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NAFDAC (BIO-PESTICIDE LABELLING) 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 labelling of bio-pesticides manufactured, imported, distributed, sold or used in Nigeria.

Objective

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

Application

- Part II Labelling Information, Name and Address of Manufacturer, Declaration, Direction, Date Marking, Trademark, 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) A bio-pesticide 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-pesticides shall be conspicuous to indicate the name of the bio-pesticides, manufacturing location, address of the manufacturer and the name of the holder of Certificate of Registration.
- (2) Where a bio-pesticide 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.

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

Declaration of ingredients on label

- 5. The inner and outer label of a bio-pesticide shall indicate the —
- (a) genus and specie name of the microorganism or active ingredient;
- (b) minimum number of active viable cells per gram of bio-pesticide of the active genus or specie of the microorganism;
 - (c) class of the bio-pesticide;
 - (d) excipient;
 - (e) type of formulation; and
 - (f) net weight.

Direction on the use of bio-pesticide

- 6. The direction on the use of bio-pesticides shall be indicated on the label to include
 - (a) method of application;
 - (b) field application;
 - (c) pre-harvest interval or re-entry period, where applicable; and
 - (d) time and rate of application.

Net account

- 7.—(1) Bio-pesticides label shall indicate the content of the active ingredients contained in the bio-pesticides and in the case of
 - (a) liquid bio-pesticides, 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-pesticides 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-Pesticides 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-pesticide 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-pesticide shall be specified on the inner and outer label of the package.

Storage condition

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

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-pesticide shall not soundalike or look-alike to a registered bio-pesticide.
- 11. The inner and outer label of a bio-pesticide 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-pesticides 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 the bio-pesticide is not to be ingested,
 - (ii) that a person shall wear appropriate Personal Protective Equipment (PPE) while handling bio-pesticides,
 - (iii) that the product is kept out of the reach of children,
 - (iv) warning or cautions, hazard statements, and colour band,
 - (v) the method for disposing the package or containers of used biopesticides, and
 - (vi) first aid and note to physicians.
- 13. The toxicological information on the label of a bio-pesticide shall include information —

Toxicological information

- (a) identifying any significant hazard regarding the storage, distribution, display, handling, and disposal of the bio-pesticides;
 - (b) on procedures to alleviate the hazard;
- (c) on decontamination procedures and disposal of the bio-pesticides, and the empty package; and



- (d) essential to the treatment of a person poisoned or otherwise injured by the bio-pesticides 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-pesticides shall not refer or lay claim to an endorsement directly or indirectly, to a professional body or association, except as approved by the Agency.

Prohibition

- 15. A person shall not -
- (a) advertise bio-pesticides except it has been registered and the advert material has been approved by the Agency; and
- (b) display, screen or otherwise present an advertisement of a biopesticides unless 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.

Forfeiture after conviction

- 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

- (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 regulation, "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 —

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

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

"Batch number" means the number or a combination of numbers and letters specifically given to a bio-pesticide. product which is linked to the manufacturing history of the product;

"Bio-pesticide" means any substance derived from such natural materials as animals, plants and microorganisms that control pests and pathogens;

"Date of Expiry" means any date after which bio-pesticide is not recommended for use;

"Label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to a package or container of fertilizer;

"Labelling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article;

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

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

"Package" means suitable container in which any bio-pesticide 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 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.

20. These Regulations shall be cited as the Bio-pesticides Labelling Regulations, 2024.

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

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