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**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004
PESTICIDE REGISTRATION REGULATIONS, 2021**



ARRANGEMENT OF REGULATIONS

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S. I. No. 83 of 2021

**NATIONAL AGENCY FOR FOOD AND DRUGS
ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004
PESTICIDE REGISTRATION REGULATIONS, 2021**

[7th Day of July, 2021]

Commence-
ment.

In exercise of the powers conferred on it by Sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 and Section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other 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 Minister of Health makes the following Regulations—

1. These Regulations shall apply to the registration of pesticides that are manufactured, imported, exported, advertised, sold, distributed or used in Nigeria. Scope of application.

2.—(1) A pesticide shall not be manufactured, formulated, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations. Prohibition.

(2) A person to whom a certificate of registration has been issued 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.

3. Notwithstanding regulation 2 of these Regulations, a person shall obtain authorisation from the Agency before importation of any unregistered pesticides, where the pesticide is— Exceptions.

(a) imported for experimental or research purpose and not for distribution or sale ;

(b) imported in the event of national disease outbreak or emergency ;

(c) bulk importation for a farm use only ; and

(d) bulk importation of technical grade for the purpose of manufacturing formulated pesticide within the country.

4.—(1) A person shall not submit application for the registration of pesticide unless such pesticide is to be manufactured or formulated in an establishment known, acceptable and approved by the Agency. Application for the registration of pesticide.

(2) Application for pesticide registration shall be made by filing an application and supported with relevant documents in such form as the Agency may, from time to time prescribe.

(3) Each application for registration shall be accompanied with a non-refundable fees prescribed by the Agency from time to time.

B 3286

Effective assessment of a new pesticide formulation.

5.—(1) Efficacy assessment of a new pesticide to be introduced into the market shall be carried out to ensure that the pesticide meets market demand.

(2) The assessment shall be carried out for two (2) cropping seasons or as may be prescribed by the Agency.

(3) The assessment shall be conducted in two (2) different agro-ecological zones or as may be prescribed by the Agency.

(4) The assessment shall be monitored by a research institute approved by the Agency.

Submission of application.

6.—(1) Every completed application for the registration of a new pesticides product shall be submitted with the following and any other document as may be required by the Agency—

(a) original certificate of analysis of the pesticide product ;

(b) certificate of manufacture and free sale of pesticide product from the statutory body responsible for the safety of the product in the country of origin, if imported ;

(c) radioactive test certificate on the new pesticide product ;

(d) Power of Attorney or an agreement duly notarised in the country of origin from the manufacturer to register the pesticide product in Nigeria, if it is an imported pesticide ;

(e) specimen label of the new pesticide product ; and

(f) evidence of any special labeling claims on the character, quality and safety of the new pesticide product.

(2) An applicant shall ensure that all documents submitted to the Agency in respect of registration of new pesticide product are valid and genuine.

(3) Product chemistry of the new pesticide product to be submitted to the Agency shall include the following—

(a) the product composition, normal concentration, physical and chemical characteristics ; and

(b) standard laboratory analytical methods for each active ingredient, impurity or inert ingredient that is toxicologically significant.

(4) Other studies conducted in respect of the new pesticide product shall include—

(a) environmental fate ;

(b) degradation ;

(c) metabolism in plants and animals ;

(d) mobility, that is, the stability thereof ;

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(a) the product composition, normal concentration, physical and chemical characteristics ; and

(b) standard laboratory analytical methods for each active ingredient, impurity or inert ingredient that is toxicologically significant.

(4) Other studies conducted in respect of the new pesticide product shall include—

(a) environmental fate ;

(b) degradation ;

(c) metabolism in plants and animals ;

(d) mobility, that is, the stability thereof ;

- (e) accumulation ;
- (f) hazard to human or domestic animals ;
- (g) toxicity, whether by oral, dermal and inhalation ;
- (h) teratogenicity or reproductive studies ;
- (i) mutagenicity ;
- (j) hazard to non-target organisms including birds and fishes ;
- (k) product performance including efficacy trials in Nigeria ; and
- (l) any other requirement as may be prescribed by the Agency.

7. The applicant shall state the residue level for the pesticide in all its intended usage in the country and this will be compared with the tolerance level as may be determined by the Agency.

Residue level.

8. The instructions for use of the pesticide product shall include—

The use of pesticide product.

- (a) dosage and direction for use ;
- (b) fields of application ;
- (c) methods of application ;
- (d) targeted pest ;
- (e) re-entry period ;
- (f) pre-harvest period ; and
- (g) target crop.

9.—(1) All pesticides shall be legibly labelled in English language and may include any other language.

Labelling information.

(2) All pesticide labels shall be as approved by the Agency.

(3) All information required to be indicated on the label shall be prominent, and distinct.

(4) Labelling shall be informative, accurate and shall not be false or misleading.

(5) Labelling of pesticides shall be in accordance with the Agency's Labelling requirement.

(6) The label of a pesticide shall conspicuously specify the name and manufacturer, location address and the name of the Certificate of Registration Holder.

10. All Pesticides shall be clearly labelled with the following precautionary statements—

Precautionary statement.

(a) a statement directing the user to read the label, this statement shall be in the following form "READ THE LABEL BEFORE USE" ;

- (b) this Pesticide is not to be ingested ;
- (c) a person shall wear appropriate personal protective equipment while handling this pesticide ;
- (d) this pesticide should be kept out of reach of children ; and
- (e) other warning or cautions and hazard statements.

Issuance of Certificate of Registration.

11.—(1) Where the Agency considers the application to be satisfactory and having met all the requirements prescribed by the Agency for registration, the product shall be issued with a Certificate of Registration.

(2) Where the application for registration is unsatisfactory, the applicant shall be informed in writing, stating all the reasons for non-registration.

Validity of Registration.

12.—(1) A pesticide registration shall be valid for 5 years from the date of registration or as may be prescribed by the Agency.

(2) The Agency may suspend or revoke a certificate of registration issued to an applicant, where it discovers that—

(a) the quality, safety and efficacy as prescribed to be complied with by the Agency in the documentation for registration has not been complied with or grounds on which the pesticide was registered were later found to be false or incomplete ;

(b) new information has become available to the Agency, which portrays the pesticide as unsafe, dangerous or ineffective ;

(c) the premises on which or on part of which, the pesticide is manufactured, packaged or stored by or on behalf of the holder of the certificate of registration are unsuitable for the manufacturing, packaging or storage of the pesticide ;

(d) the Holder of Certificate of Registration has given notice to the Agency in writing of the intention to suspend the product registration for a period not exceeding 5 years ;

(e) there are adverse effect on non-targeted animal or plant ; and

(f) any other reason as may be deemed fit by the Agency.

(3) A person whose certificate of registration has been suspended under these Regulations, shall give a notice to the Agency in writing of any intention to reintroduce the product registration and the notice shall—

(a) state the reason for reintroduction ;

(b) be accompanied with prescribed fees for the renewal of the Certificate of Registration ;

(c) be accompanied with copies of the current label for the pesticide ; and

(d) other relevant documents as may be prescribed by the Agency.

13. The Agency shall have power to seal up any premises used or being used in connection with any offence under these Regulations until such time as the product is removed or such time as the commission of such offence ceased or such reasonable time as the Minister may deem fit in the circumstance.

Power to seal.

14.—(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 1 year or to a fine not exceeding N800,000.00 or to both ; and

(b) a body corporate, to a fine not exceeding N5,000,000.00.

(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 ;

(b) partner or officer of the firm ;

(c) trustee of the body corporate concerned ;

(d) any person concerned in the management of the affairs of the body corporate ; or

(e) person who purports to act in a capacity referred to in paragraphs (a) to (d) of this sub-regulation,

is liable to be proceeded against and punished for the offence 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.

15. A person convicted of an offence under these Regulations shall forfeit to the Federal Government—

Forfeiture after conviction.

(a) any 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 instruments used in any manner to commit or to facilitate the commission of the offence.

16.—(1) The Pesticide Registration Regulations 2005 is revoked.

Revocation.

(2) The revocation of the Regulations specified in sub-regulation (1) shall not affect anything done or purported to have been done under the revoked Regulations.

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

Enforcement of these Regulations.

18. In these Regulations—

“Agency” means National Agency for Food and Drug Administration and Control ;

“Advertising” means the publicity of goods and description of all products (which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines, digital and social media, and any other documents) made orally, online or otherwise or by means of projected light and sound recordings ;

“Applicant” means a person who applies for or request for a service from the Agency ;

“Bulk importation” means bringing in of large quantity of product into a country from abroad ;

“Container” means any form of packaging of pesticide for sale as a single item, whether by completely or partially enclosing the pesticide and includes wrappers, which may enclose several units or types of packages when such is offered to the consumer.

“Distribute” means to supply, transport, store or sell ;

“Export” means to take goods from Nigeria to other countries ;

“Formulation” means the combination of various ingredients designed to render the product useful and effective for the purpose intended for the formulation or the form of pesticide as purchased by users ;

“GMP” means Good Manufacturing Practice ;

“Growth Regulator” means any substance or mixture of substances intended through physiological action for accelerating or retarding the growth and development of organisms ;

“Import” means to bring in good from other countries into Nigeria ;

“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 a pesticide ;

“Labelling” means any written, printed or graphic matter that is present on the label, accompanying the pesticide, including that for the purpose of promoting its sale or disposal ;

“Manufacture” means prepare, compound, make the active or other ingredients, to add substances, mix, formulate, package or re-package, label or otherwise treat the active ingredient with a view to its sale, but does not include the carrying on of bona-fide research or experiment relating to a pesticide or doing of an act or thing that forms part of or is incidental to such research or experiment ;

“Pest” means any insect, rodent, bird, fish, mollusc, nematode, fungus, weed, micro-organisms, virus or any other kind of plant or animal life that is injurious to human or animal health, crop, stored produce, processed foods, wood, cloths, fabrics or other inanimate objects ;

“Pesticide” means any chemical substance or mixture of substances intended for preventing, destroying, repelling or mitigating the effect of any pests of plants and animal and shall include herbicides, insecticides, rodenticides, fungicides, molluscicides, nematocides, repellants, attractants, insect growth regulators used in agriculture, public health, horticulture, food storage or a chemical substance used for similar purpose ;

“Proceeds” means any property derived or obtained, directly or indirectly, through the commission of the offence ;

“Residue” means the quantity of pesticides that may remain in food, animal feed and the environment ;

“Sell” includes to offer for sale and to provide pesticide as part of a service of pest control notwithstanding that the pesticide is described as free or included in the service ; and

“Tolerance Level” means the maximum permissible quantity of pesticides that may remain in or on food and animal feed.

19. These Regulations shall be cited as the Pesticide Registration Regulations, 2021. Citation.

MADE at Abuja this 7th day of July, 2021

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health