agriculture,
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Department:
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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). The purpose of this document is to outline requirements for registration of Group 3 fertilizer products.

The intention of these guidelines is to distinguish between the registration requirements of Group 3 fertilizer products and biological remedies. Although the same product(s) (e.g. growth stimulants & micro-organisms) may be registered either as bio-fertilizer or biological remedies or both, it is preferred to register products that are intended to improve plant growth, yield or soil fertility as Group 3 fertilizer.

According to the OECD[1] there are "no documented cases of adverse effects on humans due to the use of traditional bio-fertilizers and no adverse effects on mineral cycling" and "bio-fertilizers are normally placed in the environment to inter alia enhance plant growth and they are considered to consist of beneficial micro-organisms".

The principled Concept of Familiarity, as defined below in section 2.7 of this report, must be applied throughout the guidelines, i.e. the use of internationally accepted databases linked with publicized experience and knowledge. These principles, utilized in the risk/safety assessment process, which is dynamic rather than static, are very important.

If the product has no claims pertaining to bio-remedies and its active ingredients are known and with no deleterious effects, the product will be classified as a Group 3 fertilizer product. This document is effective as from 1st March 2016.

2 DEFINITIONS

2.1 "Bio-fertilizer", "Plant Bio-Stimulant", "Plant Growth Enhancer" or "Plant Strengthener" is any substance or micro-organism or combination thereof which is applied to seed, plant or root environment with the intention to stimulate natural processes in plants to benefit their nutrient use efficiency and/or tolerance to abiotic stress

2.2 "Biological Remedy" and "Bio-pesticides" means any chemical substance or biological remedy, or any mixture or combination of any substance or remedy intended or offered to be used 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 biological remedy in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), or the Hazardous Substances Act, 1973 (Act 15 of 1973). (Agricultural remedy as defined in Act 36 of 1947.)

2.3 "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.

2.4 "Group 3 Fertilizer" 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.

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

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

- either ISO 17025 accredited or ISO/IEC 17025: 2005 SANAS accredited

[1] *OECD, Safety sonsiderations 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

- 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.

2.7 "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.

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 levels of potentially harmful elements as specified in Table 12 of the Fertilizer Regulations relating to the Act. These analyses should be performed by a Reputable Laboratory.

3.3 Together with the application for registration as a Group 3 Fertilizer, proof must be provided (a) of efficacy of the product relating to each and every claim made in favour of the product and (b) that the product has no harmful or detrimental effect on the soil and plants.

3.4 This should take the form of an acceptable report of a study, investigation or analyses compiled by a competent, registered or certified individual or organisation capable of conducting such work.

3.5 This could include laboratory, growth chamber, glasshouse or field investigations, on representative material with sufficient controls, treatment levels and replicates as to make statistical analysis and the reaching of logical, scientific conclusions possible.

4. ADDITIONAL REQUIREMENTS RELATING TO PLANT GROWTH ENHANCERS

In addition to the requirements above, all applications relating to plant growth enhancers need to provide proof that the product does not have any deleterious/phyto-toxicity effects on plant growth. With this in mind, applications of at least double the recommended level, regardless of any crops mentioned on the product label, should be included in the above-mentioned trials.

Provisos:

4.1 No crop specific Phyto-toxicity Trials required.
4.2 Phyto-toxicity trials need not be representative of locality or bioclimatic regions.
4.3 No Phyto-toxicity trials will be required if the claim, contained within the application, is backed by proof obtained from internationally accepted databases that the product does not have any deleterious/harmful phyto-toxicity effects on plant growth.

5. PRIOR SUBMISSION OF PROPOSED INVESTIGATION

Potential applicants may consult the Registrar on the suitability and possible acceptability of an envisaged investigation into the efficacy of a particular product, prior to commencing the work in order to avoid wasting time and money on unacceptable studies.

- Such a submission should be made at least one month before the envisaged commencement date.

- The submission should contain details of the following:

    - The claims to be investigated
    - The envisaged experimental procedure
    - Experimental detail, including material, treatments, levels, controls, replicates and measurements
    - The scientific status of the investigator who should be registered as a professional scientist by the South African Council for Natural Scientific Professions (SACNSP).
    - The envisaged time frame of the study.

Investigations will only be necessary when a report mentioned in section 3.5 does not exist or is found to be insufficient to proof a claim.

6. FINAL REPORT

The final report to be submitted with the application for registration of the product should take the form of a typical scientific report, and contain at least the following:

- Title
- Purpose
- Literature review
- Materials and methods (Materials, location of the trial, treatments, levels, controls, replicates, experimental conditions, measurements, biometric/statistical analysis)
- Results (Descriptions, tabular presentation, statistical interpretations)
- Discussion
- Conclusion and Recommendations (including on usage and levels of application)

7. MICRO-ORGANISMS IN BIO-FERTILISERS, PLANT BIO-STIMULANTS OR PLANTSTRENGTHENERS

Bio-fertilizers (also biofertilizer), Plant Bio-stimulants or Plant Strengtheners is 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.

The use of living micro-organisms in bio-fertilizers needs to be regulated, therefore the following guidelines need to be followed when registering microbial products to be used as, or in combination with, fertilizer:

- Plant Growth Promoting Rhizobacteria (PGPR) must be registered as Group 3 fertilizers and not as pesticides because of its chelation and ATP enzymatic effects on plants.
- Any products or PGPR's that are claimed to be disease or pest suppressants must be registered as pesticides, not as fertilizers. All applications should be supported by literature from acknowledged sources and/or peer-reviewed articles from anywhere in the world showing proof that the microbes concerned do what is claimed in the registration application.
    - The Registrar requires proof that the microbes have been identified by means of accepted sequencing procedures, the sequences have been deposited in Agricultural Research Council (ARC) and that the microbes do not belong to any groups known to be potential human or animal pathogens. Any technique used must be scientifically sound and in line with the latest techniques available:
    - Bacteria = Cultural, microscopic and molecular sequencing technique
    - Fungi = Morphological, Molecular Techniques (ITS gene region) and DNA bar-cording
    - The Registrar requires field, tunnel or greenhouse trials to be done, with the standard requirement that the trials must include:
        - a control treatment where the microbe is not applied, and
        - a non-sterile soil to show the effect of the microbe when applied to a natural soil containing other microbes.

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

Before considering a Bio-fertilizer or Bio-fertilizer blended product for registration the following information should be provided:

- A mass release permit issued by Plant Health Directorate/Department of Environmental affairs should be submitted.
- Toxicological data, if applicable, should be done in accordance with the document published by the Department of Health for Agricultural Remedies and Stock Remedies, if the specific remedy claims are made
- Accession number assigned to the microbe by the manufacturer of the product
- Origin of the Microbial Culture.

Applicants should contact the Plant Heath Directorate/Department of Environmental Affairs for more details where necessary.

7.2 Imported organism

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:

- Import permits for trials from Plant Heath Directorate/Department of Environmental Affairs;
- A letter from a recognised authority, giving the applicant permission for commercialization of the organism;
- A mass release permit issued by Plant Health Directorate and Department of Environmental affairs should be submitted;
- Receipt for purchase with details of microbe collections name, country, Genus and Species identification (with up to date nomenclature); and
- Import documentation including customs and excise documents;
- Letter from microbe collection's director, regents or other control person/board giving permission for commercial use.

7.3. Formulation toxicology:

- For a formulation containing a new molecule, genus or specie, reports and summary on formulation toxicity according to OECD guidelines (1). These reports can be submitted on a compact disc (CD/DVD).
- Should there be a change in the isolate or type in the formulation an application for a formulation change should be made and a new representative sample of the active ingredient needs to be deposited and registered.

7.4 Compatibility

If the product is recommended to be applied with another biological product – subject to the principles of familiarity, or other agricultural remedy (mixing partners); compatibility between the microbes and/or the other remedy should be tested and a report must be included. All these combinations must also be supported by efficacy/phyto-toxicity/residues studies.

7.5 Quality control

Reports and summary on the physical properties and storage stability (Shelf life) of the formulated product:
These reports must be verified/compiled by an independent laboratory complying with acceptable standards such as OECD Good Laboratory Practice (OECD GLP); ISO17025, Good Manufacturing Practice (GMP), accreditation by the Medical Control Council; accreditation by SANAS. Shelf life should be determined in accordance with any available test methodology developed by the applicant, or the relevant FAO Pesticides Specifications, US EPA, and OECD etc. 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.

8. REQUIREMENTS FOR LABELS

Refer to the current regulations and to SANS Code 1268: "Labeling Practices for Agricultural Remedies and Fertilizers registered for Home and Home Garden Sector" issued by SABS, 22 November, 2013 (5). The biggest difference between fertilizer labeling requirements and agricultural remedies is on the toxicity WHO classification which is not implemented in fertilizer products.

9. FULVIC, HUMIC, AMINO AND OTHER ORGANIC ACIDS

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

- Certificate of analysis indicating the chemical composition of the product
- Analysis certificate for potentially harmful elements as prescribed in Table 12
- The presence and concentration of Humic or Fulvic acid or their salts (Certificates of Analysis done by an accredited laboratory))
- Origin (country/source/process including natural or synthetic)
- Solubility
- Alkalinity or acidity (pH)
- Carbon content
- Ash content
- Moisture content
- Trial results as prescribed under the “General Requirements”

10. SEAWEED AND PRODUCTS OF ANIMAL AND PLANT ORIGIN (Other than specified in Section 9)

Applications for registration of seaweed and products of animal or plant origin shall conform to the following standards:

- Scientific name of the product
- Country of origin
- Processing methods of the product, including natural or synthetic
- Certificate of analysis indicating the chemical composition of the product (COAs issued by independent reputable laboratory, institutions or authorities accredited for the relevant analyses).
- Analysis method used to analyse the product/active ingredients
- Analysis certificate for potentially harmful elements as prescribed in Table 12 of the Regulations of Act 36 of 1947.
- Trial results as prescribed under the “General Requirements”

11. REFERENCES

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

OECD, Safety sonsiderations 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)