

**GUIDELINES FOR IMPORTATION AND EXPORTATION OF FOOD PRODUCTS**

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

**OCTOBER, 2022**

# GUIDELINES DEVELOPMENT HISTORY

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## Document Revision History

| **Date of revision** | **Revision number** | **Changes made and/or reasons for revision** |
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| 13/05/2019 | 0 | First issue |
| 17/10/2022 | 1 | 1. Perishable and non-registrable food products to be imported shall comply with relevant specifications and/or requirements prescribed by the Authority. This change is made because perishable foods need special storage.2. The import visa is the first step to apply for import authorization; it is an authorization which confirms that the products from an eligible manufacturer can be imported in the country.3. Manufacturer’s name shall be written on the invoice, if not, the importer shall mention it in a letter, 4. Requirements for import authorizations are revised:\*Certificate of compliance or certificate of analysis may not be a mandatory requirement only for a justifiable reason approved by the Authority. Ex: if the manufacturer is located in a country with stringent regulatory authority\*Certificate of origin and Packing list are not mandatory5. The application processing time has been updated to 24 working hours (3 days).6. The validity for visa and import/export license has been updated to 6 months7. The procedure and condition for re-exportation of rejected consignment have been added8. Processing applications to import food products for special cases is added |

# FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of its functions is to regulate the import and export of food products, especially in articles 3, 8, and 9 of the above-mentioned Law.

Reference is made to the provisions of the technical Regulations No FDISM/FDIEC/TRG/004 governing the control of importation and exportation of food products;

These Guidelines provide guidance on the information and documentation required for any application, submitted to Rwanda FDA, requesting authorization to import or export food products as set in these Guidelines. Adherence to the set requirements will minimize the delays in processing applications of import and export authorizations; hence speeding up the provision of quality services to the clients.

These Guidelines also provide guidance to inspectors to minimize risks of trading and falsified products among nations, therefore preventing dumping of these products in the country.

These Guidelines will be reviewed from time to time as the need arises.

The Authority acknowledges all the efforts of stakeholders who participated in developing and validating these Guidelines.

**Dr. Emile BIENVENU**

**Director General**

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**ACRONYMS AND ABBREVIATIONS**

**Rwanda FDA**: Rwanda Food and Drugs Authority

**NGOs**: Non-Government Organizations

**COA**: Certificate of Analysis

**PoE**: Port of Entry

**GDL**: Guideline

**MoU**: Memorandum of Understanding

**PRIMS**: Pharmaceutical Regulatory information system

**GMP**: Good Manufacture practices

**ISO**: International Organization for Standardization

**CE**: Conformité Européenne

**DEFINITIONS**

In these guidelines, unless the context otherwise states:

***Authority*** means 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 the applicant under the law No 003/2018 of 09/02/2018 determining its mission, organization, and functioning, it includes licenses, permits, to whom it may concern and certificates;

***Consignment*** means a quantity of goods that are sent to a person or place to be sold;

***Donation*** means an act or instance of presenting processed foods and other regulated products regulated, to recipients in emergency or as a part of development aid in non-emergency situations;

***Exporter*** meansa person, country, or organization that sends goods or services to another country for sale;

***Export License*** means an authorization issued to an exporter by Rwanda FDA, authorizing him/her to export food products from the country;

***Importer*** meansa person or organization that brings goods or services into a country from abroad for sale;

***Import Visa*** means an authorization (example: a stamp marked on a proforma invoice) indicating that applicants’ documents have been verified and products have been granted permission to enter the country. The Import visa gives the right to the importer to confirm an order of the products that he/she has been granted that Import visa for;

***Import License*** means an authorization issued to the importer by Rwanda FDA authorizing him/her to import food products into the country after complying with the importation requirements;

***Manufacturer*** means a person/company who sells food products under their own name, or under a trade- mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf;

***Non-registrable food products*** mean foods that are exempted from the registration process, including perishable food products, as prescribed in Guidelines N0 DIS/GDL/008 for application for registration of processed food products.

***Perishable food product*** means a food product that is subject to decay, spoilage or bacteria unless it is kept in special storage conditions, including food that has a shelf life, not exceeding 30 days when kept at ambient temperatures.

**1.0 INTRODUCTION**

The safety, efficacy, and quality of food products can be highly affected by the lack of adequate control on importation and exportation. It is therefore imperative that the manufacture, importation, and exportation of food products, both nationally and internationally conform to certain set standards.

The Authority has developed these guidelines to strengthen the control of importation and exportation of these products and to assist those in the field to adhere to the legal framework during importation and exportation activities.

The main objective of these guidelines is to provide importers and exporters of food products with the necessary information to enable them to comply with the law and regulations governing the control of importation and exportation of these products.

These guidelines are organized into two chapters. The first chapter provides for the requirements and procedures to be followed up during the importation of food products while the second one outlines the requirements and procedures for the exportation of these products.

**2.0 SCOPE**

These guidelines apply to food products as specified in the law N0 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products and the law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning.

These guidelines outline requirements for the importation and exportation of food products.

# CHAPTER I: IMPORTATION OF FOOD PRODUCTS

**I.1 REQUIREMENTS**

## I.1.1. Eligibility to import food products

The following importers shall be allowed to import food products:

1. A manufacturer of food products holding an operational license issued by the Authority;
2. A wholesaler or retailer of food products holding an operational license issued by the Authority;
3. Researchers or research institutions authorized by the competent institution to conduct nutritional research or clinical trial in the country;
4. An individual or company importing a sample for laboratory testing;
5. Government institutions;
6. Non-government institutions authorized by the competent institution;
7. A beneficiary of food products donation upon presentation of the donation certificate;
8. A company or individual attending the exhibition upon presentation of the invitation;
9. A tourist, a visitor in the country or any other person for justified reasons after getting authorization from the Authority;

## I.1.2. General requirements

1. All importers of food products must ensure they are granted import authorization by the Authority prior to importation.
2. All food products must be imported by importers holding an Operational License issued by the Authority or who fall within the eligible importer category.
3. Perishable and non-registrable food products to be imported shall comply with relevant specifications and/or requirements prescribed by the Authority.
4. Food products to be imported shall not be banned or contain an ingredient that has been banned in the country of origin or in Rwanda for quality or safety purposes.
5. Before entering at port of entry, food products to be imported shall have at least a shelf life of 6 months remaining for products with an initial shelf life of 9 months or more. Products with less than 9 months of initial shelf life shall have at least 80% of the shelf life remaining.
6. Food products to be imported shall comply with labeling requirements according to related Standards.
7. All consignments of food products shall pass through the gazetted ports of entry and shall be subjected to physical inspection at the port of entry or at the importer’s premise for the consignments released under seal before being used to ensure they comply with claimed specifications.

## I.1.3. Specific requirements

### 1. Requirements to apply for Import Visa

The import visa is the first step to apply for import authorization. It is an authorization that confirms that the products from an eligible manufacturer can be imported into the country.

The following are the requirements to apply for an import visa:

1. A proforma invoice showing:
	1. Invoice number and date,
	2. Name and full address of supplier and importer,
	3. Manufacturer’s name (if not, the importer shall mention it in a letter),
	4. Country of origin of the products,
	5. A clear description of each product including brand and common names,
	6. Quantity,
	7. Value for each product and the currency.
2. The operational license of the importer.
3. Certificate of compliance of the manufacturer or the supplier, including but not limited to: ISO Certificate or Good Manufacturing Practices certificate (GMP) or Good Distribution Practices certificate (GDP) or Operational License from respective Regulatory bodies or Health certificate or Conformite Europeene (CE), or HACCP or Bureau of standards permit to use standardization mark (Ex: TBS, KEBS…) if the manufacturer is from EAC, etc.

### Note: Certificate of compliance may not be a mandatory requirement only for a justifiable reason approved by the Authority.

### Requirements to apply for Import License

After getting an Import Visa, the second step is to apply for an Import License. It is an authorization that permits the applicant to import the approved food products (particular batch numbers).

The following are the requirements to apply for an import license:

1. Import Visa
2. Commercial invoice having the following information:
	1. Invoice number and date,
	2. Name and full address of supplier and importer,
	3. Manufacturer name (if not, the importer shall mention it in a letter),
	4. Country of origin of the products,
	5. Clear description of each product including brand and common names,
	6. Quantity,
	7. Value for each product and the currency.
3. A packing list (if applicable) with the following information: Imported products and their quantities, batch/lot number, manufacturing and expiry date.
4. Certificate of analysis issued by the manufacturer or a designated laboratory, for each batch number, indicating the following information:
	1. Name and address of the manufacturer,
	2. Brand and common name of the food product,
	3. Product description,
	4. Batch/lot number,
	5. Manufacturing and Expiry date (or Best before date or expiry time after opening),
	6. Tested Parameters and their results (qualitative and/or quantitative),
	7. Document traceability references (e.g. document number, revision, etc.)
	8. Signed by authorized personnel.

### Note: Certificate of Analysis may not be a mandatory requirement only for a justifiable reason approved by the Authority.

1. A Proof of Payment of verification fees as specified in the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

### Requirements to apply for importation of registered food products

To import food products registered by Rwanda FDA, the applicant shall submit the following requirements:

1. Food registration certificate,
2. Commercial invoice,
3. Operational license,
4. Certificate of analysis for each batch number.
5. Proof of payment of verification fees as specified in the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

### Authorization to import food products for special cases

a) Requirements to apply for importation of raw materials for food manufacturing:

* Application letter addressed to the Director General of the Authority,
* Commercial Invoice,
* Operational license (applicant shall be registered as manufacturers)
* Certificate of compliance of the manufacturer for pre-packaged raw materials,
* Certificate of analysis for each batch number of pre-packaged raw materials,

b) Requirements to apply for importation of food products for research purpose:

* Application letter addressed to the Director General of the Authority,
* Authorization to conduct research issued by competent institution,
* Invoice with description of the products.

c) Requirements to apply for importation of food products for sample registration:

* Application letter addressed to the Director General of the Authority,
* Invoice with description of the products.

d) Requirements to apply for importation of food products for laboratory testing:

* Application letter addressed to the Director General of the Authority. The importer shall indicate the laboratory that will perform the testing.
* Invoice with description of the products

e) Requirements to apply for importation of perishable food products;

* Application letter addressed to the Director General of the Authority,
* Commercial Invoice showing the Manufacturer,
* Certificate of compliance of the manufacturer,
* Certificate of analysis for each batch number. In case laboratory tests cannot be performed for each batch number due to its short shelf life; in order to assure continuous self-assessment of the manufacturer, the applicant shall submit a Certificate of Analysis of tests done at least 6 months before.
* Packing list with the following information: Imported products and their quantities, Batch/lot number, Manufacturing and expiry date, and storage conditions.

f) Requirements to apply for importation of food products for donation;

* Application letter addressed to the Director General of the Authority,
* Commercial Invoice,
* Certificate of compliance of the manufacturer,
* Certificate of analysis for each batch number,
* Certificate of donation,
* Donation acceptance letter (where applicable),

g) Requirements to apply for importation of food products for exhibition

* Application letter addressed to the Director General of the Authority,
* Commercial Invoice,
* Certificate of compliance of the manufacturer,
* Certificate of analysis for each batch number of the products to be exhibited
* Commitment letter agreeing to re-export the remaining products after exhibition.

h) Requirements to apply for importation of food products declared as personal effects

* A tourist, a visitor in the country or any other person who wants to import food products for personal use, not for sale, shall request for an authorization by providing information described in the Guidelines No: DIS/GDL/073 related to importation and exportation of regulated products declared as personal effects.

i) Obligation to apply for import license for consignments without quality certificates

* Eligible importers who imported food products without certificates of analysis or fail to acquire certificates of analysis prior to importing food products, shall consent to incur the cost for laboratory testing for each batch of imported products. The tests shall be done in accredited laboratories or laboratories designated by Rwanda Standard Board. Importers must allow Inspectors to randomly take needed samples from the consignment.

**I.2. Processing applications**

* An application for import visa or for import license, fulfilling all requirements, will be processed within 3 working days.
* The applicant will be notified by the Authority, in writing, about the decision either approval or rejection.
* An authorization is issued to a certain applicant, for a particular consignment, and shall not be transferable.

**I.3. Validity of an Authorization**

- The import visa shall be valid for six (6) months from the date of issuance.

- The import license shall be valid for three (3) months from the date of issue.

### I.4. Renewal of an import license

In case an import license is expired before it is used, the applicant shall apply for renewal by submitting the following documents:

* Application letter,
* Operational license of the importer,
* Expired import license,
* Commercial invoice, and
* Payment proof of inspection fees used for the previous application.

### I.5. Inspection of imported consignments at ports of entry

1. Each consignment of food products must be inspected by the Authority at the port of entry or at importer’s premise for the consignments released under seal, before being used to ensure they comply with applicable regulations and claimed specifications.
2. The consignment must be accompanied by the following requirements:
3. A valid import license issued by the Authority,
4. A corresponding commercial invoice,
5. A certificate of analysis for each batch,
6. Bill of lading for products that require special storage conditions.
7. The imported food products must have at least a shelflife of 6 months remaining for products with initial shelf life of 9 months or more and shall have at least 80% of the shelf life remaining for products with less than 9 months’ initial shelf life.
8. The appearance of the imported food product shall reflect its true nature for example, free from foreign matters, damaged package, discoloured, etc.
9. The primary packaging of imported food product shall be clearly labelled in at least one of the official languages used in Rwanda and the labelling shall comply with the relevant food labelling standard.
10. If any message on the label is not in one of the official languages, a supplementary label translated in one of the official languages shall be used and availed to consumers. The translated information shall fully and accurately reflect the one on the original label.
11. The translation shall be signed and stamped by the manufacturer or the Embassy of the country having the original language on the label as their official language or stamped by a Notary who knows that language.
12. Food products with labels which show evidence of alteration, will be regarded as substandard and shall be condemned. Such alterations include:
13. Entire label or parts with details such as batch number, dates of manufacturer and expiry cut off,
14. Evidence of labels being removed or new ones attached or new labels being pasted over old ones,
15. Details of being erased or painted out and replaced with new details,
16. Counterfeiting.
17. The primary package shall be sealed in such a way that the product cannot be reached or tempered without damaging the seal.

### I.6 Sampling of imported products

During physical inspection, if any food product is suspected for poor quality or whenever deemed necessary, the inspector may take samples for further investigation and the consignment shall not be released until the laboratory results are available for decision-making. The inspector shall fill out the Report of findings (PV de constat).

In case of routine sampling, the consignment from which the samples have been taken shall be released to the importer for distribution.

### I.7 Release of consignments

- Once satisfied that all importation conditions have been fulfilled as required, the Inspector shall release the consignment.

For the partial shipment, the importer will write "**PARTIAL SHIPMENT**" on the import license and invoice mentioning the imported and the remaining quantities.

### I.8 Release underseal

When a consignment is not physically inspected at port of entry or needs further inspection, for example for intra-region consignments, consignments that require special storage conditions, consignments that cannot be offloaded at the port of entry, etc. shall be released and inspected at owner's premise before being used.

### I.9 Rejection of consignments

 If the physical inspection finds out that the consignment doesn’t comply with related food Standards, the products shall be condemned. The importer shall implement the decisions taken and incur the cost.

The following shall apply for such consignments:

a) The inspectors shall not release the consignment. They shall issue a Report of findings (PV de constat) stating clearly the quarantined products and the “REJECTION” decision.

Food products rejected because of safety and quality reasons shall be disposed of according to provisions of the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

The Inspectors, customs officials and representatives from other relevant Government institutions shall jointly supervise destruction of the rejected consignment. After completion of destruction, Rwanda FDA shall issue a Disposal certificate to the importer.

The Rejected product will get a print release order in the Rwanda electronic single window (ReSW) after submission of the disposal certificate.

b) Food products rejected for reasons other than their quality and safety shall be rejected and follow the procedure for re-export.

The following are reasons for re-export of a consignment:

1. Food products which are not allowed, banned or withdrawn from the Rwanda market.
2. Food products which do not meet the labelling requirements.
3. Any other reason the authority may deem necessary.

The importer shall re-export them in the country of origin or to a third country within a period of one month from the date of rejection and incur the cost.

The importer will be given a re-export Certificate by Rwanda FDA.

# CHAPTER II: EXPORTATION OF FOOD PRODUCTS

### II.1. Eligibility for Export

Only the following shall be allowed to export food products:

1. A manufacturer of food products holding an operational license issued by the Authority;
2. A wholesaler or retailer of food products holding operational license issued by the Authority;
3. Researchers or research institutions authorized by competent institution to conduct research;
4. An individual or company exporting a sample for laboratory testing;
5. Government institutions
6. Non-government institutions authorized by competent institution;
7. A company or individual attending exhibition

**II.2. General requirements**

1. All exporters of food products must ensure they are granted an export authorization by the Authority prior to exportation.
2. Exporters of food products shall have a valid Export license issued by the Authority.
3. All food products must be exported by exporters whose premises are licensed by Rwanda FDA or who fall within the eligible exporter category.
4. Non-pre-packaged/non-registrable food products to be exported shall comply with specifications and/or requirements prescribed by the Authority.
5. Food products to be exported shall comply with relevant food Standards.
6. All consignments of food products to be exported must exit through gazetted ports of exit and shall be subjected to physical inspection at the port of exit or at the exporter’s premise to ensure they comply with claimed specifications.

### II.3. Requirement for exportation of food products

All applications for an export license shall be accompanied by the following documents:

* 1. Operational license of the exporter
	2. Invoice of the product to be exported including the following information:
	+ Invoice number and date,
	+ Manufacturer name,
	+ Name and full address of exporter and importer,
	+ Country of origin of the product,
	+ Clear description of each product including brand and common names,
	+ Quantity, value for each product and the currency.
	1. A packing list (if applicable) with the following information: exported products and their quantities, Batch/lot number, Manufacturing and expiry date.
	2. Certificate of analysis issued by the manufacturer or a designated laboratory, for each batch number, indicating the following information:
	+ Name and address of the manufacturer,
	+ Brand and common name of the food product,
	+ Product description,
	+ Batch/lot number,
	+ Manufacturing and Expiry date (or Best before date),
	+ Tested Parameters and their results (qualitative and/or quantitative),
	+ Document traceability references (e.g. document number, revision, etc.)
	+ Signed by authorized personnel.
	1. Proof of Payment of verification fees as specified in the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

**II.4. Processing and validity of an export license**

* An application for an export license, fulfilling all requirements, will be processed within 3 working days.
* The applicant will be notified by the Authority, in writing, about the decision either approval or rejection.
* The export license shall be valid for six (6) months from the date of issue.

An export license is issued to a certain applicant, for a particular consignment, and shall not be transferable.

### II.5. Renewal of an export license

In case an export license is expired before it is used, the applicant shall apply for renewal by submitting the following documents:

* Application letter,
* Operational license of the exporter,
* Expired export license,
* Commercial invoice, and
* Payment proof of inspection fees used for the previous application.

### II.6. Inspection of consignments to be exported

Each consignment of food products must be inspected by the Authority at the port of exit or at the exporter’s premise prior to exportation to ensure they comply with applicable regulations and claimed specifications.

# REFERENCES

1. The law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning.
2. The law No 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.
3. The regulations No FDISM/FDIEC/TRG/004 governing control of importation and exportation of food products.

**ENDORSEMENT OF THE GUIDELINES**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Author** | **Checked by** | **Approved By** |
| **Title** | **Division Manager of Food and Drugs Import & Export Division** | **Head of Food and Drugs Inspections & Safety Monitoring Department** | **Quality Assurance Analyst** | **Director General** |
| **Names** | Theobald HABIYAREMYE | Dr. Eric NYIRIMIGABO | Théogène NDAYAMBAJE | Dr. Emile BIENVENU |
| **Signature** |  |  |  |  |
| **Date** |  |  |  |  |