agriculture,
forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINES FOR REGISTRATION OF GROUP 3 FERTILIZERS

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1 INTRODUCTION

With the increasing propagation of the use of novel natural and synthetic inorganic, organic and living products in crop production, it has become necessary to provide guidelines for their registration under Act 36 of 1947 (as amended). A clear distinction needs to be made between products that enhance or improve plant growth and those that protect plants against pests and disease. It is only the former that are regarded, for purposes of Act 36 of 1947, as Group 3 Fertilizers. These include Bio-fertilizers, Plant Bio-stimulants or Plant Growth Enhancers which are any substance or micro-organism or combination thereof which, when applied to seed, plant surfaces, or soil, colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of primary nutrients to the host plant (Vessey, 2003) and increased tolerance to abiotic stress. Bio-fertilizers add nutrients through the natural processes of nitrogen fixation, solubilizing phosphorus, and stimulating plant growth through the synthesis of growth-promoting substances. On the other hand Agriculture Remedies are excluded from this category.

2 DEFINITIONS

"Agricultural remedy" means any chemical substance or biological remedy, or any mixture or combination of any substances or remedy intended to be used

a) For the destruction, control, repelling, attraction or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof, but excluding any chemical substance, biological remedy or other remedy in so far as it is controlled under the Medicines and Related Substances Control Act, 1973 (Act 15 of 1973); or
b) As plant growth regulator, defoliant, desiccant or legume inoculant, and anything else which the minister has by notice in the Gazette declared an agricultural remedy for the purpose of this Act:

[Definition of agricultural remedy' inserted by s 1(a) of Act 60 of 1970 and substituted by s.1(b) of Act 24 of 1977.]

"Biofertilizer", "Plant Biostimulant", "Plant Growth Enhancer" or "Plant Strengthener" is any substance or micro-organism or combination thereof which is applied to seed, plant or root environment capable of modifying, and improving, plant development through a collection of different mechanisms of action.

"Colony forming units (CFU)" is the measure of viable microbial units in the formulation.

"Crop grouping" is a system based on crops that are grouped by similar phenological growth stage, development, biology, physiology and/or anatomy.

"Fertilizer" means any substance which is intended or offered to be used in improving or maintaining the growth of plants or the productivity of the soil.

"Fertilizer group 1 " is a fertilizer containing a total equal or greater than 100 g/kg of N, P or K or any combination thereof.

"Fertilizer group 2 " which is a fertilizer containing a total of less than 100 g/kg of N, P or K or any combination thereof or any other recognised plant nutrient(s) in acceptable amounts as indicated in Tables 1 -9 and 13 -15 of the Fertilizer Regulations relating to the Act.

"Fertilizer group 3 " is a natural or synthetic substance or organism/s that improve/s the growth or yield of plants or the physical, chemical or biological condition of the soil. It includes seaweed, organic acids, biofertilizers, PGPR, fertilizer coatings and moisture absorption products.

"Global Harmonised System (GHS)" is the categorization of chemicals and substances according to GHS
principles.

"Rhizosphere" is the zone of soil surrounding a plant root where the biology and chemistry of the soil are influenced by the root.

"Reputable Laboratory" is an independent laboratory, utilizing relevant analytical methods which are:

- either ISO 17025 accredited or ISO/IEC 17025: 2005 SANAS accredited.
- Agricultural Laboratory Association of Southern Africa (AgriLASA) certified for the product which was obtained in the current year of application for registration; or
- OECD Good Laboratory Practices (GLP) or
- A DAFF recognised laboratory or any reputable internationally recognized Laboratory for the relevant analyses.

[1] *OECD, Safety considerations for biotechnology. Scale-up of micro-organisms as biofertilizers. Series on Harmonization of Regulatory Oversight in Biotechnology No. 32 of the OECD (22.02.2005*). http://www.oecd.org/env/ehs/biotrack/Safety-considerations-scale-up-of-micro-organisms-as-biofertilizers.pdf

3. GENERAL REQUIREMENTS

3.1 An application must be made on a form available from the Registrar for this purpose, or clearly legible facsimile thereof on good quality A4 size paper of the same colour as the form supplied by the Registrar.

3.2 In cases where the chemical composition of the active ingredient/s is known, an analysis thereof should be provided by a reputable laboratory. Details of the method of analysis should be provided in all cases.

3.3 The application should be accompanied by a signed certificate of analysis indicating the concentrations of potentially harmful elements as specified in Table 12 of the Fertilizer Regulations, 2017 relating to the Act. These analyses should be performed by a reputable laboratory.

3.4 Together with the application for registration as a Group 3 Fertilizer, proof must be provided (a) of efficacy of the product and (b) that the product has no harmful or detrimental effect on the soil or plants.

3.5 This should take the form of an acceptable report of a study, investigation or analyses, compiled by an investigator registered with the South African Council for Natural Scientific Professions (SACNASP) or any other recognised scientific regulatory body acceptable to DAFF at an organisation with the scientific capabilities of conducting such trial /study or investigation.

3.6 This could include laboratory, growth chamber, glasshouse, or field investigation, on representative material with sufficient controls, treatment levels, and replicates as to make statistical analyses and reaching logical, scientific conclusions possible.

3.7 Where international data meeting the above criteria are submitted, they should be supportive of locally generated data.

3.8 Special attention needs to be given to selecting the most appropriate trials/investigations to be conducted. This will be directly related to any subsequent claims to be made regarding efficacy and directions for use.

3.9 Representative mono- and dicot crops from the crop groupings in table 1 should be included.

3.10 To test for phytotoxicity, trials should be conducted in such a way that treatments of at least half, normal and double are included in the trials.

3.11 Growth related claims must be based on realistic growth evaluation of at least one representative crop from the list of crop groupings (table 1) in at least one trial. Acceptable trial data will include biomass or yield in a trial of at least six weeks duration. In cases of proven efficacy other crops in the same grouping may be listed.

Note: Non-phytotoxicity and efficacy can normally be investigated in the same trial, with the right selection of crops.

3.12 Where non-statistically significant growth improvements are obtained for a crop, the trial would need to be repeated at least twice to establish an efficacy trend.

3.13 For crops not listed in table 1, a motivation for extrapolation from a requested representative crop should be made as a part of the application.

3.14 A Safety Data Sheet for the formulated product, including the contact details of the company responsible for the product in South Africa.

3.15 Formulation toxicology: For a formulation containing a new molecule, genus or specie, reports and summary on formulation toxicity according to OECD guidelines. These reports can be submitted on a compact disc (CD/DVD).

3.16 Should there be a change in the isolate or type in the formulation an application for a formulation change should be made as detailed in the introduction of section 5 and a new representative sample of the active ingredient needs to be deposited and registered.

3.17 Statistical trial results to 95% confidence should be submitted; however where there is non-significant difference and a relatively large percentage increase is obtained in supporting trials they will also be taken into consideration.

4. **REPORT ON TRIAL/STUDY/INVESTIGATION**

The report that is submitted with the application for registration of the product should take the form of a scientific report, and contain at least the following:

4.1 Descriptive title

4.2 Scientific capabilities of the organisation conducting the trial/investigation

4.3 Scientific status of the investigator/s who should be registered as a professional scientist/s with the South African Council for Natural Scientific Professions (SACNASP) or any other recognised scientific regulatory body acceptable to DAFF.

4.4 Literature review appropriate to the product. In general five reports shall suffice.

4.5 In case of the above, proof that the products investigated are identical to those in the application must be provided.

4.6 Materials and methods (Materials, location of the trial, treatments, levels, controls, replicates, experimental conditions, measurements, biometric/statistical analysis)

4.7 Results (Descriptions, tabular/graphic presentation, statistical interpretations)

4.8 Discussion

4.9 Conclusion and Recommendations (including methods of application and application rates)

4.10 Concise summary (Logical summary covering background to product development, motivation for investigation/s carried out, clear explanation of procedure adopted and results obtained/justification for any claims made).

4.11 **NB**- Raw data should be included as annexures. All data should be submitted in PDF-format and verified by the scientists involved in the investigation.

5. BIO-FERTILISERS

5.1 Specific data requirements related to all products with living microorganisms and their metabolites

5.1.1 Microbes must undergo identification by means of accepted sequencing procedures. Any technique used must be scientifically sound and in line with the latest techniques available.

5.1.2 Risk assessment in the form of a literature study approved by the Directorate: Plant Health indicating that the microbes that are not yet released in the South African environment are not potentially harmful to humans, plants, animals or the environment.

5.1.3 Proof that the microorganisms have been deposited in Agricultural Research Council (ARC) culture collection or reputable culture collections in South Africa.

5.1.4 Passport Data (also referred to as the microbes voucher)

5.2 Data requirements on microbial products manufactured in South Africa

Before considering a biofertilizer or biofertilizer blended product for registration the following information should be provided:

5.2.1 An import permit is required for an imported microorganism used during the development of products.

5.2.2 A mass release permit issued by the Directorate: Plant Health or Department of Environmental Affairs should be submitted.

5.2.3 Accession number assigned to the microbe by the manufacturer of the product and origin of the Microbial Culture.

5.2.4 If the microorganisms serving as active ingredient was sourced from South Africa, a valid Bioprospecting permit, obtained from the Department of Environmental Affairs, in relation to the National Environmental Management: Biodiversity Act (Act No. 10 of 2004), and all relevant supporting documents needs to be provided as evidence of the permit obtained.

5.2.5 In the case of microbial products that are manufactured in South Africa, proof of registration information and notification of the production facility and manufacturing equipment (e.g. fermenters) must be submitted to The Department of Trade and Industry in terms of the Non-Proliferation of Weapons of Mass Destruction Act (Act 87 of 1993).

5.3 Data requirements for imported microbial products

If the organism is to be sourced from another country, the country of origin must be declared. All valid permits must be submitted. This could include:

5.3.1 Import permits for trials from Directorate: Plant Heath Directorate or the Department of Environmental Affairs;

5.3.2 A letter from a recognised authority, giving the applicant permission for commercialization of the organism;

5.3.3 A mass release permit issued by Directorate: Plant Health Directorate or Department of Environmental Affairs should be submitted;

5.3.4 Receipt for purchase with details of microbe collections name, country, Genus and Species identification (with up to date nomenclature); and

5.3.5 Import documentation including customs and excise documents;

5.3.6 Letter from microbe collection's director, regents or other control person/board giving permission for commercial use.

5.4 Quality control and shelf life

For microbial products with living organisms, quality control and shelf life must be conducted. Full analyses reports must be provided with detailed description of methods used. A minimum period of six months is mandatory for products with living microbial organisms. The CFU stated on the label must reflect the level attained at the end of the shelf life study. Shelf life should be determined in accordance with any available reference test methodology. The method used should be described in detail in the laboratory test report. Should an applicant wish to apply for an extended shelf life for a product, this must be accompanied by supporting data.

The certificate of analysis should include the following:

5.4.1 Microorganism information:

5.4.2 The strain as part of the registration dossier.

5.4.3 Colony Morphology - to visually inspect the morphology of the microbes on solid medium. Colony morphology is used to distinguish between the microbes visually to determine the purity of the culture.

5.4.4 Gene sequencing for microorganisms is required.

5.6 Quantification of the microbial active ingredients:

5.6.1 Viable Colony Forming units (CFU) Counts of the active ingredient (microbe) or in the case of a combination of microbes, each of the microbes present in the formulation. The CFU is the number of microbial colonies able to grow on the growth medium per ml or per gram of the product as measured by serial dilutions, which represents the concentration of the viable inoculation units in the formulation.

5.6.2 Viable spore count must be determined the amount of spores present in the product expressed as spores per ml or gram of product.

5.6.3 For Mycorrhizae and other organisms that cannot be artificially cultured: spore count is done under the microscope to determine the amount of spores present in a liquid or powder, granular or pellet formulation (with the last three suspended in water at a specific dilution). This determines the concentration of spores present in the product, but not necessarily the viability of the spore.

5.7 Product purity:

5.7.1 Contamination level in the formulation indicates any other microbe in the formulation not specified on the label, and is quantified by serial dilutions and plating out onto general growth medium. Contamination levels should not exceed 1×10^5 CFU/ml or g (or 100 000 CFU/ml or CFU/g).

5.7.2 The pH - to determine acidity or alkalinity of the product.

5.7.3 Certificate of analysis for potentially harmful elements as prescribed in Table 12 of the Fertilizer Regulations relating to the Act.

5.7.4 Presence of human pathogens in the formulation. See Appendix 2.

5.8 Additional Specific trial data requirements for microbial products

For efficacy trials, the standard requirement must include:

5.8.1 A control treatment where the microbe is not applied.

5.8.2 Non-sterile soil to show the effect of the microbe when applied to a natural soil containing other microbes.

5.8.3 The product needs to be applied at normal recommended and double recommended application rates of the product

5.9 “Concept of Familiarity” is dynamic rather than static. Its applicability improves with increasing experience, and it is flexible, that it may be applied to any level or element under consideration. Familiarity is based on knowledge of and experience with:

- The bio-fertilizer;
- The plant and its interaction with micro-organisms;

- The trait(s) or characteristic(s) introduced into the micro-organism;
- The environment into which the micro-organism is introduced.

Therefore, if traditional/well known bio-fertilizers or blends are utilized, based on extensive experience (familiarity) of the product, it can be accepted as a low risk product and classified as a Group 3 product without any further requirements pertaining to toxicological data, residues etc. - provided that no claims are made towards any pesticide activity. Likewise, the same principle will apply when bio-fertilizer(s) are blended with any known organic acids and bio-products. After all, they are normally used as nutritional source for the microbes when packaged.

6. REQUIREMENTS FOR LABELS

6.1 Refer to the current regulations and to SANS Code 1268: "Labelling Practices for Agricultural Remedies and Fertilizers registered for Home and Home Garden Sector" issued by SABS, 22 November, 2013 (5) as well as fertilizer regulations, 2017.

6.2 In addition to the SANS the label must meet requirements for labelling of fertilizer products as set out in section 9 of fertilizer regulations, 2017.

6.3 The concentration of the product (in g/kg or mg/kg) should be stated on the label.

6.4 The name of the main ingredient must be written on the label

6.5 Substantiated claims relating to the efficacy of the product

6.6 Instruction of use. If the space on the front panel is insufficient the back panel can be used

6.7 A disclaimer relating to more information may be added at the discretion of the registration holder.

6.8 Specific requirements for labels with living microorganisms:
Labels for products with living microorganisms must include the following:

6.8.1 Content must be expressed as the number of viable units (spores, cells, etc.) per unit weight or volume of product. Microbial cfu count must be displayed on the label per organism claimed in the product. In addition the viable units must be indicated, e.g. spore, cells, mycelia, etc.

6.8.2 The units used for the active ingredient/s level must be, in the case of a liquid Group 3 fertiliser, in gram per millilitre, cfu per ml, and for a solid formulation Group 3 fertiliser, grams per kg.

6.8.3 The genus and species name for each microorganism must be stated on the label.

6.8.4 The shelf life and date of manufacture of the product must be stated and it must correspond to the cfu count from the certificate of analyses

7. FULVIC, HUMIC, AND AMINO ACIDS

Applications for registration of fulvic, humic, amino and other organic acids shall follow the normal application form with the following information:

7.1 Certificate of analysis from a reputable laboratory indicating the chemical composition of the product

7.2 Analysis certificate for potentially harmful elements as prescribed in Table 12

7.3 The presence and concentration of Humic or Fulvic acid or their salts (Certificates of Analysis done by a reputable laboratory)

7.4 Origin (country/source/process including natural or synthetic)

7.5 Solubility

7.6 Alkalinity or acidity (pH)

7.7 Carbon content

7.8 Ash content

7.9 Moisture content

7.10 Trial results (Phytotoxicity)

As the efficacy of these products is recognised under the right soil, moisture and climatic conditions, efficacy trials need not be undertaken although supportive documentation will be required.
However, phytotoxicity effects must be tested, as stipulated in section 4 above.
In this case the products will be registered under group 3, without any claims.
If specific efficacy is claimed and specifically proven, appropriate claims may be made for a group 3 registration.

8. SEAWEED AND PRODUCTS OF ANIMAL AND PLANT ORIGIN (Except for those listed above)

Applications for registration of seaweed and products of animal or plant origin must, in addition to the general requirements set out in section three, have the following data:

8.1 Scientific name of the product

8.2 Country of origin

8.3 Processing methods of the product, including natural or synthetic materials.

8.4 Certificate of analysis indicating the chemical composition of the product (issued by a reputable laboratory).

8.5 Validated analysis method used to analyse the product/active ingredients

8.6 Analysis certificate of potentially harmful elements as prescribed in Table 12 of Fertilizer Regulations, 2017 of Act no 36 of 1947.

8.7 Trial results according to section two of this guideline.

The efficacy of these products needs to be scientifically proven, in growth trials on representative crops stated on the product label, as stipulated in section 3.5 above. Potential phytotoxicity effects must be tested, as stipulated in section 4.

9. WATER ABSORBENT PRODUCTS.

Applications for registration of water absorbent or retention products shall follow the normal application process and provide the following information:

9.1 Identification of the product.

9.2 Certificate of analysis from a reputable laboratory indicating the chemical composition of the product.

9.3 Analysis certificate for potentially harmful elements as prescribed in table 12.

9.4 Proof of efficacy in retention of water in a suitable study (water pressure plates, infiltration columns, saturation point).

9.5 Proof of release of water to plants in growth studies under water stress conditions.

9.6 Proof of non-phyto-toxicity.

10. REFERENCES

[1]Vessey, J K 2003. Plant growth promoting rhizobacteria as biofertilizers. Plant and Soil 255: 571-586.

OECD, Safety considerations for biotechnology. Scale-up of micro-organisms as biofertilizers. Series on Harmonization of Regulatory Oversight in Biotechnology No. 32 of the OECD (22.02.2005).

APPENDIX 1: CROP GROUPINGS

Group 3 fertilizers are intended to improve plant growth, yield or soil fertility. Therefore, many proposed labels will include a large selection of crops. A whole crop group can be claimed on the label if one of the crops in each grouping category is tested. However, a minimum of three trials in total is required to indicate a trend towards efficacy of the product. The grouping is based on crops that are similar with regard to phenological growth stage, development, biology, physiology and/or anatomy. For crops not listed in the table, data must be submitted or sufficient motivation for data extrapolation given.

Possible Data Extrapolation		
Crop type	**Crop listed from**	**Extrapolation to**
Row crops: grain	Maize, sweetcorn, sorghum, millet	Whole group
Row crops: small grain	Wheat, barley, oat, rye,	Whole group
Legume crop	Dry bean, green bean, soybean, Lentils, Lupins, clover, alfalfa, lentils, peanut.	Whole group
Tree crop: Pome fruit	Apple, pear, peach,	Whole group
Tree crop: Stone fruit	Apricot, nectarine, peach, plum	Whole group
Tree crop: Citrus	Orange, lemon, mandarin	Whole group
Tree crop: Nut	Macadamia, pecan, hazelnut	Whole group
Grape vine	Table grape, wine grape	Whole group
Bulb vegetables	Onion, leek, garlic	Whole group
Root and stem vegetables	Carrot, radish	Whole group
Leafy vegetables	Cabbage, lettuce, broccoli, brussel sprout, spinach	Whole group
Cucurbits	Butternut, gem squash, cucumber, baby marrow, patty pan	Whole group
Potato	Potato	Any cultivar
Solanaceous fruits	Tomato, green pepper, paprika, chilli	Whole group

*Data must be generated for any crop not listed in the data extrapolation table.

APPENDIX 2: CONTAMINATION LEVELS AND HUMAN PATHOGEN PRESENCE

This section is based on the OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products. ENV/JM/MONO (2011)43. Tier 1 analyses, including microbial activity and analysis for *Escherichia coli* or Thermotolerant (fecal) coliforms, are the minimum requirement to adhere to. If sample tests positive for this, the full spectrum of all proposed indicator organisms as specified in Tier 2, must be tested.

Table i. Proposed OECD microbial contamination screening requirements for microbial products. Note that green represents Tier 1 level analyses and orange represents Tier 2 level analyses.

Type of Indicator	Indicator	Limit	Rationale
Microbial Activity	Aerobic Plate Count	$< 10^5$ CFU/g or mL	- indicator of aerobic bacterial contamination - often used in the food industry - many standard methods available - optional requirement if MPCA is an aerobic bacterium
	Anaerobic spore-formers	$< 10^5$ CFU/g or mL	- cause of health concerns in the food industry; indicates hygiene failures during processing - anaerobic spore-forming organisms have potential to persist in soil/water for long periods of time - standard methods for anaerobic spore-formers available - optional requirement if other hygiene indicators (i.e., Escherichia coli and Staphylococcus aureus) are screened during product manufacture and if the MPCA is a known micro-aerophile
	Yeast and Mould Count	< 1000 CFU/g or mL	- many standard methods available - general indication of yeast and mould contamination, and potential presence of mycotoxins - may be optional requirement if MPCA is a fungus
Human, fecal and environmental contamination	*Escherichia coli* OR Thermotolerant (fecal) coliforms	Absence in 1 g or mL < 10 CFU/g or mL	- indicator of fecal contamination - recent health concern involving contaminated fruits/vegetables; certain sensitive sub-populations are particularly at risk - can survive/multiply on plants and in soil and water - many standard methods available
	Staphylococcus aureus	Absence in 1 g or mL	- indicator of contamination due to improper handling - many standard methods available
	Pseudomonas aeruginosa	Monitoring*	- indicator of environmental contamination - optional requirement recommended ONLY if screening results for other hygiene indicators suggest possible presence of pseudomonads
Pathogen	*Salmonella*	Absence in 25 g or 25 mL	- U.S. EPA and Health Canada requirement - many standard methods available - often used in the food industry
	Listeria monocytogenes	Absence in 25 g or 25 mL	- recent health concern with respect to contaminated fruits/vegetables and processed meat products - can survive/multiply on foods stored under refrigerated temperatures - optional requirement particularly if screens for other hygiene indicators consistently demonstrate acceptably low levels of

			contamination. Regulatory authorities must also have a high degree of confidence in the manufacturer's quality assurance programme when deciding whether to waive routine screening for this micro-organism
	Vibrio	Absence in 25 g or 25 mL	- U.S. EPA test guideline requirement, therefore testing is mandatory for U.S. registration/authorization - not endemic in many countries - basic food handling precautions/personal hygiene habits exclude these organisms during manufacturing - isolation of specific species or pathogens (e.g., *Vibrio cholerae*) is NOT recommended unless the analytical laboratory follows appropriate biohazard protocols - optional requirement and recommended ONLY if there is a high potential for contamination or if species of Vibrio are known to naturally occur at the geographical location of the manufacturing site
	Shigella	Absence in 25 g or 25 mL	- U.S. EPA test guideline requirement, therefore testing is mandatory for U.S. registration/authorization - not endemic in many countries - most commonly related to undercooked shellfish rather than manufacturing processes; basic food handling precautions/personal hygiene habits exclude these organisms during manufacturing - isolation of specific species or pathogens (e.g., *Shigella dysenteriae*) is NOT recommended unless the analytical laboratory follows appropriate biohazard protocols - optional requirement and recommended ONLY if there is a high potential for contamination or if species of *Shigella* are known to naturally occur at the geographical location of the manufacturing site