



# OBTAINING NAFDAC APPROVAL FOR CHEMICAL MANUFACTURING IN NIGERIA

Chemical manufacturing is a regulated activity in Nigeria which comes under the purview of the National Agency for Food and Drug Administration and Control (NAFDAC). NAFDAC, through the Chemical Evaluation & Research Directorate, monitors activities relating to the importation, exportation, sales, distribution, as well as manufacturing of chemicals. Therefore, a NAFDAC approval must first be sought and obtained before commencing any form of chemical manufacturing in Nigeria.

A NAFDAC approval for chemical manufacturing is known as a "Listing". Upon compliance with certain regulatory requirements, an applicant is recognized and enlisted as a chemical manufacturer in Nigeria, and issued a Certificate in respect of same. A "Listing as a Chemical Manufacturer" or "Listing Certificate" authorizes a company to carry out any form of chemical manufacturing activity whether dilution, blending or even outright formation of chemicals and allied products.

## CHEMICAL SUBSTANCES

It is important to note that the chemicals covered by the NAFDAC in this regard include 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 and so on. Or any other substance or mixture of substances which NAFDAC may after consultation with its council declare to be a chemical substance.

## COMPLIANCE REQUIREMENTS

To obtain a Listing, there are certain regulatory requirements which must be satisfied. These regulatory obligations largely border on the NAFDAC requirements for proper

documentation, personnel, as well as safety standards to be maintained by an applicant company. In other words, NAFDAC will require an applicant company to present documents showing specific details about the company and its managers, employ personnel who possess adequate knowledge about the use and handling of chemicals, and ensure that health and safety measures are observed on the facility intended for the storage and production of chemicals.

## DOCUMENTATION

A company intending to apply for a Listing as a Chemical Manufacturer must be able to present these documents at NAFDAC:

- An application letter expressing intention to commence chemical manufacturing;
- A letter requesting facility inspection by NAFDAC;
- Evidence of business incorporation;
- Particulars of the company's directors;
- Company's memorandum and Articles of Association;
- List of chemicals to be manufactured, their composition and intended uses;
- Evidence of NAFDAC Import Permit for imported chemicals;
- Comprehensive certificate of analysis by a Public analyst;
- Product labelling with hazard pictogram in line with UN- GHS standards;
- Safety Data Sheet for the chemicals;
- Credentials, medical certificate of fitness and letter of appointment of key personnel such as Production Manager, Technical Officer, Safety Officer, Quality Control Officer and so on.

Please note that the above is not an exhaustive list of all required documentation. There are other equally important documents which must be presented, and besides these, NAFDAC may require an applicant to also submit further documents where it deems fit.

## PERSONNEL

One of the key personnel NAFDAC expect to be in the employ of an applicant is a Technical Officer. The Technical Officer must possess a minimum qualification of an OND or its equivalence in Chemistry or Chemical Engineering or any related science disciplines. The Technical Officer is to liaise between NAFDAC and the applicant company, and provide any clarification NAFDAC may require as regards the chemical production process of the company.

## FACILITY AND SAFETY MEASURES

Although NAFDAC does not itself state any particular specifications for the construction of a facility intended to be used for chemical manufacturing or special safety standards for use and handling of chemicals, such facility must however be in compliance with Good Manufacturing Practices, and must be in line with Globally Harmonized System on the Classification, Labeling and Packaging of Chemicals. To ascertain this, NAFDAC will usually carry out a facility inspection before issuing a Listing.

## LISTING CERTIFICATE

A Listing Certificate is usually issued to an applicant once NAFDAC is satisfied that all compliance requirements have been met, and all regulatory fees have been paid. This certificate is valid for two (2) years, after which the company must commence its renewal at least three (3) months before expiration.

## COMMENTARY

NAFDAC approval for chemical manufacturing in Nigeria is a novel compliance requirement which commenced in 2019, and as such obtaining a Listing may pose to be a rigorous and complicated process for new applicants. It is therefore advisable to seek guidance from compliance experts who possess skills required to navigate this compliance process.

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