REPUBLIC OF RWANDA

RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR GOOD MANUFACTURING PRACTICES OF FOOD

MAY, 2019

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law n° 003/2018 of 09/02/2018 determining its mission,organization and functioning .One of its main powers is to formulate regulations and guidelines for regulating the manufacture of food products to ensure that they comply with quality standards required for good manufacturing practices of food,

Badly manufactured food effects is one of the public health concerns not only to our country but all over the world. It is in this context that the Rwanda Food and Drugs Authority intends to put in place guidelines that provide for good manufacturing practices of food to ensure that manufactured food do not constitute harmful effects to people's health and leads to losses of life,

It is expected that these guidelines will offer a clear understanding to manufacturers and other persons concerned by the guidelines during the evaluation process, they will protect consumers from and food manufacturing industry,thus promoting health protection,business and the national economy as a whole.

RWANDA FOOD AND DRUGS AUTHORITY • RWANDA FDA

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DIRECTOR GENERAL
(RWANDA FOOD AND DRUGS AUTHORITY)

DEFINITIONS

The definitions are given for the purpose of these guidelines.

Analytical method	Means detailed description of the procedures to be followed in performing tests for conformity with the Specification
Authority	Means the RWANDA FOOD AND DRUGS AUTHORITY or its acronym RWANDA FDA.
Batch	Means the quantity of material which has been produced during a defined period of manufacture. A "batch" may actually have been produced by a batch-wise process, or may correspond to the particular time duration during the run of a continuousprocess.
Batch Number	Means a unique combination of numbers orletters, or both, used to identify a batch ad permit its history to be traced.
Batch Manufacturing Record	Means a document stating the materials used and operations carried out during the manufacture of a given batch, including details of in-process controls and the results of any corrective actiontaken.
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 process)
Chilled Foods	Means perishable foods which, to extend the time during which they remain wholesome, are kept within controlled and specified ranges of temperature above their freezing points and normally below 8^{o}C.
Cold Chain	Means an organised system governing the conditions under which frozen foods are stored and handled by the producer, distributor and retailer.
Commercial Sterility	Means the condition achieved by the application of heat, which renders the processed product free from viable microorganisms, including those of known public health significance, capable for growing in the food at the temperatures at which the food is likely to be held during distribution and storage.

Competent authority	Means any person or organization that has the legally delegated or invested authority, capacity, or powerto 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).
Critical Control Point	Means a material, or a location, or a practice, or a procedure, or a process stage where loss of control would result in an unacceptable food safetyrisk.
Documentation	Means written production procedures, instructions and records, quality control procedures, and recorded test results involved in the manufacture of aproduct.
Finished Product	Means a product which has undergone all stages of manufacture and packaging.
Food 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 in the tissues from the body's mast cells intheeyes,skin,respiratorysystemandintestinalsystem.
Food Control	Means a mandatory regulatory activity of enforcement by National or local authorities to provide consumer protection and ensure that food during production, handling, storage, processing and distribution are safe, wholesome and fit for human consumption; conform to the quality and safety requirements; and are honestly and accurately represented in its labeling as prescribed by law.
Food Poisoning	Means any illness associated with consumption of food which has been contaminated, particularly with harmful microorganisms or their toxins.
Food Spoilage	Means the deterioration of food, including that caused bythe growth of undesirable microorganisms to high level, which may result in fermentation, mould growth and development of undesirable odours andflavours.
Frozen Foods	Means foods preserved by freezing and storing at temperatures, low enough to inhibit the growth of microorganisms and to retard chemical and physical reactions to a negligible rate.
Genetically Modification Organism	Means an organism whose genetic characteristicshave been altered by the insertion of a modified gene or a gene from another organism using the techniques ofgenetic engineering

Good Manufacturing Practice	Means a combination of manufacturing and quality control procedures aimed at ensuring that products areconsistently manufactured to theirspecifications.
Hazard Analysis Critical Control Point (HACCP)	Means a system which identifies, evaluate and controls hazards which are significant for food safety.
Hazard	Means a biological, chemical or physical agent in, or condition of, food with a potential to cause an adverse healtheffect.
Hazard Analysis	Means a process of collecting and evaluating informationon the hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in HACCPPlan.
Ingredients	Means all materials, including startingmaterials, processing aids, additives and compounded foods, which are included in the formulation of theproduct.
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.
High Care Area (HCA)	Means an area designed to a high standard of hygienewhere practices relating to personnel, ingredients, equipment, packaging and environment aim to prevent contamination by microorganisms or othercontaminants.
High Risk Area (HRA)	Means a physically segregated area, designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment, packaging and environment aim to prevent contamination by pathogenic microorganisms, other microorganisms or othercontaminants.
Intermediate Material	Means a partly processed material which must undergo further processing before it becomes a Bulk Product or a Finished Product.
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 ofthe finished product.

Master Manufacturing Instructions

Means a document or documents identifying the raw materials, with their quantities, to be used in the manufacture of a product, together with a description of the manufacturing operations and procedures including identification of the plant and facilities to be used, processing conditions, in-process controls, packaging materials to be used and instructions for the removal of finished product tostorage.

Novel Foods

Means

a) A substance, including a microorganism, that does not haveahistoryofsafeuseasafoodor;

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 amajor change or;

c) A food that is derived from a plant, animal or microorganism that has been genetically modified suchthat the plant, animal or microorganism exhibits characteristics that were not previouslyobserved.

Packaging material

Means any container or material used in the packaging of a product. This may 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 mutuallyexclusive.

Preservation Index

A term deriving from the pickles and sauces industry to designate the percentage of acetic acid contained in the total volatile constituents of a product or ingredient, thus indicating probable microbialstability.

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 arenot released for use, and that finished product are not released for sale or supply, until their quality has beendeemed 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).
Quarantine	Means a process of setting aside any materials or product while awaiting a decision on its suitability for its intended use or sale.
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.
Rework	Means unincorporated food product kept for subsequent use or reprocessing.
Risk	Means the probability that a particularadverse consequence results from a hazard within a stated time under statedconditions.
Specification	Meansa document giving a description of material,machinery, equipment, process of product in terms ofits required properties or performance.

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INTRODUCTION

The RWANDA FOOD AND DRUGS AUTHORITY (RWANDA FDA) has the responsibility of protecting the health of consumers against hazards associated with consumption of food. As part of fulfilling the responsibility and in order to be in line with recent advancements in the food science and technology; RWANDA FDA is issuing these Guidelines for Good Manufacturing Practices (GMP).

These guidelines have been designed to facilitate compliance by the regulated industry and to enhance consistency in the application of the regulatory requirements. They complement the various food product safety and quality assurance measures from the beginning to the end of the manufacturing cycle.

These guidelines stipulate the minimum requirements for Good Manufacturing Practice in the food manufacturing industry. The guidelines are not static and therefore improvements can be made as deemed necessary.

The purpose of these guidelines is to outline the responsibilities of food industry managers in relation to the efficient manufacture and control of food products; thereby ensuring that such products are safe, wholesome and of the nature and quality intended. The guidelines will also be used as a reference for inspectors while carrying out inspection of local and overseas foodmanufacturing premises.

These guidelines form the basis for registration of premises and licensing offood manufacturers in the country as well as inspection of overseas food manufacturing premises for the purpose of registration of imported food products.

These guidelines are divided into three chapters. Chapter one highlight on the requirements for location and design of the manufacturing plant. The requirements for manufacture, packaging and quality management have been elaborated in chapters two. Chapter three provides the requirements for personnel hygiene, education and training.

These guidelines have been annexed with inspection checklist in order to systematically guide the Authority inspector during assessment GMP.

Adherence to these guidelines by food manufacturers will contribute substantially to the manufacture of consistently uniform batches of goodquality and safe foodproducts.

CHAPTER ONE

REQUIREMENTSFORLOCATIONANDDESIGNOFTHE MANUFACTURINGPREMISESANDEQUIPMENT

1.0 Plants and Grounds

1.1 Grounds

The requirements for grounds which are necessary for prevention of contamination include the following:

a) The grounds about a food plant under the control of the operator should be kept in a condition that will protect against the contamination offood.

b) If the plant grounds are bordered by grounds not under the operator's control and kept in the manner that may affect the quality and safety of the product, care should be exercised in the plant by inspection, extermination, or other means to exclude pests,dirt,andfilththatmaybeasourceoffoodcontamination.

1.2 Plant Construction andDesign

Plant buildings and structures should be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food- manufacturing purposes. The plant and facilitiesshould:

a) Provide sufficient space for such placement of equipment and storage of materials as is necessary for themaintenance of sanitary operations and the production of safefood.

b) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneousmaterial.

c) Permit the taking of proper precautions to protect food in outdoor bulk containers by any effective means such as using protective coverings.

d) To be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good state of repair;

e) Be (where applicable) constructed in such a manner that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packagingmaterials;

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

g) Provide adequate lighting in all areas (such as hand-washing, dressing, locker rooms and toilet rooms) of theplant.

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

i) Provide adequate ventilation using control equipment such asfans and other air-blowing equipment to minimize odours and vapors (including steam and noxious fumes) in areas where they may contaminatefood;

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

c) Where practicable, suitable arrangements should be made to indicate failure of equipment or services to equipment.

d) Defective equipment should be withdrawn from use until the fault has been rectified.

e) As necessary, analytical methods should include a control test to verify that the equipment is functioning satisfactorily.

f) Control laboratories and equipment should be kept clean, in accordance with written cleaningschedules.

g) At all times, personnel should wear clean protective clothing appropriate to the duties being performed, especially eye protection.

2.6.3 **LaboratoryReagents**

Reagents made up in the laboratory should be prepared following the defined procedures below:

a) Reagents made up in the laboratory should be preparedby persons competent to do so, following laid down procedures.

b) Labeling of reagents should indicate the concentration, standardization factor, shelf life, and storage conditions.

c) The label should be initialed or signed, and dated, by the person preparing the reagent.

d) Both positive and negative controls should be applied to verify the suitability of microbiological culturemedia.

e) Reference standards, and any secondary standards prepared from them, should be dated, and be stored, handled and used so as not to prejudice theirquality.

2.6.4 **Sampling Requirements for LaboratoryAnalysis**

Written procedures should be developed for sampling and should specify the method and rate of sampling. The requirements include:

a) Samples should be taken in such a manner that they are representative of the batches of material from which they are taken, in accordance with written sampling procedures approved by the Quality Control Manager.

b) Proceduresshould include:
   i) The method and rate ofsampling
   ii) The equipment to beused;

iii) The amount of sample to betaken;
iv) Instructions for any required subdivision of the sample;
v) The type and condition of sample container to be used;
vi) Any special precautions to be observed, especially in regard to sterile sampling or sampling of noxious materials;
vii) Cleaning and storage of sampling equipment.

c) All samples should be identified according to standard procedures
d) Each sample container should bear a secure and indelible label indicating its contents, with the batch or lot number reference, the date of sampling and identification information of the bulk containers from which samples have been drawn.
e) Sampling equipment should be cleaned after each use and stored separately from other laboratoryequipment.

f) Care should be taken to avoid contamination, or causing deterioration, whenever a material or product issampled.

g) Special care is necessary when re-sealing sampled containers to prevent damage to, or contamination of or by the contents.

h) Methods should be chosen with care to fulfil the needs of the analyses.

i) For quality control purposes, the chosen method should be that most efficacious for the accuracy and speed of results needed, and the skill of the staff concerned.

j) When possible, methods acceptable to any enforcing authority, or which are internationally acceptable, should beused.

k) In all cases method checks need to be incorporated into any analytical scheme to ensure reproducibility, repeatability and operatorindependence.

l) Reviews of the methods used should be undertaken at pre- determined intervals or at times appropriate to a developedneed.

2.6.5 **LaboratoryRecords**

Detailed records should be maintained for all tests and analyses performed in the laboratory. The recordsinclude:

a) Retention samples should be regarded as part of the laboratory record.

b) Records of the calibration procedure and results should be maintained for each instrument or item of equipment. These records should specify the date when the next calibration orservice isdue.

c) Record for test for confirmation of the reagents should be maintained.

d) Test results should be recorded in a manner that will facilitate comparative reviews of those results and the detection oftrends.

e) Analytical records taken shouldcontain:-
   i) Name of product or material and codereference;
   ii) Date of receipt andsampling;
   iii) Source of product ormaterial (including supplier and country oforigin);
   iv) Date oftesting;
   v) Batch or lotnumber;
   vi) Indication of testsperformed;
   vii) A reference to the methodsused;
   viii) Results;
   ix) Decision regarding release, rejection or otherstatus;
   x) Signature or initials of the analyst, and signature of the person taking the abovedecision.

f) Analysts' laboratory records should alsobe retained, with the basic data and calculations from which test results were derived (e.g. weightings, readings, recorded charts,etc).

2.6.6 **Sub-contraction of SampleAnalysis**

The analysis and testing may be undertaken by a contract analyst, the responsibility for Quality Control cannot be delegated to him. The following requirements must be met:

a) The nature and extent of any contract analysis to be undertaken should be agreed and clearly defined in writing, and procedures for taking samples should be setout.

b) The Contract analyst should be supplied with full details of the test method(s) relevant to the material under examination. These will need to be confirmed as suitable for use in the context of the contractlaboratory.

c) Formal arrangements should be made for the retention of samples and of records of testresults.

2.7 **Emergency Procedures for Dealing with Food Safety related Complaints and ProductRecall/Withdrawal**

A person responsible for handling the complaints and decidingthe measures to be taken should be designated, together with sufficient supporting staff to assist him or her. If this person is different from the authorized person, the latter should be made aware of any complaint, investigation orrecall.

2.7.1 **Complaint HandlingProcedure**

a) Food manufacturing plants should establish written procedures describing the action to be taken, including the need to consider a recall (if necessary), in the case of a complaint concerning a possible productdefect.

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b) Any complaint concerning a product defect should be recorded with all the original details and thoroughlyinvestigated.

c) The person responsible for quality control should normally be involved in the review of complaintinvestigations.

d) If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected or not.

e) Other batches that may contain reprocessed product from the defective batch should be investigated too.

f) All decisions made and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

g) Complaint records should be regularly reviewed forany indication of specific or recurring problems that require attention and might justify the recall of marketingproducts.

h) Action should include responding to the complaint, and must include responding to theAuthority.

i) Where the complaint is justified, steps to remove or overcome the cause and thus prevent recurrence should be taken; and the defective material which the complainant sample might represent should be deal with including possibly a product recall.

2.7.2 **ProductRecalls**

A product defect coming to the manufacturer's attention, whether through a complaint or otherwise, may lead to the need for a product recall. The measures to be taken include:

a) Product recall, should be taken after investigation and evaluation of the complaint.

b) The authorized person should be responsible for the execution and coordination ofrecalls.

c) The authorized person should have sufficient staff to handle all aspects of there calls with the appropriate degree of urgency.

d) Food manufacturing plants should establish written procedures, which are regularly reviewed and updated, for the organization of any recallactivity.

e) Recall operations should be capable of being initiated promptly down to the required level in the food distribution chain.

f) An instruction should be included in the written procedures to store recalled products in a secure segregated area while their fate isdecided.

g) All competent authorities of all countries to which a given product has been distributed should be promptly informed of any intention to recall the product because it is, or is suspected of being, defective.

h) The distribution records should be readily available to the authorized person, and they should contain sufficient information on wholesalers and directly supplied customers.

i) The progress of the recall process should be monitored and recorded.

j) Records should include the disposition of theproduct.

k) A final report should be issued, including reconciliation between the delivered and recovered quantities of theproducts.

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

2.8 Contracted Manufacturing of the Food Product

2.8.1 Responsibility of Contract Acceptor (Manufacturer)

The contract Acceptor should ensure that the terms of the contract are clearly stated in writing and that raw material and end products are covered by adequately full specifications.

a) For any special GMP requirements, during the contract agreement the contract giver should ensure that respective quality control, record transfer, coding, rejection, dispute and complaint procedures are taken intoconsideration.

b) Contract Givers should impose contractual conditions, which ensure quality standards and Good Manufacturing Practices to the contract Acceptor.

c) Contract Giver's Quality Control Manager should visit the manufacturing unit to:

i) Ensure that, within the manufacturing environment, the food can be produced safely;

ii) Agree a detailed product specification covering all aspects of product, process, pack, and delivery, embracing parameters to be used for acceptance or rejection, and any legal requirements relatingthereto;

iii) Agree levels of sampling of finished products by the customer and sample plants to be used in case of dispute;

iv) Evaluate the adequacy of the control resources, systems, methods and records of the manufacturer;

v) Agree, wherever possible, objective methods of examination, while subjective measurements should conform to recognized and accepted standards if possible.

2.9 **Novel Foods and Processes**

Novel foods and processes, including genetic modification (GM) are permissible provided they comply with National safety, environment, information and ethics requirements.

a) The use of novel foods, ingredients or processes should be limited to those that have undergone a pre-market safety evaluation and have been legally approved for use in the country.

b) Novel food and/or processes should be provided with the means of making an informed choice. This includes a declaration on the label information about what the food contains or the novel process by which it was made and an understanding of the significance of that information.

2.10 **Manufacturing for Export**

It is a responsibility of the producer to be aware of and follow the regulatory requirements of the exporting and importing countries by doing thefollowing:

a) In case food is manufactured for export, the manufacturer should obtain information on importation regulatory requirements of the importing country.

b) The manufacturer of food for export should ensure that the requirements outlined as per importation regulatory requirements of the importing country are adhered to.

2.11 **Dealing with Allergens during Food Manufacturing**

The food manufacturer should concentrate his attention on dealing effectively with "major serious allergens" (MSAs) such as milk, eggs, soya, wheat, peanuts, shellfish, fruits, tree nuts. It could also include the so- called "second eight", which includes sesame seeds, sunflower seeds, cottonseed (meal, not oil), poppy seed, molluscs, beans other than green beans, peas,lentils.

2.11.1 **Control of Allergens duringProcessing**

The following means should be followed in order to control allergens:

a) MSAs produced in more than one site, or in different buildings on the same site, serious consideration should be given to production segregation.

b) In case production segregation is not possible,separate production equipment should be used ifpossible.

c) Where shared production equipment between one or more MSA- free products and an MSA-containing product is unavoidable, the MSA-

containing product should be run as the last production of the day immediately beforecleaning.

d) Equipment used to manufacture MSAs containingproducts should be cleanedbefore

2.11.2 **Control of Allergens through ProductLabeling**

Appropriate information about the presence of MSAs in the product is necessary on the product label.

The presence or potential presence of an MSA should be separatelystated on the label, in a prominent and easily legible way, where it will clearly be seen by a potential purchaser under normal conditions of display.

Where a product contains one or more MSAs (whether as individual ingredient(s) or as components(s) in a compound ingredient, the presenceof the MSA should be stated (for example **"Contains PEANUT "to which some people may beallergic"**).

The terminology used to state the presence of MSAs in the product, shouldbe clearly understandable by the ordinary consumer. Forexample;

a) Where calcium caseinate is the MSA concerned, the information on the label should read **"Contains MILK PROTEIN" "to which some people may be allergic"**. and not **"contains CALCIUM CASEINATE"**.

b) Where a product nominally free from MSAs is produced on a production line shared with an MSA-containing product a suitable statement should be, "**May contain traces of PEANUT**". "to which some people may beallergic"

c) Where a product nominally free from MSAs is produced in the same factory building as a MSA-containing product,a suitable statement should be, "**Produced in a factory where PEANUT is also handled".**

2.12 **Food Product Development**

a) Food manufacturing facility during product development, the process should involve among others, the Quality and safety controlmanager.

b) Developing product process (concept, product design, product) process design, choice of packaging materials, shelf-life_studies, sensory evaluation of the product, as well as/or microbiological and chemical testing) should consider the Authority food safety and quality regulatoryrequirements.

2.13 **Quality Management System**

In order to achieve the objectives of Good Manufacturing Practices it is necessary to have in place:

The food manufacturing facility should have in place a comprehensive quality

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management system, so designed, documented and implemented and so furnished with personnel, equipment and resources so as to ensure that specifications set to achieve the intended product quality standards are consistently met.

2.14 Documentation

2.14.1 General Requirements

Good and effective documentation is an essential and integral part of the Good Practice system. Requirementsinclude:

a) Documents should be designed, prepared,reviewed and distributed withcare.

b) Documents should comply with the relevant stages of the manufacturing and marketing authorizations.

c) Documents should be approved, signed and dated by the appropriate responsible persons. Note that, no document shouldbe changed without authorization andapproval.

d) Documents should have unambiguous contents: the title, nature and purpose should be clearlystated.

e) Documents should be laid out in an orderly fashion and be easy to check. Reproduced documents should be clear andlegible.

f) The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.

g) Where documents require the entry of data, these entries should be clear, legible and indelible. Sufficient space should be provided for suchentries.

2.14.2 Review and Alteration ofDocuments

The document should be updated by reviewing. The following requirements should be followed:

a) Documents should be regularly reviewed andupdated.

b) When a document has been revised, a system should exist to prevent inadvertent use of the supersededversion.

c) Superseded documents should be retained for a specific period of time.

d) Anyalterationmadetoadocumentshouldbesignedanddated;

e) The altered document should include alteration history, which will involve original information and the reason for the alteration should

berecorded.

2.14.3 **RecordManagement**

Records should be well managed and the following be adhered:

a) Records should be made or completed when any action is taken and in such a way that all significant activities concerning the manufacture of food products are traceable.

b) Records should be retained for at least one year after the expiry date of the finished product.

c) Master formulae and detailed standard operating procedures relating to the system in use should be available and the accuracy of the records should be checked.

d) Data and records for storage may be recorded by electronic data-processing systems or by photographic or other reliable means.

e) If documentation is handled by electronic data-processing methods, only authorized persons should be able to enter or modify data in the computer, and there should be a record of changes and deletions;

f) Access to electronic data should be restricted by passwords or other means and the entry of critical data should be independently checked.

g) Batch records stored electronically should be protected by back-up transfer on magnetic tape, microfilm, paper printouts or other means.

h) Documents should be easilyretrieved.

2.14.4 **DocumentsRequired**

a) **Documents for Instructions andProcedures**

The documents for Instructions and proceduresinclude:

i) Ingredientspecifications
ii) Packaging materialspecifications
iii) Copy of order and/or terms of conditions ofpurchase
iv) Master Manufacturing Instructions (including flow sheets and standardrecipes)
v) Bulk ProductsSpecifications
vi) Finished ProductsSpecifications
vii) Quality Control Procedures andMethods
viii) Standard procedure for productrecall
ix) Plant OperatingInstructions
x) Cleaning Instruction, Good Housekeeping and Pest Control Schedules
xi Plant MaintenanceProcedures

c) **Documents forProgrammes**

The documents for programmes include:

i) ProductionProgrammes
ii) Trainingprogrammes
iii) QualityAudits
iv) Quality Cost Programme

d) **Documents for Records andReports**

The documents for records and reports include:

i) Records of receipt, examination, approval and issue for use of RawMaterials
ii) Records of the testing and release of Intermediates, Bulk Products and Finished Products
iii) Records of Process ControlTests
iv) In-Process Recording InstrumentCharts
v) Weight or Volume ControlCharts
vi) Batch Manufacturing Records
vii) Food handlers health records
viii) Product recalls records
ix) Customer Complaint Records
x) Quality Control Summaries andSurveys
xi) Quality Audit Reports and Records
xii) Superseded Documents

CHAPTER THREE

3.0 REQUIREMENTS FORPERSONNEL

Food manufacturing facility should have competent supervisory personnel for assuring compliance by all personnel with all requirements of personal hygiene, health and training.

3.1 Personnel HealthRequirements

The requirements ofthe personnel health status contain helpful advice. The requirements should include:

a) Employees should be medically examined by an authorized medical practitioner at the first appointment and after every sixmonths.

b) Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness (such as open lesion, sores, wounds) should be excluded from any manufacturing operation which may result in such contamination until the condition is corrected.

c) Personnel should be instructed to report such health conditionsto their supervisors as stipulated in the Food Hygiene Regulation

3.2 Personnel Hygiene andBehaviour

All persons working in direct contact with food, food-contact surfaces,and food-packaging materials should conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limitedto:

a) Wearing outer garments suitable to the operation

b) Maintaining adequate personalcleanliness.

c) Washing hands thoroughly and sanitizing in an adequate hand washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled orcontaminated.

d) Removing all unsecured jewellery and other objects that might fall into food, equipment, or containers during productionoperations.

e) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeablematerial.

f) Wearing, where appropriate, in an effective manner, hairnets, masks, headbands, caps, beard covers, or other effective hair restraints.

g) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

h) Confining eating food, chewing gum, drinking beverages, or tobacco to areas

other than where food may be exposed or where equipment or utensils arewashed.

i) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials.

3.3 **Personnel Education and Training onFood Hygiene**

Personnel should have a required qualification and trainingshould cover not only specific tasks, but best practice generally, and the importance of, and factors involved in, personal hygiene. Requirements should include:

a) Personnel responsible for identifying sanitation failures or food contamination should have a background of education, experience, or a combination thereof, to provide a level of competency necessary for production of clean and safefood.

b) Food handlers and supervisors should receive appropriate training in proper food handling techniques, food-protection principles, personal hygiene and good sanitary practices.

c) The manufacturer should provide training in accordance with a written programme for all personnel in the manufacturing facility such as personnel whose duties take them into manufacturing operations or/and control laboratories.

d) Newly recruited personnel besides acquiring basic training on the theory and practical on GMP, should receive training appropriate to the duties assigned to them.

e) Continuous training should also be given, and its practical effectiveness periodically assessed.

f) Personnel working in areas where contamination is a hazard (e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled) should be given specifictraining.

g) Visitors or/and untrained personnel should be given relevant information in advance (particularly about personal hygiene) and the prescribed protective gears before taken in the production and quality control areas under close supervision.

h) Consultant and contract staff should be qualified for the services they provide. Evidence of this should be included in the training records.

ANNEX I: GOODS MANUFACTURING PRACTICES (GMP) INSPECTION CHECKLIST

RWANDA FDA Rwanda Food and Drugs Authority	**GOOD MANUFACTURING PRACTICES (GMP) INSPECTION CHECKLIST**	***Control number*** ***Rev. #: 0***

Letter of authority to inspect: Ref. No……
Date……Name of production supervisor……
Qualification of production supervisor:……
Name of food facilit:……
Name of food processed/packed:……
Name of owner:……
Name of Director/Manager:……Address:……
Tel.No.:……
Email address:……
Food license/permit No:……of (date)……
Purpose of inspection (tick) pre-registration of premises/product

No.					
1.0	**PREMISES AND EQUIPMENTS**				
1.1	**Plant and grounds**	**Yes**	**No**	**NA**	**REMARKS**
1.1.1	Plant layout and production flow chart available	*			
1.1.2	Production authorized by the National Food Regulatory Body	**			
1.1.3	Plant kept in a condition that protects against contamination of food				
1.2	**Plant construction anddesign**				
1.2.1	Sufficient space for placement of equipment and materials provided				

1.2.2	Protective covering used to protect food in outdoor bulk containers Provided				
1.2.3	Floors, walls and ceilings constructed in such a way that they can be easily Cleaned				
1.2.4	Adequate space provided between equipments and walls				
1.2.5	Safety type light bulls or other glass Suspended over exposed food protected.				
1.2.6	Adequate lighting and ventilation Provided				
1.2.7	Adequate screening or other pest protection against pest provided				
1.3	**Sanitary operation**	**Yes**	**No**	**NA**	**Remarks**
1.3.1	Building, fixtures and other physical facilities maintained in a sanitary condition				
1.4	**Substances used in cleaning and sanitizing.**				
1.4.1	Cleaning compounds, sanitizing agents and pesticides stored in a manner that protect contamination of food				
1.5	**Pest control**				
1.5.1	Measures to exclude pests from the processing areas are in place.				
1.5.2	Insecticides and rodenticides used in the manner that will not contaminate Foods				
1.6	**Sanitation of food-contact surfaces**				
1.6.1	Food contact surfaces cleaned to prevent from contamination of food.				
1.6.2	Food contact surfaces used for manufacturing are in dry and sanitary condition.				

1.6.3	Single-service articles such as paper cups and towels handled and disposed of in a manner that protects against contamination.				
1.8	**Water supply**				
1.8.1	Water supply sufficient and safe for the operation intended and delivered from adequate source	**			
1.8.2	Running water provided in all areas where required for the manufacturing plant.				

1.9	**Plumbing**	**Yes**	**No**	**NA**	**Remarks**
1.9.1	Plumbing carry sufficient quantities of water to required locations throughout the plant				
1.9.2	The sewage and liquid disposable waste properly conveyed from the plant.				
1.9.3	Backflow of waste water and sewage prevented				
1.9.4	Adequate floor drainage provided in all areas where floors are subject to flooding-type.				
1.10	**Sewage and waste disposal**				
1.10.1	Waste are conveyed, stored and disposed of as to minimize the development of odor.				
1.10.2	Refuse receptacles constructed and maintained in a manner thatprotects against contamination of food.				
1.11	**Toilet facilities**				
1.11.1	Toilet facilities provided with self closing doors				
1.11.2	The toilet facilities kept in a good state of repair	**			
1.11.3	Doors don't open into areas where food is exposed to airborne contamination.				
1.11.4	Toilet facilities maintained in a sanitary condition.	**			

1.11.5	Plant provided with adequate toilet facilities	***			
1.12	**Hand washing facilities**	**Yes**	**No**	**NA**	**Remarks**
1.12.1	The signs directing employees to clean and sanitize their handsbefore handling unprotected foods provided				
1.12.2	Devices or fixtures such as water control valves designed and constructed to protect against recontamination of clean sanitized hands.				
1.12.3	Plant provided with adequate and convenient hand washing facilities.				
1.13	**Equipment and utensils**	**Yes**	**No**	**NA**	**Remarks**
1.13.1	Plant equipment and utensils so designed to be cleanable.				
1.13.2	Food manufacturing areas and equipment used for manufacturing human food not used to manufacture non human food-grade animal feed.				
1.13.3	Instruments used for measuring, regulating or recording conditions (temperatures, Ph, acidity) are accurate and sufficient innumber.				
1.13.4	Food contact surfaces are corrosion-resistant.				
1.14	**Storage**				
1.14.1	Adequate facilities for storage of food, ingredients and non-food chemicals provided				
1.14.2	Storage area designed to prevent pests, contamination and degradation of ingredients, finished products or packing material from dust, debris and any other environmental factors				
1.14.3	Product stocking system to allow proper product rotation in place				

2.0	**REQUIREMENTS FOR MANUFACTURE, PACKAGING AND QUALITY MANAGEMENT**	**Yes**	**No**	**NA**	**REMARKS**
2.1	**Processes and control**				

2.1.1	All production processes conducted in accordance with Good Hygienic Practice (GHP).				
2.1.2	Appropriate quality control operations employed to ensure production of safe food.				
2.1.3	Chemical, microbial or physical quality testing procedures used to identify sanitation failure.				
2.2.1	**Raw materials and other ingredients.**				
2.2.2	Raw materials cleaned asnecessary				

2.0	**REQUIREMENTS FOR MANUFACTURE, PACKAGING AND QUALITY MANAGEMENT**	**Yes**	**No**	**NA**	**REMARKS**
	to remove soil or other contaminants.				
2.2.3	Acceptance criteria of raw materials in terms of microbial, chemical, as well as physical quality and safetyare in place.				
2.3	**Manufacturing operations.**				
2.3.1	All food manufacturing operations including filling, packaging and storage conducted under safety and quality control conditions.				
2.3.2	Finished foods protected from contamination by raw materials, other ingredients or refuse.				
2.4	**Good control laboratory practices**				
2.4.1	Laboratory facilities capable of conducting analysis of the appropriate parameters present.	***			
2.4.2	Staff for laboratory analysis properly trained and managed.				
2.4.3	Quality control activities are done in accordance to the set National or International standards.				
2.4.4	Physico-chemical, biological and microbiological laboratories separated from each other.				
2.5	**Laboratory equipment and instruments.**				

2.5.1	Equipment and instruments serviced and calibrated at specified intervals by a competent person or organization.				
2.5.2	Written operation instructions readily available for each instrument.				
2.5.3	Analytical methods include a control test to verify that the equipment is functioning satisfactorily provided.				
2.6	**Laboratory reagents**				
2.6.1	Labeling of reagents indicate the concentration, standardization factor, shelf life and storage conditions.				
2.6.2	Both positive and negative controls applied to verify the suitability of microbiological culture media.				
2.6.3	Reagents made in the laboratory prepared by persons competent to do so following laid down procedures				
2.7	**Sampling requirements for laboratory analysis.**				
2.7.1	All samples identified according to standard procedures.				
2.7.2	The method used for testing acceptable to any enforcing authority or internationally acceptable.				
2.8	**Laboratory records**				
2.8.1	Test results and calibration procedures recorded in a good manner.	*			
2.9	**Product recall**				
2.9.1	Product recall taken after investigation and evaluation of the complaint				
2.9.2	The competent authorities of all countries to which a given product has been distributed promptly informed of any intention to recallthe product.				
2.9.3	The distribution records of the defective product readily available.				
2.9.4	Progress of the recall process monitored and recorded				
2.9.5	The disposal of products recorded.				

2.9.6	The effectiveness of the arrangements for recalls tested and evaluated from time to time.				
2.10	**Contracted manufacturing of the food product**				
	Responsibilities of the contract acceptor (manufacturer)				
2.10.1	The terms of the contract clearly stated in writing and that raw materials and end products meet the specification requirements				
	Responsibilities of the contract giver (importer)				
2.10.2	The contractual conditions which ensure quality standards imposed by contract giver				
2.10.3	The manufacturing unit visited by				

2.0	**REQUIREMENTS FOR MANUFACTURE, PACKAGING AND QUALITY MANAGEMENT**	**Yes**	**No**	**NA**	**REMARKS**
	contract giver quality control manager to verify the suitability for production of safe food.				
2.11	**Novel Foods and Processes**				
2.11.1	The novel foods including genetic modification (GM) legally approved for use in the country				
2.11.2	Declaration on the label of what novel foods contains.				
2.12	**Control of allergens during processing**				
2.12.1	Separate production equipment used if possible to control Major Serious Allergens (MSAs).				
2.12.2	Equipment used to manufacture MSAs containing products cleaned before being used.				
2.13	**Control of allergens through product labeling**				
2.13.1	The presence or potential presence of an MSA separately stated on the label.				
2.13	**Quality management system**				

2.13.1	The so designed, documented and implemented comprehensive Quality Management System in place				
2.14	**Documentation**				
2.14.1	Documents comply with the relevant stages of the manufacturing and marketing authorization				
2.14.2	Documents have unambiguous contents: the title, nature and purpose clearly stated.				
2.14.3	Master formulae and detailed Standard Operating Procedures are available.				
2.14.3	Documents easily retrieved.				
2.15	**Documents for Instructions and Procedures**				
2.15.1	Ingredients specifications available				
2.15.2	Packaging material specification Available				
2.15.3	Master Manufacturing Instructions (including flow sheets and standard recipes) available.				
2.15.4	Bulk products specification available				
2.15.5	Finished products specifications Available				
2.15.6	Quality control procedures and methods available				
2.15.7	Cleaning instruction, Housekeeping and pest control schedules available				
2.16	**Documents records**				
2.16.1	Quality control records available				
2.16.2	Customer complaints records available				
2.16.3	Product recall records available				
2.16.4	Food handlers health records Available				
2.16.5	Batch Manufacturing records Available				
2.16.6	Records of process control records available				
2.16.7	Records of quality audit reports				

3.0	**REQUIREMENTS FOR PERSONNEL**	**Yes**	**No**	**NA**	**REMARKS**

3.1	**Personal health requirements**				
3.1.1	Any person who appears to have illness excluded from any manufacturing operation				
3.1.2	Employees medically examined by authorized medical practitioner at first appointment and after every six months.	**			
3.2	**Personal hygiene and behavior**				
3.2.1	All persons working in direct contact with food, food contact surfaces and food packaging materials conform to hygienic practices while on duty.				
3.2.2	Employees do not wear jewelers, watches pins or other items unless secured to prevent contamination				
3.3	**Personnel education and training on food hygiene**				
3.3.1	Personnel responsible for identifying sanitation failures or food contamination have the required				

3.0	**REQUIREMENTS FOR PERSONNEL**	**Yes**	**No**	**NA**	**REMARKS**
	background of education and experience.				
3.3.2	Food handlers and supervisors receive appropriate training on proper food handling techniques and good sanitary practices.				
3.3.3	Visitors or /and untrained personnel given relevant information in advance and protective gears before taken into the production area.				

Key: * **means minor non- compliances**

** **means major non- compliances**

*** **means critical non- compliances**

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