



RWANDA FDA
Rwanda Food and Drugs Authority

**REGULATIONS GOVERNING CONTROL OF PROCESSED FOOD
PRODUCTS**

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

REGULATION DEVELOPMENT HISTORY

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Effective date of this version	Refer to the approval date

DOCUMENT REVISION HISTORY

Date of revision	Version number	Changes made and/or reasons for revision
11/08/2015	1	<ol style="list-style-type: none"> 1. This regulations replaces all other regulations previously used in the Food department namely: <ul style="list-style-type: none"> - Regulations Governing Control of Importation and Exportation of Food Products Number FDISM/FDIEC/TRG/003, Rev_0 - Regulation Governing Food fortification in Rwanda No CBD/TRG/003 Rev 1 - Regulations governing licensing to manufacture, to store, to operate as wholesale and retail seller of processed foods and related products NO CBD/TRG/028 Rev_0 2. This version establishes "Regulations for Registration of Processed Food Products" 3. The approval of this version, renders all stated existing documents OBSOLETE.



ADOPTION AND APPROVAL OF THE REGULATIONS

In exercise of the powers conferred upon Rwanda Food and Drugs 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 these regulations No.: FD/TRG/003 Version 1 governing control of processed food products.

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Director General



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ACRONYMS AND ABBREVIATIONS

FBO	Food Business operators
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
HFSS	High in Fat Sugar and Salt
POE	Point of Entry/Exit
Rwanda FDA	Rwanda Food and Drugs Authority
TV	Television

CHAPTER ONE: GENERAL PROVISIONS

Article One: Purpose of these Regulations

These Regulations enforce the legal framework for regulatory inspections for Food Business Operators, registration, control of import and export as well as control of promotion and advertisement of processed food and related products intended for sale and distribution on the Rwandan market to ensure their safety and quality and protect public health.

Article 2: Citation

These Regulations are cited as the “*Regulations governing control of processed food products.*”

Article 3: Scope

These Regulations apply to processed food and related products under Rwanda FDA’s mandate.

Article 4: Definitions

In these Regulations, unless the context otherwise requires, the following terms have the meaning ascribed to them:

1. **“Advertising”** means anything that is aimed or designed to promote the supply, sale or use of a product whether or not for financial gain, and it includes but not limited to written communication materials (for instance a notice, circular, handouts, wrappers, catalogues, billboards, posters, newspapers, magazines, digital and social media posters or other promotional documents, oral and audio materials (records, tapes, radio among others) and visual announcement (films, video recordings, television, internet, electronic media, interactive data systems among others).
2. **“Approval”** means official consent by the Authority as an acceptance of a product, a practice, or a license of processed food and related products or practices related to that in the Rwandan market.
3. **“Authority”** means the Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established by Law N° 003/2018 of 09/02/2018.
4. **“Authorization”** means a legal document providing a right to manufacture, store, import/export, operate as a wholesale and retail seller of processed foods and related products, granted by Rwanda FDA to an applicant; it includes licenses, approval notification letters, permits, certificates and any other documents deemed as such by the Authority.

5. **“Conflict of interest”** means any interest in any business related to processed food and related products, declared by a Rwanda FDA staff that may affect or reasonably perceived to affect the quality or the result of his work or remediation.
6. **“Counterfeit”** means an imitation of a food product with an intention to deceive or to defraud. Counterfeit products may include products that is deliberately and fraudulently mislabelled, products with the wrong ingredients, with an incorrect quantity of ingredients or with misleading or fraudulent packaging.
7. **“Critical non-compliance”** means the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to people or environment is highly probable, including life threatening situation. The deviation is categorized as Critical requiring immediate action, investigated and documented. A critical deficiency may consist of several related deficiencies, none of which on its own may be “Critical”, but which may together represent a” Critical” deficiency, or systems’ failure where a risk of harm was identified and should be explained and reported as such. In other words, it is a failure of the food safety management system that could results, or has resulted, in the highest risk of producing a product that is unsafe, fraudulent, which does not meet legal requirements or could damage brand reputation and poses an imminent serious risk to health. The food business may not able to rectify these issues during normal processes. The Authority determines minor non-compliances in relevant regulatory documents.
8. **“Dodging”** means the act of avoiding interaction with an inspector to prevent or delay an inspection, including but not limited to providing repetitive excuses for why an inspection cannot proceed at a particular time, closing a facility temporarily, not responding to calls or notifications, or misleading the inspector about the location of operations.
9. **“Dormant”** means inactive applications on which no written response from the applicant is provided in a period beyond three (3) months from the date of reception of any feedback from the Authority.
10. **“Food additive”** means a substance that is intentionally added to food for a technological purpose, but is not normally consumed as a food or used as a typical ingredient. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.
11. **“Food Business Operator”** means a person, or company who undertakes, whether for profit or not, any activities related to manufacturing, distribution, storing, exhibit, wholesale or retail activities of processed food products and related products.
12. **“Food fortificant”** means a substance, in a chemical or a natural form, added to food to increase its nutritive value.

13. **“Food premises and process control approval”** means a notification approval issued to manufacturers of processed food and related products, following the successful evaluation of premises suitability, machinery and equipment, and Good Manufacturing Practices.
14. **“Food product Registration”** means official recognition or approval by the Authority for food to be sold for human consumption in the country.
15. **“Food supplement”** means a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins; minerals; amino acids; a herb or other botanical product, a dietary substance for use by humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients; is intended to be taken orally in the form of tablet, capsule, powder, soft gel, gel cap, granules or liquid; is not represented for use as a conventional food or as a sole item of a meal or the diet; is labelled as dietary supplement.
16. **“Good manufacturing practices (GMP)”** means a set of practices that encompass the proper design, monitoring, and control of manufacturing processes and facilities to ensure that food products are consistently produced and tested to meet quality standards and are fit for their intended use, as required by the competent authority.
17. **“Good Storage Practices (GSP)”** means that part of quality assurance that ensures that the quality of a product is maintained by means of adequate control throughout the storage thereof.
18. **“Inspector”** means a person appointed, authorized and designated by the Authority in accordance with laws tasked with performing inspection-related duties.
19. **“Major non-compliance”** means a non-compliance or deficiency that is not a “Critical” deficiency, but could have major effects on the overall safety, efficacy and quality of the processed foods and related products. This consists of several **“Minor/Other”** related deficiencies, none of which on its own may be “Major”, but which may together represent a “Major” deficiency or systems failure and should be explained and reported as such.
20. **“Manufacturer”** means a company that carries out at least one step of manufacturing process excluding re-packaging, re-labelling and any other step that would be determined by the Authority.
21. **“Marketing”** means to promote, distribute, sell, or advertise regulated products, or/and creating a relationship of the public and/or with information services regard to regulated products.
22. **“Market Authorization”** Means a legal document issued by the competent Authority for the purposes of marketing or free distribution of regulated product which has been approved after evaluation for safety and quality.

23. **“Media”** means newspaper, magazine, journal, television, radio, the Internet, out of home, vehicle branding, posters, handbills, cinema, point of sale material, online, digital and social media, any form of projected light and sound recordings or any of such means of communication.
24. **“Minor non-compliance”** means a non-compliance or deficiency that is not classified as either “Critical” or “Major”, but indicates failure to meet the standards of premises suitability. A deficiency may be classified as **“Minor”** because there is insufficient information to classify it as “Critical” or “Major”.
25. **“Misleading information”** means information that gives a wrong idea or impression.
26. **“Obstruction”** means the deliberate act of hindering, interfering with, or preventing an inspector from performing their duties including but not limited to refusing access to premises, hiding evidence, or providing falsified record, threatening the inspector, or tampering with samples they require for analysis.
27. **“Premises”** means any plot of land, buildings, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed, intended for manufacturing, storing, exhibit, wholesale or retail activities of processed food and related products.
28. **“Premises License”** means an authorization granted to wholesalers, distributors and retailers of processed food and related products, for the commencements of business following the successful evaluation of premises suitability, machinery and equipment, and product registration where applicable.
29. **“Processed food”** means all foods, including beverages, that are altered through processes that go beyond removal of inedible or unwanted parts, drying, crushing, grinding, fractioning, filtering, roasting, boiling, refrigeration, freezing, placing in containers, vacuum packaging or non-alcoholic fermentation that are produced in a given industry.
30. **“Progressive Licensing Scheme (PLS)”** means regulatory framework designed to facilitate gradual compliance of all food business operators, including Micro, Small, Medium, and Large industries. The scheme provides a supportive pathway that enables businesses to operate legally while progressively meeting all regulatory requirements. Safety remains the first priority throughout the process, ensuring that no unsafe products are placed on the market.
31. **“Promotion”** is any communication that attempts to influence people to buy or use the regulated products. It is the publicizing of a product so as to increase public awareness or sales using of audio-visual, oral or written material through advertising, sales promotion, direct marketing publicity, trade shows, promotional meetings, participation in exhibitions, giving samples, personal selling, etc.

- 32. “Promotional material”** means any representation concerning the attributes of a product conveyed by any means whatsoever for the purpose of encouraging the usage of the product.
- 33. “Provisional Approval”** means an approval granted after the successful evaluation of premises suitability and process control, serving as a prerequisite for product registration.
- 34. “Qualified personnel”** means an individual who by possession of a recognized bachelor’s degree/advanced/diploma or its equivalent, who by extensive knowledge, training and experience, has successfully demonstrated his ability to solve or resolve problems relating to the subject matter and technical responsibilities within an enterprise.
- 35. “Raw material”** means any basic ingredients or substance which is intended for use in the production of processed food product.
- 36. “Recall”** means the action to remove food from the market at any stage of the food chain, including that possessed by consumers.
- 37. “Risk-based inspection model”** means food control strategy that prioritizes inspections based on the potential risks to human health, allowing for more efficient allocation of scarce resources in food control systems.
- 38. “Start-up”** means companies or ventures that are focused on a single product or service that the founders want to bring to market. Start-ups typically do not have a fully developed business model and lack adequate capital to move to the next phase of business.
- 39. “Substandard”** means food products that do not comply with established provisions of food products legislation such as Laws, Regulations, Guidelines, Standards, Instructions, etc. It may include but not limited to food that; are derived from diseased or infected animals, contain toxic substances, are rotten, spoiled, expired, or contaminated, contain additives that may cause a disease, are not conform to quality standards or provisions of food product regulations, are improperly labelled, are manufactured, prepared, preserved or stored under unsanitary conditions, are counterfeited, recalled, or manufactured, stored, distributed, imported/exported, exhibited, repackaged without Authorization.
- 40. “Suspension or Revocation”** means an annulment of the license, approval, certificate or authorization issued to manufacturer, storage facility, distributor, wholesaler, retailer of processed food and related products due to violation of the terms and conditions of under which it was granted.
- 41. “Therapeutic and medical food”** means food intended for the dietary management of patients. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary food products or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

42. “Traceability or product tracing” means the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.

43. “Unapproved/unregistered regulated products” means regulated products not yet released by the Authority including but not limited to food products and their respective raw materials that are not physically inspected or unauthorized for use by a competent Authority.

In these Regulations, the following verbal forms are used:

“**Shall**” indicates a requirement;

“**Should**” indicates a recommendation;

“**May**” indicates a permission; and

“**Can**” indicates a possibility or a capability.

Article 5: Obligations of Food Business Operators

- 1) Food Business Operators (FBOs) bear the primary responsibility to ensure food safety and quality during manufacturing, processing, transport, distribution, storage, and sale. It is their utmost obligation to ensure that only safe and fairly presented food is placed on the market.
- 2) FBOs shall obtain relevant authorizations from the Authority prior to manufacturing, preparing, importing/exporting, storing, selling, exhibiting, distributing, retail, advertising or promoting any processed food and related products.
- 3) Where the FBOs plan to close down the business or cease manufacturing, preparation, importation/exportation, storage, sale, exhibition, distribution or retail of any processed food and related products, they shall formally notify the Authority in writing within the timelines specified in the relevant guidelines.
- 4) FBOs shall provide the Authority with required authentic information relating to their applications. FBOs shall allow Rwanda FDA inspectors to conduct physical inspections anytime the Authority deems necessary.

CHAPTER TWO: PREMISES LICENSING, PROCESS CONTROL AND INSPECTIONS

Article 6: Provisions for Food Premises and Process Control – Provisional Approval and Premises Licenses.

- 1) Every FBO shall possess a valid Provisional approval of food Premises and process or Premises license issued by the Authority.
- 2) Requirements for the Provisional approval of food Premises and processes shall be determined in relevant guidelines.

- 3) The Authority shall conduct an inspection for confirmation of compliance with the licensing requirements in order to grant Provisional approval of a substantial modification. Provisional approval to operate as manufacturers, or a premises license for distributors, wholesalers and retailers of processed food and related products shall not be granted where the Authority finds the applicant not complying with the requirements prescribed in these Regulations and relevant regulatory documents.
- 4) The approval or premises license may be suspended or withdrawn if any of the conditions under which it was granted are violated.

Article 7: Application for Premises and Process Control – Provisional Approval and Premises License

- 1) An application shall be submitted electronically to the Authority, accompanied by all required documents as described in the relevant guidelines. An application is considered complete upon submission of all required documents, thus the licensing process shall be counted-on thereof. An application is considered incomplete until all requirements are fulfilled.
- 2) Inspection fees, where applicable, shall be part of the application fee. When deemed necessary, re- inspection carried out due to unsuccessful initial inspections may attract an inspection fee in addition to the application fee paid.
- 3) For manufacturers of processed food and related products, the Authority, upon receipt of a complete application dossier shall conduct inspections to determine the premises, machinery/equipment suitability, process control in order to issue provisional approval. Any steps that shall fail to comply with the requirements shall render the application ineligible for the provisional approval.
- 4) For wholesalers and retailers of processed food and related products, the Authority shall conduct inspections upon receiving a complete application to assess the suitability of the premises. Any premises that fail to meet the required standards shall not be eligible for a premises license. An inspection report shall be filled by inspectors and signed by both parties and shall be presented to the applicable technical committee meeting for deliberation purpose.
- 5) Dossier at application level or inspection level that are dormant for a period exceeding 90 days shall be rejected, and the applicant/Client shall be required to reapply again, with prescribed fees where applicable. Similarly, any data submitted beyond the predefined timelines required to reach a conclusion shall be treated as a new application, exempt from applicable fees.

Article 8: Premises suitability

- 1) Premises shall be made of permanent building materials and must be located away from sites or activities that may compromise the safety and quality of processed food and related products. Related requirements shall be determined in relevant guidelines.

- 2) Specifically, premises in which processing involves flammable substances such as spirits with at least 30% alcohol v/v and/ or premises having any access to neutral spirits as raw material or other chemical substances susceptible to cause hazards shall strictly be located in industry-designated areas.
- 3) Every premises dealing with processed food and related products shall be designed, constructed and maintained in a manner appropriate to the nature of the operations to be carried out and have reasonably enough space to demarcate processes, allow free movement and avoid cross contamination. Further details will be will be outlined in the relevant guidelines.
- 4) All premises meant for manufacturing of processed food and related products shall be located at designated sites. Premises meant for manufacturing of processed food and related products with water from natural sources as raw material shall comply with regulatory requirements set by relevant b competent Authority.
- 5) The Authority may provide guidance for the layout, design and site location for FBO's prior to construction, after satisfactory review of the following preliminary documents including a Letter of intent, proposed premises layout or architectural site plan, and process flowchart(s).

Article 9: Machinery and equipment suitability

All machinery and equipment used in production of processed food and related products shall be food grade, hygienically designed, well maintained and calibrated if applicable. The specifications for machinery and equipment shall be detailed in the relevant guidelines.

Article 10: Compliance to GMP and GSP

- 1) Manufacturers of processed food and related products shall exercise GMP principles by having a quality assurance and quality control system that will ensure food safety from the reception of raw materials to the final product and ensure traceability. The details about the systems are elaborated in relevant guidelines.
- 2) Premises involved in storing, distribution, wholesaling and retailing of processed food and related products shall comply with the Good Storage as detailed in relevant guidelines. Distributors shall be responsible for the suitability of all vehicles used in transportation of the products to ensure their safety and quality.
- 3) Rwanda FDA GMP compliance shall be required for specific imported food products as defined in relevant guidelines. The Authority may conduct GMP inspection for purposes other than product registration. The details about the systems shall be elaborated in relevant guidelines. The GMP inspection covers Premise suitability and process control.

Article 11: Mandatory food product registration

Before issuing a market authorization for food products manufacturers, food products shall be sampled and tested for safety and quality evaluation performance for the sake of registration. For non-registrable products the Authority may test for safety parameters. Details shall be stipulated in relevant guidelines for food product registration.

Article 12: Qualified personnel in charge of production

- 1) A manufacturing facility shall have a qualified personnel in charge of production, quality assurance and/or quality control of processed food and related food products;
- 2) Qualified personnel in charge of production, quality control and/ or quality assurance of processed food and related food products shall possess at least bachelor's degree qualification of related food business to ensure food safety. For start-ups and early stage small businesses, A-level qualifications supplemented with related professional training may be approved by the Authority after analysis. Other relevant qualifications for remaining categories may be accepted after analysis and approval by the Authority. Details are provided by the Authority in the relevant guidelines.
- 3) Food manufacturer, wholesalers, distributors and retailers shall formally notify the Authority of the name of appointed authorized personnel and the specific functions which have been delegated for the purpose of approval. Key positions shall be occupied by qualified full-time personnel.
- 4) Qualified personnel responsible for production, quality control, and/or quality assurance of processed foods and related products shall be permanent staff and shall be present at all times during processing activities.
- 5) Any personnel directly involved in production of processed food products and related products shall be healthy. Diseases that will be regularly checked may be specified by the Authority in relevant guidelines.

Article 13: Appointment of inspectors

The Authority shall appoint inspectors to inspect food manufacturers, wholesalers, distributors and retailers of food products. The inspectors shall have the relevant qualification in terms of academic education, training, and experience to effectively take part in the inspection.

Article 14: Conflict of Interest

To avoid any conflict of interest, all inspectors shall declare any conflict of interest upon appointment, or at any time there is a need, by filling a conflict of interest declaration form as stipulated in relevant documents.

Article 15: Powers of inspectors

Food Business Operators shall be obligated to co-operate with inspectors. To enforce compliance for conducting inspections, an inspector appointed following these Regulations shall, upon production of evidence that he/she is authorized:

- 1) At any reasonable time permitted by Rwandan laws to enter any premises, other than premises used only as a private dwelling house, where he/she has reason to believe it is necessary to visit, including any premises of any person who carries out any of the activities referred to in these Regulations;
- 2) To carry out inspections, examinations, tests, and analyses as he/she considers necessary;
- 3) To inspect and take copies of extracts from any relevant book, document, data or record pertaining to the inspection activities in whatever form it is held at, or in the case of computer data or records accessible at the premises;
- 4) To take possession of any food or raw material samples for examination and analysis and any other article, substance, book, document, data or record in whatever form they are held at, or in the case of computer data or records accessible at, the premises;
- 5) To interview any person whom, he/she finds at the premises and has reasonable cause to believe can give relevant information; and
- 6) To require any person to offer assistance/explanations as considered necessary concerning any matter within that person's control and responsibilities;
- 7) To recommend closure of a given facility found in violation of these regulations. The modalities of implementation are detailed in the relevant guidelines.

Article 16: Creation of incentives to comply with food safety

The Authority may introduce some incentives to motivate food business operators (FBO) to comply with food safety requirements. These may include but not limited to Progressive Licensing Scheme (PLS) to support small business units to improve on the safety, quality and wholesomeness of their products or offer special recognition of compliance after a given period of time of compliance. Relevant guidelines shall determine the modalities for the scheme.

Article 17: Grant or refusal of Food Premises and Process Control – Provisional Approval and Premises License

- 1) The inspection framework may be based on a risk-oriented approach, whereby the frequency, scope, and intensity of inspections shall be proportionate to the assessed risk level of the regulated business or product. Specific requirements and procedures for implementation shall be prescribed by the Authority in accordance with relevant guidelines."

- 2) After assessment of the inspection findings by the competent committee in charge of licensing provisions, the Authority shall grant or deny a Provisional Approval letter/ Premises license to manufacturers of processed food products and related products that comply or did not comply with the minimum technical requirements prescribed in these regulations and relevant regulatory documents, prior to issuing product market authorization.

Article 18: Validity and specificity of Food Premises and Process Control – provisional approval/premises license

- 1) Food Premises and Process Control – Provisional Approval/ **Premises license** shall be valid for a period of sixty (60) months/ five (5) years.
- 2) Food Premises and Process Control – Provisional Approval may be suspended or withdrawn/revoked, if any of the conditions under which it was granted are violated.
- 3) Any premises found with expired Food Premises and Process Control – Provisional Approval/ Premises license, shall be closed until the approval/license is renewed.
- 4) Food Premises and Process Control – Provisional Approval /premises licence issued to an applicant shall not be transferred to another applicant or premises.
- 5) No Food Business Operator shall engage in manufacturing, wholesaling and/ or retailing of processed food products and related products without prior written approval from the Authority.
- 6) Applications for marketing authorization/premises license renewal shall be made at least sixty (60) calendar days before the expiry date of the valid license.
- 7) Upon reception of a complete application for license renewal, the Authority shall assess the compliance history of the establishment and determine whether physical, desk or virtual inspections may be performed.

Article 19: Approval of variations

- 1) Any change(s) to the information appearing on the license shall be notified to the Authority within a period of five (5) working days.
- 2) Any variation to information of a licensed food establishment and/or registered food product shall only be effected upon the Authority's approval according to the conditions, procedures and requirements prescribed in the relevant guidelines.

Article 20: Establishment of Technical and Advisory Committee

The Authority may establish technical and/or advisory committees comprising of internal and/or external experts from different scientific fields with clear terms of reference to advise the Authority on decision making on regulatory matters.

Article 21: Publication of regulated premises on the Authority’s website

Approved or Licensed premises as well as premises with revoked, suspended provisional approval/premises licenses shall be published on the Rwanda FDA website, and on any other media, as the Authority may decide from time to time.

Article 22: Display of the license and signpost

The approval /premises license shall be conspicuously displayed in the authorized premises. A licensed or Authorized premises shall be identified by a clearly displayed signpost.

Article 23: Compliance with the Law on Occupational Health and Safety

The premises shall comply with the requirements of the relevant law Regulating Labour and Occupational Health and Safety in Rwanda.

Article 24: Documentation and related controls

All records—including, but not limited to, complete production and quality control records, invoices, purchase orders, import authorizations, sales and distribution records throughout the supply chain for all food products, as well as administrative records of the staff—shall be properly kept and readily available to the inspection service when requested or needed. All incoming and outgoing food products must be reviewed and approved by the duly authorized and responsible personnel prior to receipt or dispatch, ensuring compliance with all applicable quality, safety, and regulatory requirements.

CHAPTER THREE: ENFORCEMENT INSPECTIONS

Article 25: Collaboration with other institutions

- 1) In order to execute its mandate, the Authority may establish mechanisms for collaboration with other government institutions. Detailed modalities shall be outlined in the relevant guidance.
- 2) Rwanda FDA may delegate recognized organizations/competent Authority to conduct part or whole inspection and/or may authorize public or recognized private laboratories to carry out official analyses on their behalf.
- 3) Rwanda FDA may recognize or rely on the outcomes of the activities conducted by other public institutions and/or recognized organizations to make regulatory decisions.

Article 26: Post Marketing Surveillance and food safety monitoring

The Authority shall conduct unannounced post market surveillance and food safety monitoring inspections either at the production premises or on the market to ensure consistency in compliance and enhance public health protection. Modalities for Food Post Marketing Surveillance and safety monitoring shall be detailed in relevant guidelines. In addition, the Authority may perform sampling and testing that may help in regulatory decisions including seizure, recalls and safe disposals in the event of non-compliance with applicable standards.

Article 27: Product Risk based Sampling and Inspection Model

To ensure the rational use of resources, the Authority may establish a risk-based sampling and inspection model that will be based on the category of manufacturer, wholesaler, importer/exporter, type of products based on their associated risk to public health and safety. The model shall establish the requirements applicable to each category, along with the respective sampling and inspection plans, as outlined in the pertinent regulatory guidelines.

CHAPTER FOUR: FOOD PRODUCT REGISTRATION

Article 28: Product to be registered

- 1) This Chapter applies to the registration of both domestic and imported processed foods, Fortified food products, Food additives and food fortificants, Breast milk substitutes and complementary foods, and therapeutic and medical foods.
- 2) This Chapter does not apply to food supplements that are regulated under the Presidential Order N° 67/01/2009 of 20/10/2009 establishing food supplement regulation.

Article 29: Obligation to register processed food products

All processed food products shall be registered before they are placed on Rwandan market. Any manufacturer, brand owner, importer, or related representative of processed food products and related products shall bear the primary responsibility to register any processed food prior to sale or distribution.

Article 30: Exemption from registration

Notwithstanding the provision of Article 29 of this regulation, a processed food may be exempted from the registration requirement as determined by the Authority in relevant Guidelines.

Article 31: Requirements for registration of processed food products

A person who intends to apply for registration of a processed food shall submit a complete application according to established technical requirements and procedures as determined by the Authority in relevant guidelines.

Article 32: Evaluation of the application dossiers

- 1) The Authority, upon the receipt of the application, shall evaluate the product dossier for safety and quality compliance. The evaluation is carried out in accordance with relevant national or international standards, and where there is no standard, any other regulatory requirements as prescribed by the Authority in relevant guidelines.
- 2) The Authority, during the evaluation of the applications, shall take into account the scientific information, evidence and/or risk analysis. Reliance and recognition of systems may be applied, where appropriate, using tools and instruments that can optimize the risk-based decision making.
- 3) The Authority may, during application evaluation, require the applicant to submit additional information or requirements besides the established requirements on the basis of the evaluation findings and risk analysis.
- 4) Where the Authority requests additional samples, documents, information, or clarifications, the Authority shall hold the processing of the application until the applicant complies with the requirement.
- 5) Where the applicant fails to submit the additional requirement within a period of 90 working days without a written notification to the Authority, the application shall be considered invalid. The application that becomes invalid under this regulation may submit another application which shall be considered as a new application.

Article 33: Approval or refusal of a registration application

- 1) The Authority, upon evaluation of the application, shall grant registration of a food product if it is satisfied that the food product intended to be registered complies with the prescribed standard and regulatory requirements.
- 2) The registration of a food product, unless otherwise revoked, shall be valid for a period of five (5) years from the date it was approved and may be renewed upon submission of an application.
- 3) A list of food products approved for registration will be published on website and made accessible to the general public. The Authority shall reject unsuccessful application. The situations that may lead to the rejection are established in the relevant Guidelines.

Article 34: Revocation, cancellation or suspension of registration

The Authority may revoke, cancel or suspend the registration of a food product at any time under the conditions determined in the relevant Guidelines.

Article 35: Variation on registered product and registration renewal

- 1) Any change to a registered food product shall be notified to the Authority for approval according to the conditions, procedures and requirements prescribed in the relevant Guidelines.
- 2) An application for registration renewal shall be submitted to the Authority at least ninety (90) working days before the registration certificate expiry date. Failure to renew the marketing authorization within the specified period, may result in the application being considered as new.

CHAPTER FIVE: PROMOTION AND ADVERTISEMENT OF FOOD PRODUCTS

Article 36: Content of promotional materials

- 1) Promotional materials shall be consistent with the approved product information in line with conditions under which it has been registered.
- 2) Promotional materials shall not contain misleading information or unverifiable statements or omissions regarding quality and safety or value which likely induce product misuse or give rise to undue risks.
- 3) Promotional materials for a product shall present information that is reasonably balanced between contra-indications and safety. All nutrition and health claims shall be scientifically substantiated. Promotional materials shall be available in any of the official languages of Rwanda.

Article 37: Obligation to obtain approval of promotion and advertisement materials

- 1) FBOs shall obtain written authorization prior to promotion and advertisement of their products. Any alterations in the format and content of the approved advertisement shall be approved by the Authority before use. Food products exempted from registration shall comply with applicable regulatory requirements as determined in relevant guidelines, prior to their promotion and advertisement.
- 2) FBOs have the obligation to ensure, during the entire promotion, advertisement and marketing practices, that the approved content is strictly adhered to.

Article 38: Prohibitions and restrictions

The following acts are prohibited:

- (a) To advertise or promote any food product unless the advertisement, promotion or artwork has a written approval issued by the Authority.

- (b) Advertisements which unfairly undermine any product of a competitor, either directly or by implication, are prohibited.
- (c) Promotions shall not state or imply that a product is “100% safe”, has “no adverse effects” or that its “use will not cause harm”.
- (d) Promotional advertisements shall not in any way discourage the public from seeking the advice of a healthcare provider.
- (e) An advertisement to the general public shall not refer to the Authority or any employee of the Authority.
- (f) Any form of communication that brings or is likely to mislead or deceive or create fear or distress to individuals or community is prohibited.
- (g) Any advertisement which uses baseless claims such as “Number one product”, “the best product” or incomplete (hanging or floating) comparatives and superlatives in promoting a product are prohibited.
- (h) Any advertisement which may directly or indirectly induce or attract children (under 18 years) to use any food product is prohibited.
- (i) Breast milk substitutes shall not be promoted to the general public. This provision does not, however, preclude the dissemination of information to health professionals as provided for in relevant regulatory requirements.
- (j) The use of claims for therapeutic or prophylactic action; claims which could be interpreted as advice of a medical nature from any person; claims that a food will prevent, alleviate or cure any disease or condition affecting the human body; and claims that health or an improved physical condition may be achieved by consuming any food, is prohibited.
- (k) Product endorsement by any given personality directly or indirectly suggesting that the consumption of a food product has contributed to the success of their particular endeavours is prohibited.
- (l) To deploy deceptive marketing strategies such as pyramid schemes or any other unauthorized marketing strategy for food products.
- (m) Promotion and advertisement providing incentives or bonus that influence increased use of food high in saturated fatty acids, trans fatty acids, free sugars and/or salt (HFSS) in a specifically targeted vulnerable population group as defined by the Authority in specific guidelines are prohibited.

To safeguard public health and reduce exposure among vulnerable populations, the Authority may establish relevant prohibitions and/ or restrictions on promotions and advertisement for specific category of processed food. Food category and modalities shall be detailed in relevant guidelines.

Article 39: Specific requirements for alcoholic beverages promotion and advertisement

- 1) In addition to the general requirements for the advertisement of foods, the following requirements apply to alcoholic beverages using texts or conventional symbols with the same meaning:
 - (a) ‘Drink Responsibly’
 - (b) ‘Not for sale to persons under 18 years of age’
 - (c) ‘Not recommended for pregnant women’
 - (d) Alcohol impairs judgement and ability to handle machinery and vehicles.
- 2) The regulatory warnings shall be displayed as continuous scrolling text for the entire duration of the TV and social media advertisement.
- 3) Where regulatory warnings are read on TV and Radio media they shall be clear, audible and paced similarly as the rest of the advertisement.
- 4) An advertisement shall not promote or depict excessive consumption of alcohol.
- 5) An advertisement shall not imply that consumption of alcoholic beverage is required for: social or professional achievement; personal success; any sporting activity; sexual prowess; pleasure; resolution of social, physical or personal problems; appetite or intellectual abilities.
- 6) No advertisement shall enhance or promote vices, general misconduct or be offensive to public policy.

Article 40: Administrative process for application for promotion or advertisement

An application to promote or advertise a food product shall be prepared in accordance with requirements as provided in the guidelines on promotion and advertisement of food products available on Rwanda FDA website.

Article 41: Validity of approval

The approval for promotion or advertisement shall be valid for five years (60 months), provided that the marketing authorization is valid.

Article 42: Withdrawal of approval

The Authority may withdraw the approval for an advertisement or promotion if:

- a) The grounds on which the approval was granted were later found to be false or incomplete;
- b) There is a practice that involves the contravention of obligations or the breach of prohibited or restricted provisions of these regulations.
- c) There is new scientific evidence against claims contained in the advertisement.

Article 43: Exemptions

Prior approval may not be required for the following:

- a) Advertisement limited to a manufacturer's corporate advertising, provided information specific to the products is not included.
- b) Manufacturer's advertisement appearing within own licensed premises in a form prescribed by the Authority.
- c) Advertisement carried out by or endorsed by a Government institution in the interest of public health.
- d) Advertisement of products complying with the applicable regulatory requirements in one-off event including the exhibition events during the event duration.

CHAPTER SIX: CONTROL OF IMPORTS AND EXPORTS OF PROCESSED FOOD PRODUCTS

Article 44: Requirements for importation and exportation of processed food products

- 1) All importers/exporters of processed food products and related products must comply with eligibility requirements specified in relevant guidelines.
- 2) All food products to be imported/exported in Rwanda shall be registered in accordance with established registration modalities, except otherwise approved by the Authority.
- 3) Importers/exporters shall notify the Authority upon arrival of imported/exported food products at point of entry/exit for physical inspections.

Article 45: Import and Export Authorization

Importer/Exporter of food products shall apply to obtain relevant authorizations from the Authority for each consignment of processed food products to be imported or exported. An Export Authorization is required only when requested by importing country.

The Authority may apply a risk-based approach to issuing import/export authorizations based on the modalities described in the relevant guidelines.

The Authority may waive authorization requirements for consignments under special exemptions as provided under this article.

Article 46: Suspension or revocation of registration or import/export authorization

The Authority may suspend or revoke an import/export authorization if the products or the importer/exporter fail to comply with certain regulatory requirements. The conditions under which the authorization is revoked or suspended shall be described in the relevant guidelines.

Article 47: Special considerations / exemptions

In special circumstances including but not limited to products declared as personal effects, emergency situations or any other situation as may be declared by the competent authorities, article 44 (3) may not be applied. All required documents for application are described in relevant Guidelines.

Article 48: Safety and Quality requirements for importation of food products

- 1) All food products to be imported/exported into or outside Rwanda shall comply with relevant Standards and/or regulatory requirements described in relevant Guidelines.
- 2) The Authority grants an import/export Authorization if it is satisfied with the food product's safety and quality in accordance with the established requirements for importation or exportation, and/or applicable specific requirements.

Article 49: Point of entry/exit

Food products shall be imported or exported only through official designated and gazetted points of entry/exit. Food products that may be found to have been imported or exported through other non-gazetted points of entry shall be classified as smuggled goods and subject to the enforcement administrative sanctions under applicable laws and regulations.

Article 50: Inspection, Sampling and Laboratory Testing

- 1) All food product consignments shall be subject to physical inspection by the Authority upon arrival at the designated point of entry/exit or any other approved location. The Authority may take a sample of any imported/exported food products during inspection and conduct laboratory testing to assess compliance with relevant standards and claims.
- 2) The Authority may apply a risk-based inspection model, where the frequency and intensity of inspection are determined based on the modalities described in the relevant guidelines.

Article 51: Release, Retention, Quarantine, and Handling of Non-Compliant Food Products

- 1) The Authority shall release the food consignment upon ensuring it satisfactorily complies with the applicable regulatory requirements. The Authority may retain or quarantine any consignment of food products suspected of non-compliance, pending further investigation or laboratory test results.
- 2) Food products found to be non-compliant with regulatory requirements shall be handled in accordance with the relevant guidelines.

CHAPTER SEVEN: FINAL PROVISIONS

Article 52: Prohibitions

For purposes of public health protection, any food products that do not meet regulatory requirements, including but not limited to safety and quality requirements are prohibited from being manufactured, exhibited, imported/exported, sold, distributed, donated, advertised or promoted. Therefore, no person shall manufacture, sell, donate, import/export, store, distribute or exhibit unsafe food products.

Article 53: Penal Offences

Should the offences in Annex A of these regulations result in death, disability, serious injury, foodborne disease outbreak or otherwise deemed criminal; penal proceedings shall override administrative sanctions as per the Law N°. 059/2023 of 04/12/2023 amending Law No. 68/2018 of 30/08/2018 determining offences and penalties in general, Article 132 *bis* that reads “A person who produces, sells, distributes or imports foods, beverages, medications or other products which are substandard or which may be harmful to the human being, commits an offence.”

Article 54: Other Regulatory Actions

The Authority may take other regulatory actions based on Minor, Major and Critical non-compliances when making decisions following the outcome of inspections:

- a) **Critical non-compliance:** Is a failure of the food safety management system that could result, or has resulted, in the highest risk of producing a product that is unsafe, fraudulent, which does not meet legal requirements or could damage brand reputation and poses an imminent serious risk to health. The food business may not be able to rectify these issues during normal processes. The Authority will determine minor non-compliances in relevant regulatory documents.
- b) **Major non-compliance:** The absence of, or a significant failure to implement and/or maintain compliance to the provisions of this regulation. The Authority will determine major non-compliances in relevant regulatory documents and conduct inspection to verify implementation of corrective action within a given timeframe.
- c) **Minor non-compliance:** It represents either a management system weakness or minor issue that could lead to a major non-compliance if not addressed. The Authority will determine minor non-compliances in relevant regulatory documents.

Article 55: Suspension of the authorization

The Authority may issue a warning letter, suspend, or revoke an authorization if any of the conditions under which it was granted are violated. Further details will be outlined in relevant guidelines.

Article 56: Reinstatement

A premises whose license/Provisional licenses is revoked may be reinstated in licensed premises after one (1) year from the day his or her revocation was issued. However, in the interests of the service, the Authority may define a different timeline after meticulous consideration of the report provided by the licensee.

Article 57: Appeals and Review

- 1) An authorization holder or applicant may notify the Authority of his or her grounds when he/she:
 - (i) Objects to any suspension or revocation of the authorization, or any notice served;
 - (ii) Objects to the refusal of authorization or the imposition of any condition may notify the Authority of his desire to make written representations to, or be or appear before and be heard by, a person appointed by the Authority for that purpose.
- 2) Any person aggrieved by a decision of the Authority may appeal to the Authority for review of a decision within thirty (30) working days from the date of the notice. The Authority shall within thirty (30) working days from the date of receiving the written notification and make its own decision whether to vary, reject or uphold the decision.
- 3) Where the Authority receives notification pursuant to provisions of paragraph 1 of this Article, the Authority shall appoint a person to consider the matter. The person appointed shall determine the procedure to be followed concerning the consideration of any objection.
- 4) The person appointed by the Authority, shall consider any written or oral objections made by the objector or complainant in support of its objection, and shall make a recommendation to the Authority.
- 5) A recommendation shall be made in writing to the Authority, and a copy of it shall be sent to the complainant concerned, or to its nominated representative. The Authority shall take into account any recommendation made within fourteen days of receipt of such recommendation.
- 6) The Authority shall inform the complainant whether it accepts the recommendation and, if not, the reasons for its decision. If a person is dissatisfied with a decision after review, he/she may appeal to the supervising Authority of Rwanda FDA or the supervising Authority whose decision shall be final.

Article 58: Management of deviations

The Authority may deviate from the existing provisions of regulatory document or product standard requirements only if they do not affect the safety and quality of product or public health. All deviations must be documented and shall be approved by the Authority. Detailed management of deviations shall be documented in specific and relevant guidelines.

Article 59: Management commitment to food safety

Management of a food manufacturing plant is required to avail sufficient resources to ensure the implementation of effective food safety practices, establish and maintain a positive food safety culture, and apply continual improvement, where appropriate, taking into account developments in science, technology, and best practice.

Article 60: Administrative sanctions

Any person who deals in food products in the manners that contradicts with provisions of these regulations shall be sanctioned with administrative sanctions and administrative fines as stipulated in Annex A of these regulations. The administrative fines consisting of fines shall be paid within thirty (30) days from the signature of the decision imposing fines. Commitment to pay by instalments for a period of at least three (3) times shall be accepted on special cases. Any accepted payment in instalment shall not exceed twelve (12) months.

Article 61: Power to issue guidelines

The Authority shall issue guidelines, Standard Operating Procedures (SOPs), and forms necessary for the implementation of these regulations.

Article 62: Repealing

All prior provisions contrary to these Regulations are hereby repealed.

Article 63: Commencement

These Regulations shall enter into force on the date of signature and publication.

ANNEX-A: FAULTS AND ADMINISTRATIVE SANCTIONS

S/N	FAULT/ OFFENCE	ADMINISTRATIVE SANCTION
1.	Manufacturing, importation, sale, storage & distribution unapproved/unregistered regulated products.	<ul style="list-style-type: none"> - Warning letter to the manufacturer or importer/exporter - Fine: The value of condemned products plus charges for disposal and test related costs (when disposal and/ or testing is compulsory) subjected to the initial manufacturer or importer/exporter in case of second time violation.
2.	Manufacturing, importation, sale, storage & distribution of substandard/unsafe, recalled, counterfeit/falsified, expired and fraudulent regulated products.	<ul style="list-style-type: none"> - Warning letter - Fine: The value of condemned products plus charges for disposal and test related costs (when disposal and/ or testing is compulsory) - Suspension of the authorization in the event of repeated offence and the above fine. - Revocation of the authorization.
3.	Violation of closure by Rwanda FDA: Illegal opening of premises closed by the Rwanda FDA, and / or illegal resuming of any activity previously prohibited by Rwanda FDA.	Fine: 500,000 FRW.
4.	Absence of qualified personnel/ responsible technical person in an authorized facility dealing with regulated products.	Fine: 500,000 FRW.
5.	Operating without license or Provisional Approval.	Fine: 1,000,000 FRW.
6.	Operating with expired license or Provisional Approval.	<p>Fine: 100,000 FRW</p> <p>Note: for each delay, a 25% increment, on the original fine shall apply monthly from the second month after expiry of the license. This charge of 25% increment shall not go beyond 6 months after expiry of the license. A period after which the applicant shall be required to apply as a new application.</p>
7.	Transport of regulated products in inappropriate or non-complying conditions.	Fine: 200,000 FRW and Disposal of condemned products when the safety and quality is compromised.
8.	Any change to the authorization without notifying the Authority within the prescribed timelines.	Fine: 100,000 FRW
9.	Violation of quarantine.	<ul style="list-style-type: none"> - Closure. - Fine: 500,000 FRW. - Double the value of the quarantined and sold products in case the products are quantified.
10.	Obstruction to joint enforcement inspection.	<ul style="list-style-type: none"> - Closure. - Fine: 500,000 FRW for each day of obstructions.

		<ul style="list-style-type: none"> - Law enforcement organs to secure search warrant and execute the search and seizure.
11.	Dodge joint enforcement inspection.	<ul style="list-style-type: none"> - Closure. - Fine: 500,000 FRW. - Law enforcement organs to secure search warrant and execute the search and seizure. - Forced entrance.
12.	Obstruction and/or dodging the routine inspection.	<ul style="list-style-type: none"> - Warning letter. - 500,000 FRW for each day of obstructions. - Closure of the application in case of a three-times repeated dodging.
13.	Use of non-permitted or untraceable raw materials and/or additives.	<ul style="list-style-type: none"> - Warning letter - Fine: 1,000,000 FRW - Disposal of the condemned products
14.	Use of prohibited or unsuitable primary packaging materials other than the ones provided for in respective product registration, such as plastic bottles for alcoholic beverages or glass bottles.	<ul style="list-style-type: none"> - Closure. - Fine: double the value of condemned products or packaging material plus charges for disposal and test related costs (when disposal and/ or testing is compulsory). - Disposal of the condemned products.
15.	Use of branded packaging materials from other industries.	<ul style="list-style-type: none"> - Warning letter. - Disposal of the condemned products. - The owner of property to be alerted so he/ she may claim intellectual property violations.
16.	Use of unauthorized secondary packaging materials.	<ul style="list-style-type: none"> - Quarantine of products and replacement of packaging material. - Warning letter.
17.	Use of branded packaging materials from other industries.	<ul style="list-style-type: none"> - Quarantine of products and replacement of packaging material. - Fine: 250, 000 FRW. - Warning letter.
18.	Poor hygiene in the premises susceptible to compromise food safety and quality.	<ul style="list-style-type: none"> - Closure of operations and immediate cleaning or cleaning under local Authority supervision. - Fine: 500,000 FRW. - Disposal of present products at the time of inspection.
19.	Operating with pending administrative fines due to malpractice beyond payment period.	<ul style="list-style-type: none"> - Closure. - Revocation of license or Provisional Approval (If applicable). - Denial of next service.
20.	Disposal of regulated unfit products without Rwanda FDA supervision.	<ul style="list-style-type: none"> - Double the value of the products in case they are quarantined.
21.	Transferring/ using a valid license of a licensed premise to or by unlicensed premises.	Fine: 1,000,000 FRW and revocation of license.
22.	Failure to provide invoices, contracts or any distribution reports detailing the	Fine: 500,000 FRW.

	value of non-complying and fraudulent regulated products at the time of inspection	
23.	Relocation or opening an additional line or change of products without notifying the Authority	<ul style="list-style-type: none"> - Fine: 300,000 FRW and - Warning letter to apply for relocation and additional line
24.	Storage of expired products with products with valid shelf-life	<ul style="list-style-type: none"> - Temporary closure. - Double the value of the condemned products while still in valid shelf-life.
25.	Misuse of Regulatory licenses.	<ul style="list-style-type: none"> - Fine: 1,000,000 FRW. - Revocation of the license and Temporary closure.
26.	Intentional violation or omission of recommendations provided by the Authority.	<ul style="list-style-type: none"> - Fine: 1,000,000 FRW. - Revocation of the license and Temporary closure.
27	Violation of the provisions on promotion and advertisement on the first time	- Written warning and order to withdraw the promotional material
28	Violation of the provisions on promotion and advertisement on the second time	- Administrative fine of five hundred thousand Rwandan Francs (500,000 FRW).
29	Violation of the provisions on promotion and advertisement on the third time	<ul style="list-style-type: none"> - Revocation of the promotion and advertisement authorization and/or; - Temporary Closure until compliance and/or; - Public announcement discouraging the consideration of the promotional material
30	Self- opening new branches or premises without notifying the Authority	- A fine of 1,000,000 FRW shall apply. If the value of the products found exceeds this amount, the fine will be equivalent to double the value of the product found.

Notes

- 1) For any fault/offence detailed in this Annex, the provisions articulated in article 54 shall take effect in the event of Penal cases.
- 2) For any fault/offence detailed in this Annex, the Authority remains with the discretion to implement other regulatory actions as per the article 55; further details will be determined in relevant guidelines.

End of Document