

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

GUIDELINES FOR ESTABLISHMENT OF PACKAGED WATER PLANT IN NIGERIA

NAFDAC/EID/003/00

1.0 GENERAL

- 1.1 These guidelines are for the general public, corporate organizations and individuals that wish to engage in production of packaged potable water for public consumption.
- 1.2 These guidelines prescribe the minimum GMP requirements for personnel, materials, machine and environment for production of potable water.
- 1.3 It is important to note that no packaged water should be manufactured, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of Act Cap F33 LFN 2004 and the accompanying guidelines.

2.0 ORGANIZATION AND PERSONNEL

- 2.1 There should be an adequate organizational structure that clearly defines
 - a) Responsibility
 - b) Authority
 - c) Qualification of Personnel
- 2.2 There should be adequate personnel to perform and supervise the production and packaging of potable water.
- 2.3 Production of potable water must be under the supervision of a production manager who must possess a minimum of Ordinary National Diploma in a science based course obtained from a recognised tertiary institution.
- 2.4 In house and In process Quality Control of functions can be carried out by the production manager while comprehensive/detailed product analysis should be performed by public analyst registered by the Institute of Public Analyst of Nigeria (IPAN)
- 2.5 Personnel should be adequately clad in overall, hand gloves, nose/mouth masks, headgears and rubber shoes.

3.0 BUILDING(S)

- 3.1 The entire factory premises should be fenced to demarcate it from all other buildings (residential or commercial).
- 3.2 The factory must not be sited (located) near a cemetery, abattoir, quarry, sewage treatment plant, sawmill, oil depot (Petroleum and Vegetable) or any such establishment that could be a source of contamination for processing, production and packaging of potable water
- 3.3 The building should be designed to allow for free flow of personnel and materials to prevent cross contamination.
- 3.4 The building for the production of potable water should be purpose built or suitably adapted to comprise a minimum of five rooms designated as the cloak room, packaging material store, production room and finished product store & office.

3.4.1 CLOAK ROOM:

- a. Floor should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.
- b. Walls should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.
- c. Windows should and be screened with insect-proof nets and be constructed in such a way as not to trap dust.
- d. Wall hangers/cupboard should be provided.
- e. Shoe rack/lockers should be provided.
- f. Ventilation & Illumination should be adequate.
- g. A netted door at the entrance should be provided.

3.4.2 PACKAGING MATERIALS STORE:

- a. Floor should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.
- b. Walls should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.
- c. Windows if present should be screened with insect-proof nets and be constructed in such a way as not to trap dust.
- d. Pallets/shelves (not wooden) should be provided.
- e. Ventilation & Illumination should be adequate.
- f. An Ultraviolet sterilizing lamp should be provided and bulb changed when spent.

3.4.3 PRODUCTION ROOM:

- a. Floor should be covered with easy to clean durable materials.
- b. Drainage system should be adequate to prevent flooding.
- c. Walls should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.
- d. Windows should be screened with insect-proof nets and be constructed in such a way as not to trap dust.
- e. An air conditioner should be provided.
- f. Illumination and ventilation should be adequate.

3.4.4 FINISHED PRODUCT STORE:

- a. Floor should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.
- b. Walls should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.
- c. Windows should be screened with insect-proof nets and be constructed in such a way as not to trap dust.
- d. Pallets/shelves (not wooden) should be provided.
- e. Illumination & ventilation should be adequate.
- f. A netted door should be provided at the exit.

4.0 FACILITIES AND EQUIPMENT

4.1 SOURCE OF WATER

- 4.1.1 The source of water could either be from a borehole of minimum depths of 100ft ó 150ft depending on topography or

- 4.1.2 Public mains provided by the local water cooperation.
- 4.1.3 Use of dug out well is not allowed.
- 4.1.4 Water source should be at least 30-50m away from the nearest septic tank which may or may not be situated within the premises.

4.2 TANKS AND RESERVOIR

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

4.3 PIPES

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

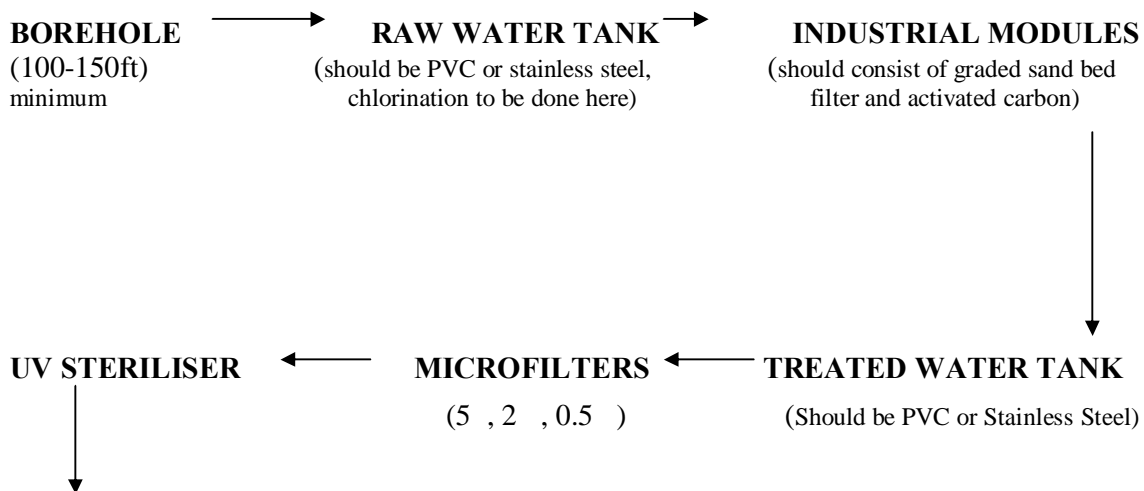
4.4 TAPS

Taps for manual filling should be made of stainless steel or PVC mounted on a stainless steel sink.

4.5 FORM FILLING AND SEALING MACHINE

The form filling and sealing machine (where available) should be designed to minimise man-material contact, safe to use, easy to clean and environmentally friendly. The equipment may be a fully or semi automated device.

4.6 WATER TREATMENT PROCESS



PRODUCTION LINE

5.0 WASHING AND TOILET FACILITIES

- 5.1 Adequate, clean washing and toilet facilities should be provided for personnel
Washing facilities should be equipped with soap or detergent, air driers or single-service towels. This should be walled and floored with easily cleaned and disinfected non shedding durable material and should have smooth surface.
- 5.2 Toilets should be away from the production or storage areas and should be easily accessible to production area.

5.3 Sewage, refuse and other wastes within the premises should be disposed of in a safe and sanitary manner.

6.0 SANITATION

6.1 Any building used in the manufacture, processing and packaging of potable water should be maintained in a hygienic condition.

6.2 Standard operating procedures assigning responsibility for cleaning must be in place. The SOP should describe in sufficient details, the cleaning schedules as well as equipment and materials to be used in cleaning the buildings and facilities.

6.3 The building should be regularly fumigated with approved fumigants in accordance with the food and drug act and the pesticides registration regulation of NAFDAC.

7.0 STANDARD OPERATING PROCEEDURES (SOPs)

7.1 Standard Operating Procedures should be written for all operations namely

7.1.1 SOP for Production

7.1.2 SOP for Quality Control

7.1.3 SOP for cleaning of factory Premises and Equipments.

7.1.4 SOP Recall and Distribution.

7.1.5 SOP for cloaking and use of toilets

7.1.6 etc.

8.0 APPLICATION FOR INSPECTION

8.1 Application for inspection of packaged water factory should be directed to:

The Director General

National Agency for Food and Drug Administration and Control

Plot 2032, Olusegun Obasanjo Way, Wuse Zone 7, Abuja.

8.2 All application should be accompanied with:

(i) Evidence of payment

(ii) Company's Certificate of Incorporation and

(iii) Product's Trademark Registration Certificate.

9.0 STATUTORY FEES FOR INSPECTION

9.1 All payments to the Agency should be in bank draft in favour of National Agency for Food and Drugs Administration and Control

9.2 All payments attract a 5% VAT charge.

9.3 Laboratory analysis for the purpose of renewal shall be 50% of the original tariff.

| S/N | PRODUCTIO N INSPECTION | RENEWAL INSPECTIO N | GMP RE- ASSESMEN T | FOLLOW UP INSPECTION | ADVISORY INSPECTION | LABORATORY ANALYSIS |
|---|------------------------------|---------------------------|--------------------------|-------------------------|------------------------|------------------------|
| SACHET | 10,000:00 | 5,000:00 | 10,000:00 | 10,000:00 | 10,000.00 | 10,000:00 |
| PET BOTTLES, JARS AND CANS | 10,000:00 | 5,000:00 | 10,000:00 | 10,000:00 | 10,000.00 | 20,000:00 |

10.0 DOCUMENTARY REQUIREMENTS FOR PRODUCTION INSPECTION OF PREMISES FOR PACKAGED POTABLE WATER.

10.1 Labelling

The product label should comply with packaged water labelling regulations stating

- Name of product
 - pack size
 - Batch No:
 - Manufacturing Date:
 - Best Before Date:
 - NAFDAC Registration Number.
 - Factory Location Address (Not P.O. Box)
- 9.0 Evidence of Payment
 - 10.0 Certificate of Incorporation of Company
 - 11.0 Evidence of Trade Mark Registration
 - 12.0 Organogram of the Company with Names and Qualification of the key officers (e.g. Managing Director, Production Manager, Quality Control Manager)
 - 13.0 Letter of Appointment and Acceptance of key officers.
 - 14.0 Credentials of the key officers.
 - 15.0 List of Production Facilities/Quality Control
 - 16.0 SOP for cleaning of factory Premises and Equipments.
 - 17.0 SOP Recall and Distribution
 - 18.0 SOP for Production
 - 19.0 SOP for Quality Control
 - 20.0 Retainership Agreement with a Hospital or Clinic (with names and signature of both parties)
 - 21.0 Food Handlers Test/Medical Fitness Tests which should include,
 - Sputum Test
 - Urine Test
 - Stool Test
 - Chest X-ray
 - Widal Test
 - 22.0 Analysis of Raw Materials and Finished Products.
 - 23.0 Agreement with Fumigation Company for regular fumigation of the factory with name and signature of both parties.
 - 24.0 Current fumigation Certificate of factory (This should be done quarterly)
 - 25.0 Geological Survey of Borehole Report
 - 26.0 Telephone Number for easy contact.
 - 27.0 Any other relevant documents.

Four sets of the above documents in the order they appear should be presented during inspection (originals for sighting).

All correspondences and applicant should be:

The Director
 Establishment Inspection Directorate
 NAFDAC
 Abuja
 NAFDAC website: www.nafdac.gov.ng.
 E-mail address: nafdac@nafdac.gov.ng.
 Telephone number:

