



GUIDELINES FOR REGISTRATION OF FOOD SUPPLEMENTS

JUNE, 2024

FOREWORD

Pursuant to the Presidential Order N° 67/01 of 20/10/2009 establishing food supplements regulation, especially in the Article 8 requiring each product intended to be marketed as food supplement to be registered by relevant regulatory authority;

Pursuant to the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning; specifically in the Article 8 paragraph 8 providing the Authority with the mission to ensure that food supplements, among other products, meet the prescribed quality standards before they are placed on the market; and the Article 9 paragraph 1 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;

These guidelines intend to prescribe the administrative, technical procedures and requirements for registration of food supplements and health foods. When submitting the application to Rwanda FDA, the applicant shall ensure to follow the instructions prescribed in these guidelines.

Prof. Emile BIENVENU
Director General

FOR PUBLIC REVIEW

DOCUMENT DEVELOPMENT HISTORY

First issue date	May 2019
Effective date of this revision	xxx/xxx/2024

DOCUMENT REVISION HISTORY

Revision number	Changes made and/or reasons for revision
0	First issue
1	<ol style="list-style-type: none"> 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 registration, 4. The following Appendices were added: <ol style="list-style-type: none"> a) Classification flowchart of food products containing additional ingredients with a nutritional or physiological effect b) Guidance on testing requirements for food supplements and health foods c) Process flow chart for evaluation of food supplements and health foods d) Variations of Food Supplement and Health Food Registration, Requirements and administrative handling depicting the process flow chart for evaluation of food products was added. 5. Annexes I, II, III were removed. These are application forms which were replaced with an online application. 6. The following Appendices were added: <ol style="list-style-type: none"> a) List of Vitamin and Mineral substances which may be used in the manufacture of food supplements; b) Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels (ULa), Vitamins.

TABLE OF CONTENTS

FOREWORD	2
DOCUMENT DEVELOPMENT HISTORY	3
DOCUMENT REVISION HISTORY	3
TABLE OF CONTENTS	4
ACCRONYMES AND ABBREVIATIONS.....	5
DEFINITIONS	6
1 INTRODUCTION	8
2 SCOPE.....	9
3 GENERAL INFORMATION.....	10
3.1 Roles and responsibilities.....	10
3.1.1 Responsibilities of the Authority.....	10
3.1.2 Responsibilities of the applicant	10
3.1.3 Responsibilities of the Local Technical Representative	10
3.2 Registration	11
3.3 Exemption from registration	11
4 REQUIREMENTS AND APPLICATION DOSSIER.....	11
4.1 General Requirements	11
4.2 Requirements for new application.....	12
4.3 Requirements for renewal application.....	13
4.4 Samples for quality control testing.....	13
4.5 Preparation and submission of the dossier by the applicant.....	13
5 EVALUATION OF THE APPLICATION DOSSIER.....	14
5.1 Assessment of application dossier.....	14
5.2 Request of additional data	15
5.3 Reliance/recognition.....	15
5.4 Expedited review process.....	16
6 DECISION MAKING	16
6.1 Application approval or rejection.....	16
6.2 Appeal	17
6.3 Validity of the registration certificate	17
7 VARIATIONS AND IMPLEMENTATION GUIDANCE.....	17
7.1 Minor variations	17
7.2 Major variations	18
8 TIMELINES	18
9 COMMUNICATION	18
APPENDICES	19
ANNEXES.....	19
ENDORSEMENT OF THE GUIDELINES.....	19

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
HACCP	Hazard Analysis Critical Control Points
IFS	International Featured Standard
ISO	International Organization for Standardization
LTR	Local Technical Representative
MAH	Marketing Authorization Holder
RDI	Recommended Daily Intake
Rwanda FDA	Rwanda Food and Drugs Authority
WHO	World Health Organization
IRMS	Integrated Regulatory Information Management System

FOR PUBLIC REVIEW

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.

“Characteristic ingredient/substance in a food supplement” means a nutrient such as vitamins or minerals or some other substance with a nutritional or physiological effect. Ingredients may also include fibre, amino acids, edible fats, fatty acids, vitamins, carbohydrates, plant extracts, herbs, bee products, prebiotics, probiotics, bone meal, dolomite, ashes, horn powder, enzymes, colostrum and organic matter.

“Claim” means any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

“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 usual name existing by common usage as an appropriate descriptive term which is not misleading or confusing to the consumer.

“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 regions, where the “country” of origin is the territory or region.

“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.

“Country of origin” means the country in which the food supplement was manufactured or produced or from which the food supplement was re-packaged.

“Diet” means the sum of food consumed by a person.

“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 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/dietary supplement” means a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins; minerals; amino acids; a herb or other botanical product, a dietary substance for use by humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients; is intended to be taken orally in the form of tablet, capsule, powder, soft gel, gel cap, granules or liquid; is not represented for use as a conventional food or as a sole item of a meal or the diet; is labelled as dietary supplement.

“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;

“Health food” means food product formulated with a conventional food matrix or macronutrient and containing dietary ingredients such as amino acids; a herb or other botanical product, for use by humans as a conventional food or drink while supplementing the diet by increasing the total daily intake of a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

“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” 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 mock-up” means a copy of the flat artwork design for a food’s label in full colour.

“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.

“Major variation/alteration/ change” means change with a high potential to affect the quality and/or safety of the product. This includes change of manufacturing site or processing technology; and change in type of packaging material, type and concentration of additives.

“Minor variation/alteration/change” means change with a low potential to affect the quality and/or safety of the product. This includes change of name and address of applicant, name and address of the manufacturer (except physical address), or name and address of the local technical representative;

and shape, size or colour of the packaging unit/ label.

“Nutrient” means any substance normally consumed as a constituent of food which provides energy or which is needed for growth, development and maintenance of life; or a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

“Packaging material” means any material meant for wrapping, enclosing and protecting food substances for sale, distribution, storage or use, including caps, corks, leads, crown, food contact surfaces and covering or coating materials which do not form part of the food and are not intended to be consumed together with such food.

“Physiological function” means functions carried out by organs, tissues and cells to maintain the body in good health or to keep the body in a state of homeostasis.

“Power of attorney” means the written and notarized authorization to conduct registration with the Authority for the specified products on behalf of the manufacturer.

“Registrant” A person or company whose food product is registered by the Authority.

“Registration certificate” means a certificate issued by the Authority as evidence that the food has been 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.

“Variant” means a similar product manufactured by the same manufacturing plant using the same ingredient(s) at the same levels but different in food additives or type of packaging materials. Products are considered as variants when the application for registration is done concomitantly.

“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 additives used, manufacturing site, packaging type and processing technology.

1 INTRODUCTION

Guidelines for registration of food supplements

- a) The Presidential Order N° 67/01 of 20/10/2009 establishing food supplements regulation, especially in its article 8 requires each product intended to be marketed as a food supplement to be registered by relevant regulatory authority.
- b) These guidelines were made to guide applicants on the procedure and requirements for registering food supplements. This document shall be used along with the above law before completing the registration form.
- c) Registration of food supplements is a process whereby the Rwanda FDA, as a competent authority with a regulatory mandate to oversee the safety and quality of food supplements and health foods, approves the sale and use of the products following a compliance assessment in accordance with relevant national, regional or international regulatory and standards requirements to safeguard the public health.
- d) The registration of food supplements is an important aspect of effective control of the quality and safety of such products. Food supplements are normally used because of their specific nutritional content, for instance as a source of vitamins, minerals, amino acids or fatty acids, to supplement the diet. They may also have a physiological effect on the body of the intended user for instance on digestion, blood pressure or cholesterol level. The rapid increase in consumption of food supplements and demand for diversified varieties enhanced their market and compelled the adoption of appropriate control measures to protect consumers' health.
- e) Business operators of food supplements bear the primary responsibility to ensure the safety of food manufacture, processing, transport, distribution, storage, and sale. It is their utmost obligation to ensure that only safe and fairly presented food is placed on the market.
- f) These guidelines describe the responsibilities of the Authority and the responsibilities of FBOs including applicants and local technical representatives where applicable; lay down strategies to adopt in using a risk-based approach during the evaluation of application dossiers which include a full assessment, reliance and recognition, as well as the expedited process for exceptional cases and conditions thereof. The guidelines also highlight requirements for registration applications of food supplements; document aspects and attributes to be considered during the review of the applications; decision making and appeal to decisions made on a particular application; and the validity of approvals granted in regard. Furthermore, the guidelines provide guidance on variations or changes made to registered food supplement products, express the requirements for a renewal application and establish a timeframe for different activities related to the registration of food supplements.

2 SCOPE

- a) These guidelines apply to food supplements, as defined in the presidential order n° 67/01 of 20/10/2009 establishing food supplements regulation. They also cover health foods which are not described in this law; as clarified in **Appendix I** providing classification of food supplements and health foods;

- b) Foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these guidelines;
- c) These guidelines intend to prescribe the administrative, technical procedures and requirements for registration of food supplements and health foods.
- d) The guidelines cover new applications, renewal applications and variations of registered food supplements and health foods.

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) The Authority is responsible for enforcement of requirements prescribed in these guidelines in accordance with all relevant laws and guidelines effective in the country.

3.1.2 Responsibilities of the applicant

- a) When applying for food supplements registration to the Authority, it is the responsibility of applicants, especially processors and importers, to follow the procedures and complying with requirements prescribed in these guidelines.
- b) It is the responsibility of food supplement business operators to provide the Authority with required information relating to those aspects of food supplement under their control during application for registration.
- c) Food supplement business operators 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 supplement registration is a process whereby the Authority, as a competent authority with a regulatory mandate to oversee safety and quality of food supplement, approves the sale and use of the products following assessment for compliance with relevant national, regional or international regulatory requirements to safeguard the public health.
- b) All food supplements should be registered, unless exempted products described in section 3.3, to ensure that the products safety and quality of the products placed on the market.

3.3 Exemption from registration

The following food products are exempted from registration:

- a) Food supplements procured and distributed through UN agencies;
- b) Donated or government self-procured food supplements;
- c) Food supplements for research; only if their safety and quality is well established and documented.

4 REQUIREMENTS AND APPLICATION DOSSIER

4.1 General Requirements

- a) Food supplements containing vitamins and minerals shall be manufactured using vitamins/pro-vitamins and mineral substances recognized by FAO and WHO. The vitamin and mineral substances which may be used in the manufacture of food supplements are listed in **Annex I**.
- b) Food supplements providing a daily intake exceeding the tolerable upper limit for vitamins and minerals specified in **Annex II** shall be registered are not regulated as foods and shall not be registered as food supplements.
- c) The minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO.
- d) Food supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific requirements on vitamins and minerals laid down in these guidelines.
- e) Unless it is specifically restricted or prohibited, any ingredient or substance other than vitamins and minerals such as botanical or bioactive substances may be used in a food only if it is safe and suitable for the purpose that it is being added.
- f) Food supplements may contain one or more, or a combination of the following ingredients:
 - i) Vitamins, minerals, amino acid, fatty acids;
 - ii) Enzymes, prebiotics, probiotics, and other bioactive substances; and

- iii) Substances derived from natural sources including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates;
- g) The addition of medicinal ingredients such as stimulants, anabolic agents, controlled substances, or approved drug active pharmaceutical ingredient (API) in food supplements is prohibited.

4.2 Requirements for new application

A separate application is required for each product and the following shall be submitted:

- a) Payment of Food supplement registration fees;
- b) Recent (at most six months) certificate of analysis for each product from a recognised laboratory with results for relevant physical parameters, heavy metals, microbiological parameters, bio-active compound testing (APPENDIX II).
- c) Samples of each product packaged in the final package ready for the market;
- d) Mock-up 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 regulator in the country of origin, or any other valid international certificate of food safety management such as GMP, ISO 22000, HACCP, FSSC 22000, or equivalent;
- h) Notarized mutual agreement if the product is manufactured on contract basis.
- i) Appointment letter of Local Technical Representatives (LTR) and a list of distributors for imported products with applicant residing outside of Rwanda. 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 the Local Technical Representative (LTR) who will apply for registration of the product. In this case, the LTR should be a business company incorporated in Rwanda and registered in Rwanda Development Board (RDB);

NOTE:

- a) Rwanda FDA reserves the right to conduct site verification/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) The Authority may request the applicant to provide additional information/data, where deemed necessary.

4.3 Requirements for renewal application

- a) An application for the renewal of registration of a food supplement or health food product shall be made 3 (three) months before the expiration of the registration.
- b) Similar requirements as initial applications are applicable to renewal applications.

4.4 Samples for quality control testing

- a) The appropriate number of samples for each product should be submitted to the Authority depending on the product packaging size as indicated in **Table 1**.
- b) 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.
- c) Samples should be appropriately labelled in English and/or any other official language used in Rwanda.
- d) The samples submitted should have been collected so as to be truly representative of the relevant product batch.

4.5 Preparation and submission of the dossier by the applicant

- a) The applicant should prepare and submit the application for product registration 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) Samples shall be submitted together with the submission letter at Rwanda FDA Head Office.

Table1: Sample size and number requirements for registration

SN	PACKAGING SIZE	NUMBER OF SAMPLES
1	Less than 20g or 20ml	3 units of secondary package (eg.box or jar)
2	21g – 100g or 21ml – 100ml	5 units
3	101g – 250g or 101ml – 250ml	4 units
4	251g – 500g or 251ml – 500ml	3 units
5	551g – 3kg or 551ml – 3L	3 units
6	More than 3kg or 3L	3 units of ¹ / ₂ kg aseptically drawn from the original package of the product and 1 empty labelled packaging

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 III**.

5.1 Assessment of application dossier

The assessment process shall include the following aspects:

- i) **Relevance and authenticity of submitted documents:** the Authority shall ensure that the data submitted are relevant to the product and authentic.
- ii) **Completeness check:** The Authority shall ensure that data in the submitted dossier is complete and in conformity with the requirements.
- iii) **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.
- iv) **Labelling information:** The label on a food supplement 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 pre-packaged food, CXS 1-1985. However, assessment for labelling 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. The label shall bear instructions for use including dosage with respect to user age, intended use and cautionary statement where applicable.

- v) **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, Rwanda FDA 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 Authority 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 of food supplements and health foods.
- 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 supplements and health foods are known to be processed from facilities with a strong food safety management system. Others are imported from trade partners which have established food safety control systems, while some others are from countries with specific agreements with Rwanda.
- d) Conditions for application of reliance or recognition may include:
 - i. Food supplements and health 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;
 - ii. Urgent need due to a critical supply shortage;
 - iii. Use in events of national interests;
 - iv. 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, Rwanda FDA should be informed to stop the process.

6.1 Application approval or rejection

- a) If a food supplement or health food evaluation is satisfactory for registration, the Authority will prepare and issue to the applicant a registration certificate.
- b) A list of food products approved for registration 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, 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 or intended use;
 - ii. Use of ingredients prohibited in food supplements;
 - iii. Falsified product;
 - iv. Forgery of 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 of the registration certificate

- a) The registration of a food supplement or health 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 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 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) Minor variations shall be handled by a simple administrative arrangement as per **Appendix IV**.
- b) 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 Appendix IV** for details and requirements) do not require prior approval, and can be implemented immediately at the time of submission. But the variations shall be notified to the Authority. If the Authority considers that a change has been inappropriately classified, the applicant/registrant will be notified accordingly within 30 calendar days.

- c) 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 Appendix IV 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 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 food supplements and health food products upon receipt of a complete dossier/ through registration procedure.	Within 60 days
2. Evaluation of food supplements or health food products through expedited process	Within 30 days
3. Evaluation of query responses	Within 14 days
4. Evaluation of minor variations requiring acceptance	Within 30 days
5. Evaluation of major variations	Within 60 days

9 COMMUNICATION

The correspondence 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, with a copy to fric@rwandafda.gov.rw.

APPENDICES

Appendix I: Classification flowchart of food products containing additional ingredients with a nutritional or physiological effect.

Appendix II: Guidance on testing requirements for food supplements and Health foods.

Appendix III: Process flow chart for evaluation of food supplements and health foods.

Appendix IV: Variations of food supplement and health food registration, requirements and administrative handling.

ANNEXES

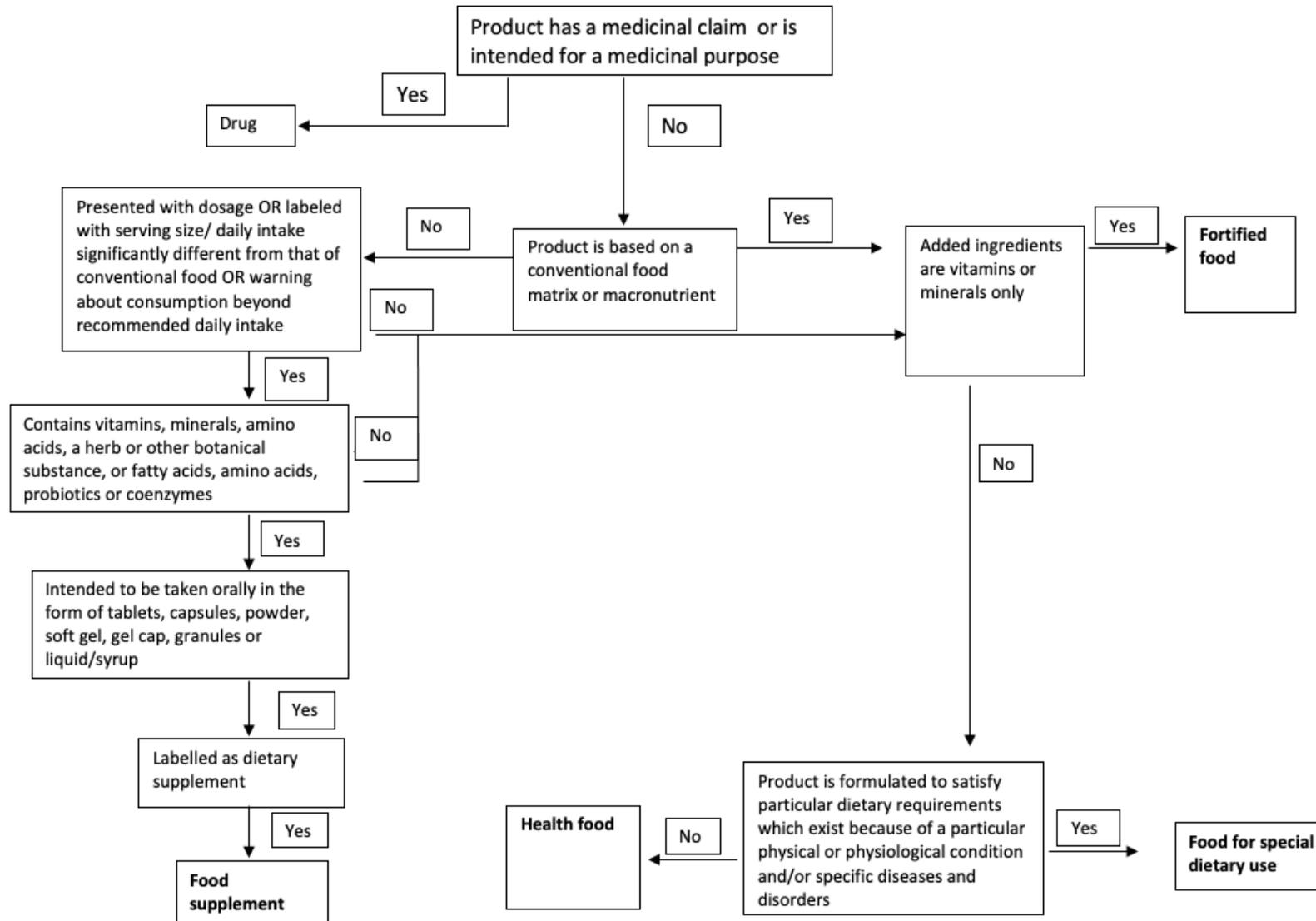
Annex I: Vitamins, minerals permitted for use in food supplements.

Annex II: Tolerable upper intake levels of vitamins and minerals.

ENDORSEMENT OF THE GUIDELINES

	Prepared by	Checked by		Approved by
Title	FRIC Division Manager	Head of Food Department	QMS Division Manager	Director General
Names	Dr. Jean Pierre MUNYAMPUNDU	Dr. Eric NYIRIMIGABO	Marie Ange UWASE	Prof. Emile BIENVENU
Signature				
Date				

APPENDIX I: Classification flowchart of food products containing additional ingredients with a nutritional or physiological effect



APPENDIX II: Guidance on testing requirements for food supplements and Health foods

1. Introduction

- a) Business operators of food supplements and health foods are required to ensure that their products are safe and that they conform with the applicable safety and quality standards. The objective of this guidance is to guide applicants for registration of food supplements and health foods on testing requirements, to ensure that the products meet the expected safety and quality standards.
- b) Routine testing on the finished products should be performed by the manufacturer to ensure that they meet the expected safety and quality standards. Product specification sheet or certificate of analysis on raw materials or intermediates may not be used to replace testing on finished products.
- c) All tests should preferably be performed by accredited or recognized laboratories.
- d) Manufacturer's in-house testing laboratory, if used, should meet the following conditions:
 - i) Test methods are validated or referenced to a recognized pharmacopeia method;
 - ii) The manufacturer's in-house laboratory is inspected as part of GMP inspections.

2. Physical test parameters

- a) The physical test parameters for different dosage forms in finished products are performed to ensure they consistently meet the required standards throughout the product life cycle.
- b) A dosage form is defined as the physical form of a dose of a product that is intended for oral. Each dosage form contains a single or mixed combination of the active components and other substances, e.g., additives or excipients, in a formulation.
- c) The key functions of dosage forms are to:
 - i) Protect the product contents from degradation or deterioration, such as oxidation, hydrolysis, or reduction.
 - ii) Provide safe and convenient delivery of the product contents.
 - iii) Improve taste or conceal the odor of the product contents.
- d) Essential test parameters are as follows:
 - i. **Disintegration** determines the rate and extent of the product contents to disintegrate within the prescribed time when placed in a liquid medium under stipulated test conditions. Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the test apparatus or adhering to the lower surface of the disk (if used) is a soft mass having no palpably firm core.

- ii. **Dissolution** is a test to measure the rate and extent of the release of the intended substance(s) from the product to form a solution under controlled conditions, i.e. if the compound(s) for a botanical is dissolved within the time frame and under specified conditions.
- iii. **Hardness** is a type of in-process control that routinely measures the mechanical integrity of the dosage form, i.e., the force that causes breakage(s). Interpretation of the hardness of the dosage form must consider the mean value and consistency of the test results for multiple dosage units. The resultant range of values provides valuable information on the consistency of the manufacturing process.
- iv. **Friability** measures the resistance of the dosage form to chipping and surface abrasion during manufacturing, handling, and transportation. Chipping and abrasion can each have a significant impact on the success of subsequent manufacturing operations such as coating and packaging and impact the consumer's expectation of the final dosage form.
- v. **pH** of liquid oral products (i.e., aqueous formulations) is susceptible to changes from exposure to atmospheric carbon dioxide (CO₂), which can affect the flavour and stability of the contents of the finished products.
- vi. **Uniformity of Dosage Units** measures how evenly distributed the active substances are distributed in the product, which can also be demonstrated by the content uniformity or mass variation.
 - 1. **Content uniformity** is based on the assay of the contents of active substances in several dosage units to determine whether the individual contents are within the set limits.
 - 2. **Mass variation/weight variation/Filling variation** is applicable for solids (including powders, granules, etc) that are packaged in single-unit containers or capsules, tablets, or liquid contents enclosed in unit-dose containers or soft capsules.
- e) The test parameters in following table should be conducted for the different dosage forms and the test results shall be documented in the reports:

Table1: Test parameters for the different dosage forms

Dosage forms		Recommended test parameters
Oral/Internal Use	Capsules	1. Disintegration or Dissolution 2. Uniformity of dosage units
	Tablets	1. Disintegration or Dissolution* 2. Hardness or friability** 3. Uniformity of dosage units
	Pills	1. Disintegration or Dissolution 2. Uniformity of dosage units
	Powder	1. Particle size variation 2. Uniformity of dosage units
	Granules	1. Disintegration or Dissolution 2. Particle size variation 3. Uniformity of dosage units (single-unit containers)

Gels/Pastilles /Gummies	1. Disintegration or Dissolution 2. Uniformity of dosage units
Teabags	1. Uniformity of dosage units
Liquids	1. Uniformity of dosage units 2. pH (for aqueous-based products) 3. Ethanol and/or methanol (if applicable) 4. Preservatives (if applicable) 5. Sucrose content (if applicable)

* Not applicable to chewable tablets; ** Not applicable for coated tablets. For non-coated tablets, hardness or friability may be included as part of in-process control testing.

- f) The appropriate testing methods and permissible limits are found in the established national/regional relevant standards if available, international pharmacopeias, e.g., British Pharmacopeia (BP), European Pharmacopeia (EP), Japanese Pharmacopeia (JP) and United States Pharmacopeia (USP). The products should meet the acceptance criteria stated in recognized relevant standards or pharmacopoeias. Should these standards be unavailable, the acceptance criteria and test methods for the test parameters may be determined by the manufacturer/product owner. Other acceptable references for test methods may include American Herbal Pharmacopoeia (AHP), Association of Official Analytical Chemist International: Official Methods of Analysis, Microbiological: Food & Drug Administration Bacteriological Analytical Manual, WHO – Quality Control Methods for Herbal Materials, International Organization for Standardization (ISO)—ICS 67 – Food Technology and ICS 67.050 – General methods of tests and analysis for food products, Food Chemical Codex (FCC), Office of Dietary Supplement, National Institute of Health. US: Dietary Supplement Analytical Methods/Reference Materials (AMRM) Program (<https://ods.od.nih.gov/Research/AMRMProgramWebsite.aspx>).

2. Heavy metals

The applicable heavy metals are specified in the table below:

Table 2: Heavy metals limits

Heavy Metal	Quantity(by weight)
1. Arsenic	5 parts per million
2. Cadmium	0.3 parts per million
3. Lead	10 parts per million
4. Mercury	0.5 parts per million

3. Microbial limits

The applicable heavy metals and microbial limits for food supplements and health foods are specified in the table below.

Table 3: Microbial limits

Microbe	Quantity (Colony-forming units (CFU) per g or ml of product)
Total aerobic microbial count	Not more than 10 ⁵
Yeast and mould count	Not more than 5 x 10 ²
<i>Escherichia coli</i> , <i>Salmonellae</i> , <i>Staphylococcus aureus</i> and <i>Listeria monocytogenes</i>	Absent

4. Nutrients and bio-active compound

- a) The testing for determination of ingredients will test the food supplement or health food for the containing vitamins, minerals, amino acids, etc. This ensures that the product complies with the limits and that there is not too little or too much of an ingredient in the product. The maximum amount ensures that too much of a vitamin or mineral will not have a detrimental effect on health and that the beneficial nutritional effect can be achieved.
- b) It is a requirement to conduct quantitative assay test for all bio-active compound claimed on the label of a food supplement of a health product, the certificate of analysis (CoA) for each bio-active compound shall be submitted for the purpose of registration. When testing of all ingredients is not possible or practical to achieve, such as cases of products containing active ingredients in form of plant or animal extracts, the certificates of analysis of key ingredients/substances in extract that are responsible for the product potency, health benefits and/or health claims made on the label are required.

5. Testing for adulterants for some product categories

Some food supplements and health food products have been reported to be adulterated with potent chemical pharmaceutical substances. Their presence can pose health risks to unsuspecting consumers. Some product categories, such as those specified in table below have been implicated frequently in adulteration cases. To ensure that such products do not contain hidden risks to unsuspecting consumers, testing for adulterants at accredited laboratories should be performed, before being registered.

Table 4: Product categories of concern and adulterants

Product Category	Specific medicinal substances to be included in the adulterant testing
Male Vitality Enhancement	1. Androgenic Steroids 2. Erotogenic Agents
Female sexual enhancement	1. Ovarian steroids
Pain Relief	1. Analgesics 2. Anti-inflammatory Agents

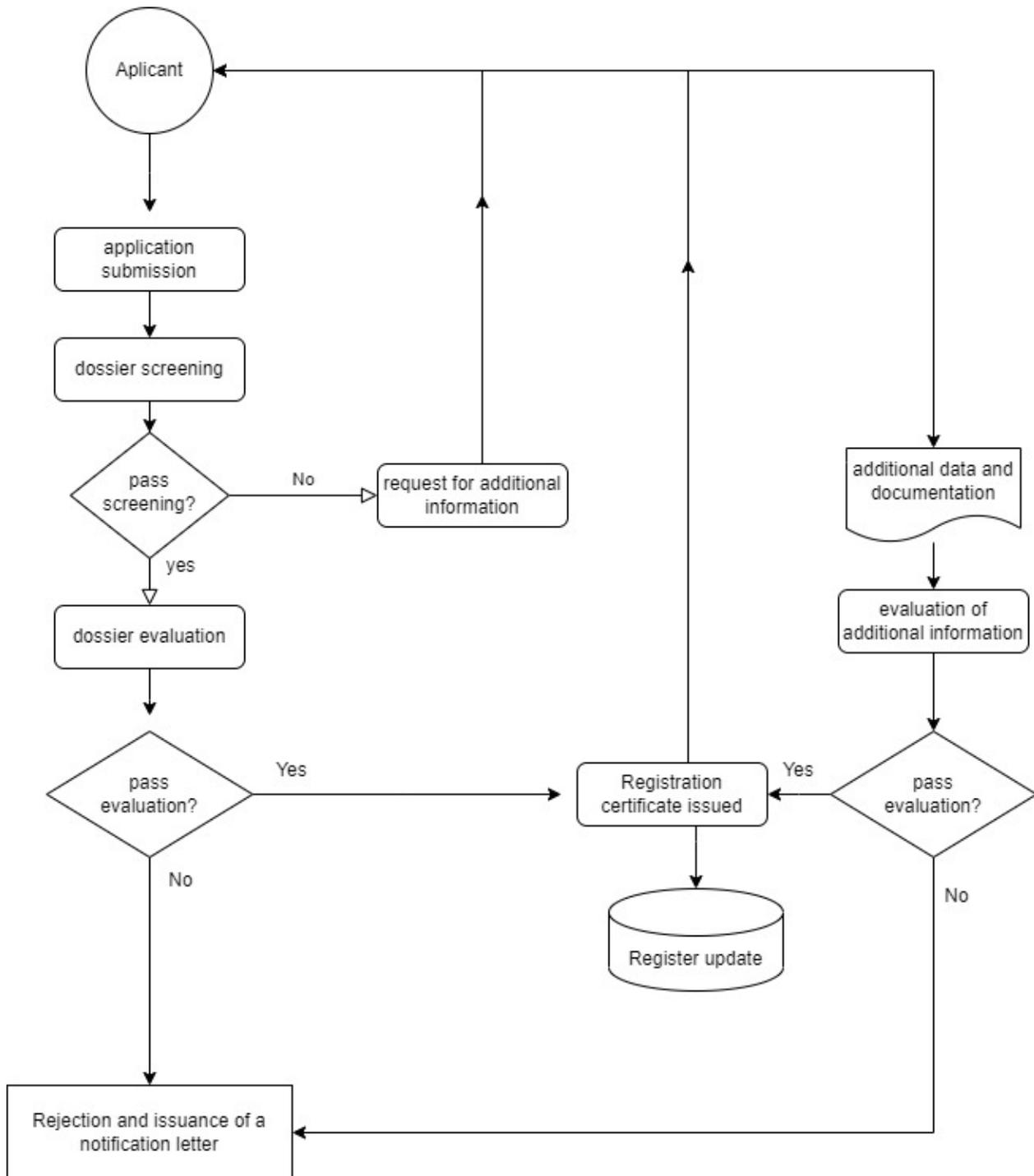
Slimming	<ol style="list-style-type: none">1. CNS Stimulants & Anorectics2. Diuretics3. Laxatives & Purgatives (including Sennosides)4. Lipid Absorption Inhibitors5. Thyroid Agents6. Thyroid Extracts
----------	---

6. Requirements for test report

- a) Physical tests, heavy metals, microbiological testing, Active ingredients, and adulterant testing should be conducted on finished products. Product specification sheet or certificate of analysis on raw materials or intermediates may not be used to replace testing on the finished products.
- b) The test report should minimally contain the following information:
 - i. Date of report
 - ii. Brand name (if applicable) and product name
 - iii. Batch number
 - iv. Name of substance(s) tested
 - v. Reference(s) to the relevant specifications and testing procedures
 - vi. Test result(s), including limit(s) of detection*
 - vii. Name and signature of analyst

*Test results should be reported quantitatively (e.g., Arsenic 0.05ppm). For test result that is reported as not detected or ND, the limit of detection must be stated on the test.

APPENDIX III: Process flow chart for evaluation of food supplements and health foods



APPENDIX IV: Variations of Food Supplement and Health Food Registration, Requirements and administrative handling

Minor variation of a registered 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
3	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 mock-up label	Cancellation of the existing certificate and issuance of a revised version
4	Change of LTR	None	Letter of the appointment of the new LTR by the MAH	Revised product registration certificate
5	Change in packaging size	The rest of label information remain unchanged	New label or mock up label	Additional product registration certificate
6	Change in packaging colour	all the other information on the certificate remain unchanged	1. Notification of change 2. Photograph of the new packaging material 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.

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 mock-up label; 4. Samples.	Cancellation of the existing certificate and issuance of a revised version.

Guidelines for registration of food supplements

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 mock up 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 mock-up label,	Revised product registration certificate
7	Change in storage conditions	None	1. Stability study 2. New mock-up label	Revised product registration certificate
8	Change in standard	None	1. Test report if there is change in safety and quality requirements, 2. Samples change in safety and quality requirements, 3. Label or mock up when applicable.	Notification letter of variation approval or updated certificate depending on changes
9	Change in additives	The additives remain compliant with applicable regulatory requirements	1. Test reports, 2. Sample, 3. Label or mock up label	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 evidences supporting the change, 2. New label or mock up label, 3. Samples	Notification letter of variation approval.
11	Additional brand name	Requires a new application		

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
*When the trademark holder has changed

FOR PUBLIC REVIEW

ANNEX I: Vitamins, minerals permitted for use in food supplements

Table 1: List of Vitamin and Mineral substances which may be used in the manufacture of food supplements

Vitamins	Unit of measurement	Minirals	Unit of measurement
Vitamin A	µg RE	Calcium	mg
Vitamin D	µg	Magnesium	mg
Vitamin E	mg α-TE	Iron	mg
Vitamin K	µg	Copper	µg
Vitamin B1 (Thiamine)	mg	Iodine	µg
Vitamin B2 (Riboflavin)	mg	Zinc	mg
Vitamin B 3 (Niacin)	mg NE	Manganese	mg
Pantothenic Acid	mg	Sodium	mg
Vitamin B6 (Pyridoxine)	mg	Potassium	mg
Folic Acid	µg	Selenium	µg
Vitamin B12 (Cobalamine)	µg	Chromium	µg
Biotin	µg	Molybdenum	µg
Vitamin C	mg	Fluoride	mg
		Chloride	mg
		Phosphorus	mg
		Boron	mg
		Silicon	mg

Table 2: Sources of vitamins permitted for use in food supplements

	Vitamin	Source
1	Vitamin A	(a) Retinol (b) Retinyl acetate (c) Retinylpalmitate (d) Beta-carotene
2	Vitamin D	(a) Cholecalciferol (b) Ergocalciferol
3	Vitamin E	(a) D-alpha-tocopherol (b) DL-alpha-tocopherol (c) D-alpha-tocopheryl acetate (d) DL-alpha-tocopheryl acetate (e) D-alpha-tocopheryl acid succinate (e) Mixed tocopherols ¹

¹ A4lpha-tocopherol <20%, Beta-tocopherol <10%, Gamma-tocopherol 50 – 70% and Delta-tocopherol 10 - 30%
Doc. No.: FD/FRIC/GDL/002 Version 2

Guidelines for registration of food supplements

		(f) Tocotrienol tocopherol ²
4	Vitamin K	(a) Phylloquinone (phytomenadione) (b) Menaquinone ³
5	Vitamin B1 (Thiamine)	(a) Thiamin hydrochloride (b) Thiamin mononitrate (c) Thiamine monophosphate chloride (d) Thiamine pyrophosphate chloride
6	Vitamin B2 (Riboflavin)	(a) Riboflavin (b) Riboflavin 5'-phosphate, sodium
7	Vitamin B 3 (Niacin)	(a) Nicotinic acid (b) Nicotinamide (c) Inositol hexanicotinate (inositol hexaniacinate)
8	Pantothenic Acid	(a) D-pantothenate, calcium (b) D-pantothenate, sodium (c) Dexpanthenol (d) Pantethine
9	Vitamin B6 (Pyridoxine)	(a) Pyridoxine hydrochloride (b) Pyridoxine 5'-phosphate (c) Pyridoxal 5'-phosphate
10	Folic Acid	(a) Pteroylmonoglutamic acid (c) Calcium-L-methylfolate
11	Vitamin B12 (Cobalamine)	(a) Cyanocobalamin (b) Hydroxocobalamin (c) 5'-deoxyadenosylcobalamin (d) Methylcobalamin
12	Biotin	(a) D-biotin
13	Vitamin C	(a) L-ascorbic acid (b) sodium-L-ascorbate (c) calcium-L-ascorbate (d) potassium-L-ascorbate (e) L-ascorbyl 6-palmitate (f) Magnesium L-ascorbate (g) Zinc L-ascorbate

² Typical levels of individual tocopherols and tocotrienols: 115 mg/g alpha-tocopherol (101 mg/g minimum); 5 mg/g beta-tocopherol (<1mg/g minimum); 45 mg/g gamma-tocopherol (25 mg/g minimum); 12 mg/g delta-tocopherol (3 mg/g minimum); 67 mg/g alpha-tocotrienol (30 mg/g minimum); (<1mg/g beta-tocotrienol (<1mg/g minimum); 82 mg/g gamma-tocotrienol (45 mg/g minimum); 5 mg/g delta-tocotrienol (<1mg/g minimum).

³ Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

Table 3: Sources of minerals permitted for use in food supplements

	Mineral	Source
1	Calcium	Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide Calcium oxide Calcium L-pidolate calcium L-threonate calcium sulphate
2	Magnesium	Magnesium acetate Magnesium carbonate Magnesium chloride Magnesium salts of citric acid Magnesium gluconate Magnesium glycerophosphate Magnesium salts of orthophosphoric acid Magnesium lactate Magnesium hydroxide Magnesium oxide Magnesium sulphate Magnesium taurate Magnesium acetyl taurate
3	Iron	Ferrous carbonate Ferrous citrate Ferric ammonium citrate Ferrous gluconate Ferrous fumarate Ferric sodium diphosphate Ferrous lactate Ferrous sulphate Ferric diphosphate (ferric pyrophosphate) Ferric saccharate Elemental iron (carbonyl+electrolytic+hydrogen reduced) Ferrous bisglycinate Ferrous L-pidolate Ferrous phosphate Ferrous ammonium phosphate ferric sodium EDTA Iron (II) taurate

Guidelines for registration of food supplements

4	Copper	Cupric carbonate Cupric citrate Cupric gluconate Cupric sulphate Copper L-aspartate Copper bisglycinate Copper lysine complex Copper (II) oxide
5	Iodine	Sodium iodide Sodium iodate Potassium iodide Potassium iodate
6	Zinc	Zinc acetate Zinc L-ascorbate Zinc L-aspartate Zinc bisglycinate Zinc chloride Zinc citrate Zinc gluconate Zinc lactate Zinc L-lysinate Zinc malate Zinc mono-L-methionine sulphate Zinc oxide Zinc carbonate Zinc L-pidolate Zinc picolinate Zinc sulphate
7	Manganese	Manganese ascorbate Manganese L-aspartate Manganese bisglycinate Manganese carbonate Manganese chloride Manganese citrate Manganese gluconate Manganese glycerophosphate Manganese pidolate Manganese sulphate
8		Sodium bicarbonate Sodium carbonate Sodium chloride Sodium citrate Sodium gluconate Sodium lactate Sodium hydroxide

Guidelines for registration of food supplements

		Sodium salts of orthophosphoric acid Sodium sulphate
9	Potassium	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium citrate Potassium gluconate Potassium glycerophosphate Potassium lactate Potassium hydroxide Potassium L-pidolate Potassium malate Potassium salts of orthophosphoric acid Potassium sulphate
10	Sodium	Sodium selenate Sodium hydrogen selenite Sodium selenite L-selenomethionine Selenium enriched yeast ⁴ Selenious acid
11	Chromium	Chromium (III) chloride Chromium (III) sulphate Chromium (III) lactate trihydrate Chromium nitrate Chromium picolinate
12	Molybdenum	Ammonium molybdate (molybdenum (VI)) Sodium molybdate (molybdenum (VI)) Potassium molybdate (molybdenum (VI))
13	Fluoride	Calcium fluoride Potassium fluoride Sodium fluoride Sodium monofluorophosphate
14	Boron	Boric acid Sodium borate
15	Silicon	Choline-stabilised orthosilicic acid Silicon dioxide Silicic acid ⁵

⁴ Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2.5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85% of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10% of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1% of total extracted selenium.

⁵ In the form of gel.

ANNEX II: Tolerable Upper Intake Levels of Vitamins and minerals

Table 1: Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels (UL^a), Vitamins

Life Stage Group	Vitamin A (µg/d) ^a	Vitamin C (mg/d)	Vitamin D (µg/d)	Vitamin E (mg/d) ^{b,c}	Vitamin K	Thiamin	Riboflavin	Niacin (mg/d) ^d	Vitamin B ₆ (mg/d)	Folate (µg/d) ^e	Vitamin B12	Pantothenic Acid	Biotin	Choline (g/d)	Carotenoids ^d
Infants															
0 to 6 mo	600	ND ^e	25	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
6 to 12 mo	600	ND	38	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Children															
1–3 y	600	400	63	200	ND	ND	ND	10	30	300	ND	ND	ND	1.0	ND
4–8 y	900	650	75	300	ND	ND	ND	15	40	400	ND	ND	ND	1.0	ND
Males															
9–13 y	1,700	1,200	100	600	ND	ND	ND	20	60	600	ND	ND	ND	2.0	ND
14–18 y	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19–30 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
31–50 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
51–70 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
> 70 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
Females															
9–13 y	1,700	1,200	100	600	ND	ND	ND	20	60	600	ND	ND	ND	2.0	ND
14–18 y	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19–30 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
31–50 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
51–70 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
> 70 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
Pregnancy															
14–18 y	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19–30 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
31–50 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
Lactation															
14–18 y	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19–30 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
31–50 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND

NOTE: A Tolerable Upper Intake Level (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. Unless otherwise specified, the UL represents total intake from food, water, and supplements. ND means Not Determined due to lack of suitable data. In the absence of a UL, extra caution may be warranted in consuming levels above recommended intakes. The UL is not meant to apply to individuals who are treated with the nutrient under medical supervision or to individuals with predisposing conditions that modify their sensitivity to the nutrient.

^aAs preformed vitamin A only.

^bAs α-tocopherol; applies to any form of supplemental α-tocopherol.

^cThe ULs for vitamin E, niacin, and folate apply to synthetic forms obtained from supplements, fortified foods, or a combination of the two.

^dβ-Carotene supplements are advised only to serve as a provitamin A source for individuals at risk of vitamin A deficiency.

^eND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

Table 2: Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels, Elements

Life Stage Group	Arsenic ^a	Boron (mg/d)	Calcium (mg/d)	Chromium	Copper (µg/d)	Fluoride (mg/d)	Iodine (µg/d)	Iron (mg/d)	Magnesium (mg/d) ^b	Manganese (mg/d)	Molybdenum (µg/d)	Nickel (mg/d)	Phosphorus (g/d)	Selenium (µg/d)	Silicon ^c	Vanadium (mg/d) ^d	Zinc (mg/d)	Sodium (g/d)	Chloride (g/d)
Infants																			
0 to 6 mo	ND ^e	ND	1,000	ND	ND	0.7	ND	40	ND	ND	ND	ND	ND	45	ND	ND	4	ND	ND
6 to 12 mo	ND	ND	1,500	ND	ND	0.9	ND	40	ND	ND	ND	ND	ND	60	ND	ND	5	ND	ND
Children																			
1-3 y	ND	3	2,500	ND	1,000	1.3	200	40	65	2	300	0.2	3	90	ND	ND	7	1.5	2.3
4-8 y	ND	6	2,500	ND	3,000	2.2	300	40	110	3	600	0.3	3	150	ND	ND	12	1.9	2.9
Males																			
9-13 y	ND	11	3,000	ND	5,000	10	600	40	350	6	1,100	0.6	4	280	ND	ND	23	2.2	3.4
14-18 y	ND	17	3,000	ND	8,000	10	900	45	350	9	1,700	1.0	4	400	ND	ND	34	2.3	3.6
19-30 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40	2.3	3.6
31-50 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40	2.3	3.6
51-70 y	ND	20	2,000	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40	2.3	3.6
> 70 y	ND	20	2,000	ND	10,000	10	1,100	45	350	11	2,000	1.0	3	400	ND	1.8	40	2.3	3.6
Females																			
9-13 y	ND	11	3,000	ND	5,000	10	600	40	350	6	1,100	0.6	4	280	ND	ND	23	2.2	3.4
14-18 y	ND	17	3,000	ND	8,000	10	900	45	350	9	1,700	1.0	4	400	ND	ND	34	2.3	3.6
19-30 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40	2.3	3.6
31-50 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40	2.3	3.6
51-70 y	ND	20	2,000	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40	2.3	3.6
> 70 y	ND	20	2,000	ND	10,000	10	1,100	45	350	11	2,000	1.0	3	400	ND	1.8	40	2.3	3.6
Pregnancy																			
14-18 y	ND	17	3,000	ND	8,000	10	900	45	350	9	1,700	1.0	3.5	400	ND	ND	34	2.3	3.6
19-30 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	3.5	400	ND	ND	40	2.3	3.6
61-50 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	3.5	400	ND	ND	40	2.3	3.6
Lactation																			
14-18 y	ND	17	3,000	ND	8,000	10	900	45	350	9	1,700	1.0	4	400	ND	ND	34	2.3	3.6
19-30 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	ND	40	2.3	3.6
31-50 y	ND	20	2,500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	ND	40	2.3	3.6

NOTE: A Tolerable Upper Intake Level (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. Unless otherwise specified, the UL represents total intake from food, water, and supplements. In the absence of a UL, extra caution may be warranted in consuming levels above recommended intakes. Members of the general population should be advised not to routinely exceed the UL. The UL is not meant to apply to individuals who are treated with the nutrient under medical supervision or to individuals with predisposing conditions that modify their sensitivity to the nutrient.

^aAlthough the UL was not determined for arsenic, there is no justification for adding arsenic to food or supplements.

^bThe ULs for magnesium represent intake from a pharmacological agent only and do not include intake from food and water.

^cAlthough silicon has not been shown to cause adverse effects in humans, there is no justification for adding silicon to supplements.

^dAlthough vanadium in food has not been shown to cause adverse effects in humans, there is no justification for adding vanadium to food and vanadium supplements should be used with caution. The UL is based on adverse effects in laboratory animals and this data could be used to set a UL for adults but not children and adolescents.

^eND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.