



Federal Republic of Nigeria

Official Gazette

No. 193	Lagos - 12th November, 2024	Vol. 00
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Government Notice No. 58

The following is published as supplement to this *Gazette* :

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Printed and Published by The Federal Government Printer, Lagos, Nigeria
FGP 84/112024/150

Annual Subscription from 1st January, 2024 is Local : ₦100,000.00 Overseas : ₦130,000.00 [Surface Mail] ₦150,000.00 [Second Class Air Mail]. Present issue ₦3,500 per copy. Subscribers who wish to obtain *Gazette* after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

**NAFDAC ACT, CAP., N1 LFN, 2004 AND FOOD, DRUGS AND
RELATED PRODUCTS (REGISTRATION, ETC.) ACT,
CAP. F33. LFN, 2004**

BIO-FERTILIZER REGISTRATION REGULATIONS, 2024



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S. I. No. 53 of 2024

**NAFDAC ACT, CAP., N1 LFN, 2004 AND FOOD, DRUGS AND
RELATED PRODUCTS (REGISTRATION, ETC.) ACT,
CAP. F33. LFN, 2004**

BIO-FERTILIZER REGISTRATION REGULATIONS, 2024

[16th Day of October, 2024]

Commence-
ment

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control ("the Governing Council") by section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act, Cap. F33. LFN, 2004 and all other powers enabling it in that behalf, the Governing Council, with the approval of the Minister, makes the following Regulations —

PART I — OBJECTIVE AND APPLICATION

1. The objective of these Regulations is to provide regulatory framework for the regulation of registration of bio-fertilizer manufactured, imported, distributed, sold or used in Nigeria

Objective

2. These Regulations shall apply to registration of bio-fertilizer manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

Application

**PART II — REGISTRATION, CLASSIFICATION, SUSPENSION, EFFICACY,
PACKAGING, STORAGE, ETC.**

3.—(1) Application for bio-fertilizer registration shall be made by submitting an application, accompanied with relevant documents prescribed by the Agency, from time to time as follows —

Application
for
registration
of bio-
fertilizer

(a) contain the particulars and description of the bio-fertilizer named in the application; and

(b) be accompanied with the evidence of payment of fee as may be prescribed by the Agency.

(2) The particulars and description of the bio-fertilizer referred in to in subregulation (1)(a) of this regulation shall consist of administrative and technical information to allow the Agency make informed decision on the product.

(3) Where the Agency considers the application for registration to be satisfactory, the applicant shall be issued a Certificate of Registration.

(4) Where the application for registration is unsatisfactory, the Agency shall refuse the application and inform the applicant in writing, stating the reason for the refusal.

(5) Registration of bio-fertilizer under these Regulations shall be for a period of five years and may be renewed.

(6) Notwithstanding the provisions of subregulation (5) of this regulation, the Agency may suspend or cancel any Certificate of Registration in accordance with regulation 3 of these Regulations.

(7) The Agency shall, from time to time, publish on its official website, the list of bio-fertilizer registered by the Agency.

(8) The Agency may refuse an application for registration, where the —

(a) procedure used for manufacturing, processing and packaging a bio-fertilizer is not adequate to reliably preserve and ensure its identity, strength, quality, and purity;

(b) laboratory report for the product is not satisfactory;

(c) Good Manufacturing Practice inspection report is not satisfactory;

(d) field trial report is not satisfactory;

(e) product labelling of the bio-fertilizer contravenes the Agency's Bio-Fertilizer Labelling Regulations; or

(f) bio-fertilizer do not meet any other reason required by the Agency.

4.—(1) The Agency may suspend, withdraw or cancel the Certificate of Registration of a bio-fertilizer where —

(a) the grounds upon which the bio-fertilizer was registered is false or incomplete;

(b) the circumstances under which the bio-fertilizer is registered no longer exist;

(c) any of the conditions or undertaking under which the bio-fertilizer is registered has been contravened;

(d) standard of quality, safety and efficacy as prescribed in the documentation for registration has not been complied with;

(e) the premises in which the bio-fertilizer is manufactured, packaged or stored by or on behalf of the holder of Certificate of Registration is unsuitable for the manufacture, package or storage of the bio-fertilizer;

(f) new information is available to the Agency which renders the bio-fertilizer unsafe, dangerous or ineffective;

(g) there is adverse effect on non-target organisms and the environment; or

(h) the holder of Certificate of Registration notifies the Agency in writing of the intention to suspend the product registered for a period not exceeding the validity of the Certificate of Registration.

(2) Where the registration of bio-fertilizer is suspended or cancelled, the Agency shall order the withdrawal from circulation of the bio-fertilizer and shall cause the suspension, cancellation or withdrawal to be published.

(3) Pursuant to the provisions of subregulation (1)(h) of this regulation, a holder of Certificate of Registration shall notify the Agency of the 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.

5. The classification of bio-fertilizer shall include —

- (a) Nitrogen fixing bio-fertilizer;
- (b) Phosphate bio-fertilizer;
- (c) Micronutrients bio-fertilizer;
- (d) Plant growth promoting rhizobacteria;
- (e) Compost bio-fertilizer; and
- (f) Mycorrhizal Fungi.

Classification
of bio-
fertilizer

6.—(1) Applicant for registration of bio-fertilizer shall carry out efficacy assessment of such bio-fertilizer to ensure the efficacy for its intended use.

Efficacy
assessment
of bio-
fertilizer

(2) The efficacy assessment shall be —

- (a) for a period of not less than two cropping seasons or as may be prescribed by the Agency;
- (b) in two different Agro-ecological Zones or as may be prescribed by the Agency; and
- (c) monitored by the Agency at an approved research institute.

7. The labelling of bio-fertilizers shall be in accordance with the Agency's Bio-fertilizer Labelling Regulations.

Labelling of
bio-fertilizer

8. The advertisement of bio-fertilizers shall be in accordance with the Agency's Bio-fertilizer Advertisement Regulations.

Advertisement
of bio-
fertilizer

9.—(1) Bio-fertilizer shall be packaged in the manner prescribed by the Agency.

Packaging of
bio-fertilizer

(2) The package of bio-fertilizer shall be designed to —

- (a) maintain the integrity of the product under required storage conditions, display and distribution;
- (b) allow 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 any required handling conditions; and
- (d) minimise the degradation or change of its contents under required storage conditions.

Storage,
distribution
and display
of bio-
fertilizer

Submission
of
mandatory
report

Disposal of
bio-fertilizer

Power to
seal
premises

Prohibition

10.—(1) Bio-fertilizer shall be stored, distributed or displayed in accordance with the conditions indicated on the label.

(2) Bio-fertilizer shall not be stored, distributed or displayed alongside with human food, human drugs, veterinary medicines, animal feed or pet food.

11.—(1) A manufacturer or importer of bio-fertilizer shall keep record of its distribution and submit a mandatory report of its activities to the Agency annually, indicating the name, address and quantity of supplies made to any company.

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

12. A holder of Certificate of Registration of bio-fertilizer shall dispose of expired, degraded or obsolete bio-fertilizer in the manner prescribed by the competent authority in the presence of staff of the Agency.

13. The Agency shall have power to seal up any premises used or being used in connection with commission of any offence in violation of these Regulations, until such time the bio-fertilizer is removed or such reasonable time as the Minister may determine.

14.—(1) Bio-fertilizer shall not be —

(a) manufactured, imported, exported, advertised, sold, distributed or used in Nigeria except it is registered in accordance with the provisions of these Regulations, and

(b) sold or distributed in units other than the package in which it has been originally presented during registration.

(2) Notwithstanding the provision of subregulation (1) of this regulation, the Agency may grant permit for the importation or production of a sample of bio-fertilizer for the purpose of field trial or research.

(3) A holder of a Certificate of Registration shall not lend, hire, sell, transfer or otherwise dispose of the Certificate of Registration to any other person without the approval of the Agency.

PART III — OFFENCES AND PENALTIES

15.—(1) A person who contravenes any of the provisions of these Regulations commits an offence and is liable on conviction, in the case of —

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding ₦800,000 or both; and

(b) a body corporate, to a fine not exceeding ₦5,000,000.

Offences and
penalties

(2) Where an offence under these Regulations is committed by a body corporate, firm or any other association of individuals, every —

(a) director, manager, secretary or other similar officer of the body corporate;

(b) partner or officer of the firm;

(c) trustee of the body concerned;

(d) person concerned in the management of the affairs of the association; or

(e) person who purports to act in a capacity referred to in paragraphs (a) to (d) of this regulation,

is liable to be proceeded against and be punished for the offence and in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

16.—(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government —

Forfeiture
after
conviction

(a) asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and

(b) any of the person's property or instrument 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.

PART IV — MISCELLANEOUS

17. The Agency shall be responsible for the enforcement of these Regulations.

Enforcement
of these
Regulations

18. In these Regulations —

Interpretation

"Agency" means the National Agency for Food and Drug Administration and Control;

"*Agro-ecological zones*" means land resource, mapping unit defined in terms of climate, landform and soils, 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, colonises the rhizosphere or the interior of the plant and promote growth by increasing the supply or availability of nutrients to the host plants;

"*Compost bio-fertilizers*" means bio-fertilizers that contain microorganism that breaks down organic matter to enrich soil with nutrients;

“*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 bio-fertilizer, to ascertain and establish the claims indicated 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;

“*labelling*” means the label and any other written, printed, or graphic matter upon an article or any of its container or wrapper, or accompanies such article;

“*Micro-nutrients bio-fertilizer*” means bio-fertilizers that contain microorganism capable of solubilising or degrading 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 capable of converting atmospheric Nitrogen into plant useable forms;

“*Phosphate bio-fertilizer*” means bio-fertilizers that mobilises and solubilises the insoluble phosphate from organic and inorganic phosphate sources; and

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

Citation

19. These Regulations may be cited as Bio-fertilizers Registration Regulations, 2024.

MADE at Abuja this 16th day of October, 2024.

MUHAMMAD ALI PATE, CON
Coordinating Minister of Health
and Social Welfare