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

Food Safety & Applied Nutrition (FSAN) Directorate

GUIDELINES FOR INSPECTION & REQUIREMENTS FOR PRE-PACKAGED FOOD MANUFACTURING/PACKAGING FACILITIES IN NIGERIA

1. **General**

1.1. These Guidelines are for the general public and in particular, manufacturers and **packers** of pre-packaged food in Nigeria.

1.2. It prescribes the minimum Current Good Manufacturing Practice (cGMP) requirements for the facilities and controls to be used in the manufacture or processing of products to ensure that they meet quality standards.

1.3. It is necessary to emphasize that, no food product shall be manufactured, imported, advertised, offered for sale, distributed or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

Step 1

2. **Application**

2.1. An application for Inspection on company's letter headed paper should be made to the Director General, NAFDAC, Attention: The Director, Food Safety and Applied Nutrition (FSAN) Directorate, NAFDAC Office Complex, Isolo, Lagos State.

2.2. The following information should be indicated in the letter;

2.3.1 Exact manufacturing location address (NOT P.O. Box)

2.3.2 Functional e-mail address and telephone number(s).

2.3. The application letter should be accompanied with photocopies of the following documents in the order below;

2.3.1. Label/Packaging materials (Art work could be presented).

2.3.2. Evidence of payment to the Agency

2.3.3. Evidence of Business Incorporation OR evidence of Business name.

2.3.4. Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be done in the name of the owner of the Trademark/Brand name as the case may be.

2.3.5. Contract Manufacturing Agreement (where applicable)

2.3.6. Organogram of the Company with Names and Qualifications of the key officers (e.g. Production Manager, Quality Control Manager).

2.3.7. Appointment and acceptance letters of the technical officer including all credentials (Degree, NYSC certificates, etc.). The technical officer should have scientific background with minimum of Ordinary National Diploma; OND or its equivalent.

2.3.8. Passport photograph of Technical Officer [To be clarified with D(FSAN)

2.4. SOP INDEX (list of SOPs mentioned below, which will be reviewed during inspection of facilities)

2.4.1. Standard Operating Procedure (SOP) for Production.

2.4.2. Standard Operating Procedure (SOP) for Quality Control.

2.4.3. Standard Operating Procedure (SOP) for Cleaning of Factory Premises and Equipment.

2.4.4. Standard Operating Procedure (SOP) for Handling Consumer Complaint.

2.4.5. Standard Operating Procedure (SOP) for Recall and Distribution.

2.4.6. List of Production Facilities and Quality Control equipment and their sources

2.4.7. Production Process flow chart

2.4.8. List of raw materials and their sources

2.4.9. Food Handler's certificate for production staff which should include the following tests: Sputum, Hepatitis B, Widal, Stool, Urinary test and Chest X-ray report (carried out biannually).

2.4.10. Certificate of analysis for raw and treated Water (where applicable).

2.4.11. Certificate of analysis for raw materials and finished products

2.4.12. Current fumigation Certificate of factory (This should be done quarterly)

2.4.13. List of storage facilities outside the manufacturing facilities (for both raw, semi processed and finished products) nationwide

Step II

3. **Vetting of application documents and Payment:**

3.1. The application is reviewed to determine payment to be made.

3.2. Payment Advice for inspection and laboratory analysis is issued by NAFDAC desk officer.

3.3. Visit:

3.3.1. www.remita.netto generate Remita invoice and print out a copy of the invoice.

3.3.2. Any nearest commercial bank for payment.

3.3.3. NAFDAC Account office to collect receipt of payment.

3.4. Attach photocopy of the receipt of payment to the application to be submitted.

Step III

4. **Submission of Application**

4.1. The reviewed application letter, accompanying documents and evidence of payment are submitted at the Liaison office of the Director (LOD), FSAN Directorate, Isolo, Lagos

State or the nearest NAFDAC office in other States.

Step IV

5. **Scheduling of Inspection**

5.1. Upon successful application vetting, the inspection is scheduled by the Directorate.

Step V

6. **Inspection**

6.1. The Inspection is conducted as scheduled. Where the Inspection is unsatisfactory a Compliance Directive is issued and communicated to the company. For satisfactory Inspection, registration samples are taken at the end of the inspection for laboratory analysis while the inspection reports are forwarded to Registration and Regulatory Affairs Directorate for further processing.

7. **Tariff**

7.1. Please refer to Tariff section

8. **Renewal Inspection of Product License**

8.1. An Application letter requesting for Renewal Inspection addressed to the Director General, NAFDAC, Attention: The Director, Food Safety and Applied Nutrition (FSAN) Directorate.

8.2. The letter will be accompanied with the following:

8.2.1. Expired Product License.

8.2.2. Approved Product Label.

8.2.3. NAFDAC Receipt of payment for renewal inspection and laboratory analysis.

8.2.4. The process of Renewal Inspection for Expired NAFDAC Registration License is same as for New Applicants. The difference is in documents submitted as indicated above.

9. **Note**

9.1. Where the facility does not have adequate laboratory equipment to carry out comprehensive analysis of both raw materials and finished products, an accredited Public Analyst should be used for the analysis.

9.2. Adequate documentation of all samples sent to Public Analyst and corresponding

analyses reports should be properly maintained within the factory.

9.3. Please note that the clock stops once compliances are issued.

REQUIREMENTS FOR PRE-PACKAGED FOOD MANUFACTURING/PACKAGING FACILITY IN NIGERIA

1. **Organization and Personnel**

1.1. There should be an adequate organisational structure that clearly defines names and qualifications of key personnel

1.2. There should be adequate number of qualified personnel to perform and supervise the various processes.

1.3. In-house and in-process Quality Control of functions may be carried out by the production manager while comprehensive/detailed product analysis should be performed by a public analyst registered by the Institute of Public Analysts of Nigeria (IPAN).

1.4. There should be adequate general and specific training for employees and should be conducted regularly by qualified individuals.

1.5. The quality control and production units shall be distinct and independent units that function and report directly to the management.

1.6. Personnel should wear clean protective apparels such as hand gloves, head covering, nose and mouth mask to protect products from contamination.

1.7. Personnel should practice good sanitation and hygienic habits. Eating, drinking, chewing and smoking in the production and storage areas should be prohibited.

1.8. All personnel should have access to medical treatment and checks for communicable diseases and the records should be kept.

1.9. Any person shown at any time to have apparent illness or open lesions that may adversely affect the safety or quality of product should be excluded from direct contact with the product until the condition is corrected.

1.10. All personnel should be instructed to report any health conditions that may have adverse effect on the production of the product.

2. **Buildings and Facilities**

2.1. The facility for the production of food products should be purpose-built or suitably adapted to comprise a minimum of four rooms designated as the cloak room, packaging material store, production section and finished product store.

2.2. There should be defined areas of adequate size to accommodate the different operations in a logical order of production flow corresponding to the sequence of the operations. The entire factory premises should be fenced to demarcate it from all other buildings (residential or commercial).

2.3. The factory must not be located near a cemetery, abattoir, quarry, sewage treatment plant, dump site, saw mill, oil depot, cement factory or any other areas that could be a source of contamination for processing, manufacturing, production and packaging of food products.

2.4. The factory should not be constructed from wooden or prefab materials.

2.5. The size must be adequate for its intended use.

2.6. The facility shall be fenced round (at least five feet high) to prevent external interference.

2.7. The building should have adequate space for the orderly placement of equipment and materials to prevent cross contamination between different materials.

2.8. The building should be designed to maintain orderly flow of personnel and materials

2.9. Floors, walls and ceilings shall be made of smooth hard surfaces that can be easily cleaned and disinfected routinely.

2.10. Floors should be smoothly cemented, covered with terrazzo, tiles or made with epoxy.

2.11. Ceiling boards should be made of non-asbestos and non-flaking material.

2.12. Windows and doors should be screened with insect-proof net and the doors should be self-closing to prevent contamination.

2.13. Adequate lighting should be provided in all areas to facilitate easy identification of materials, cleaning, maintenance and proper operations.

2.14. Adequate ventilation, cooling and exhaust systems should be provided where appropriate to minimise condensation in all the sections and in high-risk food manufacturing. Appropriate air purification systems should be put in place at the required section for high-risk food products.

2.15. Pallets or shelves should be provided for storage of materials.

3. **Cold Storage**

3.1. A cold room should be provided for materials (raw material, packaging material or finished product) that require special storage conditions and should have the following features:

3.1.1. It should be an enclosure fitted with air cooling/freezing facilities.

3.1.2. Thermometer should be installed such that it can be read off without opening the cold room.

3.1.3. Temperature-monitoring chart should be maintained to ensure that the cold chain is constantly monitored.

3.1.4. Stand-by generator or alternate power source should be installed.

3.1.5. Adequate illumination should be provided in the cold room.

4. **Production**

4.1. Where water forms part of the production process, at least one-third (1/3) the height of the wall (lintel level) from the floor shall be covered with ceramic tiles.

4.2. Functional air conditioning or cooling system shall be installed in the production section to enhance ventilation. However, for production section where heat and possibly dust from powdered raw materials emit, extractor fans and/or dust extractors shall be used to enhance ventilation in this room.

4.3. Illumination shall be via natural and/or electric lighting and the room shall be sufficiently lit.

4.4. Production equipment installed in this room should allow for smooth flow of production process and movement of personnel.

4.5. The floor and walls should be made of smooth, hard surface that can be easily cleaned and disinfected routinely.

4.6. Adequate drainage should be in place where necessary.

5. **Raw Materials and Finished Product Store**

5.1. The facility shall maintain separate rooms/sections for the storage of raw materials and finished products. These rooms could be a dry store, cool room or cold room depending on the nature of the product.

5.2. Other features required in this room shall include;

5.2.1. Adequate for its intended use.

5.2.2. Illumination shall be via natural and /or electric lighting and the room shall be sufficiently lit.

5.2.3. Depending on the nature of the product, ventilation shall be via air conditioners, extractor fans or purified air system.

5.2.4. The floor shall be made of smooth, hard surface that can be easily cleaned and disinfected routinely.

5.2.5. Storage of finished products shall be on pallets or shelves of sufficient strength to carry the weight of the products. The arrangement should allow for easy cleaning and movement of personnel.

5.2.6. Self-closing doors and windows should be screened with insect-proof net.

5.2.7. Provision should be made for separate storage for quarantined and approved items.

5.2.8. Provision of thermometer and hygrometer to monitor temperature and humidity.

5.2.9. Temperature- and humidity-monitoring chart should be maintained.

6. There should be defined areas of adequate size to accommodate the different operations in a logical order of production flow corresponding to the sequence of the operations. The operational areas should include;

6.1. Cloakroom.

6.2. Toilet facilities (which should not open directly into the production area)

6.3. Raw Materials Store

6.4. Packaging Materials Store

6.5. Production section.

6.6. Finished Products Store

6.7. Laboratory (optional)

7. **Equipment**

7.1. The design, material, construction, positioning and maintenance of equipment should be adequate and suitable for its intended use.

7.2. Layout and design must aim to minimize the risk of cross-contamination and permit effective cleaning and maintenance.

7.3. The parts of the equipment that make contact with products should be made of non-toxic/non-reactive materials such as food grade stainless steel.

8. **Water Supply and Treatment**

8.1. Water used in the production of food products and washing of production equipment, should be potable water and the facilities required should include the following; [please refer to guidelines for inspection of facility from manufacture of packaged water].

8.2. The source of water shall be public mains, spring or borehole (of not less than 150ft depth depending of the topography of the area).

8.3. The distance of the borehole from the nearest septic tank should not be less than

30meters.

8.4. The borehole should be fitted with a submersible pump of adequate power to pump the raw water out of the borehole.

8.5. Raw and Treated water tanks should be made of PVC, stainless steel or galvanized steel. In case of galvanized steel, it shall be coated internally with food grade epoxy.

8.6. Sand bed and Activated charcoal Modules should be provided.

8.7. Micro filters of adequate mesh sizes should be provided for proper filtration. The last filtration point should have the least mesh size (e.g. 0.5 microns).

8.8. Adequate UV sterilizer shall be provided at required points in the water treatment process.

8.9. The Treatment process shall comprise of;

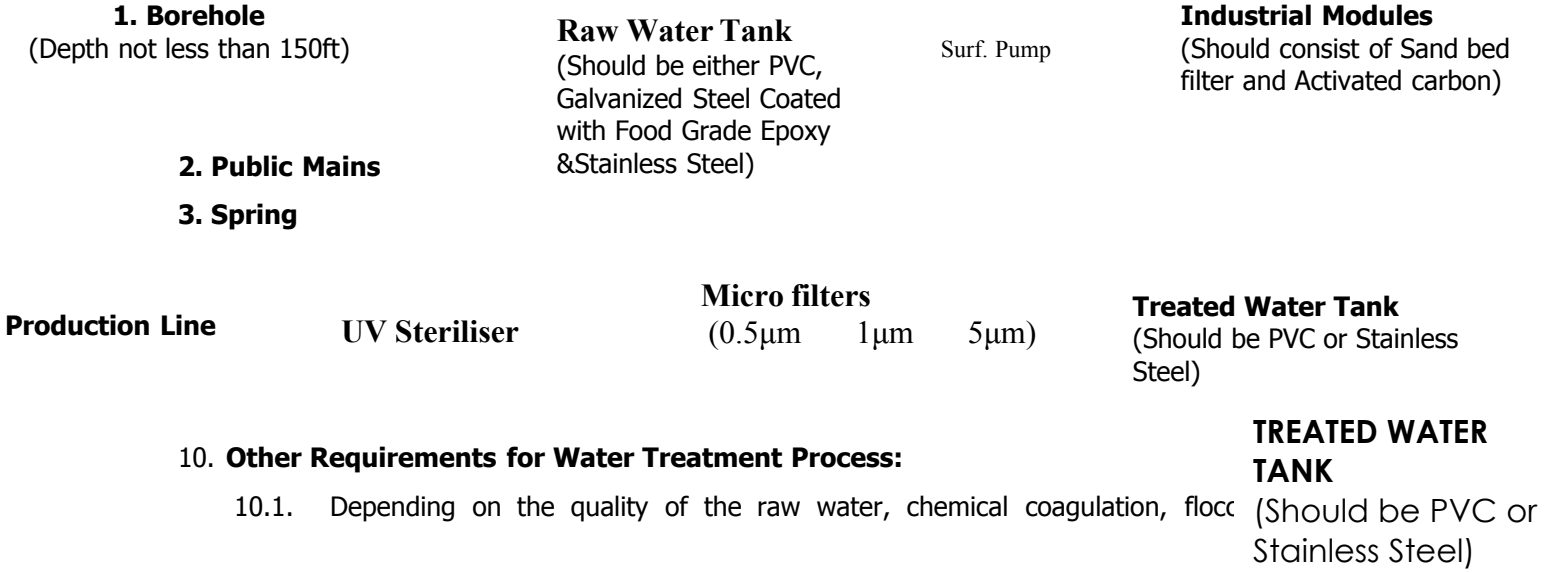
8.9.1. Dis-infection: The appropriate method of disinfection such as chlorination, reverse osmosis, ozonation etc. should be applied. Where applicable chlorination at 2-4 parts per million (ppm).

8.9.2. Filtration: This process is achieved by passing the water through sand bed filters and then through activated carbon filters to remove the chlorine, colour, odour and taste from the water.

8.9.3. Sterilization: passing the water through and appropriate size Ultra-violet sterilizer to kill off any microbes that may have escaped the disinfection stage achieve this.

9. **Water Treatment Flow Diagram**

The diagram below illustrates the flow diagram of a typical water treatment process.



10. **Other Requirements for Water Treatment Process:**

10.1. Depending on the quality of the raw water, chemical coagulation, flocc

settling with chemical coagulants like Aluminum sulphate or neutralizing the carbonic acidity in the water by the use of suitable base like the hydroxide of sodium or calcium should be used.

10.2. Hard water shall be treated by addition of water softeners such as zeolite or ion-exchange resins.

10.3. Aeration shall be carried out where raw water report shows a high iron content by exposing the water to air through aeration showers.

10.4. Chlorine concentration shall be calculated between 2 – 4 ppm and a contact time of not less than 6 hours.

10.5. The sand bed filter and the activated carbon filter should be recharged periodically depending on production output/volume.

10.6. Micro filters should be made of appropriate materials that do not shed particles into the water such as nylon, glass, stainless steel and must be installed in descending order in terms of pore size towards the UV sterilizer.

10.7. The UV sterilizer shall be fitted with an indicator or alarm system to signal when the UV bulb is burnt out.

10.8. The UV sterilizer shall be installed at the final point before the water is used for production.

10.9. All piping should be on the surface for early detection of leaks and should be made of either PVC or stainless steel.

10.10. The treatment modules should be backwashed periodically and recharge when due.

10.11. The quality of raw water determines the process to be applied.

11. **Raw and Packaging Materials and Sources**

11.1. Raw and packaging materials should be sourced from approved vendors.

11.2. All incoming materials should be stored under appropriate storage conditions and conform to specification.

11.3. Thermometer and hygrometer should be installed in the raw/packaging materials room to monitor temperature and humidity.

11.4. Temperature- and humidity-monitoring chart should be maintained.

12. **Validation of Equipment and Process**

12.1. All equipment and processes must be validated. Validation is the establishment of documented evidence which provide a high degree of assurance that a specific method, procedure, process and equipment will consistently produce a product meeting its

pre-determined specifications and quality attributes.

12.2. Types of validation include;

12.2.1. Process validation.

12.2.2. Facility qualification.

12.2.3. Computer systems validation.

12.2.4. Equipment qualification.

12.2.5. System qualification.

12.2.6. Cleaning validation.

12.2.7. Methods validation.

12.2.8. Packaging validation.

13. **Calibration of Equipment**

13.1. Calibration should be carried out on laboratory and production equipment on a daily basis before the equipment can be used for production and adequate documentation should be kept. Calibration is the act of checking or adjusting (by comparison with a standard) the accuracy of a measuring instrument. Calibration can be broken down into;

13.1.1. Physical (Temperature, Relative humidity, Pressure, Time).

13.1.2. 8.2 Analytical Instrumentation (including pH, conductivity etc.

13.1.3. 8.3 Optical (Turbidity, Osomometry, spectrophotometry).

13.1.4. 8.4 Electrical (Voltage, Current, Resistance Frequency).

13.1.5. 8.5 Dimensional (Length, Volume, Mass etc.).

13.2. Most calibration activities can be classified as either process calibration or laboratory calibration.

14. **Quality Control**

14.1. The in-house laboratory should be adequately equipped to carry out tests on the critical parameters on their raw materials, in-process and finished products.

14.2. The requirements in the laboratory include;

14.2.1. Qualified, trained and competent quality control personnel.

14.2.2. Adequate equipment to carry out the critical physical, chemical and microbiological parameters on the raw materials, in-process and finished products and documented accordingly.

14.2.3. Appropriate calibration and validation of all laboratory equipment should be carried out and documented accordingly.

14.2.4. Shelf-life studies of food products (stability studies) should be carried out to ensure that the stated shelf life on the product is adequate.

15. **Hazard Analysis And Critical Control Point (HACCP) System**

15.1. A plant should design and implement Hazard Analysis and Critical Point System. .

16. **Environmental Sanitation And Personnel Hygiene**

16.1. Appropriate sanitation measures should be taken to avoid contamination risks of all kinds:

16.1.1. The entire factory should be cleaned frequently and thoroughly in accordance with the Standard Operational Procedure (S.O.P) for cleaning.

16.1.2. Equipment should be thoroughly cleaned in strict compliance to the S.O.P and Clean-In-Place procedures, where necessary.

16.1.3. Water system, toilets and washing facilities should be appropriately located, designed, equipped and maintained in strict compliance to the S.O.P

16.1.4. Eating, Drinking and Smoking should not be permitted in the production, laboratory and storage areas.

16.1.5. All operators should wear appropriate protective apparels.

16.1.6. Production staff should undergo food handler's test at least twice a year.

16.2. Person(s) known to be suffering from communicable diseases or with open wounds or lesions should be excluded from duty until they are certified medically fit again.

16.3. Waste should be appropriately disposed of in strict compliance to the S.O.P.

16.4. Effective pest control programme should be carried out quarterly and in accordance with the SOP.

17. **Documentation**

17.1. Appropriate records of all activities should be documented and maintained accordingly [duration of documents should be specified by the Agency for All products].

18. **Consumer Complaint And Recall**

18.1. All consumer complaints should be handled by technical personnel, thoroughly investigated, documented.

18.2. If a recall is decided upon, it should be done promptly using the production batch

history and distribution records.

18.3. All records of recalled products must be kept. In the event of any recall, NAFDAC must be notified of all actions at receipt of consumer complaint, during investigation and actual recall activity. Root Cause Analysis should be carried out and Corrective Action and Preventive Action (CAPA) plan developed.

19. **Distribution System**

19.1. Record of product distribution network must be properly kept for easy recall of defective products. Distributors' names, addresses, fax, phone number, email, etc. should be maintained.

20. **Transportation And Handling**

20.1. Products should be handled and transported under conditions that prevent deterioration, contamination, spoilage and breakage to ensure that the product safety and quality is maintained up to the time of delivery to the consumer.

21. **Label**

21.1. Food product label should be in accordance with the provisions of the extant NAFDAC Pre-packaged Food (Labeling) Regulations.

21.2. Product should be labeled adequately in English language. The label should also contain the following;

21.2.1. Name of the product

21.2.2. Ingredients list (to be stated in descending order of their proportion)

21.2.3. Nutrition information / Nutritional fact

21.2.4. Net content

21.2.5. Factory Location address,

21.2.6. Lot/batch number,

21.2.7. Direction for use

21.2.8. Date marking,

21.2.9. Storage condition and

21.2.10. NAFDAC Registration number.

21.2.11. Package Disposal sign (optional)

All correspondences should be addressed to;

Director-General (NAFDAC),

Attn: The Director

Food Safety and Applied Nutrition Directorate.

National Agency for Food and Drug Administration and Control,

2nd Floor, NAFDAC Office Complex

Isolo Industrial Estate

Apapa-Oshodi Expressway, Isolo, Lagos

NAFDAC website: www.nafdac.gov.ng

E-mail address: foodsafety.nutrition@nafdac.gov.ng

Telephone no.: +234 906 095 6907

All submissions should be made at the Office of the Director, FSAN, 2nd Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (outside Lagos).