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NAFDAC (BIO-FERTILIZER LABELLING) REGULATIONS, 2024



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S. I. No. 52 of 2024

NAFDAC (BIO-FERTILIZER LABELLING) REGULATIONS, 2024

[00th Day of, 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 the labelling of bio-fertilizer manufactured, imported, distributed, sold or used in Nigeria.

Objective

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

Application

PART II — LABELLING INFORMATION, DECLARATION, DIRECTION, DATE MARKING, STORAGE, TRADEMARK, REGISTRATION NUMBER. ETC

3.—(1) Information required to be indicated on a label shall —

Labelling
information

- (a) be prominent, legible and distinct;
- (b) appear in font size and style type that is adequate for clarity and on sufficient contrasting background without obscuring design, vignette or crowding within written, printed or graphic matter;
- (c) be in English Language and may include any other language;
- (d) not be false or misleading;
- (e) be informative and accurate; and
- (f) appear on the panel of the label, displayed under customary condition of purchase.

(2) The bio-fertilizer label shall not be occupied with other information, statement or graphic not required by these Regulations in a manner as to make the label space insufficient for the display of necessary information or statement required under these Regulations.

4.—(1) The label on a bio-fertilizer shall be conspicuous to indicate the name of the bio-fertilizer, manufacturing location, address of the manufacturer and the name of the holder of Certificate of Registration.

Name and
address of
manufacturer,
holder of
Certificate of
Registration

(2) Where a bio-fertilizer is manufactured under a contract manufacturing agreement, the name and address of the manufacturing location shall be

indicated by a phrase that reveals the connection with the entity such as “Manufactured by...for...”, “Manufactured for... by...”, or any other information that expresses the facts.

(3) The site location address of the manufacturer of a bio-fertilizer shall be written on the label of any packaging components such as primary, secondary and tertiary.

Declaration
of
ingredients

5. The label on a bio-fertilizer shall indicate the —

- (a) genus and specie name of the microorganisms or active ingredients;
- (b) minimum number of active viable cells per gram or milliliter of bio-fertilizer of the active genus, species of the microorganism or active ingredient;
- (c) class of the bio-fertilizer;
- (d) excipient;
- (e) type of formulation; and
- (f) net weight.

Direction on
the use of a
bio-fertilizer

6. The direction on the use of bio-fertilizers shall be indicated on the label to include —

- (a) method of application;
- (b) field application, including target plants;
- (c) pre-harvest interval and re-entry period; and
- (d) time and rate of application.

Net content

7.—(1) Bio-fertilizer label shall indicate the content of the active ingredients contained in the bio-fertilizer and in the case of —

- (a) liquid bio-fertilizer, percentage by mass or mass per unit volume, or both, or as may be required by the Agency; and
- (b) dust, wettable powder or any other dry formulations, as a percentage by mass.

(2) Where a bio-fertilizer is not in the form specified in subregulations (1) of this regulation, the active ingredient shall include the viscosity, specific gravity, particle size or such other properties or specifications as may be determined by the Agency.

Date
marking
instruction

8.—(1) Bio-fertilizer label shall specify and legibly display the day, month and year of manufacture and date of expiration.

(2) The day and year shall be declared in uncoded number with the year to be denoted by two or four digits and the month declared in word or number.

(3) Date inscription shall be combined in accordance with subregulations (1) and (2) of this regulation and introduced with the words “Date of Manufacture” and “Date of Expiry”.

(4) Where several items are included in the outer package, which during usage by the consumer may be discarded, the marking of date shall also appear on the package that is likely to be retained by the consumer until consumption.

(5) The batch number of a bio-fertilizer shall be indicated on the inner and outer label.

(6) The batch number and date inscription shall not be pre-printed on the label.

9. The required storage condition of a bio-fertilizer shall be specified on the inner and outer label of the package.

Storage
condition

10.—(1) The trademark or brand name of a bio-fertilizer shall be indicated on the label of the bio-fertilizer in a manner as not to give wrong impression of the nature and quality, or substance of the bio-fertilizer.

Trademark
or brand
name

(2) Where the trademark indicated on the label is in conflict with any Regulations or requirements prescribed by the Agency, the Regulations of the Agency shall prevail.

(3) The trademark or brand name of a bio-fertilizer shall not sound-alike or look-alike to a registered bio-fertilizer.

11. The inner and outer label of a bio-fertilizer shall clearly show the registration number of the product, such as “NAFDAC REG. NO.”, assigned to it as indicated on the Certificate of Registration issued by the Agency.

Registration
number

12. Bio-fertilizer shall be clearly labelled with conspicuous precautionary statements written legibly and indelibly —

Precautionary
statement

(a) directing the user to read the label before use, which shall be in the following form “READ THE LABEL BEFORE USE”;

(b) indicating —

(i) that “feeding animal with bio-fertilizer is prohibited, except the Urea in the formulation of the feed for ruminant”,

(ii) that a person shall wear appropriate Personal Protective Equipment (PPE) while handling bio-fertilizer,

(iii) that the product is kept out of the reach of children,

(iv) warning or cautions, and hazard statements,

(v) the method for disposing the package or containers of used bio-fertilizer, and

(vi) first aid and note to physicians.

13. The toxicological information on the label of a bio-fertilizer shall include the following information —

Toxicological
information

(a) identifying any significant hazard regarding the storage, distribution, display, handling, and disposal of the bio-fertilizer;

- (b) instruction on procedures to alleviate the hazard;
- (c) instruction on decontamination procedures and disposal of the bio-fertilizer and the empty package; and
- (d) that is essential to the treatment of a person poisoned or otherwise injured by the bio-fertilizer and shall —
 - (i) describe the symptoms of poisoning,
 - (ii) state remedial measure, and
 - (iii) state the ingredients that may affect the treatment.

Reference to professional body or association, etc.

14. The label of a bio-fertilizer shall not refer or lay claim to an endorsement directly or indirectly, to a professional body or association, except as prescribed by the Agency.

Prohibition

15. A person shall not manufacture, import, export, distribute, advertise, display for sale, offer for sale or use a bio-fertilizer, except it is labelled in accordance with the provisions of these Regulations.

PART III — OFFENCES AND PENALTIES

Offences and penalties

16.—(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 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.

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

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

Forfeiture after conviction

(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

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

Enforcement
of these
Regulations

19. In these Regulations —

Interpretation

"Address" means where the business of manufacture, sale, distribution, storage or display of bio-fertilizer product is carried out which includes the house number, plot number, street name, Town or City, State, Country;

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

"Bio-fertilizer" means substances that contain living micro organisms which when applied to the seed, plant surface, or soil, colonizes the rhizosphere or the interior of the plant and promote the growth by increasing the supply or availability of nutrients to the host plant;

"Date of expiry" means any date after which a bio-fertilizer is not recommended for use;

"Ingredient" means any substance used in the manufacture or preparation of a bio-fertilizer and present in the final product although possibly in a modified form;

"Inner label" means primary label for the bio-fertilizer;

"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 labels and other written, printed, or graphic matter on any article or any of its containers or wrappers, or accompanying such article;

"Outer label" means secondary label for the bio-fertilizer;

"Package" means any suitable container in which any bio-fertilizer is wholly or partly placed or packed; and

"Trademark" means a mark used or proposed to be used in relation to goods for the purpose of indicating, or to indicate a connection in the course of trade between the goods and some person who have the right either as proprietor or as registered user to use the mark, whether with or without any indication of the identity of the person or mark registered under section 43 of the Trademark Act Cap. T13 LFN, 2004.

20. These Regulations may be cited as Bio-fertilizer Labelling Regulations, 2024.

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

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