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

DRAFT

Fertilizer Registration Regulations 2014
NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL
(NAFDAC)

FERTILIZERS REGISTRATION REGULATIONS 2014

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 National Agency for Food and Drug Administration and Control Cap N1 Laws of Federation of Nigeria 2004 and 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:-

Scope
1. These Regulations prescribed minimum requirements for importation, exportation, manufacture, advertisement, distribution, sale and use of fertilizers in Nigeria.

Prohibition
2. (1) Except as provided in these Regulations no fertilizer shall be manufactured, imported, exported, advertised, distributed, sold or used unless approval has been granted as appropriate in accordance with the provisions of these Regulations.

(2) Notwithstanding the provisions of subsection (1) of these Regulations, the manufacture, formulation or importation of a fertilizer as sample for the purpose of registration, field trial or research shall be undertaken with the approval of the Agency.

(3) No person shall be involved in the sale or distribution of fertilizers in units other than the packages in which it has been originally contained, wrapped or packaged.

Classification of Fertilizers
3. Fertilizers shall be classified as appropriate based on their:
   1. Composition as:
      (a) Straight fertilizers
      (b) Complex fertilizers
      (c) Mixed fertilizers
   2. Physical form as:
      (a) Solid, in form of:
         i. Powder,
         ii. Crystals,
         iii. Prills,
         iv. Granules
         v. Super granules, and
         vi. Briquette.
      (b) Liquid.
3. Nutrients content as:
   (a) Nitrogenous fertilizers either:
       i. Ammoniacal,
       ii. Nitrate,
       iii. Ammoniacal and nitrate,
       iv. Amide.
   (c) Phosphate fertilizers,
   (d) Potassium fertilizers, and
   (e) Complex fertilizers.

4. Origin,
   (a) Organic fertilizers
   (b) Inorganic fertilizers

Application for Registration
4. (1) No person shall manufacture or formulate any fertilizer unless it has been registered in accordance with the provisions of these Regulations.

   (2) The application for fertilizer registration shall be made on a prescribed application form obtainable from the Agency.

   (3) Each application for registration shall be accompanied with a non-refundable fee as the Agency may, from time to time prescribe.

Submission of Application
5. (1) Application for the registration of fertilizers shall be submitted with the following:
   (a) Power of Attorney or a contract manufacturing agreement between the manufacturer and the applicant duly notarized in the country of origin to register the fertilizer in Nigeria.
   (b) Certificate of manufacture and free sale of the fertilizer from the statutory body responsible for the safety of the fertilizers in the country of origin.
   (c) Company’s certificate of incorporation in Nigeria.
   (d) Evidence of trade mark registration
   (e) Original certificate of analysis of the fertilizer.
   (f) Field trial report of trials conducted in Nigeria by an approved research institute in more than 2 agro ecological zones for 2 cropping seasons to determine the biological efficacy and effectiveness of the fertilizers
   (g) The percentage composition of the active ingredient(s).
   (h) Evidence of substantiation of any special labeling claims on the character, quality and safety of the fertilizer.
   (i) Invitation letter for Good Manufacturing Practice (GMP) inspection from oversea manufacturers; or
   (j) Application letter for inspection of local production facility for fertilizers manufactured in Nigeria.
(k) A notarized declaration as prescribed by the Agency.
(l) Specimen labels of the fertilizer.
(m) Adequate samples of the fertilizer as determined by the Agency.
(n) Dossier in the format prescribed by the Agency.
(o) Safety Data Sheet (SDS) that contains the following information:
   i. Identification of the Materials and Supplier.
   ii. Hazard identification.
   iii. Composition/information on ingredients.
   iv. First aid measures.
   v. Fire fighting measures.
   vi. Health Hazard Data.
   vii. Stability and reactivity.
   viii. Spills or Leak procedures.
   ix. Physical and chemical properties.
   x. Toxicological information
   xi. Ecological information
   xii. Transport information
   xiii. Handling and storage condition
   xv. Exposure control
   xvi. Personal Protection Equipment.

(2) No person shall submit false notarized declaration to the Agency for the purpose of registration of a fertilizer.

Establishment inspection
6. The Agency shall undertake the inspection of an establishment for the purpose of registration of a fertilizer

Labeling
7. The labeling of fertilizer shall be legible, in English Language and shall include the 3 major Nigerian languages and in accordance with the Fertilizer Labelling Regulations 2014.

Issuance of certificate of registration
8. (1) The Agency may approve an application for the registration of a fertilizer if:
   (a) The application contains the information required under these Regulations.
   (b) The fertilizer contains ingredients that have been previously assessed or evaluated in accordance with these Regulations and meets the requirement of registration under these Regulations.
   (c) Premises where the fertilizer is to be stored, manufactured, warehoused or sold have been found suitable by the Agency.
(2) Where the Agency is satisfied with the application for registration and receives satisfactory field trial reports in respect of the fertilizer, the fertilizer shall be issued with a certificate of registration.

(3) Where the application for registration or field trial reports or both are unsatisfactory, the applicant shall be informed in writing with reasons.

Validity of Registration
9. The certificate of registration shall be valid for a period of 5 years from the date of issue.

Invalidation of Certificate of Registration
10. (1) The Agency shall suspend, withdraw or cancel the certificate of registration of a fertilizer if:
   (a) The grounds on which the fertilizer was registered were later found to be false or incomplete; or
   (b) The circumstances under which the fertilizer was registered no longer exist; or
   (c) Any of the conditions or undertaking under which the fertilizer was registered has been contravened; or
   (d) Standard of quality, safety and efficacy as prescribed in the documentation for registration are not being complied with; or
   (e) The premises in which the fertilizer is imported, manufactured, packaged or stored by or on behalf of the holder of the certificate of registration are unsuitable for the import, manufacturing, packaging or storage of the fertilizer; or
   (f) New information has become available to the Agency which renders the fertilizer unsafe or dangerous or ineffective; or
   (g) The holder of a certificate of registration notifies the Agency in writing of his intentions to stop the manufacture, importation, distribution, or sale of the fertilizer; or
   (h) There is any adverse effect on non-target animal or plant.

(2) A person whose certificate of registration has been suspended for a particular fertilizer, shall desist from dealing in that fertilizer in any manner until:
   (a) The reason for the suspension is determined and resolved.
   (b) Approval is given by the Agency to resume operations.

Demand for evidence of registration
11. A manufacturer or importer of a fertilizer shall be required to produce within forty eight hours the evidence of registration in respect of the fertilizer manufactured or imported by him or by any person duly authorized by the Agency.
Advertisement
12. No advertisement shall be published, screened or broadcast without prior approval of the Agency in accordance with the Fertilizer Advertisement Regulations 2014.

Packaging
13. (1) Every package for a fertilizer shall be approved by the Agency.

(2) The package of a fertilizer shall be designed to
   (i) Maintain the integrity of the fertilizer under normal conditions of storage, display and distribution.
   (ii) Permit the withdrawal of some or all of the contents in a manner that is safe to the user.
   (iii) Permit the closing of the package in a manner that prevents the spillage of the fertilizer under normal handling conditions.
   (iv) Minimize the degradation or change of its contents under normal storage conditions.

Storage/Distribution:
14. (1) A fertilizer shall be stored and displayed in accordance with conditions stated on the label.

   (2) A fertilizer shall not be stored or displayed with human food or animal feed.

Mandatory reports
15. (1) A manufacturer or importer of fertilizers shall keep records of distribution and submit mandatory reports to the Agency annually indicating the names and addresses of companies supplied as well as the quantities supplied.

   (2) Any establishment engaged in the manufacture, importation, distribution, sale or storage of fertilizers shall submit preliminary and final reports to the Agency of any adverse effect on non-target animals or plants and loss of effectiveness associated with fertilizers occurring in Nigeria or elsewhere.

Disposal
16. Disposal of any expired, degraded or obsolete fertilizers shall be carried out by the competent authority in the presence of staff of the Agency.

Penalty
16. (1) Any person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction:
   (a) In case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding ₦50,000 or both fine and imprisonment: and
   (b) In case of a body corporate, to a fine not exceeding ₦100, 000.

   (2) Where an offence under these regulations is committed by a body corporate or firm or
other association of individuals:
(a) Every director, manager or other similar officer of the 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 this Regulation, are severally guilty of what offence and liable to be proceeded against and punished for that offence in the same manner as if they had themselves committed the offence unless they prove that the act or omission constituting the offence took place without their knowledge, consent or connivance.

Forfeiture
17. In addition to the penalty specified in Regulation 16 above of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the fertilizer and whatsoever is used in connection with the commission of the offence.

Interpretation
18. In these regulations, unless the context otherwise requires,

“Accredited Research Institute”: means an approved standard establishment endowed for research.

“Agency” means the National Agency for food and Drug Administration and Control (NAFDAC).

"Certificate of analysis" means a certificate issued by an analyst certified for the relevant analysis, indicating the full chemical and physical composition for the particular fertilizer and its maximum levels of potentially harmful elements permitted in the fertilizer.

“Complex fertilizer”: means fertilizers that contain 2 or 3 primary nutrients of which 2 primary nutrients are in chemical combination and are usually produced in granular form.

"Container" means the packaging in which a measured amount of a fertilizer is offered for sale;

“Competent Authority” means Government agency or statutory authority.

“Field trial” means a scientific evaluation conducted by an approved research institution on a fertilizer in accordance with direction specified for the use of that fertilizer, to ascertain and establish the claims made on the label.

“Field trial centre” means a location approved for the field trial of a fertilizer.
“Fertilizer” means any substance which is intended or offered to be used for improving or maintaining the growth of plants or the productivity of the soil;

“Inorganic fertilizer” means a chemical product, of either mineral or synthetic origin generally composed of simply, mostly water soluble nutrients such as nitrogen, potassium and phosphorus that are immediately available for plant use following application.

"Label" means any writing, printed or graphic matter relating to, and accompanying the fertilizer.

'Mixed Fertilizer' means a physical mixture of two chemically compounded fertilizers or organic fertilizers that contain one or more of the plant nutrients such as nitrogen (N), phosphorus (P) and potassium (K).

“Organic fertilizers” means fertilizers manufactured from substances of animal or plant origin or a mixture of such substances.

“Original package” means fertilizer package with it labeling information together submitted to NAFDAC for vetting and subsequent Market Authorization.

“Package” means any suitable container in which a fertilizer is wholly or partly placed or packed.

'Plant nutrient' means an essential macro or micro element present in a fertilizer;

“Straight fertilizers” means fertilizers which supply only one primary plant nutrient, namely nitrogen or phosphorus or potassium.

Citation
20. These Regulations may be cited as Fertilizers Registration Regulations 2014.