NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

GUIDELINES FOR ESTABLISHMENT OF FOOD MANUFACTURING PLANTS IN NIGERIA

NAFDAC/EID/002/00

1.0 GENERAL

1.1 These guidelines are for the general public and in particular industries that want to engage in food manufacturing.

1.2. These guidelines prescribe the minimum good manufacturing practice requirements for the facilities, controls to be used in the manufacture, processing and packing of products to ensure that they meet quality standards.

1.3. The guidelines should also apply to persons that may engage in some aspects of a manufacturing process e.g. packaging.

1.4. It is necessary to emphasize that no food product should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of Act Cap F33 LFN 2004. Consequently, a food product shall not be manufactured in Nigeria unless the factory is inspected and certificate of recognition is issued by NAFDAC.

2.0 ORGANIZATION AND PERSONNEL

2.1 There should be an adequate organizational structure that clearly defines

a) Qualification of key personnel.

b) Responsibility

2.2 There should be an adequate number of qualified personnel to perform assigned duties.

2.3 Each key personnel engaged in food manufacturing should have

a) Adequate education

b) Experience

2.4 The quality control and production units shall be distinct organizational units that function and report to management independently of each other and of all other functional units

2.5 Personnel should wear protective apparel/gears, such as head, face, hand, and arm coverings to protect products from contamination.

2.6 Personnel should practice good sanitary and hygienic habits.

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

2.8 There should be adequate training for employees in the particular operations that they perform

2.9 Consultants advising on any form of manufacturing process should have sufficient education, training, and experience to advice on the subject for which they are retained.

3.0 PLANT AND FACILITIES

3.1 Building(s) used in the manufacture, processing and packing of food products should be adequately located, constructed and of suitable size to facilitate cleaning, maintenance and proper operations as appropriate to the type and stage of manufacture.

3.2 The building should have adequate space for the orderly placement of equipment and materials to prevent mix-ups between different materials.

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

3.4 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;

a. Cloakroom/ Toilet facilities (which should not open directly into the production area)
b. Raw Materials Store
c. Packaging Materials Store
d. Production Room
e. Finished Products Store

I. Quality Control Laboratory

3.5 Floors, walls and ceilings of smooth, hard surfaces that can be easily cleaned and disinfected routinely should be provided.

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

3.7 Windows and entrance doors should be screened with insect-proof netting and the doors should be self closing to prevent contamination and be constructed in such a way as not to trap dust.

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

3.9 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 level purification should be put in place at the required section.

3.9.1 Pallets or shelves (not wooden) should be provided for storage of materials in the raw materials store.

Cold Storage:

3.9.2 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:

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

b. A thermometer should be installed such that it can be read off without opening the cold room.

c. A temperature monitoring chart should be kept to ensure that the cold chain is constantly maintained.

e. A stand by generator should be installed as alternative power source.

f. Illumination should be provided in the cold room.

3.9.3 **PRODUCTION SECTION**

a. **In production section** where water forms part of the production process, the walls and floor should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.

i. A functional air conditioner or cooling system shall be installed in this room to enhance ventilation. However, for production rooms where heat and possibly dust from powdered raw materials, exhaust fans and (or) dust extractors shall be used to enhance ventilation and remove dust in this room.

ii. Illumination shall be via electric lighting and the room shall be sufficiently lit.

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

b. **Finished Product Store:**

This room shall be used for the storage of the finished products. Depending on the nature of the finished product, this room could be a dry store, cool room or cold room. Other features required in this room shall include;

i. The room shall be adequate in size for its intended use.

ii. Illumination shall be via electric lighting and the room shall be sufficiently lit.

iii. Depending on the nature of the product ventilation shall be via air conditioners or exhaust fans or limit of purified air system.

iv. The floor should be made of easily cleaned and disinfected non shedding durable material and should have smooth surface.

v. Storage of finished products shall be on pallets or shelves (not wooden) of sufficient strength to carry the weight of the products. The arrangement should allow for easy cleaning and movement of personnel.

vi. Self closing doors and windows should be screened with insect-proof netting.

vii. There should be provision for quarantine and approved products.

3.9.4 Factories sited in commercial areas are unacceptable.

3.9.5 The factory can either be a purpose ï built structure or a suitably adapted building.

3.9.5 The factory shall be constructed of cement or concrete and not made of wooden or prefab materials.

3.9.6 The size must be adequate for its intended use to facilitate cleaning and proper operation.

3.9.7 The facility shall be fenced round with block walls of at least five feet high to prevent external interference and should be plastered.

3.9.8 The factory shall not be sited less than 100 meters from a refuse dump, abattoir, graveyard, oil depot (petroleum and vegetable), canal or cement factory.

4.0 EQUIPMENT:

The design, material, construction, location and maintenance of equipment should be such as to make it adequate and suitable for its intended use. Its layout and design must aim to minimize the risk of mix-ups and permit effective cleaning and maintenance in order to avoid cross contamination, build-up of dust, dirt, food particle or any other contaminant that can affect the quality of the product. 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 etc.

5.0 WATER TREATMENT PROCESS:

Water which is used in the production of food products (production Water), washing of production equipment (Operation water) should be treated water and the facilities required should include the following;

5.1 The source of water shall be either via *public mains or spring or borehole* ***of not less than 150ft depth.***

5.2 The distance of the borehole from the nearest soak-away pit or septic tank should not be less than 50 meters.

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

5.4 **A raw water tank and treatment tank** shall be provided which should be made of treated PVC, stainless steel or galvanized steel. In case of galvanized steel, it shall be coated internally with food grade rubber paint.

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

5.6 **A treated water tank** shall be provided should be made of treated PVC, stainless steel.

5.7 **A set of serial micro filters mesh** of 5micron, 2 or 1 micron and then 0.5 micron pore sizes shall be provided.

5.8 **An industrial size UV sterilizer** shall be provided at required points in the water treatment process.

5.9 The Treatment process shall comprise of;

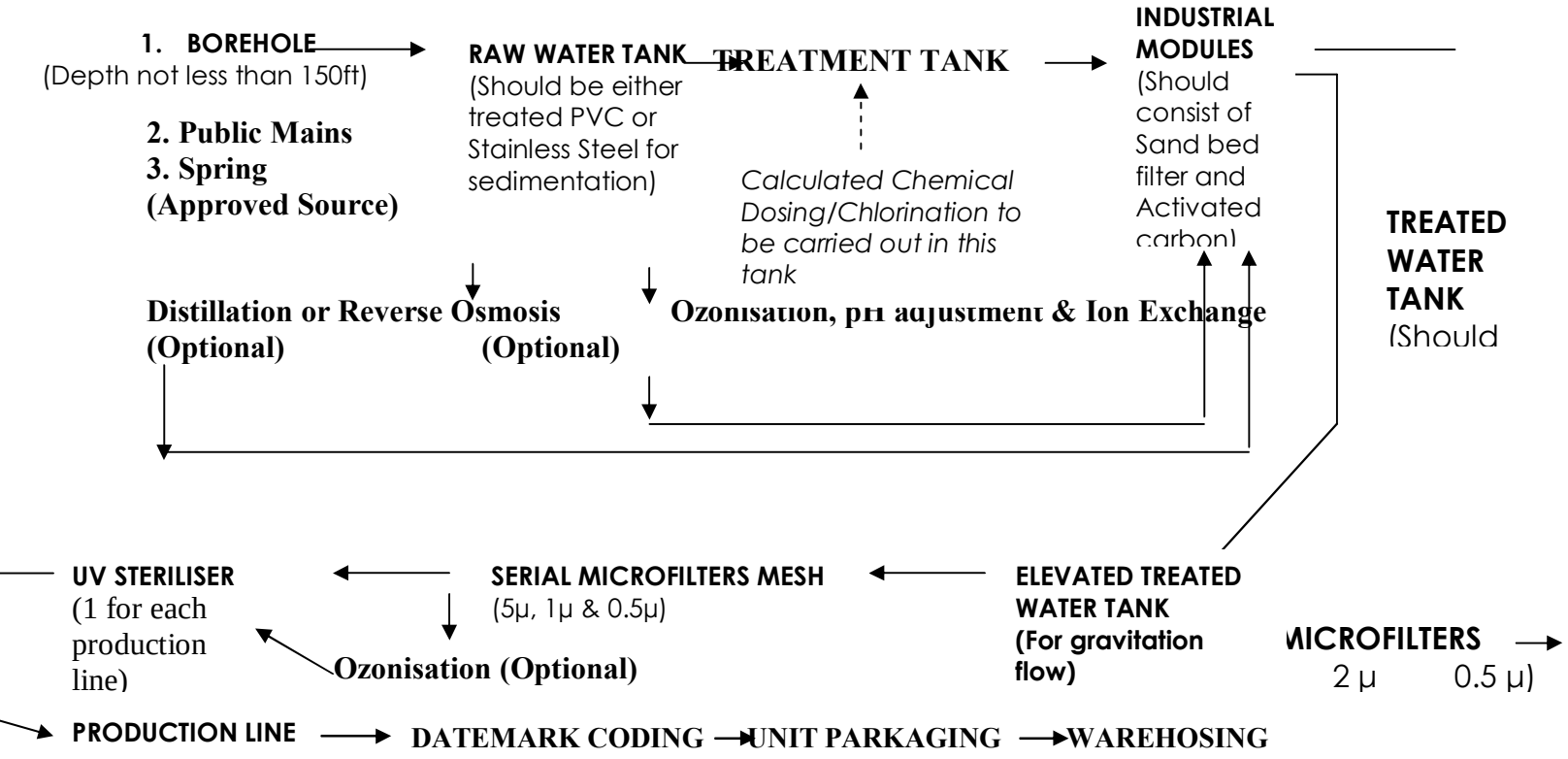
5.9.1 ***Disinfection:*** This process is carried out either through chlorination at 2 ï 4 parts per million (ppm), ozonation via an ozonator apparatus, pH adjustment, ion exchange, distillation or reverse osmosis.

5.9.2 ***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.

5.9.3 ***Sterilisation:*** This is achieved by passing the water through and industrial size ultra violet sterilizer to kill off any other microbes that may have escaped the disinfection stage.

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

WATER TREATMENT FLOW DIAGRAM



5.10 **Other Requirements for Water Treatment Process:**

5.10.1 Depending on the quality of the raw water, chemical coagulation, flocculation and settling using chemical coagulants like Aluminium sulphate or neutralizing the carbonic acidity in the water by the use of suitable base like the hydroxide of sodium or calcium.

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

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

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

5.10.5 The sand bed filter should be recharged every 1 to 5 years while the activated carbon filter is done every1 to 2 years depending on production output/volume.

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

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

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

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

6.0 RAW/PACKAGING MATERIALS AND SOURCES:

Raw and packaging materials should be sourced from approved vendors. They should be of good quality in order to produce quality products. All incoming materials should be stored under appropriate storage conditions. Where applicable, the materials should be immediately tested by quality control (QC) to ensure conformity to specification.

7.0 VALIDATION OF EQUIPMENT AND PROCESS:

All equipment and processes must be validated. Validation is the establishment of documented evidence which provide a high degree of assurance that a specific process and equipment will consistently produce a product meeting its pre-determined specifications and quality attributes.
Types of validation include;

- Process validation
- Facility qualification
- Computer systems validation
- Equipment qualification
- System qualification
- Cleaning validation
- Methods validation
- Packaging validation

8.0 CALIBRATION OF EQUIPMENT:

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;

8.1 Physical (Temperature, Relative humidity, Pressure, Time) Analytical Instrumentation (including pH, conductivity etc

8.2 Optical (Turbidity, Osomometry, spectrophotometry)

8.3 Electrical (Voltage, Current, Resistance Frequency)

8.4 Dimensional (Length, Volume, Mass etc.)

Most calibration activities can be classified as either *process calibration* or *laboratory calibration*

9.0 QUALITY ASSUARANCE:

QUALITY CONTROL

Cottage Food Producing factories are required to send samples from every batch of their finished products to a public analyst for comprehensive analysis and document same in a file while rectifying any anomaly in the parameter reading by carrying out the needed process change(s) for the overall product quality conformity .

However, for medium to large scale food industries, an in-house laboratory adequately equipped to carry out the most critical parameters on their raw materials, in-process and finished products shall be provided. A public analyst shall also carry out comprehensive analysis on every batch of finished products. The requirements in the laboratory include;

9.1 There shall be competent quality assurance personnel to man the laboratory.

9.2 The laboratory shall be adequately equipped to carry out the critical chemical and microbiological parameters on the raw materials, in-process and finished products.

9.3 There should be clear separation of responsibility between the quality assurance and production.

9.4 Adequate documentation of all analysis carried out should be properly filled.

9.5 Daily calibration and bi-annual validation of all laboratory equipment should be carried out and proper documents should be kept.

9.6 Shelf life studies of food products should be carried out to ensure that the stated shelf life on the product is adequate.

HAZARD ANALYSIS SYSTEM

9.7 The plant shall design and implement a hazard analysis system. Traditional internal audit by plants has shifted to own process assessment for associated hazards and the risk level at each stage of the production with a concurrent control measure(s) to eliminate or reduce such hazards/risk factors to the barest minimum and thus assure the quality of the product in a proactive and preventative practice.

9.8 One form of Hazard Analysis System could be derived from Industrial Guides/Codes, Research Findings, publications, Systematic Assessment of Food Environment, Assured Safer Food Catering. Etc

9.9 Ultimately, the plant should adopt and practice the principles of Hazard Analysis Critical Control Point System which is the system of choice in food safety either on voluntary basis or mandatory as in HACCP System certification.

A thorough implementation of this reduces the cost of quality, prepares the staff for external audit and assures food safety.

10.0ENVIROMENTAL SANITATION AND PERSONEL HYGIENE:

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

10.1 The entire factory should be cleaned frequently and thoroughly in accordance with the standard operational procedure (S.O.P) for cleaning.

10.2 Equipment should be thoroughly cleaned in strict compliance to the S.O.P

10.3 Water system toilets and washing facilities should be appropriately

located, designed , equipped and the sanitation shall be maintained satisfactory in strict compliance to the S.O.P

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

10.5 All operators should wear appropriate protective garments/gowning.

10.6 Production staff should undergo food handlerôs test/medical examination at least once a year.

10.7 Persons known to be suffering from communicable diseases or with wounds should be excluded from duty until they are certified medically fit again. Wastes should be adequately disposed of in strict compliance to the S.O.P.

10.8 Effective pest control program should be in place and executed satisfactorily in accordance to master validation plan.

11.0 DOCUMENTATION

The aim of documentation is to define the specification for all materials and methods of manufacture and control, to ensure that all personnel concerned with manufacture know what to do and when to do it. Documentation falls into three main categories;

10.9 **Commitment Documentation:** These are documents that describe the commitment of a factory to adhere to cGMP and HACCP plan e.g. quality manual, master validation plan, quality manual, sample collection, stability studies , HACCP record etc.

10.10 **Directive Documentation:** These are the documents that direct the technical staff on how to remain in compliance e.g Batch Formulation Records.

10.11 **Procedural Documentation:** This describes the standard operating procedures, process validation, cleaning validation, etc.

12.0 CONSUMER COMPLAINT AND RECALL:

All consumer complaints must be thoroughly investigated and documented. They should be handled by technical personnel. 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 recall, NAFDAC must be fully notified of all actions at receipt of consumer complaint, during investigation and actual recall activity.

13.0 DISTRIBUTION SYSTEM:

Record of product distribution network must be properly kept for easy recall of defective products. Distributorsônames, addresses, fax, phone, email etc should be obtained.

14.0 TRANSPORTATION AND HANDLING:

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

15.0 LABEL

Product should be labeled adequately in English language and should also be in the three Nigerian languages (Hausa, Yoruba and Igbo}any other. The label should also contain the nutrition panel stating nutrient composition and within the label should be stated the net weight/volume of content, factory address, lot/batch number, usage instruction and NAFDAC registration number.

16.0 PRODUCT REGISTRATION

The food product should be registered with NAFDAC upon factory recognition and the following documents will be submitted for the processing of the product registration during review meeting at NAFDAC state office .

- A letter requesting for production inspection addressed to the Director (EID) submitted through the state office.
- The letter will be accompanied with the Standard Operating Procedures (SOP) for quality management system, Cleaning/Sanitation/Hygiene for plant/equipment, environment and personnel, Letter of appointment, acceptance , C.V and credentials of Production or plant manager and quality Control Manager, Certificate of Food Handlers test for production staff, List of equipment, Company organogram, Certified copy of agreement/certificate of fumigation or record of plant in-house fumigation activities, , certify copy of product name trade mark acceptance/registration, Certified copy of Company registration Certificate or Business name, payment receipt of registration fees, Filled Product Registration form, Borehole drilling geological report, vetted label/primary packaging material and payment receipt of product registration fees.

17.0 TARIFF

S/N	PRODUCTION INSPECTION	RENEWAL INSPECTION	GMP RE-ASSESSMENT	FOLLOW UP INSPECTION	ADVISORY INSPECTION	GLOBAL LISTING INSPECTION	LABORATORY ANALYSIS
	10,000:00	5,000:00	10,000:00	10,000:00	10,000.00	10,000.00	20,000:00

N/B: Laboratory analysis for the purpose of renewal shall be 50% of the original tariff.
5% VAT is charged on all statutory fees

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: