NAFDAC Good Manufacturing Practice (GMP) for Food and Food Products Regulations, 2025

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[ ] **Commencement**

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control ('the Governing Council') by Section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act. Cap. F33. LFN, 2004 and of all the powers enabling it in that behalf, the Governing Council with the approval of the Minister makes the following Regulations: -

Part 1
Objective and Application

1. **Objective**

   The objective of these Regulations is to provide regulatory framework Good Manufacturing Practice (GMP) requirements for manufacturing, processing, packaging or holding of a food or food product in Nigeria.

2. **Application**

   These Regulations prescribe the minimum current good manufacturing practice requirements for manufacturing, processing, packaging or holding of a food or food product, to ensure that such food or food product meet the requirements of safety, quality, wholesomeness and suitability for food or food products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

Part II
Quality System, Personnel, Premises and Equipment

3. **Quality System**

   (1) The manufacturer shall establish a quality system which shall cover organisational structure, responsibilities, policies, procedures, processes and application of the principles of risk management, as well as appropriate resource management, compliance management and records management.

   (2) Top management of the organization shall have the responsibility to ensure that the

   (a) quality system is in place, adequately resourced and its effectiveness is continually improved and sustained; and

   (b) roles, responsibilities, and authorities are defined, communicated and implemented in the organisation.

   (3) The organizational structure shall clearly define the responsibilities, authorities, interrelationships and qualifications of all personnel in the organization as well as its place in the parent organization, where applicable.

4. **Personnel**
   (1) The manufacturer shall have sufficient number of competent personnel with appropriate education, training, and experience, or any combination thereof to perform assigned functions and achieve the quality management objectives.
   (2) Initial and continuing training shall be in the particular operations that the employee performs and in good manufacturing practices as they relate to the employee's functions. Training effectiveness shall be verified and records of training shall be kept.
   (3) Where a holder of Certificate of Registration engages a Consultants to advise on the manufacture, processing, packaging, selling or holding of food and food products, the Consultant shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.
   (4) Hygiene programmes shall be established and observed, and shall include procedures relating to health, hygiene practice and clothing of personnel.
   (5) Personnel working directly with food, food contact surfaces, and food packaging materials shall conform to hygienic practices to protect against contamination of food.
   (6) Personnel shall be medically certified fit.

5. **Premises and Equipment**
   (1) Building and equipment used in the manufacture, processing, packaging, or holding of a food and food product shall be adequately located, designed, constructed, adapted, maintained and suitable to facilitate cleaning, maintenance, proper operations and safety of operators as appropriate to the type and stage of manufacture.
   (2) The facility shall not be located in an area that may be a potential source of contamination.
   (3) The building shall have adequate space for the orderly placement of equipment and materials and shall have orderly flow of personnel, materials and processes through the building to prevent contamination, cross contamination and any adverse effect on the quality of the product.
   (4) There shall be dedicated and self-contained facilities for the production of food and food products that cause hypersensitivity or allergic reactions to minimize the risk of hazards due to cross-contamination.
   (5) The manufacturer shall establish a program for preventive and breakdown maintenance of all equipment and instruments.
   (6) Operating systems for waste treatment and disposal shall adequate and not constitute a source of contamination in areas where food is exposed.
   (7) There should be adequate pest control system in place that will not compromise the quality of the product
   (8) Equipment, containers and utensil in contact with food shall be designed to withstand the environment and suitable for the intended use.
   (9) Cold storage compartment for storage shall be fitted with temperature-monitoring device.

Part III
Qualification and Validation, Documentation, Production, Materials Management, Quality Assurance System

6. **Qualification and validation**
   (1) Premises, Equipment and processes for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.
   (2) Critical processes shall be validated, continually monitored and periodically re-validated.
   (3) Changes to processes, systems, equipment, or materials that may affect product quality or process reproducibility shall be re-validated prior to implementation.

7. **Documentation**
   (1) The manufacturer shall establish and maintain a documentation system based upon instructions, records and reports covering the various manufacturing and control operations and all activities performed as appropriate to the quality system.
   (2) Pre-established procedures for general manufacturing operations and conditions shall be kept available together with specific documents for the manufacture and control of each batch. The set of documents shall enable the history of the manufacture of each batch of food or food product to be traced.
   (3) The manufacturer shall ensure adherence to good documentation practices.
   (4) Records pertaining to food and food product shall be maintained for at least 1 year after the expiration date or best before date of the food or food product.
   (5) Data shall be stored in retrievable manner and adequate measures taken to ensure data integrity, confidentiality and security shall be established, implemented and maintained.
   (6) Data may be stored by means of electronic , photographic or other data processing systems , which shall first be validated, to ensure that the data will be appropriately be stored during the anticipated period of storage
   (7) Data stored by these system shall be readily available in legible form and shall be provided to the Agency on request.
   (8) The electronically stored data shall be protected by methods such as duplication or back up and transfer onto another storage system, against loss or damage of data and audit trails shall be maintained.
   (9) Adequate measures to ensure data integrity, confidentiality and security shall be established, implemented and maintained.

8. **Production**
   (1) Procedures and instructions shall be established for production and process control to ensure that a food and food product has the characteristics and quality, it purports or is represented to possess. The procedures and instructions shall be followed and records maintained.
   (2) Any deviation from the procedures and instructions shall be reported, investigated, recorded and justified.

(3) Food and food product that do not meet the pre-established standard shall be documented and thoroughly investigated.
(4) There shall be adequate in-process control for production operations.
(5) Measures shall be taken to mitigate risks of cross-contamination.

9. **Materials management**
(1) The manufacturer shall maintain a list of approved suppliers from whom it shall source all materials and services.
(2) Adequate measures shall be taken to ensure that materials meet established specifications before use.
(3) Materials and products shall be stored under the appropriate conditions established by the manufacturer, and in an orderly fashion, to permit batch segregation and stock rotation.
(4) Cleaning, lubricating, fumigating, sanitizing and pest control materials shall not contaminate equipment and materials.

10. **Quality Assurance System**
(1) A manufacturer of food or food products shall have a quality assurance system place that identifies, implements, monitors and verifies critical factors in the manufacturing, processing, packaging, holding and distribution of food and that effectively prevents contamination or adulteration of food and ensures food safety.
(2) Quality assurance system shall meet the following requirements;
(a) Provide mechanisms to
(i) identify specific ingredients or food additives and the amounts used in a food;
(ii) control the use of food additives and nutrients as may be prescribed by the Agency:
(b) Ensure that
(i) information on food label is complete and accurately represents the food;
(ii) controls are put in place to prevent mislabeling food.
(iii) shelf-life studies are carried out to establish the best before, use by, and other relevant date markings for food or food products.
(c) Other requirements as may be prescribed by the Agency.
(3) There shall be measures in place to deal with deviations or defects that could affect food safety in their quality assurance program.

11. **Quality Control**
(1) Manufacturer of food or food products shall establish and maintain a quality control system.
(2) Where a manufacturer has established a quality control unit, the quality control department shall be under the authority of a person with appropriate qualifications.
(3) The manufacturer shall retain samples of each batch of finished food or food product for at least one year after the best before or expiry date.
(4) Where manufacturer contracts out the analysis of the food or food product, the analysis shall be carried out by an approved laboratory.

(5) Where the analysis of materials or products is contracted, the contract shall be in written form, clearly spelling out the responsibilities of each party.
(6) Appropriate records for all laboratory analysis shall be kept and maintained.
(7) Materials shall not be released for use, sale or distribution unless their quality has been adjudged satisfactory and approved by the authorized person.
(8) The manufacturer shall retain samples of each batch of finished products for at least 1 year after the expiry date.

Part III
Contract Manufacture, Complaints and Product Recall, Self-Inspection, Cleaning and Sanitation

12. **Contract manufacture**
(1) Where the whole or a part of the manufacturing process of a food or food products is contracted, the contract shall be in written form, clearly spelling out the responsibilities of each party.
(2) The contract acceptor shall be subject to inspections carried out by the Agency and the contract giver.
(3) The contract-acceptor shall not subcontract any of the work entrusted to him under the contract without written authorization from the contract-giver.

13. **Complaints and product recall**
(1) Complaints and other information concerning potentially defective products shall be carefully investigated, recorded and reviewed according to written procedures by the manufacturer.
(2) The manufacturer shall establish and maintain a system to recall from the market, promptly and effectively, products known or suspected to be defective.
(3) The manufacturer shall inform the Agency of any safety issues or defect that could result in the recall or abnormal restriction on supply of a food or food product within and outside the country as well as any regulatory action taken against the company by relevant authorities by virtue of non-compliance with requirements.
(4) Records of recall activity shall be kept and maintained.
(5) The food or food product recall shall be in accordance with the Agency's NAFDAC Recall, Handling And Disposal of Unwholesome and Adulterated Food and Food Products Regulations.

14. **Self-inspection**
(1) The manufacturer shall establish a routinely implemented self-inspection programme designed to monitor the implementation of GMP.
(2) The recommended corrective and preventive actions shall be implemented and records maintained.

15. **Cleaning and sanitation**
(1) Cleaning and sanitizing programmes shall be established and validated by the organization to ensure that the establishment, equipment and food contact surfaces are cleaned and sanitized.

(2) Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer's instruction.
(3) A factory shall be equipped with adequate sanitary facility.
(4) Cleaning in place (CIP) systems shall be separated from active product lines.
(5) Cleaning and sanitation programmes shall be monitored and documented to ensure their continuing suitability and effectiveness.

16. **Pest control**
(1) Suitable and effective pest control programme shall be in place.
(2) Pets shall not be allowed in any area of a food factory.
(3) Pursuant to regulation 16 (2) of this regulations, guard or guide animals may be allowed in some areas of a factory if the presence of the animals is unlikely to result in contamination of food, food-contact surfaces, or food packaging materials.
(4) Animals referred to in regulation 16 (3) shall be excluded from processing areas to prevent contamination of food.

17. **Waste disposal**
Systems shall be in place to ensure that waste materials are identified, collected, treated, removed and disposed to prevent contamination of products or production areas.

18. **Warehousing and Distribution**
Storage and transportation of finished food shall be under conditions that maintain it integrity.

19. **Defect Actions levels**
(1) Defect action levels shall apply to natural or unavoidable defects in food for human use that present no health hazard.
(2) Food shall comply with maximum defect action levels as may from time to time be established by the Agency.
(3) Food produced based on new and advanced technologies, formulations, or based on the availability of new information that comply with maximum defect action levels shall not be hazardous to health.
(4) The manufacturer, distributor and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
(5) The mixing of a food containing defects above the current defect action level with another lot of food shall not be permitted and shall render the final food adulterated.
(6) Compliance with defect action levels shall not excuse violation of the requirement of these regulations.

20. **Control of hazards**
(1) A manufacturer of food or food products shall control food hazards through the use of systems such as Hazard Analysis and Critical Control Points. The manufacturer shall:
(a) Identify any steps in their operations which are critical to the safety of food or food products

(b) Implement effective control procedures at those steps;
(c) Monitor control procedures to ensure their continuing effectiveness and
(d) Review control procedures periodically, and whenever the operations change.

21. **Prohibition**

(2) A person shall not manufacture, process, package, sell or hold a food product except as provided in these Regulations.

(3) Failure to comply with any provision set forth in these Regulations shall render such food or food product unwholesome or adulterated and such food or food product, as well as the person who is responsible for the non-compliance, shall be liable to the penalty as set forth in these Regulations.

Part IV
Offences and Penalties, Forfeiture after Conviction

22. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations commits an offence and shall be liable on conviction. In case of -
(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000.00 or to both; and
(b) a body corporate, to a fine not exceeding N5,000, 000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every: -
(a) director, manager, secretary or other similar officer of the body corporate.
(b) partner or officer of the firm.
(c) trustee of the body concerned.
(d) person concerned in the management of the affairs of the association; or
(e) person who purports to act in a capacity referred to in paragraphs (i) to (iv) of this sub-regulation, is severally liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

23. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government:-
(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and
(b) any of the person's property or instruments used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

Part V
Miscellaneous

24. **Interpretations**

In these Regulations, unless the context otherwise requires, the following terms shall have the meanings specified:

Agency means National Agency for Food and Drug Administration and Control

Batch or Lot-means the food produced during a period of time indicated by a specific code.

Cleaning in place means cleaning of equipment by impingement or circulation of flowing chemical solutions, cleaning liquids and water rinses into, onto, and over surfaces in equipment or systems without dismantling and design for purpose.

Contamination means the undesired introduction of impurities of physical, chemical or microbiological nature of foreign matter into or onto a starting/raw material, intermediate or finished product during production, sampling, packaging or repackaging, storage or transport

Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

Defect Action Levels means level of natural or unavoidable defects in food for human use that present no health hazard

Food means any article manufactured, sold or advertised for use as food or drink and includes drinking water, chewing gum, and other ingredients as may be mixed with food for any purpose whatsoever, including supplements processed for addition to animal and poultry feeds.

Food-contact surfaces means those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Good Manufacturing Practice (GMP) means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Certificate of Registration.

Pest means any objectionable animal or insect including, but not limited to, birds, rodents, flies, and larvae.

Pre-established procedures mean but not limited to, standard operating procedure, work instructions, batch manufacturing record.

Quality assurance means a program for the systematic monitoring and evaluation of the various aspects of a project, service or facility to ensure that the standards of quality re met.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of these Regulations.

Regulatory action includes product hold, recall, forfeiture, or destruction, sealing of manufacturing line or facility, withdrawal of GMP certificate or product license/registration certificate, prosecution

25. **Citation**

These Regulations may be cited as NAFDAC Current Good Manufacturing Practice for Food and food Products Regulations, 2025.

MADE at Abuja this ……. day of ……..2025

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Dr. Mansur Kabir
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)