

S. I. of 2005

**DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC.)
ACT 1996 (AS AMENDED)**

Pesticide Registration Regulations 2005

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Section 8 of the Drugs and Related Products (Registration, Etc.) Act 1996, as amended, 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 Honourable Minister of Health hereby makes the following Regulations:-

Prohibition.

1. As from the commencement of these Regulations:-
 - (i) No pesticide shall be manufactured, formulated, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of these Regulations.

***Application for the
registration of
pesticide.***

2.
 - (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 on a prescribed application form obtainable from the Agency.
 - (3) Each application form for the registration shall be accompanied by a non-refundable fee as prescribed by the agency.

***Submission of
Application.***

3.

The completed application form shall be submitted with the following:

- (1)
 - (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) an undertaking in writing that every advertisement of the pesticide shall be submitted to the Agency for approval before publication;
 - (g) specimen labels of the pesticide product; and
 - (h) evidence of any special labelling claims on the character, quality and safety of the pesticide product.

- (2) No person shall submit false notarized declaration to the Agency for the purposes of registration of any pesticide product.
- (3) Product Chemistry.
 - (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:

The studies conducted in respect of 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) hazards to human or domestic animals;
 - (g) toxicity whether by oral, dermal and/or inhalation;
 - (h) teratogenicity or reproductive studies;
 - (i) mutagenicity;
 - (j) hazard to non target organisms including birds and fishes; and
 - (k) product performance including efficacy trials in Nigeria.

(5) Residue Level:

Company should 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.

(6) Use of the Pesticide Product:

- (a) dosage and direction for use;
- (b) fields of application; and
- (c) methods of application shall be stated.

(7) Storage conditions:

- (a) method of disposal of containers;
- (b) precautions including First Aid; and
- (c) note to physician shall be stated.

***Issuance of
certificate of
registration.***

4. (1) Where the Agency is satisfied with the submissions in respect of the pesticide, the product shall be issued with a Registration Certificate.

(2) Where the submissions are unsatisfactory, the applicant shall be informed with reasons in writing.

***Repeal of 1996
Regulations .***

- 5 (1). The Pesticide Registration Regulations 1996 is hereby repealed.

- (2) The repeal of these Regulations specified in sub-regulation (1) of this regulation shall not affect anything done or purported to be done under the repealed Regulations

Penalty

6(1) A 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 ₦100,000.
- (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals :-
- (a) every director, manager, secretary or other similar officer of the body corporate; or
 - (b) every partner or officer of the firm or
 - (c) every trustee of the body concerned ;or
 - (d) every person concerned in the management of the affairs of the association ;or
 - (e) every 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.

Forfeiture

7. In addition to the penalty specified in regulation 6.of these regulations, a person convicted of an offence

under these regulations shall forfeit to the Agency the pesticide and whatsoever is used in connection with the commission of the offence.

Interpretations 8. For the purpose of these Regulations, unless the context otherwise requires:

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

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

"Pest" means any insect, rodent, nematode, fungus, weed or any other form of plant or animal or virus or bacteria or other microorganisms as determined by the Agency;

"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; and

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

Citation

9. These Regulations may be cited as the Pesticide Registration Regulations 2005.

MADE at Abuja this

day of

2005

DR. ANDEM NYONG ANDEM
Chairman Governing Council
National Agency for Food and Drug Administration
and Control (NAFDAC)