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

CURRENT GOOD MANUFACTURING PRACTICE FOR FOOD AND FOOD PRODUCTS REGULATIONS, 2019

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ARRANGEMENT OF REGULATIONS

Regulations

CURRENT GOOD MANUFACTURING PRACTICE FOR FOOD AND FOOD PRODUCTS REGULATIONS, 2019

[ ] **Commencement**

In exercise of the powers conferred on it Sections 5 and 30 of the National Agency for Food and Drugs Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Honorable Minister of Health makes the following Regulations –

1. **Scope of 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.

2. **Prohibition**

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

   (2) 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.

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 an effective quality system is in place, adequately resourced, the effectiveness continually improved and that roles, responsibilities, and authorities are defined, communicated and implemented throughout 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) Consultants advising on the manufacture, processing, packaging, selling or holding of food and food products 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 adapted to the activities to be carried out shall be established and observed. These programmes shall include procedures relating to health, hygiene practice and clothing of personnel.

(5) All personnel working in direct with food, food contact surfaces, and food packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food.

(6) All personnel shall be certified medically fit and free from open lesions, including boils, sores, or infected wounds, or any other source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated.

5. **Premises and Equipment**

(1) Any 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 be in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(7) Where the factory premises are bordered by other areas not under the operator's control and not maintained in a manner as prescribed by the Agency and care shall be exercised by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(8) All equipment, containers and utensil surfaces in contact with food shall be made of materials that are impervious, non-reactive, non-toxic, designed to withstand the environment and suitable for the intended use.

(9) Each cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with temperature-monitoring device.

6. **Qualification and validation**

(1) Equipment and processes for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.

(2) All 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) All records pertaining to a food and food product shall be maintained for at least 1 year after the expiration 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.

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) All 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) All 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) A quality assurance system shall meet all the requirements of the Agency including the following:

(a) Provide mechanisms to identify specific ingredients or food additives and the amounts used in a food;

(b) Provide mechanisms to control the use of food additives and nutrients as prescribed by the Agency:

(c) Ensure that information on a food label is complete and accurately represents the food;

(d) Ensure that controls are put in place to prevent mislabeling food.

(e) Ensure that shelf life studies are carried out to establish the best before, use by, and other relevant date markings for food or food products.

(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) A 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.

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) All 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.

(4) 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.

(3) Records of all recall activity shall be kept and maintained.

(4) The food or food product recall shall be in accordance with the extant Food Product Recall Regulations 2019.

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 all part of the establishment, equipment and food contact surfaces are cleaned and sanitized to a defined schedule, including the cleaning equipment.

(2) Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturers instruction.

(3) Cleaned and sanitized portable equipment with food contact surfaces and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination.

(4) A factory shall be equipped with adequate sanitary facility.

(5) Cleaning in place (CIP) systems shall be separated from active product lines.

(6) 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 to ensure there are no signs of pest infestation.

(2) No pets shall be allowed in any area of a food factory. 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. Effective measures shall be taken to exclude animal from the processing areas and to protect against the contamination of food on the premises.

17. **Waste disposal**

Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed off in a manner which prevents contamination of products of production areas.

18. **Warehousing and Distribution**

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as prevent deterioration of the food and the container.

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) All food shall comply with maximum defect action levels established from time to time by the Agency.
(3) Foods 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**

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. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :
   (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N400,000 or to both such imprisonment and fine; and
   (b) a body corporate, to a fine not exceeding N600, 000.

(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; or
   (b) partner or officer of the firm or

(c) trustee of the body concerned ;or
(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 (a) to (d) 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.

22. **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;
(b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.
(2) In this regulation, "**proceeds**" means any property derived or obtained, directly or indirectly, through the commission of the offence.

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

Adulterated Food and Food Products means food that has been prepared, packed, or held under condition that is unfit for human consumption whereby it may have become contaminated with filth, chemical or microbial substances and it may have been rendered injurious to health. It includes the addition or subtraction to or from food so that the natural composition and quality of the food is affected.

Agency means National Agency for Food and Drug Administration and Control

Batch/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 means 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 but not limited to product hold, recall, forfeiture, or destruction, sealing of manufacturing line or facility, withdrawal of GMP certificate or product license/registration certificate, prosecution

Re-work means Clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Unwholesome Food and Food Products means any food product which

(a) consists in whole or in part of any filthy, putrid or decomposed substances;

(b) has been prepared, packaged or stored under unsanitary conditions where it may have been contaminated with filth or whereby it may have been rendered injurious to health;
(c) is packed in a container composed in whole or in part of any injurious or deleterious substance which may render the content injurious to health;
(d) bears or contains for the purpose of colouring only other than one which is prescribed; or
(e) contains any harmful or toxic substance which may render it injurious to health or has been mixed with some other substance so as to reduce its quality or strength.

Work in process (WIP) means partially processed products that are no longer part of the raw materials inventory and not yet part of the finished product inventory, waiting for further processing or in the buffer storage.

24. **Citation**

These Regulations may be cited as Current Good Manufacturing Practice for Food and food Products Regulations, 2019.

MADE at Abuja this …….day of ……..2019

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Inuwa Abdulkadir Esq
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)