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

EXPORT REGULATIONS 2024

Comments are welcomed from Stakeholders (ending 31st January 2024)
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EXPORT REGULATIONS 2024

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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (CAP N1 LFN 2004)

Export Regulations 2024

[ ] **Commencement**

In exercise of the powers conferred on it by National Agency for Food and Drug Administration and Control by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap N1 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. **Application**

These Regulations shall apply to:

(a) regulated product; food, drug, cosmetic, medical device, packaged, water, and chemical for export and related matter.

(b) stakeholder in the business of exportation of the Agency's regulated products.

2. **Authorization**

An exporter of regulated product shall include:

(a) corporate body; government, public and private sector actors.

(b) Micro, Small and Medium Enterprise (MSME).

(c) individual farmer or group of farmers

(d) Holder of Certification of Registration or persons so authorized.

3. **Application for export**

Application for export of regulated product shall be made by submitting a complete application form, accompanied by relevant documents as the Agency may, from time to time, prescribe and shall -

(a) contain the particulars and description of the relevant product, in respect of which the application is made; and

(b) be accompanied by such fee as the Agency may, from time to time, prescribe.

4. **Inspection**

(1) The Agency shall

(a) inspect facilities for product to be exported where applicable.

(b) conduct pre-shipment examination of consignment intended for export.

(2) The Agency shall review documents as specified in regulation 3 of these Regulations for conformance.

5. **Organization and Personnel**

An exporter of regulated product shall have

(a) relevant organizational structure that defines authority and responsibility.

(b) adequate number of staff with requisite education, training and experience or any combination thereof.

(c) quality system in place to maintain the requirements for the product for export.

6. **Location, Design and Construction of Buildings and Facilities**

Location for the receipt, storage, holding, handling, and transporting of product for export shall be adequately located, constructed, and of suitable and in conformance with the Agency's Regulations and requirements.

7. **Documentation.**

(1) Record Keeping

(a) Exporters of regulated products shall establish and maintain records of export transactions.

(b) Record shall include:

(i) name and address of all the suppliers including farms from which the product is produced or shipped.

(ii) identity, quality and quantity of regulated products received and exported.

(iii) dates and time of receipt and exportation of the regulated products.

(iv) any other document as the Agency may deem fit.

(c) Record shall be retained for a minimum of five (5) years and made available for inspection by the Agency as may be required.

(2) Records Shall:

(a)Be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection or

(b) if kept at a central location and not electronically retrievable at the inspection site be made available for the inspection within 48 hours of request by the Agency.

(3) Exporter shall have Standard Operating Procedure (SOP) for activities related to export of regulated product.

8. **Storage Conditions**

Products intended for export shall be stored under specified and appropriate storage conditions.

9. **Returned damaged and expired regulated products exported**

(a) Exporter shall maintain and follow a written procedure to ensure the proper handling and disposal of Returned damaged and expired regulated products exported

(b) When condition under which exported products have been returned cast doubt on the safety, identity, strength, quality or purity, then the product shall be destroyed as prescribed by the Agency, unless examination and appropriate quality control test proves that the returned products meet appropriate specification for safety, quality and efficacy as may be applicable.

(c) In investigating the conditions which cast doubt on the safety, identity, strength, quality or purity of returned regulated products especially pharmaceuticals, the exporter shall consider among others, the condition under which the product has been held, stored or shipped before or during its return and the condition of the product and container or labelling, storage or shipping.

10. **Vehicle and equipment**

(a) Vehicle, container and equipment used in conveying regulated products for export shall be suitable and appropriately to maintain its integrity, identity and safety.

(b) Monitoring equipment shall be qualified, validated or calibrated (where applicable).

11. **Shipment packaging, container, and labelling.**

(a) Regulated product intended for export shall be conveyed in shipment packaging and container which shall not impact negatively on the on the quality, safety and aesthetic value of the product.

(b) Abbreviation, name and code used for labelling container shall be internationally and nationally accepted.

12. **Recalls**
    (a) Exporter of regulated product shall maintain and follow a written procedure for handling recalls and withdrawal of products.
    (b) The policy shall comply with the Agency's extant Recall, Handling And Disposal Of Substandard And Falsified Medicinal Products Regulations, and other requirements as may be specified by the Agency.

13. **Issuance of Certificate**
    (a) Where the Agency considers the application for export to be satisfactory and having met all the requirements prescribed by the Agency for exportation, the applicant shall be issued with appropriate certificate.
    (b) Where the application for export is unsatisfactory, the applicant shall be informed in writing, stating the reasons for non-issuance of the applicable certificate.

14. **Power to seal**
    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 Animal Feed Premix is removed or such reasonable time as the Minister may determine.

15. **Prohibition**
    (a) A person shall not export any regulated products unless it is in compliance with the provisions of these Regulations and other requirements of the Agency.
    (b) A person shall not export any regulated product that is on the Federal Government Prohibition list.

16. **Offences and Penalties**
    (1) Any person who contravenes any of the provisions of these Regulations commits an offence and shall be liable on conviction, in the case of:
        (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 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 sub-regulation,
    commits an offence and liable to be proceeded against and punished 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.

17. **Forfeiture after conviction**

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.

18. **Enforcement of these Regulations.**

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

19. **Interpretations**

In these Regulations, unless the context otherwise requires the following terms shall have the meanings specified.

Agency means the National Agency for Food and Drug Administration and Control (NAFDAC);

Batch number or Lot number means the number or a combination of numbers and letters specifically given to product which is linked to the manufacturing history of the product.

Cosmetic product means any substance or mixture of substances intended to be rubbed, poured, sprinkled or sprayed, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the complexion, skin, hair or teeth and includes deodorants and detergent powder**.**

"Drug" includes any substance of vegetable, animal or mineral origin, or any preparation or admixture thereof manufactured, sold or advertised for use in-

(a) the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal;

(b) restoring, correcting or modifying organic functions in man or in animal;

(c) disinfection or the control of vermin, insects or pests; or

(d) contraception;

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, impressed on, or attached to the packaging or the container of animal feed premix;.

"Labelling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying the product.

Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption , and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs;

"**Medical device**" means any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis,

treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal.

Medical device' also means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals, for one or more of the specific medical purpose of:

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
(c) investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life,
(d) control of conception,
(e) disinfection of medical devices,
(f) providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Facilities means buildings, pieces of equipment, or services that are provided for a particular purpose

Stakeholder means government at all levels, public and private exporter whether as big-time exporting business or as Micro, Small and Medium Enterprises (MSMEs), manufacturer, importer, distributor, wholesaler, supplier, retailer, freighters, forwarding agents and transporters.

20. **Citation**

These Regulations shall be cited as Export Regulations, 2024.

MADE at Abuja this ……day of ..... 2024.

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Chairman of the Governing Council
National Agency for Food and Drug Administration and Control
(NAFDAC)