



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

DRAFT

BIO-FERTILIZER LABELING REGULATIONS 2019

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS

(ending 13th January, 2020).

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DRAFT

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 to the labeling of bio-fertilizers manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

2. Prohibition

Except as provided in these Regulations, no person shall manufacture, import, export, distribute, advertise, display for sale or use a bio-fertilizer in Nigeria unless it is labeled in accordance with the provisions of these Regulations.

3. Labeling information

- (1) All information required to be indicated on the label shall be prominent, legible and distinct. All statements must appear in font size and style type which is adequate for clarity and on sufficient contrasting background without obscuring designs or vignettes or crowding within written, printed or graphic matter.
- (2) All information shall be in English language and may include any other languages..
- (3) Labeling shall be informative and accurate.
- (4) Labeling shall not be false or misleading.
- (5) All information and statements as required by these Regulations shall appear on the part or panel of the label which is presented or displayed under customary conditions of purchase.
- (6) The label space shall not be used to present information, statement or graphics not required by these Regulations in such a manner that will make the label space insufficient for the prominent placing of such information or statements required under these Regulations.

4. Name and Address of manufacturer, Certificate of Registration Holder

- (1) The label of a bio-fertilizer shall specify conspicuously the name and manufacturing location address of the manufacturer, and the name of the Certificate of Registration Holder.
- (2) Where a bio-fertilizer is manufactured under contract manufacturing arrangement, the name and manufacturing location address shall be indicated by a phrase that reveals the connection with the entity e.g. “Manufactured by.....for.....”, “Manufactured for.....by.....”, or any other wording that expresses the facts.
- (3) The name of the person represented as manufacturer under Regulations (5.1) – (5.2) may be the same as either the name of establishment under which the entity is registered at the time the

labelled product is manufactured OR the registered name of the parent, subsidiary or affiliated company where the related companies are under common ownership and control. The Corporate name may be followed or preceded by the name of the particular division.

- (4) The location address of the manufacturer of a fertilizer shall be complete on labels of all packaging components (i.e. Primary, Secondary and Tertiary).

5. **Declaration of ingredients**

- (1) The label of a bio-fertilizer shall indicate;
- (a) Net weight
 - (b) Genus and species name of the microorganisms/ active ingredients.
 - (c) The minimum number of active viable cells per gram/milliliter of bio-fertilizer of the active genus or species of the microorganism /active ingredient.
 - (d) Class of the bio-fertilizer.
 - (e) Type of formulation;

6. **Direction for use**

- (1) The use of bio-fertilizers shall be declared and shall include:
- (a) Methods of application
 - (b) Field application including target plants
 - (c) Time and rate of application

7. **Net content**

- (1) Bio-fertilizer label shall contain the content of the active ingredients expressed;
- (a) In the case of a liquid bio-fertilizer, as a percentage by mass, or mass per unit volume, or both, as may be required by the Agency.
 - (b) In the case of dust, wettable powder or other dry formulations, as a percentage by mass; or
 - (c) Where subparagraphs (i) and (ii) do not apply, in terms acceptable to the Agency, the active ingredient shall include the viscosity, specific gravity, particle size or such other properties or specifications determined by the Agency.

8. **Date marking instructions**

- (1) All bio-fertilizer shall specify and legibly display the day, month and year of manufacture and expiry on the label.
- (2) The day and year shall be declared by un-coded numbers with the year to be denoted by 2 or 4 digits and the month declared in letters or character or numbers.
- (3) A "Date of Manufacture" shall be used in combination with Regulation 8 (1) and 8 (2) and shall be introduced with the words "Date of Manufacture" as appropriate.
- (4) In cases where several items are included in an outer wrapper which during normal usage by the consumer will be discarded, the date shall appear on the packaging that will be retained by the consumer until consumption.
- (5) The batch number shall be indicated on the inner and outer labels of all bio-fertilizers.

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

9. Storage condition

The required storage condition shall be specified on both the inner and outer label.

10. Trade Mark/Brand Name

(1) The trade mark/brand name shall be displayed on the label in a manner that it shall not give a wrong impression of the nature, quality or substance of the bio-fertilizer.

(2) Where the trademark is in conflict with any Regulations or requirements of the Agency, the Regulations or requirements of the Agency shall supercede and prevail.

11. Registration number

The inner and outer labels of a bio-fertilizer shall clearly show the registration number of the product (NAFDAC REG. NO.) assigned to it as indicated on the Certificate of Registration in a manner as prescribed by the Agency.

12. Precautionary statement

- (1) Bio-fertilizers shall be clearly labelled with conspicuous precautionary statements written legibly and indelible indicating:
- (a) A statement directing the user to read the label, this statement shall be in the following form “READ THE LABEL BEFORE USE”;
 - (b) “Feeding the bio-fertilizer to animals is illegal except Urea in the formulation of feed for ruminant”.
 - (c) A person shall wear appropriate protective equipment while handling bio-fertilizer.
 - (d) Keep out of reach of children.
 - (e) Warning or cautions and hazard statements.
 - (f) Method of disposal of containers
 - (g) First aid and note to physicians.

13. Toxicological Information

- (1) The following toxicological information shall be included on the label of any bio-fertilizer:
- (a) Information identifying any significant hazards with respect to the storage, distribution, display, handling and disposal of the bio-fertilizer.
 - (b) Instruction on procedures to alleviate the hazards.
 - (c) Instruction on decontamination procedures and disposal of the bio-fertilizer and the empty package.
 - (d) Information essential for the treatment of a person poisoned or otherwise injured by the bio-fertilizer and shall;
 - i. Describe the symptoms of poisoning.
 - ii. State remedial measures.
 - iii. State the ingredients that may affect the treatment.

14. No reference to National or International bodies.

No label of a bio-fertilizer shall make reference, directly or indirectly, to a National or international body, except as prescribed by the Agency.

15. 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.

16. 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.

17. Interpretation

In these Regulations, unless the context otherwise requires;

“Address” means where the business of manufacture or sale or distribution or storage or display of cosmetic product is carried out which includes the house number, plot number, street name, Town/City, State, Country, etc.

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

“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 the growth by increasing the supply or availability of nutrients to the host plants.

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

“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 of that bio-fertilizer.

“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.

“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 bio-fertilizer.

“Inner label” means primary label for the bio-fertilizer.

“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.

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

18. Citation

These Regulations may be cited as Bio-fertilizer Labeling Regulations 2019.

MADE at Abuja thisday of2019.

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Inuwa Abdulkadir Esq

Chairman Governing Council

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