



**DRAFT**

**NATIONAL AGENCY FOR FOOD AND DRUG  
ADMINISTRATION AND CONTROL (NAFDAC)**

**BIO-FERTILIZER REGISTRATION REGULATIONS 2019**

**COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS**

**(ending 13<sup>th</sup> January, 2020).**

**PLEASE SEND ALL INPUT TO [REGULATORYAFFAIRS@NAFDAC.GOV.NG](mailto:REGULATORYAFFAIRS@NAFDAC.GOV.NG)**

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### Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honorable Minister of Health hereby makes the following Regulations:-

#### 1. Scope

These Regulations shall apply in the registration of all bio-fertilizers that are manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

#### 2. Prohibition

- (1) No bio-fertilizer shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations.
- (2) No bio-fertilizer shall be sold or distributed in units other than the package in which it has been originally contained, wrapped or packaged at registration.
- (3) Notwithstanding the provisions of Regulation 2 (1) of this Regulation, the National Agency for Food and Drug Administration and Control may grant a permit for the importation or manufacture of a sample of bio-fertilizer for the purpose of field trial or research.

#### 3. Classification of Bio-fertilizers

- (1) The classification of bio-fertilizer shall include but not limited to:
  - (a) Nitrogen fixing bio-fertilizers.
  - (b) Phosphate bio-fertilizers
  - (c) Micronutrients bio-fertilizers.
  - (d) Plant growth promoting rhizobacteria.
  - (e) Compost bio-fertilizers.
  - (f) Mycorrhizal Fungi.

#### 4. Application for Registration

- (1) Application for bio-fertilizer registration shall be made by submitting a complete application form, accompanied by relevant documents as the Agency may, from time to time, prescribe and shall;
  - (a) contain the particulars and description of the bio-fertilizer product, in respect of which the application is made;
  - (b) be accompanied by such fee as the Agency may, from time to time, prescribe.
- (2) The particulars and description of the bio-fertilizer shall be detailed enough to consist of all administrative and technical information in sufficient details as may be required to allow the Agency make informed decision about the product.

- (3) The Agency, in considering an application-
  - (a) may ask the applicant to supply such other information as it may require to enable it reach a decision on the application;
  - (b) shall satisfy itself that there is need to have the bio-fertilizer registered in Nigeria.
  - (c) may register the bio-fertilizer product in accordance with the provisions of Food, Drug and Related Products (Registration etc.) Act cap F33 LFN 2004.....legal
- (4) The registration of a bio-fertilizer under these Regulations shall, unless cancelled earlier, be valid for a period of five years and may be renewed.
- (5) The Agency shall, from time to time, publish the list of registered bio-fertilizers on the Agency's official website, notifying the registration of a bio-fertilizer.

The Agency may refuse or reject an application for registration if:

  - (a) it is found that the method, facilities or controls used in the manufacture, processing, and packaging of the bio-fertilizer are inadequate to ensure and preserve its identity, strength, quality, and purity consistently.....legal
  - (b) laboratory report for the product is unsatisfactory
  - (c) good manufacturing practice inspection report is unsatisfactory
  - (d) the field trial report is unsatisfactory
  - (e) product labeling contravenes the bio-Fertilizer Product Labeling Regulations 2019.
  - (f) or any other reason the Agency may deem fit.

**5. Efficacy Assessment for Bio-fertilizer:**

- (1) The applicant shall carry out;
  - (a) Efficacy assessment of a bio-fertilizer to be introduced into the market shall be carried out to ensure that bio-fertilizer approved would be efficacious for its intended use.
  - (b) The assessment shall be for two (2) cropping seasons or as may be prescribed by the Agency.
  - (c) The assessment will be conducted in two (2) different agro-ecological zones or as may be prescribed by the Agency.
  - (d) The assessment shall be monitored by the Agency at approved research institute(s).

**6. Labeling**

The labeling of bio-fertilizers shall be in accordance with the Bio-fertilizer Labeling Regulations 2019.

**7. Advertisement**

All advertisement of bio-fertilizer shall be in accordance with the Bio-fertilizer Advertisement Regulations 2019

**8. Suspension or cancellation of Certificate of Registration**

- (1) The Agency shall suspend, withdraw or cancel the certificate of registration of a bio-fertilizer if;
  - (a) The grounds on which the bio-fertilizer was registered were later found to be false or incomplete; or
  - (b) The circumstances under which the bio-fertilizer was registered no longer exist; or

- (c) Any of the conditions or undertaking under which the bio-fertilizer was registered has been contravened; or
  - (d) Standard of quality, safety and efficacy as prescribed in the documentation for registration are not being complied with; or
  - (e) The premises in which the bio-fertilizer is imported, or thereof manufactured, packaged or stored by or on behalf of the holder of the certificate of registration are unsuitable for the import, manufacturing, packaging or storage of the bio-fertilizer; or are not in compliance with the requirements of current Good Manufacturing Practice (cGMP), as may be determined by the Agency
  - (f) New information has become available to the Agency which renders the bio-fertilizer unsafe or dangerous or ineffective; or
  - (g) The Certificate of Registration Holder notifies the Agency in writing of any intention to suspend the product registration for a period not exceeding the validity of the certificate of registration.
  - (h) There is an adverse effect on non-target organisms and environment.
- (2) Where the registration of bio-fertilizer is suspended or cancelled, the Agency shall order the withdrawal from circulation of that bio-fertilizer and shall accordingly cause the suspension, cancellation or withdrawal to be published.
  - (3) A Certificate of Registration holder may notify the Agency of his intention to resume marketing of a registered product and shall submit relevant document and pay the prescribed renewal fee for product registration where the product registration certificate has expired.

## 9. **Packaging**

- (1) The packaging of a fertilizer shall be in a manner as approved by the Agency.
- (2) The package of a bio-fertilizer shall be designed to;
  - (a) Maintain the integrity of the product under required storage conditions, display and distribution.
  - (b) Permit the withdrawal of some or all of the contents in a manner that is safe to the user.
  - (c) Permit the closing of the package in a manner that prevents the spillage of the Bio-fertilizer under required handling conditions.
  - (d) Minimize the degradation or change of its contents under required storage conditions.

## 10. **Storage, Distribution and Display**

- (1) Bio-fertilizers shall be stored, distributed or displayed in accordance with the conditions stated on the label.
- (2) Bio-fertilizers shall not be stored, distributed or displayed with human food, animal feed or pet food.

## 11. **Mandatory reports**

- (1) A manufacturer or importer of bio-fertilizers shall keep record of distribution and submit a mandatory report to the Agency annually indicating the names and addresses of companies supplied as well as the quantities supplied.

- (2) Any manufacturer or importer engaged in the manufacture, importation, distribution, sale or storage of bio-fertilizers shall submit preliminary and final reports to the Agency of any adverse effect on non-target organisms and environment and loss of efficiency associated with the bio-fertilizers occurring in Nigeria or elsewhere.

## 12. Disposal

The Certificate of Registration holder shall ensure that the disposal of any expired, degraded or obsolete fertilizers shall be carried out in a manner prescribed by the Agency.

## 13. Penalty.

- (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :
  - (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and
  - (b) a body corporate, to a fine not exceeding N100, 000.
- (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-
  - (a) director, manager, secretary or other similar officer of the body corporate; or
  - (b) partner or officer of the firm or
  - (c) trustee of the body concerned ;or
  - (d) person concerned in the management of the affairs of the association ;or
  - (e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

## 14. Forfeiture after conviction

- (1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-
  - (a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;
  - (b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.
- (2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

## 15. Interpretation

In these Regulations, unless the context otherwise requires,

**“Agency”** means the National Agency for Food and Drug Administration and Control (NAFDAC).

**“Agro-ecological zones”** means land resource, mapping unit defined in terms of climate, landform and soils, and/ or land cover, and having specific range of potentials and constraints for land use.

**“Approved Research Institute”** means a certified establishment in Nigeria for conducting research.

**“Bio-fertilizer”** means substances which contain living microorganisms which when applied to the seed, plant surface, or soil, colonizes the rhizosphere or the interior of the plant and promote growth by increasing the supply or availability of nutrients to the host plants.

**“Certificate of analysis”** means a certificate issued by an analyst certified for the relevant analysis, indicating the full chemical, biological, and physical composition for the particular bio-fertilizer.

**“Compost bio-fertilizers”** means bio-fertilizers that contain microorganism that breaks down organic matter to enrich soil with nutrients.

**“Container”** means any form of packaging of bio-fertilizer for sale as a single item whether by completely or partially enclosing the bio-fertilizer and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

**“Disposal”** means the action or process of getting rid of any expired, degraded or obsolete bio-fertilizer.

**“Field trial”** means a scientific evaluation conducted by an approved research institution on a Bio-fertilizer in accordance with direction specified for the use of that bio-fertilizer, to ascertain and establish the claims made on the label.

**“Label”** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to a package or container of food.

**“Micro-nutrients bio-fertilizer”** means bio-fertilizers that contain microorganism that can solubilize or degrade micronutrients in soils.

**“Mycorrhizal fungi”** means fungi that lives in symbiotic association with roots of higher plants

**“Nitrogen fixing bio-fertilizer”** means a bio-fertilizer using living microorganisms that can convert atmospheric Nitrogen into plant useable forms.

**“Phosphate bio-fertilizer”** means bio-fertilizers that mobilizes and/or solubilizes the insoluble phosphate from organic and inorganic phosphate sources.

**“Plant growth promoting rhizobacteria”** means bio-fertilizer that promotes plant growth by improved nutrient availability and production of plant growth substances.

**16. Citation**

These Regulations may be cited as Bio-fertilizers Registration Regulations, 2019.

**MADE at Abuja this .....day of .....2019.**

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**Inuwa Abdulkadir Esq**

**Chairman Governing Council**

**National Agency for Food and Drug Administration and Control (NAFDAC)**

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