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TANZANIA BUREAU OF STANDARDS

CRITERIA FOR GMP AUDIT OF HIGH-RISK FOOD MANUFACTURING FACILITIES

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ACKNOWLEDGEMENT

These Criteria have been developed based on the General Principles of Food Hygiene (CXC 1-1969), 10 Principles of GMP in Food Manufacturing Industries, WHO GMP requirement as per TRS 957-Annex 2, Directive 2001/83/EU as amended through Directive 2011/62/EU, experience and knowledge in order to enhance food manufacturers to comply with Good Manufacturing Practices (GMP) requirements.

I would like to express my sincere gratitude to all members of the Directorate of Quality Management who contributed to the drafting and writing of these criteria.

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Habakuki Kalebo

PRODUCT AND PREMISES REGISTRATION MANAGER

FOREWORD

Food Safety and Quality in food manufacturing industry are summation of the intangible factors necessary and sufficient to assure performance of desired functions aiming at consistently getting safe food of acceptable quality. It cannot be tested into a food product only, but must be built into it by reliable workers in every phase of processing and production. The excellence of a company's products reflects the integrity, competence, and pride of all those involved in the design, production, and marketing of the food products.

One of the most well-known sets of requirements that have a major impact on providing consistently, assurance of safe food of acceptable quality in the food industries is *Good Manufacturing Practices (GMP)*. These criteria address the requirements for premises, equipment, personnel, quality and process controls, documentation, storage, validations, and manufacturing processes including packaging and labeling.

These should be considered as general criteria and should be adopted to meet individual needs, making sure that the established standards of safety and quality for food are still achieved.

These *Criteria for GMP Audit* shall be used to justify GMP status as a prerequisite prior to registration of high-risk food products into Tanzania. It is my hope that, the Criteria will be useful during assessment of food manufacturing facility on compliance to GMP requirements.

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DIRECTOR OF QUALITY MANAGEMENT

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DEFINITIONS

The definitions are given for the purpose of these criteria.

Allergen	Means a food substance which, in some sensitive individuals, causes an immune response causing bodily reactions resulting in the release of histamine and other substances into the tissues from the body's mast cells in the eyes, skin, respiratory system and intestinal system.
Analytical method	Means detailed description of the procedures to be followed in performing tests for conformity with Specification
Bulk Product	Means any product which has completed all processing stages up to, but not including, packaging (not applicable to those products where processing takes place inside the container and the latter is itself therefore part of the processing)
Competent authority	Means any person or organization that has the legally delegated or invested authority, capacity, or power to perform a food control regulatory function.
Contract manufacture	Means manufacture or partial manufacture ordered by one person or organization (the Contract Giver) and carried out by a separate person or organisation (the Contract Acceptor).
Documentation	Means written production procedures, instructions and records, quality control procedures, and recorded test results involved in the manufacture of a product.
Finished Product	Means a product which has undergone all stages of manufacture and packaging.
Food Hygiene	Means all conditions and measures necessary to ensure the safety and suitability of food from production to consumption
Food Safety	Means assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eatern according to its intended use
Genetically Modification	Means a process of altering the genetic characteristic of an organism by the insertion of a modified gene or a gene from another organism using the techniques of genetic engineering
Good Manufacturing Practice	Means practices involving combination of manufacturing as well as safety and quality control procedures (control system), aimed at ensuring that products are consistently manufactured to their specifications.

Ingredients	Means all materials, including starting materials, processing aids, additives and compounded foods, which are included in the formulation of the product.
In-process Control	Means a system of checks made and actions taken during the course of manufacture to ensure that materials at any stage comply with the specification for that stage, and that the processing and processing environment comply with the conditions stated in the Master Manufacturing Instruction.
Manufacture	Means a complete cycle of production of a food from the acquisition of all materials through all stages of subsequent processing, packaging and storage to the dispatch of the finished product.
Novel Foods	Means a) a substance, including a microorganism, that does not have a history of safe use as a food or; b) a food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes the food to undergo a major change or; c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that the plant, animal or microorganism exhibits characteristics that were not previously observed.
Packaging material	Means any container or material used in the packaging of a product. This my include materials in direct contact with the product, printed packs, including labels, carrying statutory and other information, and other packaging materials including outer cartons or delivery cases. These categories are, of course, not necessarily mutually exclusive.
Processing	Means the transformation of raw ingredients into food, or of food into other forms.
Quality Assurance	Means the total of the organized arrangements made with the objective of ensuring that finished products are of the quality required for their intended use.
Quality Control	Means part of GMP that ensures raw materials are not released for use, and that finished product are not released for sale or supply, until their quality has been deemed satisfactory.

Quality Management	Means a comprehensively designed and correctly implemented system of Quality Assurance (QA) that incorporates Good Manufacturing Practices (GMP) and Quality Control (QC).
Raw Material	Means any material, ingredient, starting material, semi-prepared or intermediate material, packaging material, etc, used by the manufacturer for production of a product.
Registration of product	Means an official authorization by the Bureau for purpose of launching or release to the market after evaluation for safety and quality.
Rework	Means the process of collection defects or non-conformities found in a product or process during the production or manufacturing stage.
Risk	Means the probability that a particular adverse consequence results from a hazard within a stated time under stated conditions.
Specification	Means a document giving a description of material, machinery, equipment, process of product in terms of its required properties or performance.
Validation	Action of proving and documenting that any process/procedures and methods actually and consistently lead to the expected results.
Validation process	Means a process of collection and evaluation of data throughout the product life cycle which provide documented scientific evidence that the process is capable of consistently delivering quality products

INTRODUCTION

These GMP Audit Criteria stipulate the minimum requirements for Good Manufacturing Practice in *High-Risk* food manufacturing facility. These Criteria are not static and therefore improvements can be made as deemed necessary.

The purpose of these Criteria is to outline the responsibilities of food facility managers in relation to the efficient manufacture and control of *High-Risk* food; thereby ensuring that such products are safe, wholesome and of the nature and quality intended. The criteria will also be used as a reference for auditors while carrying out GMP audit of overseas *High Risk Food Manufacturing Facilities* for the purpose of registration of imported High Risk food products in Tanzania.

These GMP Audit Criteria comprises of three chapters; Chapter one highlights the requirements for location and design of the manufacturing plant. Chapter two elaborate the requirements for manufacture, packaging and quality management. Chapter three provides the requirements for personnel hygiene, education and training.

Adherence to these criteria by food manufacturers will contribute substantially to the manufacture of consistently uniform batches of quality and safe food products.

CHAPTER ONE

1.0 REQUIREMENTS FOR FOOD MANUFACTURING PREMISES DESIGN AND EQUIPMENT

1.1 General requirements for premises

a) Plant layout and operation flow should minimize or prevent cross contamination of food.

b) Plant should be kept in a condition that protects against contamination of food.

c) Production facility should be authorized by the *Competent National Body* responsible for regulating food safety in the country where it is located.

1.2 Premises

1.2.1 Ventilation and Lighting

a) Provide adequate ventilation by using control equipment such as fans and other air-blowing equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food;

b) Provide adequate lighting in all areas of the plant depending on the nature of operation.

c) Provide well-protected safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation to prevent food contamination.

1.2.2 Floors, Walls and Ceiling

a) The premises should be constructed in such a manner that floors, walls, and ceilings are adequately cleaned and kept clean and in good state of repair;

b) The surface of floors, walls and partitions should be made of impervious materials that are easy to clean and where necessary disinfect.

1.2.3 Cleaning agents and facilities

1.2.3.1. Cleaning facilities

Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas.

Appropriate cleaning and maintenance procedures should be in place to ensure effective implementation without compromising food safety

1.2.3.2. Cleaning agents

The requirements for substance used in cleaning which aim at preventing contamination include the following:

a) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures should be free from undesirable microorganisms and should be safe and adequate under the conditions of use.

b) Cleaning compounds, sanitizing agents and pesticide chemicals be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

1.2.4 Personal hygiene facilities and toilets

a) Plant should be provided with adequate toilet facilities.
b) Toilet facilities should be provided with self-closing doors.
c) The toilet facilities should be kept in a good state of repair and maintained sanitary condition.
d) Toilet doors should not open into areas where food is exposed to avoid contamination.
e) Plant should be provided with adequate and convenient hand-washing facilities.
f) Plant should be provided with readily understandable signs directing employees to clean and sanitize their hands before handling unprotected food.
g) Devices or fixtures, such as water control valves, should be designed, constructed and maintained to protect against recontamination of clean and sanitized hands.
h) Suitable changing facilities for personnel should be provided and separated from production area.

1.2.5 Water Supply

a) The water supply should be sufficient and safe for the operations intended.

b) Running water at a suitable temperature and required pressure, should be provided in all areas where required for the manufacturing plant.

1.2.6 Pest control

a) Effective measures should be taken to exclude pests from the processing areas and to protect against the contamination of food.

b) Use where applicable, insecticides or rodenticides in a manner that will not contaminate food, food-contact surfaces, and food-packaging materials.

1.2.7 Waste management

a) Provide and maintain adequate drainage and waste disposal systems and facilities.

b) The facilities should be designed and constructed to prevent food and water contamination.

c) Waste should be so conveyed, stored, and disposed of as to minimize the development of odor and potential for the waste becoming an attractant and harborage or breeding place for pests and microbes.

d) Refuse receptacles including dust bins should be constructed and maintained in a manner that protects against contamination of food.

e) Plumbing should be of adequate size, design, installed and maintained to prevent back flow, cross connections and backup of sewer gases of waste water and sewage.

1.2.8 Storage

a) Adequate facilities for storage of food, ingredients and non-food chemicals should be provided.

b) Storage area should be designed to prevent pests, contamination and degradation of ingredients, finished products or packaging material from dust, debris and any other environmental factors.

c) Product stocking system should be in place to allow proper product rotation.

d) Accurately temperature measuring and/or recording device(s) should be fitted in cold storage facilities.

1.3 Equipment

a) Equipment should be constructed and installed in such a manner that aisles or working spaces are provided between equipment and walls. They should be adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces.

b) Plant equipment and utensils should be designed to allow cleaning, maintenance, disinfection and facilitate inspection for pests.

c) Food contact surfaces should be corrosion-resistant, smooth and non-porous.

d) All food-contact surfaces, including utensils and equipment should be cleaned as frequently as necessary to prevent food contamination.

e) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture non-human food such as animal feed.

f) Instruments used for measuring, regulating, or recording conditions (temperatures, pH, acidity, water activity) should be accurate and sufficient.

g) Regular calibration of all measuring equipment (weight, volume, temperature etc.) should be carried out using appropriate standards.

h) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment, should be treated in such a way that food is not contaminated.

CHAPTER TWO
2.0 REQUIREMENTS FOR CONTROL OF MANUFACTURING OPERATIONS

2.1 Processes and Controls

a) All production processes should be conducted in accordance with Good Hygienic Practice (GHP) and Good Manufacturing Practice (GMP) principles.

b) Appropriate quality control personnel should be employed to ensure production of safe food.

c) Chemical, microbial, or physical quality testing procedures should be used to identify sanitation failures or possible food contamination.

d) The sampling requirements for in-process control, acceptable limits and monitoring process should be based on standards and procedures in place.

e) Defective batch should remain quarantine pending rework or recovery of material or outright rejection.

2.2 Raw Materials and other Ingredients.

a) The raw materials and other ingredients to be used should be *Generally Recognized as Food (GRAF)* and *Generally Recognized as Safe (GRAS)*.

b) Raw materials and other ingredients should be cleaned as necessary to remove soils and other contaminants.

c) Acceptance criteria of raw materials in terms of microbial, chemical as well as physical quality and safety specifications should be in place.

d) Incoming materials should be procured according to specifications and their compliance with food safety and suitability specification should be verified.

e) First in / first out or first expiry principle should be adopted.

f) Criteria for selection of vendors and list of approved vendors should be available.

g) Areas for under-test, approved and rejected raw materials should be separately available and marked.

h) Each batch of raw materials used should contain the same ingredients and their respective nutrient(s) concentrations or/and other health benefit components declared by supplier throughout the shelf life.

2.3 Manufacturing Operations.

a) All food manufacturing operations including filling, packaging and storage should be conducted under safety and quality control conditions.

b) Finished food products should be kept separate from raw materials and other ingredients or refuse to prevent contamination.

c) Packaged finished products should be quarantined until checked and approved by quality control for compliance with the appropriate product specification.

d) Packaging design and materials should be safe and suitable for food use, provide adequate protection for products to minimize contamination, prevent damage and accommodate proper labelling.

e) Packaging materials should be appropriate for maintaining stability of the product throughout the shelf life.

2.4 Good Control Laboratory Practices

a) Laboratory facilities should be capable of conducting analysis of the appropriate parameters.

b) Laboratory personnel should be properly trained and well managed.

c) Quality control activities should be done in accordance to the set national or international standards.

d) Physico-chemical, biological and microbiological laboratories should be separated from each other.

e) Specifications approved by Quality Control including analytical parameters should be established for all raw materials, intermediate and finished products.

f) Suitable test-methods validated in the context of available facilities and equipment should be adopted or developed.

g) In-house testing can be supported by external laboratories (if necessary), accredited by an official national or international authority for the specific analysis required.

2.5 Laboratory Equipment and Instruments

a) Equipment and instruments should be serviced and calibrated at suitable specified intervals by an assigned competent person(s) or organization.

b) Written operation instructions should be readily available for each instrument.

c) Analytical methods including a control test to verify that the equipment is functioning satisfactorily should be provided.

2.6 Laboratory Reagents

a) Reagents made up in the laboratory should be prepared by competent personnel and as per documented procedures.

b) Reagents should be suitable for use and labeled to indicate the concentration, standardization factor, shelf life, and storage conditions.

c) Both positive and negative controls should be applied to verify the suitability of microbiological culture media.

2.7 Sampling Requirements for Laboratory Analysis

a) Written sampling procedures should be developed and maintained specifying the method and rate of sampling.

b) All samples should be identified according to standard procedures.

c) Sampling methods used should be acceptable to any enforcing authority nationally and/or internationally.

2.8 Laboratory Records

a. Detailed records should be maintained for all tests and analyses performed in the laboratory.

b. Calibration records should be kept in a good manner that will facilitate comparative reviews of those results and the detection of trends.

c. Analytical records taken should contain: -
   i. Name of product or material and code reference;
   ii. Date of receipt and sampling;
   iii. Source of product or material (including supplier and country of origin);
   iv. Date of testing;
   v. Batch or lot number;
   vi. Indication of tests performed;
   vii. Reference to the methods used;
   viii. Results;
   ix. Decision regarding test results;
   x. Signature or initials of analyst, and signature of person taking the above decision.

2.9 Validation and Process Validation

a) Validation studies of processing, testing and cleaning should reinforce Good Manufacturing Practices and be conducted in accordance with defined procedures.

b) Processes and procedures should undergo periodic critical re-validation to ensure that they remain capable of achieving the intended results.

c) Records and conclusions of validation studies should be prepared and maintained.

2.10 Product Rework

a) Rework procedures/guidelines should be developed, documented and utilized.

b) Records on re-testing and re-evaluation criteria for the non-conforming product after rework should be retained.

c) A reworked batch should meet all the original product specification including stability characteristic and be given a new batch number.

2.11 Product Stability Study

a) Procedures for determining shelf life and storage conditions of the product which outline the testing plan, conditions, intervals and acceptance criteria should be available.

b) Records of tested samples and frequency of testing for determining shelf life and storage conditions should be retained.

c) Stability study reports should be prepared and retained.

2.12 Complaint and Product Recall / Withdraw

a) Customer complaints handling procedures for receiving, assessing and managing all concerning the quality and safety of the products should be in place.

b) A designated person shall be responsible for handling complaints.

c) Records of complaints and adverse effects should be retained.

d) The procedures for product recall/withdraw should be available and clearly define responsibilities, reporting, communication to the competent food safety regulatory authorities and reconciliation.

e) Product recall should be done after investigation and evaluation of the complaint.

f) The distribution records of the product should be readily available.

g) The progress of the recall/withdraw process should be monitored and recorded.

h) The effectiveness of the arrangements for recalls should be tested and evaluated from time to time.

2.13 Disposal of Wastes

a) Proper disposal procedures for disposing of wastes or rejected products/materials should be available and comply with regulations of the country where the manufacturing facility is located.

b) All rejected products should be stored in designated controlled areas to prevent misuse and contamination.

c) Wastes disposal records including the reason for rejection and disposition method used should be retained.

2.14 Contract Manufacturing of the Food Product

a) Contract manufacturing shall have a written contract agreement between the contract giver and contract acceptor, which clearly describe the duties and responsibilities of each party.

b) The contractual conditions, which ensure quality standards should be imposed by contract giver.

c) The contract should include GMP principles/requirements to be followed accordingly by the acceptor as prescribed in these criteria.

d) The contract giver shall be responsible for assessing the competence of the contract acceptor to be assured on carrying out successfully the product manufacture /tests required as per requirements stipulated in the contract.

e) The contract giver shall ensure that all products and materials delivered by the contract acceptor comply with required specifications.

f) The contract acceptor shall ensure that all products or materials received are suitable for their intended purposes.

2.15 Control on Product Design and Development

a) The Manufacturer should be capable of conducting research and development of the products placed in the market by observing among other things Tanzania food safety regulatory requirements such as food labeling requirements including claims.

b) The department/unit dedicated for product designs**,** formulation and development should carry out such business process using appropriate developed procedures.

c) The developed procedures should include the handling of enquiry associated with reformulation of the product following regulatory requirements.

d) The responsible department/unit should collaborate with the laboratory in the facility particularly on testing the realization of what has been designed/formulated/developed/claimed about the product**.**

e) Product design, formulation and development can be supported by external competent R&D Department/ Institution outside the manufacturing facility (if necessary) on contract bases.

2.16 Novel Foods and Processes

a) The novel foods including genetic modification (GM) should be legally approved for use in the Tanzanian market.

b) Novel foods and processes, including genetic modification (GM) should be clearly declared on the label.

2.17 Control of Allergens

a) Procedures for allergens management should be in place and utilized (where applicable).

b) Presence of allergens such as milk, egg and their derivatives should be identified in raw materials and products.

c) Equipment used to manufacture Major Serious Allergens (MSAs)-containing products should be separated or cleaned before being used.

d) The presence or potential presence of MSA should be clearly stated on the product label.

2.18 Self Inspection and Quality Audit

a) The facility should constitute a self-inspection team supplemented with quality audit procedures to evaluate the performance on implementation of GMP requirements.

b) The self-inspection should be conducted at interval of at least once a year.

c) Records of the observations made during the inspection, action proposed and taken, relevant time frames for completion and any statement made on the actions taken should be retained.

2.19 Quality Management System

(a) The food manufacturing facility should have in place a comprehensive quality management system, so designed, documented, implemented, and furnished with personnel, equipment and resources to ensure that specifications set to achieve the intended product quality and safety standards are consistently met.

2.20 Documentation

a) Documents should be designed, prepared, reviewed and controlled to provide an audit trail.

b) Documents should be approved, signed and dated by appropriate and authorized person.

c) Documents should have unambiguous contents; the title, nature and purpose.

d) The record should be made at the time of each operation in such a way that all significant activities concerning production are traceable.

e) Site Master File and detailed Standard Operating Procedures should be available.

f) Documents should be easily retrievable.

2.21 Documents for Instructions and Procedures

The documents for Instructions and procedures include: -

a) Ingredient specification
b) Packaging material specification
c) Master Manufacturing Instructions including flow sheets
d) Bulk Products Specification
e) Finished Products Specification
f) Quality Control Procedures and Methods
g) Cleaning Instruction, Housekeeping and Pest Control Schedules

2.22 Documents for Records

The documents for records and reports include: -

a) Quality Control Records
b) In-process control records
c) Customer Complaint Records
d) Product recall records
e) Food handlers' health records
f) Batch Manufacturing Records
g) Quality Audit Records

CHAPTER THREE
3.0 REQUIREMENTS FOR PERSONNEL AND TRAINING

3.1 Personnel general requirements

a) Manufacturing and testing of products should be conducted by approved technical staff.

b) The heads of production and quality control/quality assurance should be independent from each other.

c) There should be adequate number of personnel employed in direct proportional to the work load.

d) The personnel duties and responsibilities should be clearly identified and recorded as job description or by other suitable means.

3.2 Personnel training requirements

a) There should be a training policy of personnel at various levels.

b) Food handlers, analysts, supervisors and other personnel should receive appropriate training on proper food handling techniques, good laboratory practices, good sanitary practices, personal hygiene and GMP principles.

c) Visitors and/or untrained personnel should be given relevant information in advance and protective gears before taken into the production area.

3.3 Personnel health requirements

a) Employees should be medically examined by authorized medical practitioner at first appointment and after every six months or as per national health policy.

b) Any person who appears to have illness should be excluded from any manufacturing operation.

c) Records of such medical examination should be retained.

d) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials should conform to hygienic practices while on duty.

e) Employees should not wear jewellery, watches, pins or other items unless secured to prevent contamination.

4.0 REFERENCES

1. TZS 109: 2023 (1st Ed) **Food processing units – Code of hygiene**

2. TZS 184: 1984 (1st Ed) **Food processing units – Infant and child food General hygiene requirements.**

3. Good Manufacturing Practices (GMP) Guidelines – 2009 Edition, Version 2 (GUI-0001) / March 4, 2011. Health Canada / Health Products and Food Branch Inspectorate. http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli conform/gmp-bpf/docs/gui-0001-eng.pdf.

4. FAO and WHO. 2023. General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome. https://doi.org/10.4060/cc6125e.

5. WHO GMP requirement as per TRS 957-Annex 2, Directive 2001/83/EU as amended through Directive 2011/62/EU