RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REGISTRATION OF PROCESSED FOODS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) was established by the law Nº 003/2018 of 09/02/2018 determining its mission, organization and functioning; with the mandate to protect the public health through regulation of different products including processed food.

It is unequivocal that unsafe and poor-quality food does not only negatively impact health, but also impedes socio-economic growth in agribusiness, trade, and tourism. Food Business Operators (FBOs) bear the primary responsibility to ensure that only safe and fairly presented food is placed on the market.

On the other hand, competent national regulatory authorities play a pivotal role in determining appropriate food control strategies taking into consideration public health, scientific information, risk-based analysis, consumer concerns, as well as compliance profiles to ensure the safety, quality, and traceability of both domestically produced and imported food for national consumers and export markets. Food control involves food registration amongst other strategies for food safety and quality oversight.

Pursuant to the provisions prescribed in the law stated above, especially in its Article 8 paragraph 8 providing the Authority with the mission to ensure that processed food, food supplements and fortified food meet the prescribed quality standards before they are placed on the market; and the Article 9, paragraph1 granting the Authority the power to formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products under this Law;

Rwanda FDA prepared these guidelines to provide guidance to FBOs on procedure and requirements for registration of processed food to ensure that they comply with relevant laws, regulations and standards. Therefore, adherence to these guidelines will ensure that all relevant information and documentation are provided in product dossiers submitted for food registration. This will facilitate uniform submissions and consistent evaluation of the dossiers.

The Authority acknowledges collaboration and efforts of all stakeholders who contributed in preparation and validation of these guidelines.

Prof. Emile BIENVENU
Director General

DOCUMENT DEVELOPMENT HISTORY

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DOCUMENT REVISION HISTORY

Revision number	Changes made and/or reasons for revision
0	First issue
1	1. The updated template for guidelines was used; 2. Re-arrangement of contents and texts. Chapters 1, 2, 3 and 4 were replaced; 3. Concepts of risk-based strategies in food registration were added. These include product listing, reliance/recognition aspects, expedited procedure considerations, and exemption from food registration, 4. The appendix depicting the process flow chart for evaluation of processed food is included, 5. The following Annexes were included: a) Requirements for registration of domestically processed foods; b) Requirements for registration of foods for particular nutritional uses; c) Requirements for listing of imported processed foods; d) Sample size and number requirements for food registration; e) Variations of food registration, requirements and administrative handling.

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ACCRONYMES AND ABBREVIATIONS

BRC	British Retail Consortium
FAO	Food and Agriculture Organization
FBO	Food Business Operator
FSSC	Food Safety System Certification
GMP	Good Manufacturing Practices
GMO	Genetically Modified Organism
HACCP	Hazard Analysis Critical Control Points
IFS	International Featured Standard
ISO	International Organization for Standardization
Rwanda FDA	Rwanda Food and Drugs Authority
WHO	World Health Organization
IRMS	Integrated Regulatory Information Management System

GLOSSARY / DEFINITIONS

For the purposes of these guidelines, the following definitions shall apply:

"Applicant" means a person or company who submits to the Authority an application for registration or listing of processed food;

"Authority" means the Rwanda Food and Drugs Authority or the acronym "Rwanda FDA";

"Brand name" means a trade name for the food.
"Codex" means Codex Alimentarius or "Food Code" which is a collection of international standards, guidelines, codes of practice and recommendations developed by the Codex Alimentarius Commission (CAC) to protect the health of consumers and ensure fair practices in the food trade. CAC is an international organization run jointly by the FAO and WHO;

"Common name" means the name of the product as described in Codex standard CXS 1-1985;

"Competent Authority" means the authority taking responsibility for food control; it is usually that of the country of origin unless specific agreements exist within defined territories or region, where the "country" of origin is the territory or region;

"Competent Authority" means the official government organisation having jurisdiction over the national food safety control system;

"Container" means any packaging of food for delivery as a single item, whether by completely or partially enclosing the food and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer;

"Food Business Operator (FBO)" means the person/company who undertakes, whether for profit or not, any activities related to any stage of the processed food chain;

"Food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing, packaging, labelling, and distribution of food;

"**Food control**" means a regulatory activity of enforcement to provide consumer protection and ensure that all food during production, handling, storage, processing, and distribution are safe, wholesome, and fit for human consumption; conform to food safety and quality requirements; and are honestly and accurately labelled;

"Food registration" means official authorization by the Authority for a FBO to legally put a processed food on the market;

"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;

"**Foods for particular nutritional uses (FPNUs)**" are foods which, owing to their special

composition or manufacturing process, are clearly distinguishable from food for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability;

"**Good Manufacturing Practice (GMP)**" means a combination of manufacturing and quality control procedures aimed at ensuring that food products are consistently manufactured to their specifications;

"Hazard Analysis and Critical Control Point (HACCP)" means a system, which identifies, evaluates, and controls hazards which are significant for food safety along the food chain;

"Hazard" means a biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect;

"Ingredient" means any substance, including a food additive and excluding processing aid, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form;

"**Label mock-up**" means a copy of the flat artwork design for a food's label in full colour;

"Label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, or impressed on or attached to a container of food;

"Label "means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food;

"Law" means Law N° 003/2018 of 09/02/2018 establishing the Rwanda Food and Drugs Authority (Rwanda FDA) and determining its mission, organization and functioning and Law N° 47/2012 of 14/01/2013 relating to the regulations and inspection of food and pharmaceutical products;

"Listing" means simplified registration process whereby importers submit information to the Authority regarding the products they, or will supply on the Rwandan market;

"Local Technical Representative (LTR)" means a person or company residing in Rwanda, nominated in writing by MAH to deal with all matters related to registration and post-registration of imported products;

"Novel foods" means foods or ingredients that do not have a significant history of human consumption in Rwanda or foods produced by a method that has not previously been used, or with no existing relevant standard available in Rwanda. Novel foods include pure chemicals, genetically modified foods, cloned animals, whole foods new to a particular world region, and foods processed by a new technology. Assurance of safety and nutritional quality of the food supply are key reasons for the regulation of novel foods;

"Power of attorney" means a written and notarized authorization to conduct registration with the Authority for the specified products on behalf of the manufacturer or the product brand owner;

"Prepacked food" means packaged or made up in advance in a container, ready for offer to the consumer, or for catering. Prepacked food does not cover foods packed on the sales premises at the

consumer's request or prepacked for direct sale;

"Processed food "means food that has been modified from its original fresh or whole state for different reasons including safety, to extend the shelf life, increase the nutrient content, or to enhance the flavour profile, texture or appearance, among others;

"**Registrant**" A person or company whose food product is registered by the Authority;

"**Registration dossier**" means the set of documents and information that are submitted by applicant in support of the application for registration according to the requirements specified in these guidelines;

"**Requirements**" means the criteria set down by the competent authorities relating to trade in food products covering the protection of public health and conditions of fair trading;

"Traceability/Product tracing" means the ability to follow the movement of a food through specified stage(s) of production, processing, and distribution;

"Traceability/Product tracing" means the ability to follow the movement of a food through specified stage(s) of production, processing, and distribution;

"Variation" means a change in the manufacturing process, product specifications, formulation (proportion of ingredients) for a previously registered food product. A variation also includes, but is not limited to, a change in the product name, in additives used, manufacturing site, packaging type and processing technology.

1 INTRODUCTION

a) Unsafe food negatively impacts health, but also influences socio-economic growth in agribusiness, trade, and tourism.

b) Food Business Operators (FBOs) bear the primary responsibility to ensure the safety of food manufacture, processing, transport, distribution, storage, and sell. It is their utmost obligation to ensure that only safe and fairly presented food is placed on the market.

c) The guidelines covered scope; describe the responsibilities of the Authority and the responsibilities FBOs including applicants and local technical representatives where applicable; explain food registration pathways/procedures notably registration and listing, and types of food products required to follow a specific pathway/procedure; lay down strategies to adopt in using risk-based approach during evaluation of application dossiers which include full assessment, reliance and recognition, as well as expedited process for exceptional cases and conditions thereof. The guidelines also highlight requirements for registration of various applications depending on the type of products, document aspects and attributes to be considered during the review of the applications, decision making and appeal to decision made on a particular application, and the validity of approvals granted in regard with food registration service. Furthermore, the guidelines provide guidance on variations or changes made on registered or listed food products, express the requirement for renewal application before the approvals expire and established timelines for different activities.

2 SCOPE

a) These guidelines intend to provide guidance to FBOs on procedure and requirements for registration of processed foods.

b) The guidelines apply to processed foods, both domestic and imported, to be supplied on Rwandan market; but do not apply to food/dietary supplements and health foods as they are covered by a separate guideline.

c) The guidelines also cover new applications, renewal applications and variations of registered food products.

3 GENERAL INFORMATION

3.1 Roles and responsibilities

3.1.1 Responsibilities of the Authority

a) It is the responsibility of the Authority to determine appropriate food control strategies taking into consideration public health, scientific information, risk-based approach, consumer concerns, as well as compliance profiles to ensure the safety, quality and traceability of domestically produced and imported food for national consumers and export markets.

b) Processed food should either be registered or listed. All domestically processed foods and imported high risk foods are subject to registration procedure as described in these guidelines. On the other hand, low risk imported processed food will be subjected to listing.

3.1.2 Responsibilities of the applicant

a) It is the responsibility of applicants, especially processors and importers, to follow the procedures and complying with requirements described in these guidelines.

b) It is the responsibility of FBOs to provide the Authority with required information relating to those aspects of food under their control during application for food registration or listing.

c) FOBs are responsible to ensure the quality, safety and traceability of food products they supply to the market.

3.1.3 Responsibilities of the Local Technical Representative

a) The LTR is responsible for monitoring the product in the market and inform the Authority immediately after the detection of any problem such as a serious manufacturing defect, accidental contamination of the product or counterfeiting of the product, that relate to the registered product.

b) It is the responsibility of LTR to facilitate communication between the applicant and the Authority on matters that relate to the product.

c) The LTR is responsible for handling product recalls whenever necessary.

3.2 Registration

a) Food registration is a process whereby the Authority, as a competent authority with a regulatory mandate to oversee safety and quality of processed food, approves the sale and use of the products following assessment for compliance with relevant national, regional, or international regulatory and standards requirements to safeguard the public health.

b) All domestically processed foods should be registered, unless exempted products described in section 3.4, to ensure that the products safety and quality of the products placed on the market. In this regard, all food domestically produced must conform to safety and quality

requirements set out in applicable standards and must have been manufactured/processed in licensed facilities and in accordance with GMP.

c) Rwanda FDA regulations governing control of importation and exportation of food products requires all imported Food for Particular Nutritional Uses (FPNUs) to be registered before they are placed on the market. The FPNUs covered by these guidelines include:
   i. infant formulae,
   ii. follow-up formulae,
   iii. complementary foods,
   iv. foods for special medical purposes,
   v. other Foods for Special Dietary Uses (FSDUs) not falling under the above-mentioned categories.

d) FOBs intended to place on the market novel foods should submit sufficient data to the Authority for assessment of their safety and quality compliance before use. Examples of novel foods include:
   i. Food, food ingredients or other substances which consist of micro-organisms, fungi or algae or are isolated from them;
   ii. Food or food ingredients which consist of plants or animals, mineral or synthetic materials or have been isolated from them, excluding food and food ingredients obtained by traditional ways of reproduction or for which it has been noted for a long time that they are safe to be consumed;
   iii. Food and food ingredients to which has been applied a production process not currently used, and in cases when it causes significant changes in the composition or structure of food or food ingredients which have an effect on their nutritional value, the metabolism or the level of undesirable substances;
   iv. Food or food ingredients with new or intentionally modified primary molecular structure;
   v. Food and food ingredients containing or consisting of genetically modified organisms;
   vi. Food and food ingredients, excluding food additives (aromas and enzymes), produced from the GMO, but which do not contain any GMOs;

3.3 Listing

a) Listing is a simplified registration process whereby every importer of processed food products, excluding those indicated in section 3.2, submits information to the Authority regarding the products they, or will supply on the market.

b) Listing of food products is essential for their quality, safety and traceability. The traceability of food along the food chain is an essential element in ensuring food safety as it enables the Authority to carry out inspection audits for regulatory interventions in cases unsafe or fraudulent food products incidences on the market.

3.4 Exemption from registration and listing

The following food products are exempted from registration or listing:

a) Non-registrable foods include but not limited to; those that do not fall into the mandate of Rwanda FDA such as agricultural/farm food produce such as unprocessed cereals, pulses, roots and tubers, fruits, vegetables, nuts, oil seeds, spices, raw meat and fish, fresh eggs, raw milk.

b) Perishable foods with shelf life not exceeding 30 days when kept at appropriate storage conditions;
c) Imported processed foods for charity, donation or government self-procured products;
d) Processed food products for one-off events or use in events of national interests;
e) Processed foods sold by organization or society to members or guests at events or gathering, where the trade in food is not the purpose of the event or gathering;
f) Processed foods procured and distributed through UN agencies;
g) Processed foods for research; only if their safety and quality is well established and documented.

4 REQUIREMENTS AND APPLICATION DOSSIER

4.1 Requirements for food registration and listing

a) Requirements for registration of domestically processed foods are described in **Annex I**.

b) Requirements for registration of imported foods products for particular nutritional uses covered by these guidelines are described in **Annex II**.

c) Requirements for food listing are described in **Annex III**.

4.2 Samples and testing for quality control

a) Test results provided in the certificate of analysis by the applicant should be of high quality and reliability. Test parameters should cover important safety and quality attributes of the product, as per guidance prescribed in **Test Parameter requirements for Processed Food Registration, Doc No: FD/FRIC/CKL/007.**

b) The appropriate number of samples for each product should be submitted to Rwanda FDA depending on the product packaging size as prescribed in **Annex IV**. However, additional tests might be requested depending on the safety and quality risk(s) identified during the product review.

c) In case of independent quality testing by the Authority for verification purpose, testing policy will apply risk-based approach and be specific for each product. The tests to be performed are guided by the **Test Parameter requirements for Processed Food Registration, Doc No: FD/FRIC/CKL/007**; although additional tests may be performed depending on risk identified during the product review.

d) Samples should be appropriately labelled in English and/or any other official language used in Rwanda.
e) The samples submitted should have been collected so as to be truly representative of the relevant product batch.

4.3 Preparation and submission of the dossier by the applicant

a) The applicant should prepare and submit the application for product registration or listing according to requirements and conditions specified in these guidelines.

b) The application shall be submitted to online system via Regulatory Management System in place, accessible at https://irims.rwandafda.gov.rw/portal/.

c) Request of additional information or documents by the Authority and their submission by the applicant may be done via email at info@rwandafda.gov.rw, when deemed necessary.

d) The application supporting documents shall be submitted in any official language used in Rwanda (English, French or Kinyarwanda). If any material submitted in a dossier is another language, it shall be accompanied by an accurate and notarized complete English, French or Kinyarwanda translation version.

e) Payment of fees shall be made in accordance with the Regulations No. ODG/IMPO/TRG/001 governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority.

f) A separate registration application is required for each food product. This does not apply to listing procedure.

g) Samples shall be submitted at Rwanda FDA Head Office.

5 EVALUATION OF THE APPLICATION DOSSIER

Upon the receipt of the application, the Authority shall evaluate the dossier for safety and quality conformity in accordance with prescribed requirements and risk analysis. The process for evaluation of a food application is depicted in **Appendix I**.

5.1 Assessment of application dossier

The assessment process shall include the following aspects:

a) **Relevance and authenticity of submitted documents**: the Authority shall ensure that the data submitted are relevant to the product and authentic.

b) **Completeness check:** The Authority shall ensure that data in the submitted dossier is complete and in conformity with the requirements.

c) **Quality and safety assessment**: The Authority shall ensure that the data submitted are of acceptable quality and safety, complying with the relevant national/regional or codex standards or any other regulations or specifications prescribed by competent authorities; taking into account national laws. Quality assessment basically looks at ingredients, while safety assessment involves evaluation for unacceptable presence of contaminants such as heavy metals and mycotoxins, physical contaminants, pesticide residues, and microbial contaminants and veterinary drug residues among others.

d) **Labeling information**: the label on a food product shall be assessed for compliance with the East African Community Standard for Labelling of pre-packaged foods—specification, RS EAS 38 or the Internationally adopted Codex Alimentarius General Standard for the labelling of prepackaged, CXS 1-1985. However, assessment for compliance with relevant standards or regulations in countries/regions of origin may be applied for food products imported from

outside of the EAC, provided that they present no public health concerns or deception to consumers.

Product label claims are assessed in accordance with the East African Community Standard for Claims on foods — General requirements (EAS 804) or the relevant CODEX guidelines and standards.

e) **Packaging material**: food packaging materials shall be capable of maintaining the quality and safety of the food and shall comply with applicable standards or regulations.

5.2 Request of additional data

If the submitted information and documents are incomplete or the outcomes of the evaluation find them insufficient for decision making, the Authority may require the applicant to submit additional information and documents, including the samples and additional testing.

5.3 Reliance/Recognition

a) To streamline the quality and safety evaluation of food products, the Rwanda FDA has the opportunity to make greater use of tools that could optimize the risk-based decision making. In this regard, the Authority may use reliance and recognition strategies in registration and listing of food products.

b) Procedures and mechanisms for reliance and recognition can be in a number of ways that facilitate the process including the use of memoranda of understanding, mutual recognition agreements, equivalence agreements or any other trade agreements and unilateral recognition.

c) Some food products are known to be processed from facilities with a strong food safety management systems. Others are imported from trade partners which have established domestic food safety systems, while some others are from countries with specific agreement with Rwanda.

d) Conditions for application of reliance or recognition may include:
   i. Processed foods imported from countries or regions with which Rwanda has trade agreement or any food control equivalence agreements. For example, in case of food products processed in EAC, the Authority shall recognize valid certificates of product certification awarded by national quality system institutions of other Partner States (such as TBS, KEBS, etc.) in accordance with provisions prescribed in the East African Community Standardization, Quality assurance, Metrology and Testing (SQMT) Act, 2006.
   ii. Foods processed in facilities holding food safety certificates issued by a national competent authority which has formal/mutual agreement with Rwanda FDA;
   iii. Processed foods from facilities with a traceable valid food safety certificate such as FSSC 22000, ISO 22000, HACCP, BRC, GMP or equivalent issued by accredited body;
   iv. Food products imported from countries or regions with trusted or reference food control systems such as stringent food control Authorities, provided that the products are verified for quality and safety compliance;

v. History of conformity of the food products, including market surveillance experience, and the outcome of the risk assessment.

5.4 Expedited review process

a) The Authority may consider expediting review of applications with exceptional cases. Expedited review means that the application would be reviewed ahead of other pending applications, i.e., the application will be placed at the beginning of the appropriate review queues.

b) Exceptional cases which Rwanda FDA will consider for expedited review include applications for food products that meeting the following criteria, among others:
   i. Use for public health interventions supplied by FBOs;
   ii. Urgent need due to a critical supply shortage;
   iii. Products donated from international organization;

c) The expedited review process shall be followed on a risk–benefit analysis that takes into account all available information; and different review approaches including full assessment, reliance or recognition may applied.

6 DECISION MAKING

a) Processing of the application for which additional information or sample have been required by the Authority shall be kept on hold until the requested additional information, documents or samples are provided by the applicant. The additional information, documents and/or samples should be provided to the Authority within 60 calendar days after the applicant is communicated the outcomes of the assessment with request to address identified queries.

b) Should the applicant decide to withdraw the application before the completion of the evaluation, the Authority should be informed to stop the process.

6.1 Application approval or refusal

a) If a food product evaluation is satisfactory for registration or listing, the Authority will prepare and issue to the applicant a registration certificate or a notification letter, respectively.

b) A list of food products approved for registration and listing will be published on website and made accessible to the general public. The information to enter in the register include the product brand name, the product common name, product category, the registration certificate number or notification number, manufacturer, and the validity period of the registration for registered products.

c) Should an application be unsuccessful, the applicant will be issued with a notification letter. The situations that may lead to rejection include, but not limited to,
   i. Products unfit for human consumption,
   ii. Counterfeited products,
   iii. Forged documents.

6.2 Appeal

a) Any applicant aggrieved by a decision of the Authority may appeal to the Authority for review of a decision within thirty (30) calendar days of the receipt of the rejection notice and provide credible arguments supported with relevant evidence.

b) If the Authority still rejects the application after review of the appeal, the applicant may appeal to the Board of directors whose decision shall stand.

6.3 Validity registration and listing

a) The registration and listing of a food product under these guidelines, unless otherwise revoked, shall be valid for a period of five (5) years and may be renewed upon the application.

b) The Authority shall cancel, suspend, or withdraw the registration or listing of a product under the following conditions:
   i. The circumstances under which it was registered or listed no longer exist;
   ii. The grounds on which it was registered is later found to be false;
   iii. The Authority receives a notice issued by the registrant on intention to withdraw from dealing with the product;
   iv. Any of the provisions under which it was registered has been contravened;
   v. The standard of quality and safety, as prescribed in the documentation of the application dossier is not being complied with;
   vi. The premises, in which the product is manufactured, packaged or stored by or on behalf of the holder of the registrant is unsuitable for the manufacture, packaging or storage of the food;
   vii. If new scientific developments reveal that the product or ingredient(s) used are proved to have a significant health effect to the consumer.

7 VARIATIONS AND IMPLEMENTATION GUIDANCE

a) The registrant may wish to introduce changes or alteration on a registered or listed product. The changes can be classified as either minor variation or major variation.

b) Whenever the registrant is unclear about the classification of a particular change, the Authority should be contacted for guidance prior to any change/alteration.

7.1 Minor variations

a) Changes that could have no effects on the overall safety and quality of a registered product are considered as minor variations.

b) Minor changes shall be handled by a simple administrative arrangement.

c) Minor changes with no effects on the safety or quality of the food products, such as change of food packaging unit, shape and colour or change in distributors (see **Annex V** for details and requirements). Such changes do not require prior approval, but they shall be notified to

the Authority and can be implemented immediately at the time of submission. If the Authority considers that a change has been inappropriately classified, the applicant/registrant will be notified accordingly within 30 calendar days.

d) The minor variation cases requiring acceptance by the Authority prior to their implementation shall only be implemented on the receipt of a letter of acceptance or registration certificate, where applicable, from the Authority. In case of the registration certificate issuance, the initial validity period shall remain unchanged.

7.2 Major variations

a) Major variations are changes that could have effects on the overall safety and quality of the registered food product. Examples of major variations may include, but not limited to, change of manufacturing site, processing technology or ingredients (see Annex VII for details and requirements).

b) Major changes in the registration will require review of the data package submitted by the registrant and, where necessary, additional data would be requested and evaluated before approval of the request.

c) Prior acceptance by the Authority is required before the changes can be implemented. A letter of acceptance or a registration certificate, where necessary, will be issued for all major variations if and when the variation is considered acceptable. In case the registration certificate issuance, its initial validity period shall remain unchanged.

8 RENEWAL

a) An application for the renewal shall be made 3 (three) months before the expiration of the registration or listing.

b) The requirements for renew are stated in the relevant Annexes indicated in section 4.1.

9 TIMELINES

a) The evaluation of applications received in food registration service will be handled in accordance with the timelines indicated in the table below.

b) The timelines countdown will start once Food Registration service has received a complete set of the application after passing the screening.

Process/Procedure	**Timeline**
1. Evaluation of domestically processed food products upon receipt of a complete dossier	Within forty-five (45) working days
2. Evaluation of imported Foods for Particular Nutritional Uses (FPNUs) and novel foods upon receipt of a complete dossier	Within sixty (60) working days

3. Evaluation of imported food products with low risk upon receipt of a complete dossier/ through listing procedure	Within forty-five (45) working days
4. Evaluation of food products through expediated process	Within thirty (30) working days
5. Evaluation of food products query responses	Within fourteen (14) working days
6. Evaluation of minor variations requiring acceptance	Within thirty (30) working days
7. Evaluation of major variations	Within forty-five (45) working days

10 COMMUNICATION

The correspondences between the applicant and the Authority in cases such as food registration inquiry or request of clarification regarding food registration services shall be made through the official email at info@rwandafda.gov.rw.

APPENDIX

Appendix I: Process flow chart for evaluation of food products

ANNEXES

1. ANNEX I: Requirements for registration of domestically processed foods;
2. ANNEX II: Requirements for registration of foods for particular nutritional uses;
3. ANNEX III: Requirements for listing of imported processed foods;
4. ANNEX IV: Sample size and number requirements for food registration;
5. ANNEX V: Variations of food registration, requirements and administrative handling.

ENDORSEMENT OF THE GUIDELINES

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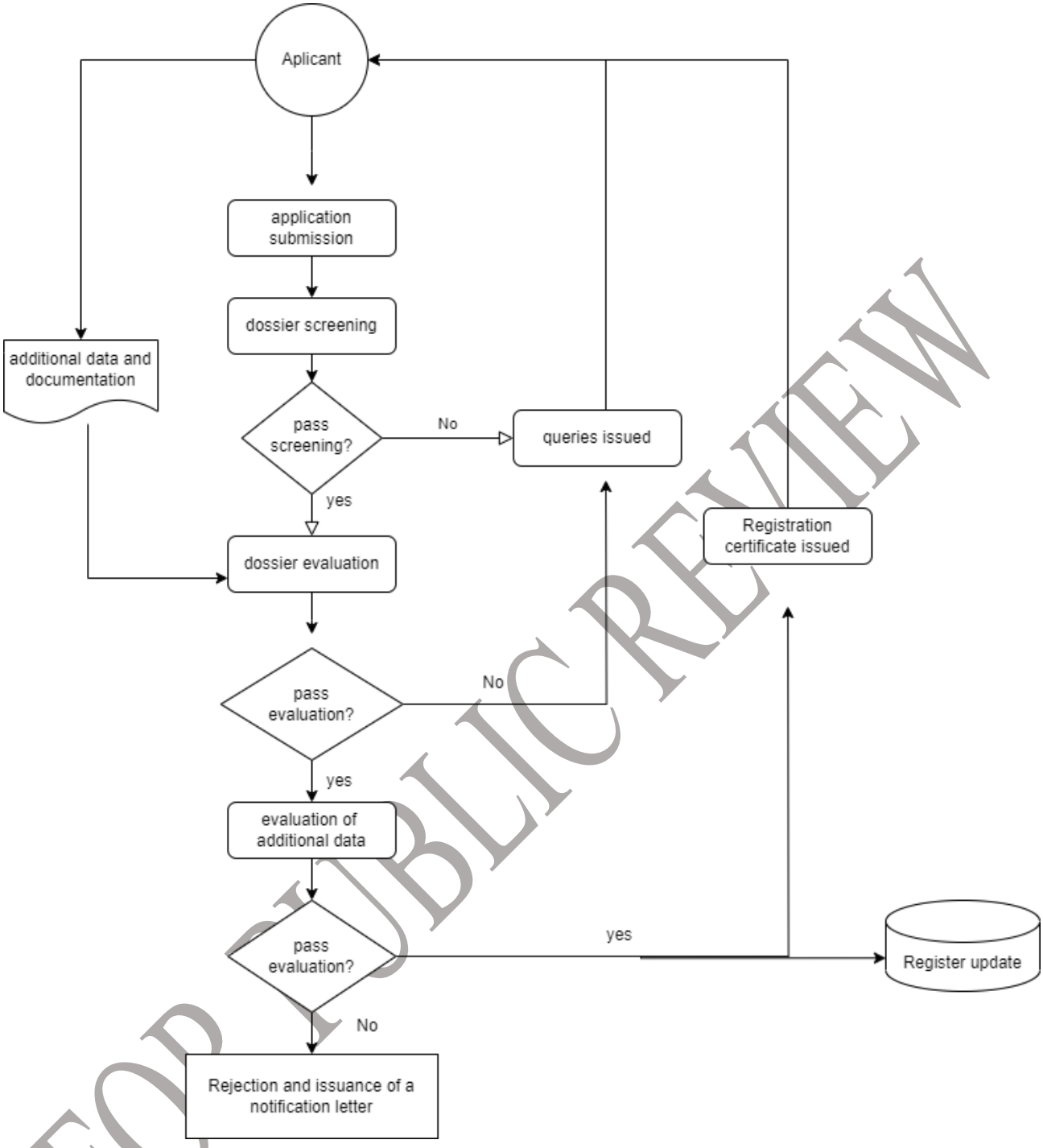
Appendix I: Process flow chart for evaluation of food products



ANNEX I: REQUIREMENTS FOR REGISTRATION OF DOMESTICALLY PROCESSED FOOD PRODUCTS

Applicants of domestically processed foods shall submit a separate application for registration of each product under their control, providing all the information as specified in these guidelines.

1. General requirements for Product Registration

a) Payment of product registration fees;

b) A valid Premises License issued by Rwanda FDA;

c) Application for GMP inspection;

d) Recent certificate of analysis (CoA) for each product that shows testing of parameters stipulated in the **Test Parameter requirements for Processed Food Registration, Doc No: FD/FRIC/CKL/007;**

e) Samples of each product. For bulk packages, mock samples shall be provided as per sample size and number requirements (Annex IV);

f) Mock-up label/ label artwork of each product. The labelling shall comply with the standard for labelling of pre-packaged foods —specification, RS EAS 38, and specific standards applicable to the product;

g) Certificate of trademark registration issued by Rwanda Development Board (RDB);

h) The product process flow chart;

2. Specific requirements for Product Registration

The following additional requirements shall apply on food for particular nutritional uses:

i) Shelf-life study data;

NOTE:

a) In case a food processing facility is not yet GMP licensed by Rwanda FDA and no such application has been submitted, the applications for product registration and GMP inspection should be made simultaneously. No application for food registration shall be accepted without a valid GMP compliance certificate or inspection application;

ANNEX II: REQUIREMENTS FOR REGISTRATION OF FOODS FOR PARTICULAR NUTRITIONAL USES

(1) Applicants of foods for particular nutritional uses (FPNUs) should submit a separate application for registration of each product under their control, providing all the information as specified in these guidelines;

(2) All imported FPNUs should go through full safety and quality evaluation before they are registered by Rwanda FDA. The FPNUs covered by these guidelines include:

i) infant formulae,
ii) follow-up formulae,
iii) complementary foods,
iv) foods for special medical purposes,
v) other Foods for Special Dietary Uses (FSDUs) not falling under the above-mentioned categories.

1. General requirements for Registration applications

a) Payment of product registration fees;

b) Recent certificate of analysis (CoA) for each product that shows testing of parameters stipulated in the **Test Parameter requirements for Processed Food Registration, Doc No:** FD/FRIC/CKL/**007;**

c) Samples of each product packaged in the original packaging material in accordance with the sample size and number requirements (Annex IV);

d) Mock label/ label artwork of each product;

e) Documentation to substantiate any claims made about the product. The evidence used to substantiate claims should be based on authoritative references, documented history of use, scientific opinion from scientific organizations or regulatory authorities and good quality scientific evidence from human studies. Claims should comply with the CODEX General Guidelines on Claims (CAC/GL 1-1979) and Guidelines for use of Nutrition and Health Claim (CAC/GL 23-1997);

f) Shelf-life study data;

g) Proof of registration/approval from a regulatory body in the country of origin, or any other valid food safety certificate such as ISO22000, FSSC2200, HACCP, IFS, BRC or equivalent.

2. Specific requirements for Registration applications

h) For infant and follow-up formula; melamine, radiation, GMO, and dioxin free certificates, as well as antibiotics residues and hormones laboratory test reports shall be provided;

i) If a product brand or trademark owner is not the manufacturer, a notarized mutual agreement between the brand or trademark owner and the manufacturer shall be provided;

j) If the LTR intends to submit the application of registration of a product, the brand or trademark owner shall provide a notarized Power of Attorney giving permission to Local Technical Representative (LTR) to apply for for registration of the product. In this case, the LTR should be a business company incorporated in Rwanda and registered by the competent authority;

k) If the product is being registered by the manufacturer/ MAH, the latter may appoint LTRs/ distributors of the products.

NOTE:

a) Rwanda FDA reserves the right to conduct Good Manufacturing Practices (GMP) assessment of the product manufacturing facility/sites at a fee paid by the applicant as prescribed in the current Regulations No. ODG/IMPO/001 governing tariff, fees and charges on services rendered by Rwanda FDA;

b) Rwanda FDA may request the applicant to provide additional information and documents when deemed necessary.

3. Applications for Renewal of imported FSDUs registration

The requirements as initial applications are applicable to renewal applications.

b) As a result of review outcomes and risk(s) identified thereof, Rwanda FDA may require a food processing facility to complete GMP compliance process and submit the Certificate before the product may be considered for registration;

c) Rwanda FDA may request the applicant to provide additional information when deemed necessary;

d) Any health, nutrition, or functional claim made on a food label should be substantiated. The evidence used to substantiate claims should be based on authoritative references, documented history of use, scientific opinion from scientific organizations or regulatory authorities and good quality scientific evidence from human studies.

3. Applications for Registration Renewal

The requirements as initial applications are applicable to renewal applications except the RDB Trademark Registration Certificate and the product process flow chart which shall not be submitted.

ANNEX III: REQUIREMENTS FOR LISTING OF IMPORTED PROCESSED FOODS

1. General requirements for listing of imported processed food products

a) Payment of product registration fees;

b) Recent certificate of analysis (CoA) for each product that shows testing of parameters stipulated in the **Test Parameter requirements for Processed Food Registration, Doc No: FD/FRIC/CKL/007;**

c) Samples of each product. For bulk packages, representative samples and mock-up label/label artwork or a clear label picture shall be provided. The representative samples should be in accordance with sample size and number requirements (Annex IV);

d) Certificate of safety compliance or equivalent issued by a competent authority in the country origin. Examples may include, but not limited to, proof of registration/approval from a regulatory body in the country of origin, or any other food safety certificate such HACCP, ISO22000, IFS, BRC, FSSC 22000.

NOTE:

a) Rwanda FDA may request the applicant to provide additional information or documents when deemed necessary during the assessment.

b) Any health, nutrition, or functional claim made on a food label should be substantiated. The evidence used to substantiate claims should be based on authoritative references, documented history of use, scientific opinion from scientific organizations or regulatory authorities and good quality scientific evidence from human studies. Claims should comply with the CODEX General Guidelines on Claims (CAC/GL 1-1979) and Guidelines for use of Nutrition and Health Claim (CAC/GL 23-1997).

2. Applications for Renewal

The requirements as initial applications are applicable to renewal applications.

ANNEX IV: SAMPLE SIZE AND NUMBER REQUIREMENTS FOR FOOD REGISTRATION

SN	Product Categories	Product	Pack Size	Number of samples
1	Milk products	UHT Milk	10 – 100 mL	3 Bottles/Packs
			100 – 2000 mL	3 Bottles/Packs
			> 2000 mL	Representative samples in 3 containers of 500 mL or 1L
		Yoghurt	500 L	3 Packs/Bottles
		Ice-cream, softy, ice candy, ice-lolly	300 g	3 Packs
		Milk powder	500 g	3 Packs
		Butter, butter oil, ghee, margarine, cream, bakery Shortening, peanut butter	200 g	3 Packs
		Cheese, cheese spread	All	2 Pieces
2	Cereal and cereal products	Flour	All	4 Packs of 500 g
		Corn flakes, macaroni products, corn flour, custard powder, noodles	All	3 Packs
		Biscuits and Rusks	200 g	3 packs
		Rice	All	2 kg
3	Processed pulses, seeds, and nuts and their products	Nuts and seeds	200g	3 Packs
		Baked beans	All	4 Packs
4	Processed tubers, roots, plantains, and their products	Processed plantains	All	3 Packs
		Chips	All	3 Packs
5	Soft drinks	Carbonated soft drinks	All	3 Bottles
		Fruits flavoured drink	All	3 Bottles/packs
6	Processed fruit and vegetable drinks	Fruit juice, fruit drink, Fruit squash	1L	2 Bottles
7	Liquors, spirits, and other distilled beverages	Local alcoholic beverages (Gin, whisky, vodka, spirit, brandy, wine)	200 -500 mL	3 Bottles
		Imported alcoholic beverages (Gin, whisky, vodka, spirit,	250 mL - 1L	2 Bottles

		brandy, wine, liquor, rum)		
8	Beers and wines	All	All	3 Bottles
9	Banana and Plant-Based Alcoholic Drinks	Banana-based alcoholic Beverages, plant flavoured alcoholic drinks, juices and other alcoholic beverages	200 -500 mL	3 Bottles
10	Sugar and Honey	Cane sugar, refined sugar, cube sugar, dextrose, died glucose syrup, and other sugars,	500 g	3 Packs
11		Icing sugar, honey, syrup, synthetic syrup,	All	3 Packs of 250 g or more
		Artificial Sweetener	100 g	3 Packs
12	Iodate salt (edible)	Edible salts	200 g	2 Packs
		Iodized salt, Iron fortified salt	200 g	2 Packs
13	Fats and Oils	Edible oils, cooking oil, fats	All	Representative samples in 2 containers of 1L
14	Tea and Coffee	Tea and tea products, herbal infusions	Less than 20 g or 20 mL	Two units of secondary package (e.g. Box or Jar)
		Coffee and coffee products	500g	3 Packs
		Instant tea, instant coffee, instant coffee-chicory mixture	100g	3 Packs
15	Cocoa and cocoa products	Chocolates	All	3 Packs of 200 g
16	Spices and Condiments	Processed spices and condiments (e.g., curry powder, pilau masala, ginger, turmeric…)	50g	10 Sachets
17	Vinegar	Natural vinegar	All	Representative samples in 2 containers of 1L
		Artificial vinegar	All	Representative samples in 2 containers of 1L
18	Processed insects and their products	Processed insects and their products	50-200 g	3 Packs or representative samples in pack of 1 kg
19	Processed Fish and Seafood	Processed fish and Seafood	50- 200 g	3 Packs or representative samples in pack of 1 kg samples
20	Processed meat and meat products	Processed meat and meat products	50- 200 g	3 Packs or representative samples in pack of 1 kg
		corned beef	all	4 Packs
		Canned sausage	all	4 Packs
21	Eggs product	Processed eggs	50- 200 g	3 Packs or representative samples in pack of 1 kg

22	Processed fruits and fruit products	Tomato sauce, Ketch-up, tomato paste	300 g	3 Packs
		Jam, jelly, marmalade, tomato puree	300 g	3 Packs
		Chili oil, chili sauce, canned tomatoes	All	4 Packs
23	Drinking water	Packaged drinking water, mineral water	300 - 500 mL	3 Bottles
			500 - 1000 mL	3 Bottles
			> 1000 mL	Representative samples in 3 containers of 500 mL
24	Vegetable and vegetable products	Vegetable powder	all	4 Packs or equivalent to 500 g
25	Food for infants and follow-up formula	Food for infants and follow-up formula	500 g	3 Packs
26	Food supplements and similar	Food supplements and similar	50 - 800 g	5 Sachets
27	Food additives	Food additives	50- 200 g	3 Sachets or representative samples in containers of 1L or packs 1Kg
28	Confectionaries	Confectionery, chewing gum, bubble gum	50- 200 g	2 Sachets
29	Other processed food products	Baking powder	100g	3 Packs

ANNEX V: CLASSIFICATION, REQUIREMENTS, AND IMPLEMENTATION GUIDANCES FOR VARIATIONS

A. Minor variation of a registered food product

#	Description of the change	Conditions to be fulfilled	Requirements/Supporting data	Decision
1	Change in the name or address of the MAH/ Registrant	When MAH is not the manufacturer	1. Proof of change of the name issued by a competent authority in the country. 2. Revised mutual agreement between manufacturer and MAH 3. New label if the name of MAH appears on the label	Revised product registration Certificate
2	Change in the name and/or address of a manufacturer	No change in the location of the manufacturing site and in the manufacturing processes.	1. Copy of the modified premises license or a formal document from a relevant official body in which the new name and/or address is mentioned. 2. New label	Cancellation of the existing certificate and issuance of a revised version
2	Replacement of a registered product brand name	When MAH and Manufacturer are unchanged	1. Copy of the letter of acceptance of the new brand name issued by a competent authority 2. Revised label or mockup label	Cancellation of the existing certificate and issuance of a revised version
3	Change of LTR	None	Letter of the appointment of the new LTR by the MAH	Revised product registration certificate
4	Change in packaging size	The rest of label information remain unchanged	New label or mockup label	Additional product registration certificate
5	Change in packaging color	All the other information on the certificate remains unchanged	Photograph of the new packaging material and/or with label.	Notification letter of variation approval

Note: a letter notifying the Authority of the changes intended by the applicant shall be sent together with the supporting data. The letter shall be as explicit as possible in order to avoid unnecessary delays.

B. Major variation of a registered food product				
#	**Description of the change**	**Conditions to be fulfilled**	**Supporting data**	**Decision**
1	Change in manufacturing site physical address	MAH is unchanged	1. Valid manufacturing/ Premises License issued by a competent authority. 2. GMP certificate, where applicable; 3. New mockup label; 4. Samples.	Additional product registration certificate if the initial certificate is not cancelled. Otherwise, an updated version will be issued.
2	Change in type of packaging material	When the processing technology (filling line) does not change.	1. Samples, 2. Label or mock-up label, 3. New shelf-life study, where applicable.	Additional product registration certificate.
3	Change packaging type material	When the processing technology (filling line) changes	1. Samples, 2. label or mock-up label, 3. New shelf-life study, where applicable 4. Manufacturing or Premises License issued by a competent authority.	Additional product registration certificate.
4	Change in ingredient proportions.	The change does not affect the common name of the product.	1. Samples 2. Test reports, 3. Label or mockup label if the ingredient descendent order changed.	Notification letter of variation approval.
5	Change in processing technology.	The change does not affect the type a product.	1. Updated manufacturing/ Premises License issued by a competent authority, 2. Samples, 3. Recent test reports.	Notification letter of variation approval
6	Change in shelf life.	No change to the primary packaging in direct contact with the food or to the processing technology.	1. Revised shelf-life study report, 2. Updated label or mockup label.	Revised product registration certificate.
7	Change in storage conditions.	None	1. Stability study 2. New mockup label.	Revised product registration certificate
8	Change in standard	None	1. Test report if there is change in safety and quality requirements,	Notification letter of variation approval or updated certificate

			2. Samples change in safety and quality requirements, 3. Label or mockup when applicable.	depending on changes.
9	Change in additives	The additives remain compliant with applicable regulatory requirements	1. test reports, 2. Sample, 3. Label or mockup label 3. Payment of appropriate fee in case the change in additives leads to variant(s) of a registered product.	Notification letter of variation approval or an additional certificate if the additives lead to variants of a registered product.
10	Change in intended end user	No change in ingredients	1. Scientific evidence supporting the change, 2. New label or mockup label, 3. Samples	Notification letter of variation approval.

Note: a letter notifying the Authority of the changes intended by the applicant shall be sent together with the supporting data. The letter must be as exhaustive as possible in order to avoid unnecessary delays. All major variation applications are subject to payment as per the Regulation related to fees and tariffs.