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Short Title

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60 NAFDAC (Fertilizer Registration) Regulations, 2024

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NAFDAC (FERTILIZER REGISTRATION) REGULATIONS, 2024



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NAFDAC (FERTILIZER REGISTRATION) REGULATIONS, 2024

[16th Day of October, 2024]

Commencement

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 the registration of fertilizer manufactured, imported, distributed, sold or used in Nigeria.

Objective

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

Application

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

3.—(1) An application for fertilizer registration shall be accompanied

with relevant documents prescribed by the Agency, from time to time as follows—

(a) contain the particulars and description of the fortilizer negred in the

Application for registration

- (a) contain the particulars and description of the 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 fertilizer referred 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 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 7 of these Regulations.

- (7) The Agency shall, from time to time, publish on its official website, the list of registered fertilizer.
- (8) The Agency may refuse an application for registration, where the —
- (a) procedure used for manufacturing, processing and packaging a 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 fertilizer contravenes the Agency's Fertilizer Labelling Regulations; or
 - (f) fertilizer do not meet any other reason required by the Agency.

Classification of fertilizer

- 4. The classification of fertilizer shall include —
- (a) composition
 - (i) straight fertilizer,
 - (ii) complex fertilizer, and
 - (iii) mixed fertilizer;
- (b) physical form —
- (i) solid, in form of powder, crystal, prill, granule, super granule, and briquette, and
 - (ii) liquid;
- (c) nutrients content —
- (i) nitrogenous fertilizer which includes ammoniacal, nitrate, ammoniacal and nitrate and amide.
 - (ii) phosphate fertilizer,
 - (iii) potassium fertilizer,
- (iv) complex fertilizer, and
- (v) soil conditioner;
- (d) origin
 - (i) organic fertilizer, and
 - (ii) inorganic fertilizer;
- (e) nature-
 - (i) non-reactive,
 - (ii) reactive,
 - (iii) bio-degradable, and
 - (iv) persistent; and
- (f) any other classification prescribed by the Agency.

5.—(1) The applicant shall carry out efficacy assessment of the fertilizer to be introduced into the market, to ensure that the fertilizer is efficacious for its intended use and purpose.

Efficacy assessment of fertilizer

Labelling

Advertisement

Suspension

cancellation

of

of Certificate

Registration

- (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 approved research institute.
- **6.** The labelling of a fertilizer shall be in accordance with the Agency's fertilizer labelling regulations.
- 7. The advertisement of fertilizer shall be in accordance with the Agency's fertilizer advertisement regulations.
- 8.—(1) The Agency may suspend, withdraw or cancel the Certificate of Registration of a fertilizer, where
 - (a) the grounds upon which the fertilizer was registered is false or incomplete;(b) the circumstances under which the fertilizer is registered no longer
 - exist;
 (c) any of the conditions or undertaking under which the fertilizer is
 - registeredis contravened;
 (d) standard of quality, safety and efficacy as prescribed in the
 - documentation for registration is not complied with;

 (e) the premises in which the 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 fertilizer; (f) new information is available to the Agency which renders the 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 fertilizer is suspended or cancelled, the Agency shall order the withdrawal from circulation of the 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

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and pay the prescribed renewal fee for product registration where the product registration certificate has expired. 9.—(1) Packaging of fertilizer shall be in the manner approved by the

Packaging

- Agency. (2) The package of a fertilizer shall be designed to —
- (a) maintain the integrity of the fertilizer under the required condition of storage, display and distribution;
 - (b) permit the withdrawal of the content 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 fertilizer under required handling conditions; and
- (d) minimise the degradation or change of its contents under required storage conditions.

Storage,

10.—(1) Fertilizer shall be stored, distributed or displayed in accordance with the condition indicated on the label.

distribution and display of fertilizer

(2) Fertilizer shall not be stored, distributed or displayed with human food, animal feed or pet food.

Submission mandatory report

11.—(1) A manufacturer or importer of 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 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.

Disposal of fertilizer

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

Power to seal

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 fertilizer is removed or such reasonable time as the Minster may determine.

premises

14.—(1) Fertilizer shall not be —

Prohibition (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 in its registered package during registration.
- (2) Notwithstanding the provisions of subregulation (1) of this regulation, the Agency may grant a permit for the importation or production of a sample of fertilizer for field trial or research purposes.
- (3) A holder of Certificate of Registration under these Regulations 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 — Offences and penalties

- (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000 or both; and
 - (b) a body corporate, to a fine not exceeding N5,000,000.
- (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.

Enforcement of these Regulations

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

Interpretation

18. In these Regulations —

"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, with specific range of potentials and constraints for land use;

"approved research institute" means an establishment certified to conduct field trial research in Nigeria;

"Certificate of Registration" means a document which describes the particulars and conditions under which a product is registered and indicates the assigned NAFDAC Reg. No. for a product;

"complex fertilizer" or "compound fertilizer" means fertilizer that contains two or three primary nutrients of which two primary nutrients are in chemical combination and are usually produced in granular form;

"disposal" means the action or process to get rid of any expired, degraded or obsolete fertilizer;

"field trial" means a scientific evaluation conducted by an approved research institution on a fertilizer in accordance with direction specified for the use of the fertilizer, to ascertain and establish the claims made on the label;

"fertilizer" means any substance which is intended or offered to be used to improve or maintain the growth of a plant or the productivity of the soil:

"Good Manufacturing Practice (GMP)" means the part of quality assurance which ensures that a product is consistently produced and controlled to the quality standard appropriate to the intended use and as required by the certificate of registration;

"inorganic fertilizer" means a chemical product, of mineral or synthetic origin generally composed of simply, mostly water soluble nutrients such as nitrogen, potassium and phosphorus that are immediately available for plant use following application;

"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;

"mixed fertilizer" means a physical mixture of two chemically compounded fertilizer or organic fertilizer that contain one or more of the plant nutrients such as nitrogen (N), phosphorus (P) and potassium (K);

"organic fertilizers" means any fertilizer manufactured from any substance of animal or plant origin or a mixture of such substance;

"package" means any suitable container in which a fertilizer is wholly or partly placed or packed; and

"straight fertilizer" or "single fertilizer" means any fertilizer which supplies one primary plant nutrient, namely nitrogen, phosphorus or potassium.

19. These Regulations may be cited as Fertilizer Registration Regulations, 2024.

Citation

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

Muhammad Ali Pate, CON Coordinating Minister of Health and Social Welfare