



**REGULATIONS GOVERNING CONTROL OF IMPORTATION
AND EXPORTATION OF FOOD PRODUCTS**

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



REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	12/08/2022
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24/11/2022	0	First issue

ADOPTION AND APPROVAL OF THE REGULATIONS

*In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article No 9 of the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these Regulations No. **FDISM/FDIEC/TRG/003 Rev_0** Governing Control of Importation and Exportation of Food Products, made this **16/11/2022**.*

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Director General





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CHAPTER I: GENERAL PROVISIONS

Article one: Purpose of these Regulations

The purpose of these Regulations is to provide a legal framework for the effective and efficient control of importation and exportation of Food Products in a transparent, non-discriminatory process of their importation and/or exportation.

Article 2: Citation

These Regulations may be cited as the “*Regulations N° FDISM/FDIEC/TRG/003 Rev_0, Governing Control of Importation and Exportation of Food Products.*”

Article 3: Application

These regulations shall apply to the authorization of importation or exportation of Food Products, for public, private and non-profit organizations and personal use, as stipulated in Article 3 of Law No 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

“**Authority**” means the Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under Article 2 of the Law No 003/2018 of 09/02/2018 and determining its mission, organization, and functioning;

“**Authorization**” means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning; it includes import visa, import/export licence, To Whom or other certificates.

“**Authorized person**” means

- 1° any person who holds a licence to manufacture, import, export, distribute, wholesale or retail food products issued in terms of Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and Law No. 47/2012 of 14/01/2013 Relating to the regulation and inspection of food and pharmaceutical products; or
- 2° any person approved as such by the Authority in relation to this regulation.

“**Certificate of Analysis**” means an official document that meant to testify quality control data for a particular lot/batch of product,



“Certificate of Compliance” means a Certificate given by an authorized institution in the exporting country confirming that the manufacturer or distributor operate in that country complying with requirements related to food manufacturing.

“Fee” means the regulatory service fee charged in correspondence with service issued as prescribed in the Tariff of Fees for services rendered by Rwanda FDA Regulations in accordance with Article 9 and Article 32 of the Law No 003/2018 of 09/02/2018 and determining its mission, organization and functioning.

“Food product” means any animal or plant products that have been processed or transformed from their original state and are intended for human or animal consumption including but not limited to beverages, food supplements, tobacco, food additives and food fortificants;

“Manufacturer” means a person or corporation, or other entity engaged in the business of manufacturing Food Products;

“Premises” means any plot of land, buildings or boats, aircrafts, 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 used by food handlers.

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.

CHAPTER II: IMPORTATION / EXPORTATION OF FOOD PRODUCTS

Article 5: Obligation to obtain an Import Visa

Any person intending to import any food products shall apply for an Import Visa for each consignment prior to applying for import license. The Visa is issued by the Authority in accordance with these Regulations and guidelines for importation and exportation of food products.

All required documentation for application shall be made as described in Guidelines No.: FDISM/FDIEC/GDL/002 for importation and exportation of food products.

Article 6: Obligation to obtain an import/export Licence

- 1° Any person intending to import/export any product shall apply for an import/export license issued by the Authority in accordance with these Regulations and guidelines for importation and exportation of food products.
- 2° All required documentation for application shall be made as described in Guidelines No.: FDISM/FDIEC/GDL/002 for importation and exportation of food products.
- 3° The import license is conditional to physical inspection in order to confirm safety and quality of products with regards to related claimed specifications.
- 4° An authorization to import/export shall not be granted where the Authority finds the applicant not complying with the requirements for importation or exportation. The applicant shall be informed in writing about the decision and the reasons thereof.

Article 7: Special cases

In special circumstances including but not limited to products declared as personal effects, emergency situations or any other as may be declared by the competent authorities, the article 6 and 7 may not be applied. All required documentation for application shall be made as described in relevant Guidelines.

Article 8: Quality and safety Requirements for importation of food products

All food products to be imported shall comply with related quality Standards and requirements described in Guidelines No.: FDISM/FDIEC/GDL/002 for importation and exportation of food products.

Article 9: Management of deviations

All National deviations provided by the Standards, shall be considered as mandatory and shall be complied with for importation and exportation of food products.

Other deviations from specification limits of tested parameters must be documented and shall be approved by the Authority only if they do not affect the product's quality and safety.

Article 10: Importation of registered and listed food products

- 1° All food to be imported to Rwanda shall be either registered or listed.
- 2° Products for particular nutritional use, food associated with adulteration risk and food with stringent regulatory requirements shall be registered with Rwanda FDA prior to importation.

Such food products shall be imported by the Local Technical Representatives or any other company authorized by the marketing authorization holder or by the manufacturer.

- 3° All low-risk food products shall be listed and imported by any importer who notified the Authority

Article 11: Eligibility to import/export food products

Applicants eligible to import/export food products include:

- 1° A manufacturer of food products holding a valid operational license;
- 2° A wholesaler or retailer of food products holding operational license;
- 3° Researchers or research institutions authorized by competent institution to conduct nutritional researches or clinical trial in the country;
- 4° An individual or company importing a sample for laboratory testing;
- 5° Government institutions and non-government institutions;
- 6° A beneficiary of food products donation;
- 7° A company or individual attending exhibition upon presentation of the invitation;
- 8° A company or individual attending exhibition;
- 9° A tourist, a visitor in the country or any other person for justified reasons;
- 10° Any other reason as the Authority may find it relevant to allow importation or exportation of food products.

Article 12: Physical inspection of food products

- 1° All consignments of food products to be imported or exported shall be subjected to physical inspection at port of entry or at importer's premise for the consignments released under seal, before being sold or used to ensure they comply with claimed specifications.
- 2° The Authority may take samples for quality control testing.
- 3° If the physical inspection finds out that the consignment doesn't comply with Food Standards, the products shall be condemned (seized, confiscated, rejected, destroyed...).

- 4° No person shall obstruct or hinder Rwanda FDA inspectors in the exercise of their powers or performance of their duties.
- 5° The Authority, when deemed necessary and for justified reasons, may release underseal an imported consignment while waiting for the client to comply with importation requirements and/or to obtain a full release of the imported products for their intended use.

Article 13: Gazetted/approved ports of entry and exit

Food products shall be imported or exported only through Gazetted ports of entry and exit.

CHAPTER III: VALIDITY, REFUSAL AND SUSPENSION OR WITHDRAWAL OF AN IMPORT/EXPORT AUTHORIZATION

Article 14: Validity of an Authorization

- 1° An import Visa shall be valid for 6 months from the date of its issuance.
- 2° An import/export License shall be valid for 6 months from the date of its issuance
- 3° An authorization is issued to an applicant, for a particular consignment, and shall not be transferable.

Article 15: Suspension or withdrawal of an authorization

An authorization may be suspended or withdrawn where the Authority finds that any of the conditions under which authorization was granted for was violated. The conditions include but not limited to the following:

1° Conditions for suspension:

- a) Request by the license holder due to impossibility to use the authorization
- b) Deceptive or misleading information in the application for authorization
- c) A suspicion that the product has effect on the safety of the consumer

2° Conditions for withdrawal:

- a) Scientific information that the product is not fit for human consumption
- b) Obstruction to physical verification of product by Rwanda FDA inspectors
- c) Abandonment of the business by the license holder

The notice of suspension or withdrawal shall be issued by the Authority to the applicant.

CHAPTER IV: RENEWAL AND VARIATION OF AN AUTHORIZATION

Article 16 Renewal of an import license

An import license shall be renewed after 6 months from the date it was issued in case it hasn't been used by the applicant after submission of all requirements as specified in Guidelines No FDISM/FDIEC/GDL/002 for importation and exportation of food products.

Article 17: Variation of an authorization

Whenever the Authority varies, amends, or imposes any new condition on the authorization requirements, the Authority shall communicate the return of such authorization to be duly endorsed within reasonable time.

An application shall be made to the Authority for review and approval of any variation made on the details of the issued authorization.

CHAPTER V: MISCELLANEOUS PROVISIONS

Article 18: Establishment of Advisory Committee

- 1°. The Authority shall establish Import and Export Control Advisory Committee with clear terms of reference;
- 2°. The committee shall be composed of internal and external multidisciplinary experts with specialization in relevant fields to assess all safety and quality issues on importation and exportation of food products.

Article 19: Compliance with other requirements

A company that has been granted with an authorization shall comply with any other requirements as may be specified by the Authority.

Article 20: Administrative sanctions

Any person who contravenes the provisions of these Regulations, shall be liable to the administrative measures and sanctions under **Annex A**:

- 1° Importation, sale, storage and distribution of substandard, counterfeit/falsified, expired and fraudulent food products;
- 2° Importation, sale, storage and distribution of unapproved (unauthorized) food products;

- 3° Importation/Exportation of unregistered or unauthorized food products without special approval given by the Authority
- 4° Obstruction of inspectors from Rwanda Food and Drugs Authority
- 5° Failing to dispose of the rejected consignment within the recommended timeline
- 6° Failing to re-export consignment that were recommended for re-exportation within the recommended timeline
- 7° Sale, storage and distribution of food products in unauthorized premises
- 8° Arrival of food products into the country without import Visa/License or special authorization;

In case the consignment complies with safety and documentary requirements for import license on the consignment already in Rwanda without visa/license, the importer shall pay a fine of 5% of the value of condemned products before being issued with an import license.

Article 21: Appeal and review

- 1° Any person aggrieved by a decision of the Authority may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (30) days from the date of notice.
- 2° The Authority shall, within thirty (30) days from the date of receiving the application, review, reject or vary its own decision.
- 3° If a person is dissatisfied with the decision after review, he may appeal to the Minister of the supervising Ministry.

Article 22: Power to issue guidelines

The authority shall issue Guidelines, Standards Operating Procedures, forms and formats necessary for the implementation of these Regulations.

Article 23: Revision of these Regulations

The revision of these regulations shall be done at least after three (3) years from the date of their publication, except in case of special circumstances. Amendment shall be communicated to the public in due time.



Article 24: Commencement and repealing

These regulations come into force on the date of signature and publication by the Authority.
All Provisions contrary to these regulations are hereby repealed.

End of Document

ANNEX A: FAULTS AND ADMINISTRATIVE SANCTIONS

Fault	Administrative sanction
1. Importation of regulated products without fulfilling some of the requirements for the first time including certificate of compliance for import visa and/or certificate of analysis for import licence.	Warning letter
2. Importation of regulated products without fulfilling some of the requirements for the second time including certificate of compliance for import visa and/or certificate of analysis for import licence.	Refusal to grant import authorization/ Application letter
3. Importation of unregistered or unauthorized regulated products without special approval by the Authority	Rejection of the consignment and order the re-export or safe disposal of the product at the cost of the importer
4. Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products.	25% to 50% of the product value found in violation
5. Obstruction of inspector from Rwanda Food and Drugs Authority	100,000 Frw for each day of obstructions
6. Failure to re-export consignment that were recommended a re-exportation within the recommended timelines	10, 000 Frw for each extra day
7. Sale, storage and distribution of food products in unauthorized premises	Not more than 5% of value of the products
8. Arrival of food products into the country without import Visa/License or special authorization;	Not more than 5% of the value of the products