

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

(Rwanda FDA Law No. 003/2018 of 09/02/2018, Article 9)

# REGULATION DEVELOPMENT HISTORY

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| --- | --- |
| **DRAFT ZERO**  | 12/09/2022 |
| **ADOPTION BY RWANDA FDA** | 17/10/2022 |
| **STAKEHOLDERS CONSULTATION**  | …/11/2022 |
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## DOCUMENT REVISION HISTORY

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# 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/004******Rev\_0*** *Governing Control of Importation and Exportation of Food Products, made this ……… 2022.*

**Dr. Emile BIENVENU**

**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 No FDISM/FDIEC/TRG/004 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

**“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 and other certificates.

**“Authorized person”** means

a) any person who holds a licence to manufacture, import, export, distribute 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

b) any person approved as such by the Authority.

**“Certificate of Analysis”** refers to quality control data for a particular lot/batch of product,

**“Certificate of Conformance”** means a Certificate given from the exporting country after inspecting the consignment before shipment, in relation to quality and safety of such particular consignment.

**“Fee”** means the income prescribed in the Fees Regulations in accordance with Article 9 and Article 32 of the Law No 003/2018 of 09/02/2018.

**“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 with the exception of pharmaceutical products, tobacco, food additives and food fortificants;

**“Good Manufacturing Practice”** means that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control.

**“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: 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 6: 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.

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 7: Obligation to obtain an import/export Licence

Any person intending to import/export any product shall apply for an import/export license issued by the Authority in accordance with these Regulations.

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 8: Special cases

In special circumstances including but not limited to products declared as personal effects, the article 6 and 7 shall not be applied.

All required documentation for application shall be made as described in relevant Guidelines.

**Article 9: Importation of registered food products**

A food product registered by Rwanda FDA shall be imported by the marketing authorization holder or any other company authorized by the marketing authorization holder or by the manufacturer in case he/she is the marketing authorization holder.

## Article 10: 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;

## Article 11: Physical inspection of food products

* 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 used to ensure they comply with claimed specifications.
* The Authority may take samples for quality control testing.
* If the physical inspection finds out that the consignment doesn’t comply with Food Standards, the products shall be condemned.
* No person shall obstruct or hinder Rwanda FDA inspectors in the exercise of their powers or performance of their duties.

## Article 12: 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 13: 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 14: Refusal to grant an Authorization**

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 for refusal.

**Article 15: Suspension or withdrawal of an authorization**

An authorization may be suspended or withdrawn where the Authority finds that the applicant violated any of the conditions under which authorization was granted for; or has ceased to be fit to carry out the business.

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

## The Authority shall establish Import and Export Control Advisory Committee with clear terms of reference;

##  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 as per Annex which comprises of administrative fines for:

## manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products.

## Obstruction of inspector from Rwanda Food and Drugs Authority 100,000 Frw for each day of obstructions

## 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 institution whose decision shall be final.

## 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.

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**ANNEX: FAULTS AND ADMINISTRATIVE SANCTIONS**

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| **Fault** | **Administrative sanction** |
| * + - 1. 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 |
| 1. Obstruction of inspector from Rwanda Food and Drugs Authority
 | 100,000 Frw for each day of obstructions |