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NAFDAC (BIO-PESTICIDE REGISTRATION)
REGULATIONS, 2024



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S. I. No. 56 of 2024

NAFDAC (BIO-PESTICIDE 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. These Regulations provide regulatory framework for the registration of bio-pesticides manufactured, imported, distributed, sold or used in Nigeria.

Objective

PART II — BIO-PESTICIDE REGISTRATION, SUSPENSION, CLASSIFICATION, EFFICACY AND ETC

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

Application

3.—(1) An application for bio-pesticides registration shall be accompanied with —

Application
for
registration
of animal
feed premix

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

(b) the evidence of payment of fee as may be prescribed by the Agency; and

(c) other relevant documents prescribed by the Agency, from time to time.

(2) The particulars and description of the bio-pesticides 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 bio-pesticides 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 4 of these Regulations.

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

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

(a) procedure used for manufacturing, processing and packaging a bio-pesticides 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-pesticides contravenes the Agency's Bio-pesticides Labelling Regulations; or

(f) bio-pesticides do not meet any other requirement prescribed by the Agency.

Suspension
or
cancellation
of
Certificate
of
Registration

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

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

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

(c) any of the conditions or undertaking under which the bio-pesticides is registered, is 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 bio-pesticides 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-pesticides;

(f) new information is available to the Agency which renders the bio-pesticides 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-pesticides is suspended or cancelled, the Agency shall order the withdrawal from circulation of the bio-pesticides 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-pesticide shall include —

- (a) microbial pesticide;
- (b) biochemical pesticide; and
- (c) plant incorporated protectant pesticide.

Classification
of Bio-
pesticide

6.—(1) Applicant for registration of bio-pesticide shall carry out efficacy assessment of such bio-pesticide to ascertain its efficacy for its intended user.

Efficacy
assessment
of bio-
pesticide

(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.

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

Labelling of
bio-pesticide

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

Advertisement
of bio-
pesticide

9.—(1) Packaging of bio-pesticides shall be in the manner approved by the Agency.

Packaging of
bio-pesticide

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

(a) maintain the integrity of the bio-pesticides 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 bio-pesticides under required handling conditions; and

(d) minimise the degradation or change of its contents under required storage conditions.

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

Storage,
distribution
and display
of bio-
pesticide

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

Submission
of
mandatory
report

11.—(1) A manufacturer or importer of bio-pesticides 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-pesticides 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 bio-pesticides occurring in Nigeria or elsewhere.

Disposal of
bio-
pesticides

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

Power to
seal
premises

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-pesticides is removed or such reasonable time as the Minister may determine.

Prohibition

14.—(1) Bio-pesticides 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 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 bio-pesticide 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

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

(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.

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 (AGENCY);

"Agro-ecological Zones" means land resource, mapping unit defined in terms of climate, landform and soils, and 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;

"Biochemical pesticides" are naturally occurring substances that control pests by non-toxic mechanisms;

"Bio-pesticides" means pesticides derived from such natural materials as animals, plants and microorganisms that control pest and pathogens;

"Competent Authority" means a government agency or body statutorily authorised and responsible for carrying out the function;

"Disposal" means the action or process of getting rid of any expired, degraded or obsolete bio-pesticide;

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

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

“*Plant incorporated protectant pesticide*” means pesticidal substances produced by plant containing added genetic materials.

Citation

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

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

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