



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

PESTICIDE REGISTRATION REGULATIONS 2018

**COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS
(ending 29th August, 2018).**

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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 prescribe the minimum requirements for the registration of pesticides intended for importation, exportation, manufacture, distribution, advertisement, sales and use of pesticides.

2. Prohibition.

No pesticide shall 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.

3. Exceptions

- (1) Notwithstanding Regulation 2, a person shall obtain authorization from the Agency for the importation of unregistered pesticides, if the pesticide is:
 - (a) Imported for experimental or research purpose and not for distribution or sale;
 - (b) Importation in the event of national disease outbreak or emergency;
 - (c) Bulk importation for farm use only;
 - (d) Bulk importation of technical grade for the purpose of manufacturing formulated pesticide within the country.

4. Application for the registration of pesticide.

- (1) No person shall submit application for the registration of any pesticide unless such pesticide was manufactured or formulated in an establishment acceptable and approved by the Agency.
- (2) The 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 by a non-refundable fees prescribed by the Agency.

5. Efficacy Assessment for New pesticide formulation:

- (1) Efficacy assessment of a pesticide to be introduced into the market shall be carried out to ensure that pesticide approved would be efficacious for its intended use.
- (2) The assessment shall be for two (2) cropping seasons or as may be prescribed by the Agency.
- (3) The assessment will be conducted in two (2) different agro-ecological zones or as may be prescribed by the Agency.
- (4) The assessment shall be monitored by the Agency at approved research institute(s)

6. Submission of Application

- (1) The completed application for the registration of Pesticides shall be submitted with the following and any other document as prescribed by the Agency:
 - (a) Adequate samples of the pesticide product as determined by the Agency;
 - (b) Original certificate of analysis of the pesticide product;

- (c) 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;
 - (d) Radio-active test certificate where demanded by the Agency;
 - (e) Power of Attorney or an agreement duly notarized in the country of origin from the manufacturer to register the pesticide product in Nigeria if it is an imported pesticide;
 - (f) Specimen labels of the pesticide product; and
 - (g) Evidence of any special labelling claims on the character, quality and safety of the pesticide product.
- (2) No falsified documents for the registration of pesticide shall be submitted by applicant to the Agency.
- (3) Product chemistry of the pesticide to be submitted to the Agency shall be made up of;
- (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 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 any other requirement as prescribed by the Agency:

7. Residue Level:

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.

8. Use of the Pesticide Product

The instructions for use of the pesticide product shall include;

- (1) Dosage and direction for use
- (2) Fields of application;
- (3) Methods of application;
- (4) Target pest;
- (5) Re-entry period;
- (6) Pre-harvest period;
- (7) Target crop.

9. Labelling

- (1) No person shall sell or distribute any imported pesticide unless it is legibly labelled in English and may include any other Nigerian languages.
- (2) No person shall sell or distribute any locally manufactured pesticide unless it is legibly labelled

in English and may include any other relevant language.

- (3) No label shall be used on a pesticide unless it has been approved by the Agency.
- (4) The labelling of pesticides shall be in accordance with the Agency's Labelling information

10. Issuance of certificate of registration

- (1) Where the Agency is satisfied with the application 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 with reasons in writing.

11. Validity of Registration

- (1) A pesticide registration shall be valid for five (5) years from the date of registration or as prescribed by the Agency.
- (2) The Agency may suspend or revoke a certificate of registration issued to an applicant if:
 - (a) The standard of quality, safety and efficacy as prescribed in the documentation for registration is not being complied with or the 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 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 Certificate of Registration Holder has given a notice to the Agency in writing of any intentions to suspend product registration for a period not exceeding 5 years.
 - (e) There is any adverse effect on non-target animal or plant.
 - (f) Any other reason as 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) Give reasons for reintroduction,
 - (b) Be accompanied by a prescribed fees for the renewal of a Certificate of Registration.
 - (c) Be accompanied by copies of the current label for the pesticide.
 - (d) Relevant documents as may be prescribed by the Agency
- (4) No person to whom a certificate of registration has been issued under these Regulations shall lend, hire, sell, transfer or otherwise dispose of the certificate of registration to any other person without the approval of the Agency.

12. Application for dealership license:

A person who deals in the importation, exportation, manufacture, distribution and sales of pesticide shall apply to the Agency for Listing Certificate to be recognized as a marketers/distributors.

13. Good Manufacturing Practice (GMP) Inspection

The Agency shall undertake GMP inspection(s) of an establishment(s) for the purpose of registration of pesticide.

14. **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 50,000 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.

15. **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.

16. **Interpretations**

For the purpose of these Regulations, unless the context otherwise requires:

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

'Advertising' means the promotion of the sale and use of pesticides by print or electronic media, signs, displays, gifts, demonstration or word of mouth;

'Applicant' means a person who applies for or request for a service;

"Bulk importation" means bringing in of large size products /goods into a country from abroad;

"Container" means any object used to hold a pesticide product

"Dealer" means any person who imports, exports, manufactures, distributes, advertises or sells pesticides;

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

“Export” bring (goods or services) into the a country from abroad for sale;

“Formulation” means the combination of various ingredients designed to render the product useful and effective for the purpose claimed, 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 and labelling” means the written, printed or graphic matter on, or attached to, the pesticide or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide.

“Manufacture” means to do any of the following-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, molluscides, nematocides, repellants, attractants, insect growth regulators used in agriculture, public health, horticulture, food storage or a chemical substance used for similar purpose;

"Residue" means the amount of pesticides that may remain on 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;

"Tolerance Level" means the maximum permissible amount of pesticides that may remain in or on food and animal feed.

17. Repeal

- (a) The Pesticide Registration Regulations 2005 is hereby repealed.
- (b) The repeal of these Regulations specified in Regulations 17(1) shall not affect anything done or purported to be done under the repealed Regulations

18. Citation

These Regulations may be cited as the Pesticide Registration Regulations 2018.

MADE at Abuja thisday of.....2005

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**Inuwa Abdulkadir Esq
Chairman Governing Council**

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