



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

Chemical Evaluation & Research (CER) Directorate

GUIDELINES FOR LISTING OF CHEMICAL MANUFACTURERS IN NIGERIA (NEW APPLICANTS)

1. General

- 1.1. These guidelines are for the interest of the general public and in particular, chemical manufacturers in Nigeria intending to be listed as a chemical manufacturer.
- 1.2. The document aims to explain in simple terms the obligations on documentation, personnel requirement, safety standard and provides useful specification with requirements on how to be listed as manufacturer.

Step 1

2. Application

- 2.1 An applicant intending to manufacture chemicals in Nigeria shall submit a duly completed application form for listing of chemical manufacturers. The application should be signed by either the Managing Director, Production Manager or Technical Officer.
- 2.2 The form should be submitted with the following documents
 - 2.2.1 A letter requesting for facility inspection in company's letter head addressed to the DIRECTOR-GENERAL(NAFDAC),ATTENTION: Director, Chemical Evaluation & Research (CER), ISOLO, Lagos.
 - 2.2.2 The applicant should indicate the location address of the facility, the name(s) of chemical, its composition and intended uses.
 - 2.2.3 Evidence of Business Incorporation/evidence of Business name.
 - 2.2.4 Evidence of Certified True Copy of Memorandum and Articles of Association.
 - 2.2.5 Evidence of particulars of Directors.
 - 2.2.6 Evidence of NAFDAC Chemical Import Permit (where applicable)
 - 2.2.7 Technical Dossier

The technical dossier is the set of information submitted by an applicant for each substance. It shall contain the following information;

- a) The identity of the manufacturer;
- b) The identity of the substance;
- c) Information on the manufacture and use of the substance;
- d) Product labeling (or art work) with hazards pictogram in line with UN- GHS.
- e) Guidance on its safe use;
- f) Comprehensive certificate of analysis duly endorsed by a Public analyst.
- g) Proposals for further testing, if relevant
- h) Safety Data Sheet (SDS) of the manufactured substance which should have sixteen(16) sub- heading with the following information:
 - i. Identity of product and the company
 - ii. Composition and information on ingredients
 - iii. Hazardous identification
 - iv. First aid measures

- v. Firefighting measures
- vi. Accidental release measures
- vii. Handling and storage
- viii. Exposure control/ personal protection measures
- ix. Physical and chemical properties
- x. Stability and reactivity
- xi. Toxicological information
- xii. Ecological information
- xiii. Disposal consideration
- xiv. Transport Information
- xv. Regulatory information
- xvi. Other Information.

- 2.2.8 Credentials, medical certificate of fitness and letter of appointment/acceptance of key officers [Production Manager, Technical Officer, Safety Officer, Quality Control Officer etc.]
- 2.2.9 The key officers should have a minimum qualification of OND or equivalent in Chemistry/Chemical Engineering or any related science disciplines
- 2.2.10 Two (2) passport photographs of technical officer with name and company written on the back of the passport.
- 2.2.11 Evidence of payment for Listing form, Facility inspection and Listing Certificate.

Step II

3 Review of documents

- 3.1 Upon satisfactory review of the submitted documents, the company shall be scheduled for facility production inspection.

Step III

4 Facility Inspection.

- 4.1 Applicant shall have a manufacturing facility, qualified personnel and safety measures for chemical production.
- 4.2 The facility should be in compliance with Good Manufacturing Practices and in line with Globally Harmonized System on the Classification, Labeling and Packaging of Chemicals.
- 4.3 Routine inspection of the manufacturing facility shall be done periodically by NAFDAC to ascertain compliance

Step IV

5 Issuance of Listing Certificate

5.1 Once the GMP of the factory is adjudged satisfactory, other submitted documents are found to be satisfactory and full payment of prescribed fee. NAFDAC issues a listing manufacturing certificate.

5.2 For unsatisfactory inspection or documentation, a compliance directive is issued.

6 Time Line

A processing period of 30 working days is allowed between the time of submission of completed application and a satisfactory facility inspection for listing to be collected. Note that the timeline for processing is suspended when there is a compliance directive and resumes when applicant complies and communicate compliance to the Agency

7 Note

7.1 Listing certificate is valid for two years from date of issuance.

7.2 The process of renewal of Listing Certificate should commence at least three (3) months before expiration of current Listing Certificate.

8 Definition of terms

8.1 Chemical Substance

Refers as any substance, mixture of substances prepared, element in its pure form or substance in an article sold or represented for domestic or industrial use as raw material, Finished/semi-finished product, **laboratory reagent, industrial chemicals, diagnostic reagent, ink, paint, adhesives, wood preservatives & polishers, cleaning chemicals, agrochemicals, biocides, fertilizers car care chemicals etc.** Or any other substance or mixture of substances which the Agency may after consultation with the council declare to be a chemical substance.

9 Post-Notification Obligations

After notification is completed, certificate holder needs to fulfill different post-notification obligations depending on the management category of the substance.

S/N	Category	Post-notification Obligations
1	All listed chemical substances manufacture in quantities less than 100 tons per year	1. Communicate SDS(Safety Data Sheet) to downstream users; 2. Implement risk management measures 3. Keep documents on file for over 3 years; 4. Do not sell chemicals to downstream users who are not capable of implementing risk management measures; 5. Submit updates if new hazard arises;

		6. Submit report on utilization information;
2	Chemical substances manufacture in quantities greater than 100 tons per year	7. Submit item 1-6 above[Post notification Obligation] 8. Submit annual report on Chemical Safety Assessment ('CSA') to assess the hazards and risks to human health and the environment and to determine how to control them by applying suitable risk management measures

All correspondences should be addressed

Director-General (NAFDAC),

Attn:The Director

Chemical Evaluation and Research (CER) Directorate,

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

1st Floor, NAFDAC Office Complex

Isolo,

Lagos.

NAFDAC website: www.nafdac.gov.ng

E-mail: cer@nafdac.gov.ng,

All submissions should be made at the Office of the Director, CER, first Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or to the nearest NAFDAC Office (for those outside Lagos).