RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR IMPORTATION AND EXPORTATION OF FOOD PRODUCTS

DECEMBER, 2022

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FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018 and determining its mission, organization and functioning. 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/003 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

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	**01/05/2019**
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DOCUMENT REVISION HISTORY

Date of revision	**Rev No**	**Changes made and/or reasons for revision**
13/05/2022	0	First issue
24/11/2022	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, in EAC or any country having agreement with Rwanda. *Certificate of origin and Packing list are not mandatory for all applications. 5. The application processing time is 24 working hours (3 days). 6. The validity for visa and import/export license has been updated to six months 7. The procedure and condition for re-exportation of rejected consignment have been added 8. Processing applications to import food products for special cases is added

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ACRONYMS AND ABBREVIATIONS

CE: Conformité Européenne

COA: Certificate of Analysis

EAC: East African Community

GDL: Guideline

GDP: Good Distribution Practice

GMP: Good Manufacture practices

ISO: International Organization for Standardization

MoU: Memorandum of Understanding

NGOs: Non-Government Organizations

PoE: Port of Entry

PRIMS: Pharmaceutical Regulatory information system

RESW: Rwanda Electronic Single Window

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 determining its mission, organization, and functioning;

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;

Certificate of Analysis refers to 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 operates in that country complying with requirements related to food manufacturing.

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

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

Exporter means a person, country, or organization that sends goods or services to another country;

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

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;

Importer means a person or organization that brings goods or services into a country from abroad;

Import Visa means an authorization which confirms that importer and products to be imported meet eligibility criteria as provided in the Regulations for importation and exportation of food products and can be permitted to enter the country. It gives permission to the applicant to confirm an order of the food products that he/she has been granted that Import visa for;

Import License means an authorization issued to importer authorizing him/her to import food products into the country after complying with the documentation of importation requirements pending physical verification of the products. The importer will present this document during the physical inspection of the imported products.

Manufacturer means a person/company engaged in the manufacturing of food products.

Non-registrable food products mean foods that are exempted from the registration process, including perishable food products, as prescribed in Guidelines No DIS/GDL/008 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.

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.

1. BACKGROUND

1.1 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.

1.2 Scope

These Guidelines apply to food products as specified in the law No 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.

2. IMPORTATION OF FOOD PRODUCTS

2.1 Requirements

2.1.1. Eligibility to import food products

The following importers shall be allowed to import food products:

a) A manufacturer of food products holding an operational license issued by the Authority;

b) A wholesaler or retailer of food products holding an operational license issued by the Authority;

c) Researchers or research institutions authorized by the competent institution to conduct nutritional research or clinical trial in the country;

d) An individual or company importing a sample for laboratory testing;

e) Government institutions;

f) Non-government institutions authorized by the competent institution;

g) A beneficiary of food products donation upon presentation of the donation certificate;

h) A company or individual attending the exhibition upon presentation of the invitation;

i) A tourist, a visitor in the country or any other person for justified reasons after getting authorization from the Authority.

2.1.2. General requirements

a) All importers of food products must ensure they are granted import visa and license by the Authority prior to importation.

b) All applications shall be in one of the official languages accepted in Rwanda. Any document in another language, shall be translated in one of the official languages.

c) All food products must be imported by importers holding an Operational License issued by the Authority or who fall within the eligible importer category.

d) 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.

e) 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.

f) Food products to be imported shall comply with labelling requirements according to related Standards and applicable regulations and guidelines.

g) 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 sold or used to ensure they comply with claimed specifications.

2.1.3. Specific requirements

2.1.3.1 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:

a) A proforma invoice showing:

   i. Invoice number and date,

   ii. Name and full address of supplier and importer,

   iii. Manufacturer's name (if not, the importer shall mention it in a letter),

   iv. Country of origin of the products,

   v. A clear description of each product including brand and common names,

   vi. Quantity,

   vii. Value for each product and the currency.

b) The operational license of the importer.

c) Certificate of compliance of the manufacturer or the supplier, including but not limited to either: 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 Conformité Européenne (CE), or HACCP or Bureau of standards permit to use standardization mark (Ex: TBS, KEBS…) if the manufacturer is from EAC, etc.

Note:

i. Certificate of compliance 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.

ii. Products imported from countries where certificate of compliance can't be provided, will be allowed to be imported if and only if the Embassy of the country of origin or representative of diplomatic mission in Rwanda endorses the application. The endorsement confirms that products are imported from reliable sources**.**

2.1.3.2 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. It takes effect upon satisfaction of physical inspection.

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

a) Import Visa
b) Commercial invoice having the following information:

   i. Invoice number and date,

   ii. Name and full address of supplier and importer,

   iii. Manufacturer name (if not, the importer shall mention it in a letter),

   iv. Country of origin of the products,

   v. Clear description of each product including brand and common names,

   vi. Quantity,

   vii. Value for each product and the currency.

c) A packing list (if applicable) with the following information: Imported products and their quantities, batch/lot number, manufacturing and expiry date.

d) Certificate of analysis, issued by the manufacturer or a designated laboratory indicating the following information:

   i. Name and address of the manufacturer,

   ii. Brand and common name of the food product,

iii. Product description,

iv. Batch/lot number,

v. Manufacturing and Expiry date (or Best before date or expiry time after opening),

vi. Tested Parameters and their results (qualitative and/or quantitative),

vii. Document traceability references (e.g. document number, revision, etc.)

viii. Signed by authorized personnel.

Note:

i. COA can be replaced by Health certificate or Phytosanitary certificate depending on the type of product.

ii. Certificate of Analysis may not be a mandatory requirement only for a justifiable reason approved by the Authority. Example: Products manufactured in EAC member states, or if the manufacturer is located in a country with stringent regulatory authority...

iii. Products imported from countries where Certificate of analysis can't be provided, will be allowed to be imported if and only if the Embassy of the country of origin or representative of diplomatic mission in Rwanda endorses the application. The endorsement confirms that products are imported from reliable sources.

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

2.1.3.3 Requirements to apply for importation of registered food products

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

For import visa:

a) Proforma invoice,

b) Food registration certificate,

c) Operational license.

For import license:

a) Commercial invoice,

b) Certificate of analysis or health certificate (where applicable),

c) Proof of payment of verification fees as specified in the Regulations CBD/TRG/004 related to regulatory service tariff/fees and fines.

2.1.3.4 Authorization to import food products for special cases

a) Particular requirement to import raw materials for food manufacturing:

The applicant shall hold Operational license for manufacturers,

b) Particular requirements to import perishable food products:

Requirements for importation of perishable food products are provided in the Guidance Doc. N°: FDISM/FDIEC/GDC/001 on control of importation and exportation of perishable food products.

c) Particular requirements to import food products declared as personal effects:

Requirements for importation of food products declared as personal use, not for sale, are provided in the Guidelines No: DIS/GDL/073 related to importation and exportation of regulated products declared as personal effects.

d) Particular requirements to import food products for donation:

i. Certificate of donation,

ii. Donation acceptance letter (where applicable),

e) Particular requirements to import food products for exhibition:

i. Invitation to the exhibition event,

ii. Commitment letter agreeing to re-export the remaining products after exhibition.

f) Particular requirements to import food products for research purpose:

Authorization to conduct research issued by competent institution,

g) Particular requirements to import food products for education purpose:

The applicant shall explain, in the application letter, food products to be imported and how they will be used for educational purpose,

h) Particular requirements to import food products for sample registration:

The importer shall indicate, in the application letter that products are for registration and mention the required quantity.

i) Particular requirements to import food products for laboratory testing:

The importer shall indicate, in the application letter, the laboratory that will perform the testing and mention the required quantity.

j) 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 them 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 designated laboratories. Importers must allow Inspectors to randomly take needed samples from the consignment.

2.2 Processing applications

a) An application for import visa or for import license, fulfilling all requirements, will be processed within 24 working hours (3 days).

b) The applicant will be notified by the Authority, in writing, about the decision either approval or rejection.

c) An authorization is issued to a certain applicant, for a particular consignment, and shall not be transferable.

2.3 Validity of an authorization

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

b) The import license shall be valid for six (6) months from the date of issue.

2.4 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

a) Application letter,

b) Operational license of the importer,

c) Expired import license,

d) Commercial invoice, and

e) Payment proof of inspection fees used for the previous application.

2.5 Inspection of imported consignments at ports of entry

a) 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.

b) The consignment must be accompanied by the following requirements:

i. A valid import license issued by the Authority,

ii. A corresponding commercial invoice,

iii. A certificate of analysis for each batch,

iv. Bill of lading for products that require special storage conditions.

c) 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.

d) The appearance of the imported food product shall reflect its true nature for example, free from foreign matters, damaged package, discoloured, etc.

e) 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.

f) 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, fully and accurately reflecting the one on the original label, shall be submitted to the Authority, whereas a supplementary label to be availed to consumers shall clearly show: Product's common and brand name, batch number, Manufacturer, list of ingredients, storage conditions, production and expiry dates.

g) 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.

h) Food products with labels which show evidence of alteration, will be regarded as substandard and shall be condemned (seized, rejected, destroyed…). Such alterations include:

i. Entire label or parts with details such as batch number, manufacture and expiry dates are cut off,

ii. Evidence of labels being removed or new ones attached or new labels being pasted over old ones,

iii. Details of being erased or painted out and replaced with new details,

iv. Counterfeiting.

i) The primary package shall be sealed in such a way that the product cannot be reached or tempered without damaging the seal.

j) 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.

2.6 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 constant).

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

2.7 Release of consignments

Once the Inspector confirms that all importation conditions have been fulfilled as required, the consignment shall be released.
For the partial shipment, the inspector will write "**PARTIAL SHIPMENT**" on the import license and invoice mentioning the imported and the remaining quantities.

2.8 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.

2.9 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 constatzz) stating clearly the quarantined products and the "REJECTION" decision.

Food products rejected because of safety and quality reasons shall be disposed of. The owner of the products shall apply for safe disposal to be done under supervision of Rwanda FDA inspectors.

The Inspectors, customs officials and representatives from other relevant Government institutions may 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 safety shall be rejected and follow the procedure for re-export.

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

i. Food products which are not allowed, banned or withdrawn from the Rwanda market.

ii. Food products which do not meet the labelling requirements.

iii. 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 authorization by Rwanda FDA.

3. EXPORTATION OF FOOD PRODUCTS

3.1 Eligibility for export

Only the following shall be allowed to export food products:

a) A manufacturer of food products holding an operational license issued by the Authority;

b) A wholesaler or retailer of food products holding operational license issued by the Authority;

c) Researchers or research institutions authorized by competent institution to conduct research;

d) An individual or company exporting a sample for laboratory testing;

e) Government institutions

f) Non-government institutions authorized by competent institution;

g) A company or individual attending exhibition

3.2 General requirements

a) Exporters of food products shall have a valid Export license issued by the Authority.

b) All food products must be exported by exporters whose premises are licensed by Rwanda FDA or who fall within the eligible exporter category.

c) Non-pre-packaged/non-registrable food products to be exported shall comply with specifications and/or requirements prescribed by the Authority.

d) Food products to be exported shall comply with relevant food Standards.

e) 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.

3.3 Requirements for exportation of food products

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

a) Operational license of the exporter

b) Invoice of the product to be exported including the following information:

i. Invoice number and date,

ii. Manufacturer name,

iii. Name and full address of exporter and importer,

iv. Country of origin of the product,

v. Clear description of each product including brand and common names,

vi. Quantity, value for each product and the currency.

c) A packing list (if applicable) with the following information: exported products and their quantities, Batch/lot number, Manufacturing and expiry date.

d) Certificate of analysis issued by the manufacturer or a designated laboratory, for each batch number, indicating the following information:

i. Name and address of the manufacturer,

ii. Brand and common name of the food product,

iii. Product description,

iv. Batch/lot number,

v. Manufacturing and Expiry date (or Best before date),

vi. Tested Parameters and their results (qualitative and/or quantitative),

vii. Document traceability references (e.g. document number, revision, etc.)

viii. Signed by authorized personnel.

Note: COA is not a requirement for products with S-Mark that are exported to EAC member states.

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

Applications for export authorization of food products for special use shall be accompanied by an application letter clearly explaining the purpose of exporting such consignment, to whom it is directed and the country of destination.

Food products for special use include;

a) Food products declared as personal effects,

b) Food products for exhibition,

c) Food products for research purpose,

d) Food products for laboratory testing,

e) Any other reason the Authority may deem justifiable.

3.4 Processing and validity of an export license

a) An application for an export license, fulfilling all requirements, will be processed within 3 working days.

b) The applicant will be notified by the Authority, in writing, about the decision either approval or rejection.

c) 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.

3.5. 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:

a) Application letter,

b) Operational license of the exporter,

c) Expired export license,

d) Commercial invoice, and

e) Payment proof of inspection fees used for the previous application.

3.6 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/003 governing control of importation and exportation of food products.

ENDORSEMENT OF THE GUIDELINES

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