

GUIDANCE ON CONTROL OF IMPORTATION AND EXPORTATION OF PERISHABLE FOOD PRODUCTS

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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. One of the functions of the Rwanda FDA is to regulate the import and export of food products especially in articles 3, 8, and 9.

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 and Guidelines No FDISM/FDIEC/GDL/002 for importation and exportation of food products.

This Guidance provides information and documentation required in application submitted to Rwanda FDA by an importer or exporter of food products as set in this Guidance. Adherence to the set requirements will minimize the delays in processing applications of import and export authorizations; hence speed up the provision of quality services to the clients.

This Guidance also provides direction to the inspectors to minimize risks of trading sub-standard and falsified products among nations and therefore prevent dumping these products in our country. This Guidance will be reviewed from time to time as the need arises.

The Authority acknowledges all the efforts of everyone who participated in the development and validation of this Guidance.

Dr. Emile BIENVENU Director General

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GUIDANCE DEVELOPMENT HISTORY

DRAFT ZERO	23/09/2022
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ACRONYMS AND ABBREVIATIONS

Rwanda FDA: Rwanda Food and Drugs Authority

COA: Certificate of Analysis

PoE: Port of Entry **GDL**: Guidelines

MoU:Memorandum of UnderstandingGMP:Good Manufacturing Practices

ISO: International Organization for Standardization

CE: Conformité Européenne

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DEFINITIONS

In this Guidance, 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, 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 perishable foods 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 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 means a 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, labelling, 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.

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Perishable food product means processed 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.

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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.

Perishable goods pose the biggest challenge to supply chain management since their shelf life is comparatively very less as compared to others. Moreover, they are critical to handle because of the risk of getting damaged immediately. Hence, they not only need to be handled with extreme care but they also need to be transported on time. Various other factors like storage and the right temperature also play a key role in keeping their freshness intact.

The Authority has developed this Guidance to strengthen the control of importation and exportation of these perishable products and to assist assessors of related imports applications and inspectors who conduct physical inspection of such products to adhere to the legal framework during importation and exportation activities.

In addition to that, this Guidance will provide importers and exporters of perishable food products with necessary information to enable them to comply with the law and regulations governing the control of importation and exportation of these products.

2. SCOPE

This Guidance applies to importation and exportation of perishable food products. It is complemented by provisions of the Guidelines No DIS/GDL/007 for importation and exportation of food products.

3. IMPORTATION/EXPORTATION OF PERISHABLE FOOD PRODUCTS

3.1 General Requirements

- All importers/exporters of food products having a shelf life not exceeding 30 days, shall clearly mention it in application letter addressed to Director General of Rwanda FDA.
- The imported/exported perishable food products must have at least 80% of the shelf life remaining.

Note: In case the remaining shelf life is less than 80% of the initial shelf life, the applicant shall submit a distribution plan and mechanisms of ensuring the products will be consumed before their expiry date.

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3.2 Specific requirements

3.2.1 Requirements to apply for Import Visa

The following are requirements to apply for an import visa:

- a) Proforma invoice showing:
 - i. Invoice number and date,
 - ii. Manufacturer's name,
 - iii. Name and full address of exporter and importer,
 - iv. Country of origin of the products
 - v. A clear description of each product including brand and common names,
 - vi. Quantity, value for each product and the currency.
- b) Operational license of the importer.
- c) 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 Communaute Europeene (CE), HACCP, 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.

3.2.2. Requirements to apply for Import License

The following are requirements to apply for an import license:

a)Import Visa

b)Commercial invoice having 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) Packing list with the following information: Imported products and their quantities, Batch/lot number, Manufacturing and expiry date, and storage conditions.
- 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,

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- v. Manufacturing and Expiry date (or Best before date, or expiry x time after opening),
- vi. Tested Parameters and their results (qualitative and/or quantitative),
- vii. Specifications limit,
- viii. Document traceability references (e.g. document number, revision, etc.)
 - ix. Signed by authorized personnel.

Note: 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.

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

3.2.3. Requirements to apply for Export License

The following are requirements to apply for an Export license:

- a) Commercial invoice having 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.
- b) Packing list with the following information: Exported products and their quantities, Batch/lot number, Manufacturing and expiry date, and storage conditions.
- c) 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, or or expiry x time after opening),
 - vi. Tested Parameters and their results (qualitative and/or quantitative),
 - vii. Specifications limit,
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3.3 Inspection of imported consignments at ports of entry

- Perishable food products shall be inspected as fast as possible.
- Perishable food products that require special storage shall be released under seal and inspected at importer's premises.
- During physical inspection, if any perishable 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 without necessarily suspecting the food product quality, the consignment from which the samples have been taken shall be released to the importer for distribution.

3.4 Release of consignments

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

3.5 Rejection of consignments

If the physical inspection finds out that the consignment doesn't comply with requirements and related food standards, the products shall be condemned. The importer shall implement the decisions taken and incur the cost as prescribed in the Guidelines No DIS/GDL/007 for importation and exportation of food products.

4. REFERENCES

- 4.1 The Law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning.
- 4.2 The Law No 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.
- 4.3 Regulations No FDISM/FDIEC/TRG/004 governing the control of importation and exportation of food products.
- 4.4 Guidelines Doc. No: FDISM/FDIEC/GDL/002 for importation and exportation of food products.

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ENDORSEMENT OF THE GUIDANCE

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