-case conditions of use, is negligible or,

(b) there is evidence that the agricultural remedy is essential to prevent or control a serious danger to human health, animal health or the environment; or

(c) not approving the agricultural remedy would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

(7) With reference to subregulation (6), approval or renewal of an agricultural remedy may be granted for a specific period, and for restricted uses following the publication of the risk assessment report for public comment by the applicant.

Refusal to register

9. The Registrar may refuse to register an agricultural remedy if the agricultural remedy does not meet the requirements for registration as contemplated in regulation 8.

PART II

PERIOD OF VALIDITY AND RENEWAL

Period of validity and application for renewal

10. (1) A certificate of registration issued under section 3 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 period of three years.

(2) The registration holder shall apply for the renewal of registration of the agricultural remedy from two months (60 days) before the period of validity of the registration lapses;

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

(a) proof of payment of the prescribed renewal fee;

(b) a copy of the current registration certificate;

(c) in the case of a registration certificate that was issued in the circumstances described in regulation 8(3), where relevant, a copy of daughter/parallel contract(s) signed and dated within six months of the submission of the renewal application;

(d) information required by regulation 34(4);

(e) a declaration that the agricultural remedy does or does not contain active ingredient(s) and/or co-formulant(s) or biological organisms regarded as a substance of concern;

(f) a declaration that no new scientific evidence is available, to the best of the applicant's knowledge, on the agricultural remedy's potential health effects for vulnerable groups, especially children;

(g) where relevant, signed and dated letter from the manufacturing source of the active ingredient(s) issued within six months of renewal submission;

(h) 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;

(i) where relevant, proof of compliance with the Extended Producer Responsibility Scheme for the Pesticide Sector regulation, 2023, as published in Government Notice No. R. 3177 of 23 March 2023;

(j) where relevant, records of compliance with regulations 37 and 38.

(4) Notwithstanding sub-regulation (2), the Registrar may upon payment of the prescribed late penalty fees accept an application for late renewal if it is submitted within 30 days after the period of validity of the registration has lapsed.

Request for labels

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

Approval to renew a registration

12. (1) If the Registrar is satisfied that an application for the renewal of a registration meets the application requirements under regulation 10(3), the Registrar shall renew the registration and issue the registration certificate subject to conditions of renewal.

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

Refusal of an application for renewal

13. The Registrar may refuse to renew an agricultural remedy, if—

(a) the agricultural remedy does not meet the requirements under regulation 10(3)

(b) conditions of registration imposed on the registration certificate are not met

Return of registration certificate

14. (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 writing of the reasons for the cancellation of such registration; or

(ii) registration of the agricultural remedy concerned has lapsed,

(b) within 14 days of approval of the transfer of a registration of an agricultural remedy to another person or

(c) on cancellation 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 within fourteen days of its loss.

PART III

LABELLING AND CONTAINER

General

15. (1) The classification and labelling of the agricultural remedy shall be in accordance with the GHS and the Regulations for Hazardous Chemical Agents, 2021, as published in Government Notice No. R. 280 of 29 March 2021.

(2) No agricultural remedy shall be distributed or sold without a label or package leaflet approved by the Registrar.

Languages

16. All labels and package leaflets shall be in English but may contain other languages provided that the information given is identical to the approved label.

Label presentation

17. (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 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/leaflets.

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

(5) All labels shall be accompanied by additional information defining what the hazard statement, GHS pictograms and signal words on the label mean, as well as safety behaviours required to reduce exposure and/or risk. This information can be in the form of a removable leaflet for containers or part of QR codes (Quick Response Codes) and is additional to the minimum requirements for labels included under regulations 18, 19 and 21, as applicable.

Main display panel

18. (1) The main panel of agricultural remedy shall show the following information:

(a) product name of the agricultural remedy, which may include a distinctive brand or trademark and the common name of its active ingredient;

(b) agricultural remedy type, which shall be descriptive of its general purpose;

(c) formulation type of the agricultural remedy;

(d) instruction to the user to read the label, which shall be in capital letters in the following form—"READ THE LABEL BEFORE USE" or "READ ATTACHED PACKAGE LEAFLET BEFORE USE", as relevant;

(e) instruction to the user on storage which shall be in capital letters—KEEP OUT OF REACH OF CHILDREN AND ANIMALS;

(f) the statement, as follows:

(i) the words "ACTIVE INGREDIENT:" or ACTIVE INGREDIENTS:" as the case may be;

(ii) the common chemical name of the active ingredient(s) expressed (according to ISO) or other locally used common name, or, in the absence of either, the chemical designation according to IUPAC;

(iii) if the active ingredient is a microbiological organism or macrobiological organism, it must be identified by genus and species (and if appropriate, also by subspecies and/or isolate/strain number);

(iv) active ingredient content expressed as X g a.i. per kg (for solids including mosquito coils, viscous liquids, aerosols or volatile liquids) or X g a.i. per l (for other liquids), or any other applicable units of measure in accordance

with regulation 23. For vaporising mats, contents are expressed as mg/mat;

(v) if the active ingredient is a microbiological or macrobiological organism, content must 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, or macrobial units per container at 20 degrees Celsius;

(g) a declaration of the net quantity of the agricultural remedy in the container in accordance with the Legal Metrology Act, 2014 (Act No. 9 of 2014);

(h) 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 or above the trademark or trade name;

(i) where applicable, the registration holder's name; company registration number, physical contact details and telephone number;

(j) information on the date of manufacture, batch number, shelf-life or expiry date, as stipulated in the relevant guidelines.

(k) where applicable, the UN number in accordance with the National Road Traffic Act, 1996 (Act No. 93 of 1996).

(l) the applicable GHS pictograms, signal word(s), hazard statement(s), and a minimum of two precautionary statement(s), giving precedence to the most important/severe hazards.

(m) the phrase "In case of poisoning, call the following number" with the contact details of a national or provincial poison information centre and the phrase "Emergency number" with the number of the registration holder's own disaster management centre or its contracted disaster management service provider.

(n) where relevant, the mode of action group code according to the guidelines provided by HRAC, FRAC and IRAC.

(o) If a remedy is deemed "restricted", it will contain the phrase "RESTRICTED USE AGRICULTURAL REMEDY" at the top of the main display panel of the label along with the appropriate restriction statement. This text will be in an appropriate font size compared to the remainder of the text on the label to ensure it is clearly legible and unlikely to be overlooked, the text will be red and contained in a block to enhance visibility.

(p) The heading "DIRECTIONS FOR USE" will be replaced with the heading "RESTRICTED USES".

Secondary display panels

19. (1) The secondary panels of the registered agricultural remedy shall show all the following information:

(a) safety information should include the following: hazard statement(s), precautionary statement(s), a list of the chemical identities of all co-formulants contributing to the final GHS classification of the agricultural remedy, and information on the pre-harvest interval/withholding period.

(b) under the heading "RESISTANCE WARNING STATEMENT" and where applicable, resistance statements, warnings and mode of action group codes as described by HRAC, FRAC or IRAC.

(c) under the heading "DIRECTIONS FOR USE", IPM/IVM advice, waiting periods for follow-up crops, compatibility statements, mixing instructions, and the actual uses of the agricultural remedy. Any restrictions on use should be included under the heading "USE RESTRICTIONS".

(d) include "NOTICE TO THE USER: This agricultural remedy is to be used only in accordance with the instructions on the label. It is an offense under Act No. 36 of 1947 to use this agricultural remedy for any purpose or in any manner contrary to the directions on the label";

(e) reference to the relevant and applicable phrases of the SA National Standard for the aerial application of pesticides SANS 10118 if the agricultural remedy is registered for aerial application;

Small pack

21. Where the information required by regulations 18 and 19 cannot fit on the container, the container may be labelled to include the information referred to in regulation 18 sub-paragraphs (a), (b), (c), (d), (f), (g), (h), (i), (k), (l), (m) and (n), and regulation 19 sub-paragraphs (a), (b) (c) and (d) while the rest shall be presented in a brochure/leaflet QR code attached to the container of the agricultural remedy.

Outer packaging

22. 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 b y regulation 18 sub-paragraphs (a) and (k).

Units of measurements

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

Container

24. (1) The size and type of every container for an agricultural remedy shall be approved by the Registrar.

(2) An agricultural remedy container must satisfy the relevant requirements of the UN Transport of Dangerous Goods with respect to packaging and fastenings, or, where applicable, the UN IMO International Maritime Dangerous Goods Code, including the following requirements —

(a) is in good condition and legibly labelled;

(b) it is sufficiently durable, designed and manufactured to contain the agricultural remedy safely under normal conditions of storage, display and distribution;

(c) the container shall not resemble any container that commonly contains food or beverages and cannot mistakenly be identified as containing food or beverages;

(d) it must be closed or sealed in a manner that permits the safe handling of the agricultural remedy and prevents accidental exposure of the user;

(e) the container is made of a material that is compatible with the agricultural remedy and will not be adversely affected by the agricultural remedy;

(f) it is constructed to minimize the degradation or change of its contents resulting from any interactions;

(g) it is designed and manufactured to prevent spillage when pouring out the contents in case of a liquid agricultural remedy.

PART IV

IMPORTATION OF AN AGRICULTURAL REMEDY INTO THE REPUBLIC

General

25. (1) No person shall import an agricultural remedy into South Africa unless that person is in possession of a valid registration certificate or a letter as specified in regulation 12(2), issued under these Regulations.

(2) No person shall import any agricultural remedy into South Africa unless the agricultural remedy is registered, packed and labelled according to these regulations.

(3) Notwithstanding what is set out under sub-regulations (1) and (2), the Registrar may, in writing, permit the importation of any consignment of agricultural remedy which does not comply with the requirements referred to in sub-regulations (1) and (2).

Application for an import permit

26. An application for the importation of an agricultural remedy shall contain at least the following:

(a) proof of payment of the applicable fees;

(b) name of the agricultural remedy;

(c) common chemical name, biological name, scientific name, or other name (as relevant) of the active ingredient of the agricultural remedy and the amount contained in the agricultural remedy;

(d) details of the manufacturer of the active ingredient or formulated product, as relevant;

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

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

(g) designation of the person representing the applicant;

(h) contact details of the applicant (telephone and email address);

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

(j) where relevant, batch number;

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

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

(m) details of the bonded warehouse, in case it is for export;

(n) copy of foreign registration or authorisation document in case of import for export;

(o) copy of the research plan approved by a suitably qualified person, where applicable; and

(p) where relevant, proof of compliance issued in terms of other applicable South African legislation(s) and regulations governing such agricultural remedy.

Decision on the permit application

27. (1) The Registrar may approve an import permit application made under regulation 26 if the Registrar is satisfied that—

(a) the agricultural remedy does not contain active ingredient(s) and/or co-formulant(s) regarded as a substance of concern or the agricultural remedy is not banned in the Republic; unless if it is for export or a derogation has been granted by the Registrar in accordance with regulation 8(6); and

(b) import is for experimentation, laboratory analysis, relabelling or some other purpose other than for sale.

(c) import permit application meets the requirements under regulation 26.

Port of entry

28. (1) Unless the Registrar directs otherwise, no person shall import any agricultural remedy in terms of section 16 of the Act into the Republic of South Africa 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; and

(e) O.R. Tambo International Airport.

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

PART V

MANUFACTURING ESTABLISHMENTS

Requirements for establishments

29. (1) An establishment where an agricultural remedy is manufactured, controlled, stored, packed or labelled shall have measures to contain fire or spillage to the environment, well-maintained sprinkler systems, run-off containment on the boundaries of the site in the event of flooding or fire, and other appropriate fire management measures.

(2) The premises of such establishment shall be kept orderly and clean.

(3) The area at such establishment which is used for the performance of 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

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

(a) there is compliance with the Regulations for Hazardous Chemical Agents, 2021, as published in Government Notice No. R. 280 of 29 March 2021;

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

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

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

(e) comprehensive records lists and quantities of the agricultural remedy under production or storage as well as the source(s) indicating 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 be —

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

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

PART VI

ADVERTISING OF AN AGRICULTURAL REMEDY

General

31. (1) A registered agricultural remedy may be advertised to the public.

(2) No advertisement for an agricultural remedy may contain a statement, that deviates from, conflicts with, or goes beyond the scope of the approved label or data filed in support of the application for its registration.

(3) No person shall advertise any agricultural remedy that is not registered under the Act.

(4) No advertisement for an agricultural remedy may contain pictures of children.

(5) An advertisement shall not contain any visual representation of potentially dangerous practices such as mixing or application without sufficient protective clothing, use near food, or use by or in the vicinity of children.

(6) An advertisement shall draw attention to the appropriate precautionary statements and hazard pictograms. The Warnings on Television must be at least a font size 10 and shown for 10 seconds.

(7) An advertisement shall not guarantee or imply guarantees, such as "more profits with" or "guarantees high yields" unless definite evidence to substantiate such claims is available.

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

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

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

(b) comparison with another agricultural remedy;

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

(d) statements such as "non-toxic", "non-harmful", "non-polluting" or "non-hazardous" or similar statements indicating the agricultural remedy as not hazardous, or other statements that are inconsistent with the agricultural remedy's GHS classification on its label or packaging;

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

Details of advertisements

32. (1) An advertisement for an agricultural remedy referred to in regulation 31 shall contain—

(a) the registered name of the agricultural remedy;

(b) where relevant, the restriction category;

(c) the applicable GHS signal word and hazard statement;

(d) the name and amount(s) of the active ingredient(s) which it contains;

(e) the registration number of the agricultural remedy with a reference to the Act as "Reg. No. ... Act No. 36 of 1947";

(f) the statement to encourage the user to read the label; and

(g) the name, contact details and address of the registration holder.

PART VII

SALE OF AGRICULTURAL REMEDY

General

33. (1) No person may distribute or sell a registered agricultural remedy with a composition, container or labelling not approved by the Registrar.

(2) An agricultural remedy shall be distributed or sold in accordance with the conditions of registration.

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

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

(5) No person shall sell an agricultural remedy for any purpose or any manner of application other than those stated by the label of such agricultural remedy.

(6) Any person who sells an agricultural remedy, including through internet sales, shall provide safety instructions, training and awareness to the distributors, advisors and users of pesticides on safety instructions for human health and the environment.

PART VIII

DISPOSAL OF CONTAINERS AND AGRICULTURAL REMEDY

General

34. (1) No person shall dispose of agricultural remedies and their empty containers or parts in such a manner as to endanger humans and their environment.

(2) Where applicable, all containers must be recycled as a waste management measure as outlined in the Extended Producer Responsibility Scheme for the Pesticide Sector regulation, 2023, as published in Government Notice No. R. 3177 of 23 March 2023.

(3) An agricultural remedy shall be disposed of in terms of the National Environmental Management Waste Act (Act 59 of 2008).

(4) Comprehensive records shall be kept of empty containers and agricultural remedies disposed of as per sub-regulations 34(2) and 34(3) including results of quality control tests conducted, and shall be—

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

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

PART IX

RECORDS AND RETURNS TO BE FURNISHED

Agricultural remedy sales information reporting

35. (1) For the purpose of interpreting these Regulations, a quantity of agricultural remedy sold by the registration holder also 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 to the Registrar a sales information report annually and include all the following information:

(a) registration holder's name, postal address and telephone number;

(b) date of the report;

(c) calendar year covered by the report;

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

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

(3) A report referred to in sub-regulation 35(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 in a form and manner directed by the Registrar.

(4) The registration holder shall keep all original records and supporting data that relate to the sales information included in a report under sub-regulation 35(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

36. If the Registrar reasonably believes, 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, at the cost of the registration holder, require the registration holder to submit the sales information for that agricultural remedy in a report prepared by an independent auditor.

Reporting on potentially harmful or unacceptable effects

37. The holder of a registration of an agricultural remedy shall immediately notify the Registrar in a form and manner directed by the Registrar of any new information concerning that active ingredient(s) or co-formulant(s) contained in that agricultural remedy, which suggests that the agricultural remedy no longer complies with the criteria as set out in regulations 8(1) sub-paragraphs (c),(d), and (f).

Reporting on adverse reactions

38. If during the registration process or at any time after the registration of an agricultural remedy, the registration holder has factual or scientific evidence of any adverse effect or risk of the agricultural remedy to human health or the environment, the registration holder shall immediately submit such evidence to the Registrar in writing.

Access to information

39 The Registrar shall maintain a quarterly updated list of registered agricultural remedies.

PART X

SAMPLING AND PERMISSIBLE DEVIATIONS

Sampling of agricultural remedy

40. (1) An agricultural remedy that is sold in containers shall be sampled in the presence of the registration holder or representative by selecting at different places from stock of the number of containers required to obtain a significant quantity for a sample, subject to the following conditions:

(a) such containers shall be similarly labelled, and the agricultural remedy therein shall originate from the same batch;

(b) 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;

(c) 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) 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) A sample shall be forwarded to an analyst together with a certificate referred to in terms of section 15(4)(b) of the Act as set out in Annexure C.

(4) 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 D.

(5) A copy of the certificate of the designated analyst's analytical report as set out in regulation 40(4) shall be provided to the registration holder for each sample that was taken.

(6) A sample of an agricultural remedy may—

(a) if a certificate referred to in regulation 40(4) indicates that such sample does not possess the chemical, physical or other properties specified in the application for registration, or does not comply with any requirements referred to in these regulations, it shall be retained until the action arising from such certificate is concluded; or

(b) otherwise be disposed of according to the conditions contemplated in the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008) and applicable regulations at the cost of the registration holder.

Permissible deviations in active ingredient contents

41. (1) Notwithstanding anything to the contrary 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 40(4) 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	±2.5% of the declared content
Note: In each range, the upper limit is included.	

PART XI

APPEAL AGAINST THE DECISION OF THE REGISTRAR

General

42. (1) An appeal in terms of section 6 of the Act shall be submitted to the Minister within 60 days from the date on which the reasons for the decision were made, and shall be 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 proof of payment of the prescribed fee.

(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 their interest in that decision or action.

Address for submission of appeals

43. An appeal referred to in regulation 42(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 Reform and Rural Development, Agriculture Building, 20 Steve Biko Road, Agriculture Place, Arcadia, Pretoria.

PART XII

General

Offences and penalties

44. Any person who contravenes 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

45. (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

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

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

Repeal of certain regulations

47. The following regulations are hereby repealed:

(a) Regulations relating to Agricultural Remedies, 2023, published as Government Gazette Notice R.3812 of 25 August 2023; and

(b) Regulations relating to Agricultural Remedies, 2006, published as Government Gazette Notice R.935 of 22 September 2006; and

(c) Regulations relating to registration of Fertilizers, Farm Feeds, Agricultural Remedies, Stock Remedies, Sterilising Plants and Pest Control Operators Government Gazette Notice R.1449 of 1 July 1983.

Short title and commencement

48. (1) This regulation shall be called the Regulations Relating to Agricultural Remedies, 2024, and shall, except regulations 3, 8, 10, 34, 35, 37, 38 and 39 come into effect on the date of publication.

(2) Regulations 34, 35, 37 and 38 shall come into effect after 6 months from the date of publication.

(3) Regulation 8(1)(d) and regulation 10(3)(e) shall come into effect on 01 September 2024.

(4) Regulations 3(h)(viii), (xiii), (xiv) and (xv) and regulation 39 shall come into effect 12 months from the date of publication.

(5) Regulations 3(h)(vi) and (xvi) shall come into effect 24 months after from the date of publication.

ANNEXURE A

CRITERIA FOR LOW-RISK PRODUCTS, SUBSTANCES OF CONCERN AND RESTRICTED AGRICULTURAL REMEDY

1. Low-risk product

Active substances or biological organisms fulfill the low-risk product criteria when having one or more of the following characteristics—

(i) Criterion 1. Active substances without significant hazardous properties identified;

(ii) Criterion 2. Active substances for which it is not possible to differentiate between the exposure associated with its use as agricultural remedy with its environmentally relevant exposure levels or its other uses in the food chain;

(iii) Criterion 3. Active substances for which no consumer exposure linked to the mode of application is foreseen; and

(iv) Criterion 4. Microorganisms that are not of human health concern, or of concern to the health of other non-target animals.

2. Substances of concern

Agricultural remedy active ingredients and their formulations fulfill the substances of concern criteria when such agricultural remedy has one or more of the following characteristics—

(i) Criterion 1: agricultural remedy active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A or 1B of the GHS or;

(ii) Criterion 2: agricultural remedy active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A or 1B of the GHS or;

(iii) Criterion 3: agricultural remedy active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A or 1B of the GHS or;

(iv) 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 dichloro diphenyl trichloroethane (DDT) used for malaria vector control by the Department of Health; and

(v) Criterion 5: agricultural remedy active ingredients listed under the Montreal Protocol

3. Restricted agricultural remedy

Agricultural remedy formulations fulfill the restricted agricultural remedy criteria when such agricultural remedy has one or more of the following characteristics—

(i) Criterion 1: agricultural remedy formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard or;

(ii) Criterion 2: agricultural remedy formulation that meets the criteria of acute toxicity categories 1 or 2 of the GHS;

(iii) Criterion 3: Agricultural Remedy active ingredients and formulations listed by the Rotterdam Convention in its Annex III; and

(iv) Criterion 4: agricultural remedy active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.

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ANNEXURE B

agriculture, land reform & rural development

Department:
Agriculture, Land Reform and Rural Development
REPUBLIC OF SOUTH AFRICA

Republic of South Africa
Registrar: Act 36 of 1947
Private Bag X343
0001 Pretoria

FERTILIZER, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT NO 36 OF 1947), AS AMENDED

APPLICATION FOR THE REGISTRATION OF AN AGRICULTURAL REMEDY

INFORMATION FOR APPLICANTS

1. The application form must be duly completed in all respects. Where applicable, the requested information can be submitted as separate numbered attachments.
2. The application form and draft label must be submitted in triplicate with an explanatory covering letter.
3. The application must be submitted to the Registrar: Act 36 of 1947, Agriculture Place, 20 Steve Biko Street, Arcadia, Pretoria.0001
4. Every application must be accompanied by the prescribed registration fee.
5. Only one copy is required of supportive studies (e.g., toxicological data, efficacy data, residue data, physical specifications, and any other relevant studies). See Lists I and II as well as all relevant guidelines as listed on the DALRRD website.
6. Lists I and II are supplied as check lists and an index to ensure that the applicant has provided all relevant data.
7. For further information visit our website (Directorate: Agricultural Inputs Control) at www.dalrrd.gov.za

Indicate as appropriate:

Agricultural Remedies containing a new active ingredient:			
Agricultural Remedies where source of active ingredient and/or formulation is not identical to that of a registered product:			
Registration transfer:			
Amendments to an existing registration:			
Parallel registration:			
Daughter registration:			
Other:			
Will product be marketed under own label:	YES:	NO:	
Proposed date of marketing:			

1. APPLICANT		
Identification:	Name of applicant/corporate name of company, and company registration number:	Name of distributor/agent in country (list of distributors/agents can be attached):
Status: (Importer/formulator/distributor)		
Physical address:		

Postal address (and postal code)		
Telephone: (and area code)		
Fax: (and area code)		
E-mail address:		

2. PRODUCT				
Designation (description of product):	Tradename:			
	Trademark holder:			
Function of product (e.g., insecticide, herbicide, plant growth regulator, etc.):				
Intended use (e.g., public health, industrial, agriculture, forestry):				
Target pest(s) and host(s):				
Method, dosage rates and frequency of application:				
Type of formulation:		CropLife International / FAO* code		
Existing reg. no. (if relevant):		Customs Tariff Code: (Brussels Tariff Nomenclature)		
Registration in SEARCH** country/ies (please indicate)				
Registration in other country/ies (please indicate)				
Is the product registered in country of manufacture and formulation:	If yes, submit evidence		If not, why not?	
Is this product a parallel or daughter registration?				
Original product registration holder name:				
Original product trade name and registration number:				

3. ACTIVE INGREDIENTS (Technical grade)			
Active ingredient(s) common name(s):	Manufacturer (Name and physical address of manufacturing site)	Min. a.i. % purity:	Range %:

4. FORMULATION	
Formulator (Name):	Physical address of formulation site:

Composition (where relevant, include the acid and salt content of the a.i.)					
Ingredients (where relevant, include acid and salt content of a.i.)	Function (e.g., emulsifier)	CAS number	g/L	g/kg	Range

5. TOXICOLOGY AND GHS CLASSIFICATION (formulated product)			
Final GHS classification of the formulation *(Note: A full classification rationale must accompany the application)*			
GHS hazard class	GHS hazard category	GHS hazard statement code	Based on calculated or experimental data?
GHS pictograms			
GHS signal word			
Summary of environmental effects:			
Toxicity to bees:			
Toxicity to birds:			
Toxicity to earthworms and soil micro-organims:			
Toxicity to other non-target organisms:			
Persistence in the environment:			
Other effects:			

6. PACKAGING	
Packaging material / container (e.g., plastic jug, glass bottle, etc.)	
Pack size(s):	
Disposal of empty container(s):	
Name of registered Producer Responsibility Organization according to the Regulations Regarding Extended Producer Responsibility:	

7. DECLARATION BY APPLICANT OR THE DULY APPOINTED REPRESENTATIVE

Tradename of product:	
For and on behalf of ..... I hereby certify that the abovementioned information and data provided in support of this application are, to the best of my knowledge, true, correct and complete.	
..... Name in full (printed)	..... Signature
..... Date	..... Official title and SACNASP registration number
Official stamp of applicant / company	FOR OFFICIAL USE Registration is: Recommended ☐ Not recommended ☐
	Date

NOTES:

*CropLife International = Formerly GCPF (Global Crop Protection Federation), formerly GIFAP (International Group of National Association of Manufacturers of Agrochemical products).

**SEARCH = Southern and East Africa Regulatory Committee for Harmonization of Pesticide Registrations

ACTIVE INGREDIENT (TECHNICAL GRADE) **LIST I**

The dossier accompanying the application must provide full details (as applicable) of the information requested in the lists, i.e., details on the methods used, summaries of methods and results used in toxicology and ecotoxicology studies, method of analyses, etc. Applicants are advised to use CIPAC methods for physical and chemical properties.

ACTIVE INGREDIENT (a.i.) Technical grade		**Official use only**
1. DESIGNATION		
a. Common name (ISO)		
b. Manufacturer or development code		
c. Chemical name (IUPAC)		
d. CAS number		
e. Chemical group		
f. Structural formula		
g. Empirical formula		
h. Patent status Is the a.i. under patent? Who is the patent holder? Expiry date:		

2. PHYSICAL AND CHEMICAL PROPERTIES (Active ingredient – technical grade)

a.	Physical state		
b.	Colour		
c.	Odour		
d.	Density at 20 °C		
e.	Vapour pressure at 20/25 °C		
f.	Volatility		
g.	Hydrolysis DT_{50} ... Days ... °C ... pH		
h.	Photolysis		
i.	Solubility in water ... °C ... pH		
j.	Solubility in organic solvents		
k.	N-octanol / water partition coefficient		
l.	Boiling point °C		
m.	Melting point °C		
n.	Decomposition temperature °C		
o.	Method of analysis and impurities		

3.	**TOXICOLOGY (Active ingredient – technical grade)**		
a.	ADI		
b.	Acute oral LD_{50} mg/kg		
c.	Acute dermal LD_{50} mg/kg		
d.	Acute inhalation LC_{50} mg/L/hour		
e.	Skin irritation / Skin corrosion		
f.	Eye irritation / Eye damage		
g.	Respiratory or Skin Sensitization		
h.	Germ Cell Mutagenicity		
i.	Carcinogenicity		
j.	Reproduction Toxicity		
k.	Specific Target Organ Toxicity – single exposure		
l.	Specific Target Organ Toxicity – repeated exposure		
m.	Aspiration Hazard		
n.	Sub-chronic toxicity 90-day NOEL mg/kg/day		
o.	Chronic toxicity NOEL mg/kg/day		
p.	Metabolism (rat)		
q.	Other studies		

4.	**ECOTOXICOLOGY (Active ingredient – technical grade)**		
a.	Birds (2 species)	LD_{50} mg/kg	
		NOEL	
		LD_{50} mg/kg	
		NOEL	
		Reproduction	
b.	Fish (2 species)	LD_{50} mg/kg	
		NOEL	
		LD_{50} mg/kg	
		NOEL	
		Reproduction	
		BCF	
c.	Daphnia	LC_{50} mg/L	
		NOEL	
d.	Algae	LC_{50} mg/L	
		NOEL	

e. Bees	LD_{50} µg/bee		
f. Earthworms	LC_{50} mg/kg		
g. Soil micro-organisms	EC/LC_{50} mg/kg		

5. BEHAVIOUR IN ENVIRONMENT (Active ingredient – technical grade)		
Behaviour, ways of degradation, degradation products in soil		
a. Major metabolites		
b. DT_{50} (days)		
c. Mobility		
d. Absorption		
e. Mobility of metabolites		
Behaviour, ways of degradation, degradation products in water		
f. Major metabolites		
g. DT_{50} (days)		
h. Surface		
i. Ground		

MODE OF ACTION		
a. IRAC code		
b. HRAC code		
c. FRAC code		
d. Description of mode of action		

6. PLANT RESIDUES		
a. Major metabolites		
b. Metabolism		
c. Behaviour of residues		
d. Crop		
e. MRL CODEX		
f. MRL country		
g. PHI and MRL proposed		
h. Method of residue analysis		

7. REGISTRATION STATUS IN OTHER COUNTRIES		
Indicate whether substance is registered / restricted / banned. Provide reasoning.		
a. Japan		
b. EU		
c. Australia		
d. USA		
e. Other		

FORMULATED PRODUCT **LIST II**

The dossier accompanying the application must provide full details (as applicable) of the information requested in the lists i.e., details on the methods used, summaries of methods and results used in toxicology and ecotoxicology studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties.

FORMULATED PRODUCT		**Official use only**
1. PHYSICAL AND CHEMICAL PROPERTIES		
a. Physical state / formulation type		
b. Colour		
c. Odour		
d. Storage stability		
e. Shelf life		
f. Density		
g. Bulk density		

h. Flammability		
i. Flash point		
j. Compatibility with other pesticides		
k. pH		
l. pH of 1% aqueous dilution		
m. Oxidizing properties		
n. Corrosiveness		
o. Water content		
p. Wettability		
q. Solubility in water		
r. Foaming		
s. Particle size		
t. Suspensibility / emulsifiability		
u. Emulsion stability		
v. Volatility		
w. Viscosity		
x. Other properties (where applicable)		
y. Method of analysis		

2. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
a. Symptoms of human poisoning		
b. First aid treatment		
c. Skin contact		
d. Eye contact		
e. Inhalation		
f. Ingestion		
g. Antidote		
h. Note to physician		

3. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE		
a. Fire-fighting measures		
b. Procedures in case of spillage		

4. USES (New label claims with this application)		
a. Crop/area of use		
b. Target organism		
c. Rate		
d. Stage of treatment		
e. Directions for use		
f. Residue data and pre-harvest interval		
g. Phytotoxicity		
h. Contraindications		

5. MINIMUM LABEL REQUIREMENTS		
a. Product identification		
b. Hazard statements (full description)		
c. Precautionary statements (full description)		
d. First aid/note to physician (as applicable)		
e. Pictograms in line with GHS		
f. Signal word		
g. Directions for use		

ANNEXURE C

agriculture, land reform & rural development

Department:
Agriculture, Land Reform and Rural Development
REPUBLIC OF SOUTH AFRICA

CERTIFICATE IN RESPECT OF THE TAKING OF SAMPLES IN TERMS OF SECTION 15 OF ACT No. 36 OF 1947

Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedy Act, 1947 (Act No. 36 of 1947)
(To be completed in duplicate)

I hereby certify that the accompanying sample of Agricultural Remedy identified by the above serial number, was taken by me on _____ day of _____ 20_____
At _____ in the presence of _____
*(Name of owner/person in charge of stocks/witness)

from the stock of

_____
(Name and address of seller)

PARTICULARS OF AGRICULTURAL REMEDY FROM WHICH SAMPLES WERE TAKEN

1. Name of Registration holder/Company _____
2. Trade name _____
3. Name of agricultural remedy _____
4. Registration number _____ .Act 36/1947
5. Manufacturer details _____
6. Composition of Agricultural Remedy
   6.1 Chemical composition

   _____
   (List chemicals which appear on the label)

   _____

   6.2 Physical properties

   _____

   _____
7. Conditions of the container from which sample was taken _____
8. Estimated quantity of Agricultural Remedy from which sample was taken:
   8.1 Number of containers

   _____

   8.2 Capacity of containers

   _____
9. Remarks

   _____

_____
Signature of witness **Inspector**

35

ANNEXURE D

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 _____

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) _____ _____|_____

I
Other ingredients (if required)

(a) _____ _____|_____

(b) _____ _____|_____

(c) _____ _____|_____

Remarks _____

_____

Signature of analyst

_____

* Delete whichever is applicable.

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

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