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

PORTS INSPECTION DIRECTORATE

GUIDELINES FOR EXPORTATION OF FOOD, DRUG, COSMETICS AND MEDICAL DEVICES

NAFDAC/PID/EXP/FCMD/2018/00

1. GENERAL

1.1 These guidelines are for the interest of the general public and in particular exporters of Food(Registered Food Product, Processed & Semi Processed Food Commodities), Cosmetics, Drugs, and Medical Devices.

1.2 It is necessary to emphasize that, no Food, Cosmetics, Drugs and MedicalDevices shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provision of Act Cap N1 LFN 2004 (Formerly decree 15 of 1993) and the accompanying guidelines.

1.3 NAFDAC does not take responsibility for the mode of transportation of the product and other related risks associated with it.

1.4 NAFDAC will not issue any certificate to export product that has already left the shores of the country.

2. DOCUMENTATION

Applicants intending to export Food, Cosmetics, Drugs and Medical Devices shall submit the following:

2.1 An application letter by the company written on company's letter head addressed to the:

Director-General,
National Agency for Food and Drug Administration and Control (NAFDAC),
Plot 2032 Olusegun Obasanjo Way,
Wuse Zone 7,
FCT,
Abuja.

And **Attention:**
The Director
Ports Inspection Directorate,
NAFDAC Complex,
Yaba, Lagos State.

Or

The Directors (NEZ, NWZ, NCZ, SSZ, SEZ, SWZ)
NAFDAC, (In the Appropriate Geographical Zones)

2.2 The application shall indicate the following:

- **2.2.1** Full Name and Address of Manufacturer's warehouse. Or Manufacturing Facility
- **2.2.2** Product intended for Export
- **2.2.3** Quantity
- **2.2.4** Pack size
- **2.2.5** Batch number
- **2.2.6** Manufacturing Date and Expiry or Best Before Date(Date markings)
- **2.2.7** Destination of intended Export
- **2.2.8** Reason for Export (Where applicable)
- **2.2.9** Consignee's name and address
- **2.2.10** Valid Phone Number of the Applicant

2.3 Accompanying Documents: For Registered Regulated Products (**Drugs, Food, Cosmetics, Medical Devices, Agrochemicals, Animal Food and Animal Feed**) the applicant shall submit the following: together with the Application Letter

- **2.3.1** Product Registration license issued by NAFDAC (Where applicable)
- **2.3.2** Factory cGMP Certificate or GHP
- **2.3.3** NXP forms for commercial export
- **2.3.4** Copy of registration with Nigeria Export Promotion Council
- **2.3.5** Profoma invoice
- **2.3.6** Packing list
- **2.3.7** Sample of product to be exported
- **2.3.8** Original copy of Certificate of Analysis (**For Registered Products**)
- **2.3.9** Letter of '**No Objection'** for 3rd party exporters
- **2.3.10** Importation documents endorsed by NAFDAC (**For CFS)**
- **2.3.11** Quality Specification by importing countries
- **2.3.12** An endorsed copy of the International passport indicating the exporters'/Representatives' approval to travel to the designated country with the data page. (**For Export Approval for Personal Effects**)

2.4 Accompanying Document for Processed and Semi-Processed:

For Processed and Semi Processed food commodities, in addition to **2.2** and **2.3** above listed documents, the applicant shall present the photocopies of the following:

2.4.1 Phytosanitary Certificate from Nigeria Agricultural Quarantine

Services (NAQS).

3. **INSPECTION:**

Inspection is a key element of Certification. It is the physical auditing of the systems, equipments, documents, personnel and building of manufacturing or warehousing facilities as the case may be. There are different types of inspections. These includes but not limited to the following:

- CGMP Inspection
- GHP Inspection
- GAP Inspection
- Surveillance Inspection
- Investigative Inspection

3.1 The choice of Inspection will depend on the product involved and the procedure and processes involved. Sometimes, the Inspection may involve a combination of the categories listed above

3.2 On receipt of application, inspection is conducted by the Agency at the company's warehouse and sample of the products are drawn for laboratory analysis.However, finished registered products whose CGMP has expired will need an inspection of the facilities for renewal of the GMP. The systems to be accessed in case of establishment auditing are as follows:

- The building to include the structural architecture, flooring and plumbing.
- Personnel
- Equipment & Facility
- Raw materials and their Processing
- Source of water supply and purification system where applicable
- Documentation.

4. **Laboratory Acess/ Analysis:**

In order to ensure, that products for export are safe and of desirable quality, a specified samples of the products are sent to NAFDAC laboratories in Yaba or Oshodi

depending upon the product line; Food product for Oshodi Laboratory while Drugs, Cosmetics and Medical Devices are sent to Yaba Laboratory for analysis and appropriate pronouncement on the quality of the products.

It suffices to state here, that for all analyses for export purposes, apart from full compendia or validated in house analysis required for the product in question, it is necessary that analyses such as listed below be carried out by NAFDAC.

Examples of tests (by NAFDAC) for food products

Food	Test
Garri	Cyanogenic glycoside
	Pesticide residue
	Storage organism – mycotoxin test

5. **CERTIFICATION/ISSUANCE OF EXPORT CERTIFICATES:**

After the appropriate Laboratory analysis and pronouncement on the safety and quality of the product, coupled with satisfactory inspection, the product for export is certified and the appropriate export certificate is issued as an evidence of certification.Depending on the product to be exported, route of transport, use and source of the product, a **Combined Certificate of Manufacture and Free Sale (CCMFS), Certificate of Free Sale (CFS), Certificate of Pharmaceutical Product (COPP), Export Permit, export Certificate or Health Certificate** will be issued by NAFDAC if the report of inspection and result of the Laboratory analysis are satisfactory as well as other documents as spelt out in section 2.

- **5.1 COPP:** Certificate of pharmaceutical products for Registered Drugs
- **5.2 CCMFS:** Combined Certificate of Manufacture & Free Sales for Registered Products (Food, Cosmetics, Medical Devices, Agrochemicals, Animal Food, Animal Feed)
- **5.3 HEALTH CERTIFACATE:** For Processed and Semi-Processed Food Products
- **5.4 EXPORT CERTIFICATE**: For Products Exported through the Land Borders to Ecowas Countries
- **5.5 EXPORT CLEARANCE/PERMIT:** For Regulated Product Samples for MachineTrials Prior to Import of Machine,
- **5.6 EXPORT APPROVAL:** For Personal Effects (10kg maximum for a single product and 30kg maximum for various products)

6. **TARIFF:** As determined by the Inspection Directorate .

7. TIME LINES:

S/N	PROCESS	TIMELINE
7.1	Assessment of Documents & vetting of Sample	**one working day**
7.2	Request for Physical Inspection	**Within 48hours of application**
7.3	Perishable products	**ASAP**
7.4	Warehouse Inspection	**5 working days**
7.5	Laboratory Analysis	**2 weeks**
7.6	Issuance of Export Certificate for Registered Products	**Maximum of Five working days from the date of submission**
7.7	Issuance of Health Certificate after receiving Satisfactory Report of Inspection and Laboratory Analysis	**2 days maximum**
	Total Number of Working Days	**28 Working Days or 6 Weeks**

NOTE: ***the processing clock stop when there is Compliance Directive (Query) and resumes when applicant complies and communicates the same to the Agency***.

8. CORRESPONDENCE

All correspondence in respect of exportation of regulated products should be addressed to:

The Director,
Ports Inspection Directorate,
NAFDAC Laboratory Complex,
Edmund Crescent,
Medical Compound,
Yaba,
Lagos State.

E-mail Address: ports@nafdac.gov.ng

GLOSSARY

CGMP- Current Good Manufacturing practice.

GHP- Good Hygienic Practice.

GAP- Good Agricultural Practice.

Surveillance Inspection- Inspection carried out as a follow up to GMP Inspection routinely to ensure that the Industries are still keeping up to best practices.

Investigative Inspection- Inspection carried to ascertain or to arrive at the true situation when there is an alert information or complaint about regulatory practices of a particular Industry.

NXP Form-Nigeria Export Proceed Form.

Letter of 'No objection"- is an authorization given by the Marketing Authorization Holder to a third party to import or export its Product(s).