



Regulations N° CBD/TRG/003 Rev. N° 1 governing Food Fortification in
Rwanda

The Republic of Rwanda



**REGULATIONS N° CBD/TRG/003 Rev. N° 1 GOVERNING
FOOD FORTIFICATION IN RWANDA**
(Rwanda FDA law N°. 003/2018 of 09/02/2019, Article 8)

Rwanda Food and Drugs Authority

P.O. Box 84 Kigali



Regulations N° CBD/TRG/003 Rev. N° 1 governing Food Fortification in
Rwanda


TABLE OF CONTENTS.....	i
ADOPTION AND APPROVAL OF THE REGULATIONS	ii
CHAPTER I: GENERAL PROVISIONS.....	1
Article 1: Purpose of these regulations	1
Article 2: Citation and Commencement.....	1
Article 3: Application.....	1
Article 4: Interpretation.....	1
Article 5: Mandatory food fortification and standards.....	3
Article 6: Restriction on manufacture and sale of unfortified food	4
Article 7: Exemption of fortification.....	4
Article 8: Voluntary food fortification.....	4
CHAPTER 2: DUTIES AND RESPONSIBILITIES	5
Article 9: Manufacturer of fortified food products	5
Article 10: Representatives of food products.....	6
Article 11: The Authority	6
Article 12: Institution in charge of nutrition	7
Article 13: Institution in charge of setting standards	7
CHAPTER 3: NON-COMPLIANCE AND SPECIFIC DIRECTIVES	8
Article 14: Quality assurance and logo	8
Article 15: Use of food fortification logo.....	8
Article 16: Non-compliance with food fortification process	8
Article 17: Administrative sanctions.....	8
Article 18: Decision on food seized.....	9
Article 19: Marketing of fortified products.....	9
Article 20: Labelling	9
Article 21: Repealing provision	9



Regulations N° CBD/TRG/003 Rev. N° 1 governing Food Fortification in
Rwanda

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon the Board of Directors of Rwanda Food and Drugs Authority by Article N°9 of the Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning, in its meeting resolutions of 8th August 2019 delegating power to the management of the authority, hereby ADOPTS and ISSUES these regulations N° CBD/TRG/003 Rev. N° 1, related to food fortification in Rwanda, made this 14th day of January, 2020.


.....

Dr. Charles KARANGWA
Acting Director General
Rwanda Food and Drugs Authority



CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these regulations

The purpose of these regulations is to provide a legal framework for the effective and efficient fortification of salt, wheat flour, Milled Maize (Corn) Products, edible oil and fats, sugar, processed cereal based food for older infants and young children, and processed cereal based food for old children and adults in Rwanda.

Article 2: Citation and Commencement

These regulations may be cited as the *“Regulations N° CBD/TRG/003 Rev. N° 1, Governing fortification of food in Rwanda”* and shall come into operation on the date of publication.

Article 3: Application

These regulations applies to food fortification of selected food vehicles manufactured, distributed, packaged, labeled, stored, transported, imported, displayed for sale, and sold in Rwanda that must be fortified. These regulations shall not apply to any unprocessed food.

Article 4: Interpretation

In these regulations, unless the context otherwise requires-

“**Authorized officer**” means any officer appointed by the Authority to carry out duties under the provisions of these regulations;

“**Authority**” means the Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under Article 2 of the Law “**Law N° 003/2018**” means Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning; “**Law N° 47/2012**” means Law N° 47/2012 of 14/01/2013 relating to the regulations and inspection of food and pharmaceutical products;

“**Institution in charge of standards**” means the government agency responsible for defining and publishing product, process and service standards;

“**Institution in charge of nutrition**” means the government agency responsible for policy and coordination of actions related to nutrition of the whole population;



Regulations N° CBD/TRG/003 Rev. N° 1 governing Food Fortification in
Rwanda

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

“**Manufacturer**” means a person engaged in preparation, processing, fortification, compounding, formulating, filling, refining, transformation, packing, packaging, or re-packaging of food;

“**Edible oil**” means edible vegetable oils, fats or animal fat for sale for human consumption;

“**Food**” means an article other than drugs, cosmetics and tobacco used as food or drink for human consumption and includes any substance used in the manufacture or treatment of food;

“**Food fortification**” means the practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health (WHO, *Guidelines on food fortification with micronutrients*);

“**Food vehicle**” means any food product, such as flours and other staple foods, selected for fortification by the institution in charge of food administration;

“**Fortified food**” means food into which one or more micronutrient(s) have been added in accordance with these regulations;

“**Micronutrients**” means a natural or synthesized vitamin, mineral, or trace element that is essential for normal growth, development and maintenance of health;

“**Nutrient**” means any chemical substance needed by the body to provide heat or energy, to build and repair tissues, and to regulate life processes which are found chiefly in foods or synthesized in the laboratory like vitamin and mineral supplements or in the body through biosynthesis;



“**Nutrition facts**” means a statement or information on food labels indicating the nutrient and the quantity of said nutrient found or added in the processed foods and food products;

“**Premix**” means a mixture of a micronutrient(s) and another ingredient, often the same food that is to be fortified, that is added to the food vehicle to improve the distribution of the micronutrient mix within the food matrix and to reduce the separation (segregation) between the food and micronutrient particles (WHO, *Guidelines on food fortification with micronutrients*);

“**Processed foods or food products**” means food that has been subjected to some degree of processing like milling, drying, concentrating, canning, or addition of some ingredients which changes partially or completely the physico-chemical and or sensory characteristics of the food’s raw material;

“**Representative**” means any importer, distributor, wholesaler or aggregator that distributes (but does not manufacture) imported food products covered by the food fortification regulation in Rwanda;

“**Sale or sell**” means sell by wholesale or retail and include import, offer, donate, advertise, keep, expose, display, transmit, consign, convey or deliver for sale, authorize, or direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange supply or dispose of, to any person whether for a consideration or otherwise;

“**Unprocessed food**” means food that has not undergone any treatment that results in substantial change in the original state even if it may have been divided, deboned, skinned, peeled, ground, cut, cleaned, trimmed, fresh-frozen or chilled.

Article 5: Mandatory food fortification and standards

The fortification of the following food vehicles is hereby made mandatory: salt, wheat flour, milled maize (corn) products, edible oils and fats, and sugar. In addition, the fortification of complementary foods and maternal supplements is likewise hereby made mandatory. Such fortification shall conform to the relevant standards set by the institution in charge of standards, namely:

1. RS EAS 35 – Fortified Salt-Specification
2. RS EAS 767 – Fortified Wheat Flour-Specification
3. RS EAS 768 – Fortified Milled Maize (Corn) Products-Specification



Regulations N° CBD/TRG/003 Rev. N° 1 governing Food Fortification in
Rwanda

4. RS EAS 769 – Fortified Edible Oils and Fats
5. RS EAS 770 – Fortified Sugar-Specification
6. RS 339 – Fortified Processed Cereal Based Foods (FPCBF) For older infants and young children – Specification
7. RS 348 – Fortified Processed Cereal Based Foods (FPCBF) For old children and adults – Specification

The Authority shall, at its discretion, establish criteria and timelines for the enforcement of the fortification mandate, considering factors including but not limited to time required for industry adjustments, and manufacturer production volume and revenue.

The Authority may require other food products to be fortified based on recommendations from the institution in charge of nutrition. Such requirements and the corresponding standards shall be incorporated into these regulations.

Article 6: Restriction on manufacture and sale of unfortified food

No person or entity shall be authorized to manufacture, import or expose for sale any food regulated under these regulations unless that food meets the minimum requirements for fortified food as prescribed in the existing national standards.

Article 7: Exemption of fortification

The Authority, after being satisfied that there is an emergency or food shortage, the food products required by these regulations to be fortified may be allowed to be availed in their original state. The Authority shall authorize their manufacturing and distribution in Rwanda. Such food products shall be labeled, stored, distributed, transported and made available for sale only at specified locations and under conditions prescribed by the Authority. In addition, such food products shall abide by all food regulations and laws in force in Rwanda.

Article 8: Voluntary food fortification

Manufacturers who opt to fortify other food vehicles that are not part of the mandatory food vehicles to be fortified shall do so based on the respective national standards.



CHAPTER 2: DUTIES AND RESPONSIBILITIES

The following duties, responsibilities and attributions shall apply to each of the parties involved with food fortification-

Article 9: Manufacturer of fortified food products

- (1) Undertake the fortification of food products for which fortification is mandatory in accordance with these regulations.
- (2) Include, on the label, information that indicates the nutrients and their quantities added in the food, as specified by the relevant standard.
- (3) Conduct internal checks to ensure that the food is manufactured, packaged, labeled, stored, transported and maintained in accordance with national standards.
- (4) Follow the applicable national standards when opting to fortify other food products that are not part of the mandatory food vehicles to be fortified.
- (5) Report quarterly on the production and distribution of fortified food products to the Authority.
- (6) Apply for the food fortification logo according to the requirements described in the logo guidelines.
- (7) Cooperate with the Authority and its authorized officers in their respective duties of monitoring and inspecting premises and products for compliance with this and other relevant regulations.
- (8) In case of Safety and Quality assurance:
 - In the manufacture of fortified food, manufacturer shall use fortificants or premix that comply with the national standards or and international standards for such fortificant or premix or as may be approved by the Authority from time to time.
 - Every manufacturer of a fortified food shall develop, maintain and routinely follow procedures for safety and quality assurance throughout the manufacturing processes to ensure that the final product complies with these regulations and any other regulations made under the Law N° 47/2012 and 003/2018.



Article 10: Representatives of food products

Representatives of food products shall ensure that imported food products comply with the requirements of these regulations and relevant national standards upon entry in the country.

Article 11: The Authority

- (1) May require other food products to be fortified based on recommendations from the institution in charge of nutrition.
- (2) Shall establish a quality assurance system for food fortification.
- (3) Shall monitor and ensure that food products required to be fortified are properly fortified and labeled with information that indicates the specific micronutrients they were fortified with.
- (4) Shall impose, after notice and hearing, administrative sanctions when there is non-compliance with any provisions regulating food fortification.
- (5) Shall administer the food fortification Logo.
- (6) Shall inspect periodically, premises and operations of all licenses after initial fortification, and license renewal for fortification.
- (7) Shall conduct inspections and investigations at any premises where food is received, held, manufactured, packaged, labeled, stored, displayed, distributed, or sold by any person, whether or not that person is required to hold a license, whenever there is a reasonable basis to question compliance with regulatory requirements of activities, operations, or of food fortification therein.
- (8) May take samples of any food or premix and analyze them or have them analyzed for compliance with standards.
- (9) May examine and make copies of or from any books, documents, notes, or other records the authorized officer reasonably believes might contain information relevant to determining compliance with regulatory requirements.
- (10) May interview or question any licensee, owner of the premises, or any person using premises, and their employees, agents, contractors and workers, all of whom shall cooperate fully and truthfully with any inspection or investigation.
- (11) May stop, search and detain any aircraft, ship, vehicle or other means of transport or storage in which the authorized officer reasonably believes food is contained or



conveyed and examine, open, take samples and analyze or have analyzed any food or materials found therein.

- (12) May seize and detain any food the authorized officer reasonably believes does not comply with regulatory requirements, upon providing the licensee or owner of the food, or if they are unavailable, any other person on the premises where the food is located, written notice of seizure and detention and the grounds thereof.

Article 12: Institution in charge of nutrition

Provides recommendations to the Authority on other food products, currently not covered by these regulations, to be fortified, as well as on the micronutrients and their respective levels in the fortified food products.

Article 13: Institution in charge of setting standards

Set standards for food products to be fortified and premixes, based on guidance from the institution in charge of nutrition and the Authority.



CHAPTER 3: NON-COMPLIANCE AND SPECIFIC DIRECTIVES

Article 14: Quality assurance and logo

The Authority, shall establish a quality assurance system for food fortification. As part of this system, the right to use a fortified food logo on fortified food products will be granted to companies successfully abiding by the guidelines and processes related to fortification.

Article 15: Use of food fortification logo

- (1) No person or entity shall use the food fortification logo for labeling of fortified food unless that food is registered and licensed by the Authority to be fortified.
- (2) The Authority may suspend or revoke the right to use the food fortification logo upon satisfaction that the requirements for manufacture of fortified food using the applicable checklist in use at that particular time are not complied with.

Article 16: Non-compliance with food fortification process

A food product shall be considered as non-compliant with the fortification process and not be allowed to be put in the market if-

- (1) The product does not comply with these regulations or the relevant national standards;
- (2) The premix used is different from those approved by the Authority;
- (3) The process of fortification does not conform to these regulations.

Article 17: Administrative sanctions

Without prejudice to criminal and civil provisions, the Authority, after notice and hearing, shall impose any or all of the following administrative sanctions when there is non-compliance with any provisions regulating food fortification-

- (1) Denial of registration of the food products by the Authority, with such food products not being allowed to be put on the market;
- (2) Order the recall of the food products;
- (3) Cease and desist orders;
- (4) License and or registration restrictions;
- (5) Suspension or revocation;
- (6) Adverse publicity;



- (7) Order to reprocess or recondition the food products;
- (8) Seizure and destruction of food products determined not to be in compliance with legal requirements;
- (9) Order the representative to re-export or destroy the food products that are imported at the representative's expense;
- (10) Monetary fines.

Article 18: Decision on food seized

If any food seized and detained in accordance with the provisions of Article 12, item 12 is determined to meet regulatory requirements, the food shall be returned immediately to the premises of seizure.

If any food is determined not to meet regulatory requirements, the food shall be destroyed, re-exported or otherwise disposed of at the expense of the manufacturer or representative in accordance to the provisions of these regulations.

Article 19: Marketing of fortified products

All food products fortified in accordance with these regulations are entitled to label and marketing claims about their fortification and the added micronutrients they contain. The marketing, promoting and advertising shall be made according to regulations in force.

Article 20: Labelling

In addition to the labeling requirements set by food labeling regulations, fortified food shall be conspicuously labeled including the following;

- (1) The labelling of fortified foods shall be made in accordance with the relevant standards
- (2) The label for fortified food shall bear food fortification logo as prescribed in the logo guidelines.

Article 21: Repealing provision

All prior provisions contrary to these regulations are hereby repealed.