RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING GOOD MANUFACTURING PRACTICES OF FOOD PRODUCTS

(Rwanda FDA law N° 003/2018 of 09/02/2018, Article 9)

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02/09/2022	0	First Issue

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Foods Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these Regulations N° FDISM/FDIC/TRG/008 Rev_0 Governing Good Manufacturing Practices of food Products, made this 16.../..12../2022

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Director General

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ABBREVIATION AND ACRONYMS

RWANDA FDA: Rwanda Food and Foods Authority
GMP: Good manufacturing Practice
CAPA: Corrective and Preventive Actions
WHO: World Health Organization
MOU: Memorandum of Understanding
ISO: International Organization for Standardization
HACCP: Hazard Analysis and Critical control point

CHAPTER ONE: GENERAL PROVISIONS

Article one: Purpose of this regulation

The purpose of these regulations is to put in place a legal framework to ensure effective and efficient implementation of good manufacturing practices (GMP) for food products manufacturers.

Article 2: Citation

These regulations may be cited as the "Regulations No. FDISM/FDIC/TRG/008 Rev_0 Governing Good Manufacturing Practices of Food Products.

Article 3: Scope

These regulations shall apply to all types of food products; as stipulated under Article 3 of the Law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization, and functioning.

All requirements of this regulation are generic and are intended to be applicable to all manufacturers of the food products: Processed food for humans and animals, food supplements and fortified foods regardless of size and complexity.

Article 4. Definitions

In these regulations, unless the context otherwise requires:

"Applicant" means any legal or natural person, established within or outside Rwanda, seeking to obtain or having obtained the certificate of compliance with good manufacturing practice to manufacture food products.

"Authority" means the Rwanda Food and Foods Authority or its acronym "Rwanda FDA", established by the Law N° 003/2018 of 09/02/2018.

"Batch": defined quantity of a product produced and/or processed and/or packaged essentially under the same conditions

"Correction" means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

"Corrective action" is an action to eliminate the cause of a noncompliance and to prevent recurrence

"Critical control point" means a step in the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level, and defined critical limit(s) and measurement enable the application of corrections.

"Critical non-compliance" means a failure of the management system that could results, or has resulted, in the production of product that is unsafe, fraudulent, which does not meet legal requirements or could damage brand reputation.

"Major non-compliance" means the absence of, or a significant failure to implement and/or maintain conformance to the requirements of the applicable standard or part of the standard without and agreed justification as to why.

"Minor non-compliance" It represents either a management system weakness or minor issue that could lead to a major non-compliance if not addressed.

"Facility" means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in Rwanda.

"Food" any animal or plant products that have been processed or transformed from their original state and are intended for human or animal consumption with the exception of pharmaceutical products, tobacco, food additives and food fortificants;

"Food products" refer to processed food for humans and animals, food supplements and fortified foods.

"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 in the eyes, skin, respiratory system and intestinal system.

"Hazard" food safety hazard means any biological, chemical or physical agent in food with the potential to cause an adverse health effect.

"Qualified personnel" means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties.

"Rework" 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.

"Recall" means an action taken by the manufacturer to remove food product from the market or to retrieve any such product from any person to whom it has been supplied, because the product may:

i. be hazardous to health;
ii. fail to conform to any claim made by its manufacturer relating to its safety and quality
iii. or not meet the requirements under this regulation.

CHAPTER II: GOOD MANUFACTURING PRACTICES INSPECTION

Article 5: Obligation to obtain a certificate of compliance with GMP

1) No person shall manufacture food products and without prior authorization from the Authority. Failure to comply shall result in administrative sanctions.

2) Every manufacturer of food products shall possess a valid certificate of compliance with GMP issued by the Authority.
   The requirements to obtain a GMP certificate are detailed in the relevant guidelines. The Authority shall conduct inspection for confirmation of the compliance to this Regulation and relevant guidelines. A GMP certificate shall not be granted where the Authority finds the applicant not complying with the requirements prescribed in these regulations and relevant regulatory documents.

Article 6. Types and Purpose of GMP inspections

1) The GMP inspection is mandatory to all food products and manufacturers. It is based on food safety management system (FSMS). GMP inspection shall cover several areas including but not limited to facilities, employees, operation control, documentation, equipment, and food defence.
2) There shall be four (4) types of GMP the following categories:

   i. Routine GMP inspection is a full inspection of all applicable components of GMP and licensing provisions. It may be indicated when the manufacturer is newly established, requests for renewal of a manufacturing license, has a history on non-compliance with GMP, has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, has not been inspected during the last 3 to 5 years.
   ii. Concise GMP inspections.
   iii. Follow-up GMP inspections.

iv. Special GMP inspections

Article 7: Requirements for GMP application

1) Food manufacturers whether foreign or local shall apply for GMP inspection by submitting all required documents as outlined in the guidelines for good manufacturing practices of food products. The application shall be made based on the following categories: New application, renew, variation and relocation.

2) The Authority shall, upon being satisfied by the application, conduct an assessment to verify the compliance with following GMP requirements.

1º The Authority may, during the assessment of the dossier, require the applicant to submit additional documents, information, data, or clarification to support the application for GMP inspection.

2º Where the Authority requires additional documents, information, and data and or clarification pursuant to paragraph 1º of this Article, the processing of the application shall not proceed until the applicant submits the additional submission.

3º Where the applicant fails to submit requested information according to paragraph 2º of this Article, within a period of ninety (30) days from the date of request, the application shall be considered withdrawn and a new application shall be required.

4 º Pursuant to the requirements of sub paragraph 3 of this Article, the applicant may by giving reasons in writing request for an extension of time for submission of additional documents, information, data and or clarification requested by the Authority.

5º If the applicant fails to provide satisfactory responses to the requested information according to sub paragraph 2º of this Article for the fourth time, the application shall be withdrawn and a new application shall be required.

6º An application withdrawn pursuant to paragraph 3º and an application rejected pursuant to paragraph 5º of this Article shall only be considered for GMP inspection upon submission of a new application as per the requirements of these Regulations.

Article 8: Methods of GMP inspection

The GMP inspection shall be conducted using one of the following method:

1° **Physical inspection:** Shall be conducted by physically visiting the manufacturing site. The applicant holding third party food safety certificate of compliance shall be evaluated by conducting site visit before issuing GMP Certificate.

2° **Virtual:** Facilities for virtual/remote interactive inspections is conducted upon discretion of the Authority. The criteria for selection of applicants for virtual/remote interactive inspections shall be as follows:

i. Authority has declared force majeure on physical inspection
ii. Application that meets requirements in Article 9 that still need further clarification.

3° **Joint Inspection:** The Authority may participate in the joint GMP inspection with regulatory Authorities from other countries such as East African Partner States and unless notified, this regulation shall apply.

Article 9. Reliance and Recognition

The Authority may rely on regulatory decisions from regional and international on decisions with regards to GMP inspection compliance inspected and approved by countries or agencies with mutual recognition or cooperation agreements or partnerships with Rwanda. The criteria to be considered for reliance and recognition shall be detailed in the relevant guidelines.

Article 10: Desk review

After receiving the application, the Authority conducts an assessment of the application by desk review or use any other inspection report from a relevant regulatory body to satisfy itself that the application has complied with the conditions for good manufacturing practice.

CHAPTER III: AREAS OF GMP INSPECTION

A system for quality and food safety management shall be applied by all manufacturers to ensure the production of safe and suitable food at all stages of the food processing from reception of raw materials up to the final product.

Article 11: Good hygiene practices

1) Manufacturers shall adopt practices and measures to ensure food is produced under appropriate hygienic conditions in order to reduce the likelihood of introducing a contaminant which may adversely affect the safety of food, or its suitability for consumption, at all stages of the food processing.

2) Manufacturers shall ensure that the prerequisite programmes are fully established, implemented and maintained to assist in controlling food safety hazards. The major components of prerequisite programmes are detailed in the relevant guidelines issued by the Authority.

Article 12: Control of operation

Every manufacturer shall plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products, this can be achieved by: i) establishing criteria for the processes; implementing control of the processes in accordance with the criteria; ii) keeping documented information to the extent necessary to have the confidence to demonstrate that the processes have been carried out as planned. If operations are not controlled appropriately, food may become unsafe or unsuitable for consumption.

Article 13: Identification of hazards and establishment of control measures

1) Manufacturers shall apply Hazard Analysis Critical Control Point (HACCP) from reception of raw materials up to final product with purpose of supplying the safe food to the consumers and providing other significant benefits, such as efficient processes that focus on critical areas resulting in fewer recalls through identification of problems.

2) Before product is released, manufacturers shall ensure that the HACCP system is designed, validated and implemented in accordance with the following principles:
    i. Conduct a hazard analysis and identify control measures.
    ii. Determine the Critical Control Points (CCPs).
    iii. Establish validated critical limits.
    iv. Establish a system to monitor control of CCPs.
    v. Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit or when a CCP has occurred.
    vi. Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended.
    vii. Establish documentation concerning all procedures and records appropriate to these principles and their application.

3) The above seven principles will be detailed in the guidelines for good manufacturing practice of food products issued by the Authority.

Article 14. Administration and Management

A manufacturer shall ensure that the organizational structure is established, responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety system. A manufacturer shall have a GMP implementation team composed of, but not limited to qualified and competent personnel in charge of production and qualified and competent- personnel in charge of quality control.

A manufacturer shall ensure that qualified competent personnel are fulltime employees and do not serve other related business.

Article 15. Documentation

1) Manufacturers shall maintain documentation and records for all manufacturing processes.

i. Documentation categories

a) Manufacturers shall keep retained documents that cover what is called "records".
b) Manufacturers shall keep maintained documents that will cover procedures, policies, etc. that would have been referred to as just "documents".

ii. Good documentation practice

The following documents shall be maintained:

a) Manufacturer shall design, prepare, review and distribute documents and the prepared documents shall comply with the relevant parts of the manufacturing and marketing authorizations.
b) Manufacturer shall ensure that the documents:
c) Are at least in one of the official languages accepted in Rwanda
d) are approved, signed, and dated by appropriate authorized persons and a document shall not be changed without authorization;
e) have unambiguous contents and the title, nature, and purpose should be clearly stated and laid out in an orderly fashion and easy to check.
f) be regularly reviewed and kept up to date.

2) A manufacturer may keep data and record electronically or may have data-processing systems or by photographic or other reliable means. In that case, the manufacturer shall ensure that concerned personnel have access to that information.

Article 16: Good practices in quality control

1) A manufacturer shall not release finished food products for sale or supply, until their quality has been judged satisfactory. In order to comply with good practices in quality control, manufacturer

i. Shall have a testing laboratory with capacity to test critical parameters as described in the guidelines for GMP of food products issued by the Authority.
ii. Shall designate a person with appropriate qualifications in charge of the testing laboratory.

iii. Shall have adequate resources including; equipment, reagents, personnel, furniture and other related materials to ensure that all the Quality Control arrangements are effectively and reliably carried out.

iv. Shall ensure that testing cover raw materials, in-process/intermediate and final product.

v. Shall ensure that laboratory operations are carried out in accordance with written testing procedures with validated/ standardized methods.

Article 17: Complaints handling

A manufacturer shall ensure that all customer complaints received are registered, handled and responded to with the aim of resolving any issues in a timely and efficient manner.

Article 18: Traceability system

1) The Manufacturer shall ensure that the traceability system is in place in order to identify incoming material from the suppliers and the first stage of the distribution route of the end product.

2) When establishing and implementing the traceability system, the following shall be considered as a minimum:
   i. relation of lots of received materials, ingredients and intermediate products to the end products;
   ii. reworking of materials/products;
   iii. distribution of the end product.

Article 19: Emergency preparedness and response

A manufacturer shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety which are relevant to the role of manufacturing.

Article 20: Self-inspection

1) A manufacturer shall conduct self-inspection/internal audit at planned intervals to:
   i. Ensure compliance with good manufacturing practice in all aspects of production and quality control.
   ii. detect any shortcomings in the implementation of GMP and to recommend the necessary corrective actions.

2) There shall be an effective follow-up program and the company management shall evaluate both the self-inspection report and the corrective actions as necessary.

Article 21: Change control

Written procedures shall be in place to describe the actions to be taken if a change is proposed to a raw material, product component, process equipment, process environment or site, method of production or testing or any other change that may affect product quality or reproducibility of the process.

All changes that may affect product quality or reproducibility of the process shall be formally requested, documented and accepted.

CHAPTER IV: GRANTING,AND VALIDITY OF CERTIFICATE OF COMPLIANCE WITH GMP

Article 22: Granting certificate of compliance with GMP

Certificate of compliance with GMP is granted to food manufacturing facility complying with all good manufacturing practices requirements.

Manufacturers shall ensure that the GMP certificate is obtained before release of products on market:

a) When additional lines are included.
b) When two or more different premises on different sites are for one company.

Article 23: Suspensions and revocations

1) A warning letter may be issued to the applicant or the authorization be suspended or revoked where the Authority finds the applicant not complying with any of the requirements or conditions in this regulation; or has ceased to be fit to carry on the business.

The Authority shall cancel, suspend or withdraw a certificate of compliance with good manufacturing practice certificate of compliance with good manufacturing practice of a manufacturing facility if the facility contravenes following licensing requirements:

i. Any of the conditions under which the certificate of compliance with good manufacturing practice was issued no longer exist.
ii. The information on which the approval was given is later found to be false.
iii. The circumstances under which the approval was given no longer exist.
iv. Repeated violation of the regulatory administrative sanction or decision.

2) Where the certificate of compliance with good manufacturing practice is suspended, withdrawn or cancelled, the Authority shall issue a notice to the management of the facility. The Authority shall take steps including closure to ensure that the manufacturing, wholesale or distribution activity is stopped until otherwise decided by the Authority.

3) Measures towards enforcing this article may include the publication of the Rwanda FDA's action on its website and other relevant media.

4) An authorization holder or applicant may notify the Authority of his or her grounds when he or she:

a) Objects to any suspension or revocation of authorization, or to any notice served, regulations governing licensing to manufacture, to store, to operate as wholesale and retail seller of processed foods and related products.

b) Objects to the refusal of authorization or the imposition of any condition, may notify the Director General of its desire to make written representations to, or be or appear before and be heard by, a person appointed by the Director General for that purpose.

Article 24: Regulatory Action(s)

1) The Authority shall take the regulatory actions based on Minor, Major and Critical category of non-compliances as stipulated in the relevant guidelines for good manufacturing practices of food products. The following regulatory decisions shall be taken:

i. Manufacturers complying with the requirements stipulated in this regulation will be issued certificate of compliance with GMP.

ii. Manufacturer with minor non-compliances shall provide corrective action report.

iii. Manufacturer with Major non-compliances shall:

a) be issued with warning letter

b) be requested to provide corrective action report

c) be issued with temporary withdrawal or suspension of the authorization

d) Follow-up inspection to verify implementation of corrective action

i. Critical non-compliances include withdrawal of the authorization and suspension of registration in case of registered products.

ii. Legal proceedings shall be applied in case of criminal act.

Article 25: Appeals

1) Any person aggrieved by a decision of the Authority may appeal to the Authority for review of a decision within 15 working days from the date of notice.

The Authority shall within 30 working days from the date of appeal application review, vary or reject its own decision.

2) If a person is dissatisfied with a decision after review, he/she may appeal to the supervising authority of the Authority whose decision shall be final.

Article 26: Administrative sanctions

Any person who contravenes the provisions of these regulations commit an administration and upon conviction shall be liable to the penalties prescribed in Authority regulations related to regulatory service tariff/fee and fines in force.

Article 27: Establishment of a scientific and advisory Committee

The Authority may establish a scientific and advisory committee comprising of internal and or external experts from different fields and scientific research to advise the Authority on Good Manufacturing Practices inspection matters.

Article 28: Commencement

These regulations shall enter into force upon their approval and publication on the Authority's website.

Article 29: Certificate and Validity

a) Upon fulfilling the requirements, the Authority shall issue a Certificate of good manufacturing practice.
b) The certificate shall be valid for a period of three (3) years.

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