



RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING FOOD FORTIFICATION
(Rwanda FDA Law N° 003/2018 of 09/02/2018, Article 9)

REGULATION DEVELOPMENT HISTORY

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Document Revision History

Revision number	Changes made and/or reasons for revision
0	First issue
1	<ol style="list-style-type: none">1. The regulations No CBD/TRG/003 Rev No 1 were revised to revoke provisions of mandatory food fortification and make fortification a voluntary measure for business operators.2. A new provision was introduced to prohibit the fortification of alcoholic drinks and Energy drinks.

FOR PUBLIC REVIEW

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations No.: FD/FRIC/TRG/001 Version 2 governing food fortification on this/...../2025

Prof. Emile BIENVENU

Director General

FOR PUBLIC REVIEW

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CHAPTER I: GENERAL PROVISIONS

Article One: Purpose of these Regulations

The purpose of these regulations is to provide a legal framework for the effective and efficient fortification of all fortified foods manufactured, imported, exported, distributed, advertised, and sold in Rwanda.

Article 2: Citation

These regulations may be cited as the “Regulations N° CBD/TRG/003 Rev. N° 0, Governing fortification of food in Rwanda” and shall come into operation on the date of publication.

Article 3: Scope

These regulations apply to food fortification of processed food products manufactured, distributed, stored, transported, imported, and sold in Rwanda.

These regulations do not apply to infant formula, Food for Special Dietary Uses (FSDUs), dietary supplements, energy drinks, alcoholic drinks and the Bio-fortification process.

Article 4: Definitions

“**Authority**” means the Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established by Law N° 003/2018 of 09/02/2018.

“**Essential nutrient**” means any substance normally consumed as a constituent of food which is needed for growth and development and/ or the maintenance of life and which cannot be synthesized in adequate amounts by the body.

“**Food fortificant**” means a substance, in a chemical or a natural form, added to food to increase its nutritive value.

“**Fortification**” means deliberately increasing the content of essential micronutrients in food to improve the nutritional quality of food and to provide public health benefits with minimal risk to health.

“**Fortified food**” means food that underwent the fortification process as per the regulations N° CBD/TRG/003 Rev. N° 0, Governing fortification of food in Rwanda.

“**Food vehicle**” refers to the specific food product that is selected to have nutrients added to it. These vehicles are chosen because they are widely consumed and can be easily and effectively fortified.

“**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.

“**Manufacturer**” means a company that carries out at least one step of manufacturing process excluding re-packaging, re-labeling and any other step that would be determined by the Authority.

“**Micronutrient**” means essential dietary nutrients including vitamins, minerals or trace elements that are required in very small quantities and are vital to the development, disease prevention and well-being of human beings.

“**Nutrient**” means any substance normally consumed as a constituent of food:

- (a) which provides energy; or
- (b) which is needed for growth, development and maintenance of life; or
- (c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

“**Nutrition Claim**” means any representation which states, suggests, or implies that a food has nutritional properties which are not limited to the energy value but include protein, fat, carbohydrates, vitamins and minerals.

“**Premix**” means a blend of fortificants and diluents formulated to provide specified and determinable amounts of micronutrients.

“**Processed food**” means all foods, including beverages, that are not consumed fresh, but are altered through processes that go beyond minimal procedures such as washing, peeling and removal of non-edible parts, cutting, squeezing, mixing or refrigeration.

In these Regulations, the following verbal forms are used:

- “**Shall**” indicates a requirement;
- “**Should**” indicates a recommendation;
- “**May**” indicates a permission; and
- “**Can**” indicates a possibility or a capability.

CHAPTER II: FOOD FORTIFICATION

Article 5: Voluntary food fortification

Vitamins and minerals in a form that is bio-available to the human body may be added to foods, whether or not they are usually contained therein, in order to take into account, in particular:

- (a) A deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients; or
- (b) The potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits; or

- (c) Evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

Article 6: Mandatory salt fortification and standards

The fortification of salt is hereby made mandatory. Such fortification shall conform to the relevant standards set by the institution in charge of standards, namely: RS EAS 35- Fortified salt-Specifications.

Article 7: Obligations to Food Business Operators

- (a) Manufacturers of fortified food products shall do so based on relevant product standards.
- (b) Every manufacturer of a fortified food shall develop, maintain and routinely follow good manufacturing practices to ensure compliance with relevant food safety and quality regulations.

Article 8: Provisions for forms and amounts of added micronutrients

- (a) Only vitamins and/or minerals listed in Annexes I and II, may be added to foods, subject to the rules laid down in these regulations.
- (b) The purity criteria for vitamin formulations and mineral substances listed in Annexes I and II shall be in accordance with CODEX and other relevant pharmacopeia.
- (c) When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts set in the relevant product standard.
- (d) The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount set in the relevant product standard.
- (e) The added essential nutrient shall be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution, and use.

Article 9: Labelling, presentation and advertisement of fortified food products

- (a) The labelling of products to which vitamins and minerals have been added shall bear a statement indicating such addition, an approved fortification logo may be added.
- (b) The form of the vitamins and minerals uses shall be declared on the list of ingredients.
- (c) The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not mislead or deceive the consumer as to the nutritional merit of a food that may result from the addition of these nutrients. Any form of the advertisement shall be approved by the Authority.
- (d) Nutrition labelling of fortified products shall be compulsory and aligned with relevant nutrition labelling standards.
- (e) The labelling, presentation and advertisement of fortified products shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients.

Article 10: Packaging requirements

All fortified foods shall be packed in a manner that takes into consideration the nature of the fortificant added and their effect on the shelf life of the food i.e. storage temperature, light, moisture content etc.

CHAPTER III: FINAL PROVISIONS

Article 11: Prohibitions and restrictions

Vitamins and minerals may not be added to:

- (a) Beverages containing more than 0.5 % by volume of alcohol
- (b) Energy drinks
- (c) Additional foods or categories of foods to which particular vitamins and minerals may not be added may be determined in the light of scientific evidence and taking into account their nutritional value.

Article 12: Repealing provision

All prior provisions contrary to these regulations are hereby repealed.

ANNEX I: VITAMINS WHICH MAY BE ADDED TO FOODS AND THEIR FORMULATIONS

1. Vitamin formulations

VITAMIN A	Retinol Retinyl acetate Retinyl palmitate
VITAMIN D	Beta-carotene Cholecalciferol Ergocalciferol
VITAMIN E	D-alpha-tocopherol DL-alpha-tocopherol D-alpha-tocopheryl acetate DL-alpha-tocopheryl acetate D-alpha-tocopheryl acid succinate
VITAMIN K	Phylloquinone (phytomenadione)
VITAMIN B1	Thiamin hydrochloride Thiamin mononitrate
VITAMIN B2	Riboflavin Riboflavin 5'-phosphate, sodium
NIACIN	Nicotinic acid Nicotinamide
PANTOTHENIC ACID	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
VITAMIN B6	Pyridoxine hydrochloride Pyridoxine 5'-phosphate Pyridoxine dipalmitate
FOLIC ACID	Pteroylmonoglutamic acid
VITAMIN B12	Cyanocobalamin Hydroxocobalamin
BIOTIN	D-biotin
VITAMIN C	L-ascorbic acid Sodium-L-ascorbate Calcium-L-ascorbate Potassium-L-ascorbate L-ascorbyl 6-palmitate

ANNEX II: MINERALS AND MINERAL SUBSTANCES WHICH MAY BE ADDED TO FOODS

**MINERALS
CALCIUM**

MINERAL SUBSTANCES

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 sulphate

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

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)

COPPER

Cupric carbonate
cupric citrate
cupric gluconate
cupric sulphate
copper lysine complex

IODINE

Sodium iodide
sodium iodate
potassium iodide
potassium iodate

ZINC	Zinc acetate zinc chloride zinc citrate zinc gluconate zinc lactate zinc oxide zinc carbonate zinc sulphate
MANGANESE	Manganese carbonate manganese chloride manganese citrate manganese gluconate manganese glycerophosphate manganese sulphate
SODIUM	Sodium bicarbonate sodium carbonate sodium citrate sodium gluconate sodium lactate sodium hydroxide sodium salts of orthophosphoric acid sodium selenate sodium hydrogen selenite sodium selenite sodium fluoride
POTASSIUM	Potassium fluoride potassium bicarbonate potassium carbonate potassium chloride potassium citrate potassium gluconate potassium glycerophosphate potassium lactate potassium hydroxide potassium salts of orthophosphoric acid
SELENIUM	
CHROMIUM	Chromium (III) chloride and its hexahydrate chromium (III) sulphate and its hexahydrate
MOLYBDENUM	Ammonium molybdate (molybdenum (VI)) sodium molybdate (molybdenum (VI))
FLUORIDE	
CHLORIDE	
PHOSPHORUS	

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