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

Food Safety & Applied Nutrition (FSAN) Directorate

GUIDELINES FOR INSPECTION & REQUIREMENTS FOR PACKAGED WATER FACILITY IN NIGERIA (FRESH APPLICATIONS)

1. **General**

1.1. These Guidelines are for the general public and in particular, companies involved in processing and packaging of drinking water in Nigeria.

1.2. It prescribes the minimum Good Manufacturing Practice (GMP) requirements for the facilities and controls to be used in the processing of water to ensure that it is safe and meets quality standards.

1.3. It is necessary to emphasize that, no packaged water product shall be produced, 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 I

2. **Application**

2.1. An application for Inspection on company's letter headed paper should be made to the Director General, National Agency for Food and Drug Administration and Control (NAFDAC), ATTENTION: The Director, Food Safety and Applied Nutrition (FSAN) Directorate, NAFDAC Office Complex, 2nd floor, Apapa-Oshodi Expressway, Isolo, Lagos State.

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

2.2.1. Exact location address of the manufacturing facility (NOT P.O. Box)

2.2.2. 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.

SOP Index (list of SOPs i.e. for production, quality control, recall, distribution, consumer complaint, cleaning of equipment and environment, which will be reviewed during inspection of facilities)

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

2.3.9. Food Handler's certificate for production staff which should include the Following tests: Sputum, Hepatitis B, Widal, Stool, Urine test.

2.3.10. Certificate of analysis of raw and treated Water.

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

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

2.4 2.1 to 2.3.12 should be done on-line via the NAPAMS Portal (www.napams.org)

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 is generated on-line via NAPAMS

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 on-line via NAPAMS

Step V

6. **Inspection**

6.1. The Inspection is conducted as scheduled; where the Inspection is unsatisfactory a Non-Conformance 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 uploaded to NAPAMS PLATFORM.

7. **Tariffs**

7.1. Please refer to Tariff section

8. **Note**

8.1. Micro filters should be made of appropriate materials that do not shed particles into the water and must be installed in descending order of pore size towards the UV sterilizer.

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

8.3. The UV sterilizer shall be installed at the final point before filling.

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

8.5. The treatment modules should be backwashed periodically and recharged when due

8.6. Two sets of documents must be submitted during the inspection.

8.7. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (within 15 working days) will automatically lead to the closure of the Application.

8.8. Failure to respond to concerns raised by NAFDAC on the application or inspection, will automatically lead to delay in further processing of the application.

8.9. Please note that the clock stops once Non-Conformance are issued.

REQUIREMENTS FOR PACKAGED WATER 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 water should be excluded from direct contact with water 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 drinking water.

2. **Buildings**

2.1. The facility for the production of drinking water 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, sawmill, oil depot), cement factory or any other areas that could be a source of contamination for processing, production and packaging of drinking water.

2.4. The building should be designed to allow for free flow of personnel and materials to prevent cross contamination.

3. **Cloakroom**

3.1. Cloakroom and toilet facilities should not open directly into the production area.

3.2. Floor and walls should have smooth hard surface, made of non-shedding and durable materials, easy to clean or disinfect where necessary.

3.3. Windows should be screened with insect-proof nets and easily cleanable.

3.4. Wall hangers, shoe racks and/or lockers should be provided.

3.5. A netted self-closing door at the entrance should be provided.

3.6. Illumination and Ventilation should be adequate.

4. **Packaging Materials store**

4.1. Floor and walls should have smooth hard surface, made of non-shedding and durable materials, easy to clean or disinfect where necessary.

4.2. Windows if present should be screened with insect-proof nets and should be cleanable.

4.3. Pallets and/or shelves should be provided (wooden pallets should be appropriately covered).

4.4. An ultraviolet (UV) sterilizing lamp should be provided.

4.5. Ventilation & Illumination should be adequate.

5. **Production Section**

5.1. Floor and walls should have smooth hard surface, made of non-shedding and durable materials, easy to clean and where necessary, disinfect.

5.2. Drainage system should be adequate to prevent flooding.

5.3. Windows should be screened with insect-proof nets and should be cleanable.

5.4. An air conditioner should be provided.

5.5. Illumination and ventilation should be adequate.

6. **Finished Product Store**

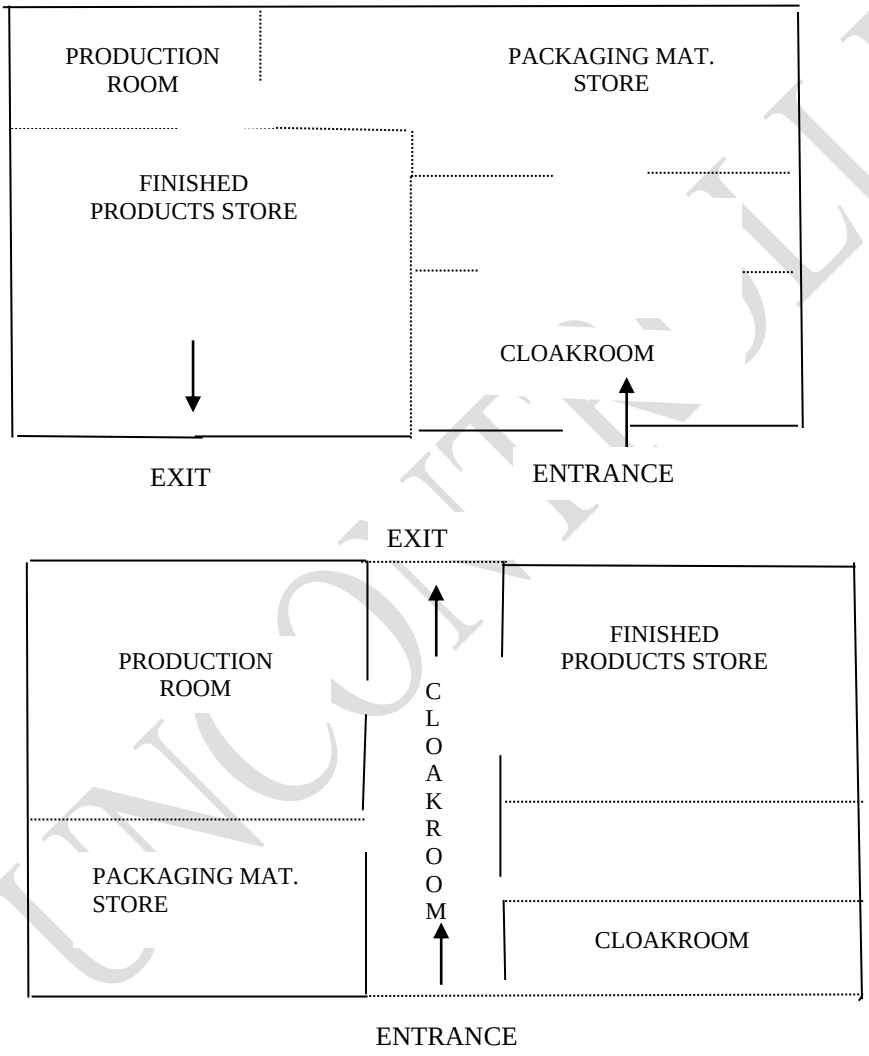
6.1. Floor and walls should have smooth hard surface, made of non-shedding and durable materials, easy to clean and where necessary, disinfect.

6.2. Windows if present should be screened with insect-proof nets and should be cleanable.

6.3. Pallets and/or shelves should be provided (wooden pallets should be appropriately covered).

6.4. Ventilation & Illumination should be adequate.

Suggested Schematic Diagram for facility layout



7. **Facilities and Equipment**

7.1. **Source of water**

7.1.1. The source of water may be from

7.1.1.1. borehole of minimum depth of 150ft depending on topography

7.1.1.2. Public mains.

7.1.1.3. Spring water.

7.1.2. Dug out well is not allowed.

7.1.3. Water source should be at least 30m away from the nearest septic tank which may or may not be situated within the premises.

7.2. **Tanks and Reservoir**

7.2.1. All tanks should be made of Polyvinyl Chloride (PVC) or stainless steel. Underground reservoir (where available) should be made of concrete and fully tiled.

7.3. **Pipes**

7.3.1. All pipes should be made of stainless steel or PVC. Use of iron pipes is not allowed.

7.4. **Form, Fill, Seal Machine**

7.4.1. The form, fill and seal machine should be designed to minimize man-material contact, safe to use, easy to clean and environmental friendly. The equipment should be a fully automated device.

7.5. **Bottling line**

7.5.1. The bottling line should be fully automated.

8. **Water treatment process**

8.1. The facilities required for the production of drinking water should include the following;

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

8.1.2. Raw and treated water tanks should be made of treated PVC or stainless steel.

8.1.3. Industrial modules containing sand bed and activated charcoal shall be provided.

8.1.4. 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).

8.1.5. An appropriate UV sterilizer should be provided at the appropriate point (just before filling) in the water treatment process.

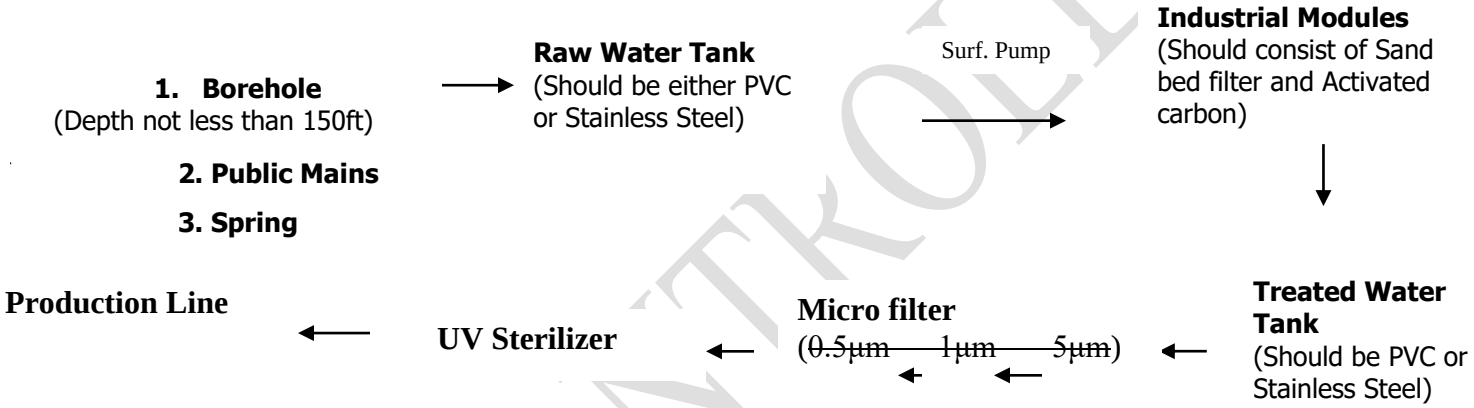
8.1.6. The Treatment process shall comprise of;

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

8.1.6.2. 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.

8.1.6.3. Sterilization: This is achieved by passing the water through appropriate ultraviolet sterilizer to kill off any other microbes that may have escaped the disinfection stage.

Simple Water Treatment flow diagram



9. **Hygiene Station and Toilet Facilities**

9.1. Hygiene station and toilet facilities should be provided for personnel and should be kept clean at all times.

9.2. Washing facilities should be equipped with food grade liquid hand soap, **hand** driers or **disposable** towels and sanitizer.

9.3. The walls and floors should have smooth surface, easy to clean and disinfect.

9.4. The hygiene station should be located before or within the cloakroom.

9.5. Toilets should not open directly to the production area.

9.6. Sewage, refuse and other wastes within the premises should be disposed in a safe and sanitary manner. The disposal should be in accordance with the laid down rules by the local Waste Management Authority.

10. **Sanitation**

10.1. Any building used in the production, processing and packaging of drinking water should be maintained in a hygienic condition.

10.2. Standard Operating Procedures (SOP) assigning responsibility for cleaning must be in place. The SOP should describe in sufficient details, the cleaning schedules and frequency, as well as equipment and materials to be used in cleaning the buildings and facilities.

10.3. The building should be regularly fumigated with approved food grade fumigants.

11. Standard Operating Procedures (SOPs) to be reviewed during factory inspection

11.1. Standard Operating Procedure (SOP) should be written for all operations namely;

11.1.1. SOP Index.

11.1.2. SOP for Production.

11.1.3. SOP for Quality Control.

11.1.4. SOP for Cleaning of Factory Premises and Equipment.

11.1.5. SOP for handling Consumer Complaint.

11.1.6. SOP for Recall and Distribution.

11.1.7. Other SOPs (as appropriate).

12. Consumer Complaint and Recall

12.1. All consumer complaints should be handled by technical personnel, thoroughly investigated and documented. The outcome of investigation should be communicated to Management in order to prevent future occurrence. If a recall is decided upon, it should be done quickly using the production batch history through the product distribution records. All records of recalled products must be kept. In event of any recall, NAFDAC must be fully 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.

13. Distribution System

13.1. 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 documented.

14. Transportation and handling

14.1. 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. All packaged water should be stored in a cool dry place and away from sunlight.

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 correspondence 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).