

Ethiopian Food and Drug Authority

Fortified foods and fortificants control directive

October, 2023

Addis Ababa/Ethiopia

**PREAMBLE**

WHEREAS to overcome on the micronutrient deficiencies which affect the public health due to lack of essential vitamins and minerals

WHEREAS to confirm the national standards related to fortified food and fortificants implement in accordance with set standards and requirements

 WHEREAS it is necessary to ensure and adequately regulate the safety and quality of fortified foods and fortificants available in the market

WHEREAS fortified foods and fortificants manufacturers, re-packers, importers, exporters and wholesalers fulfill the required standards set by the Authority

NOW THEREFORE this directive is issued in accordance with Article71 (2) of the Food and Medicine Administration Proclamation 1112/2019.

**PART ONE**

**GENERAL**

## **Short title**

This directive may be cited as **“fortified foods and fortificants Control Directive**” No.--------/2023

## **Definitions**

Not with standing to the interpretation of proclamation1112/2019 unless the context otherwise requires in this directive

1. **”Fortificants”** means a compound which contained specified micronutrients (vitamins and minerals) intended to be added to a food product
2. **``Authority”** means Ethiopian Food and Drug Authority
3. **”Proclamation”** means Food and Drug Administration Proclamation No.1112/2019
4. **”Person”** means a natural and juridical person,
5. **Any** expression in the masculine gender includes the feminine.

## **Scope of Application**

This Directive shall be applicable on all fortified foods and fortificants produced locally and imported to the country.

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| **PART –TWO** **REGISTRATION OF FORTIFIED FOODS AND FORTIFICANTS**General 1. Registration of fortified food or fortificantshall be undertaken in accordance with this directive.
2. It shall be prohibited to manufacture, import, distribute or sale any fortified food or fortificantnot registered.
3. Any fortified foods and fortificantssubmitted for registration shall meet the national Ethiopian standard or in absence of national standards, standards recognized by the Authority.

Administrative documentApplication for registration1. Application for the registration of fortified food and fortificantshall be made through e-RIS system or any other method provide by the Authority.
2. A dully-filled separate registration application shall be required for every fortified food product and fortificant manufactured at different manufacturing sites or with different packaging material.
3. Any fortified food or fortificant shall be registered by the person who owns the products or by any person represented by the owner.
4. An applicant shall submit actual sample of the proposed product for dossier evaluation and laboratory analysis, labeling information, its primary packaging and where applicable, secondary, tertiary packaging materials together with the hard and/or electronic copy of registration file.
5. Unless exempted, commitment letter for onsite inspection of Good Manufacturing Practice (GMP).
6. The Authority may require additional information or samples for clarification during evaluation of the product.
7. Where the applicant fails to submit the information required under sub-article (1) (e) of this article within six months, or the information submitted found unsatisfactory and the same queries have been reissued for the third time the application shall be deemed to be withdrawn.
8. An applicant whose application is considered withdrawn in accordance with sub-article 1 (f) of this article may lodge new registration application.
9. Authenticated representation letter shall be required where the application made through representative. Agency agreement shall be required where the registration application made by a local agent.
10. Where the applicant is a local manufacturer or importer, a valid certificate of competency.
11. Documents required and submitted in accordance with this article shall be in English or Amharic and documents other than English or Amharic shall be presented together with authenticated translation
12. Notwithstanding to sub-article (1) of this article,a fortified foods and fortificantnot registered maybe imported into the country for personal use,sample for scientific research, sample for laboratory test for registration of the product, or for donation.
13. The requirements and manner for importation of fortified food and fortificants for purpose mentioned under sub-article 2 of this article shall be governed by food importation directive.
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| **Required certificates**Applicant shall submit the following valid certificate to acquire market authorization. 1. for local manufacturer or importer, certificate of competency;
2. For imported product dated, original or authenticated copy of,
3. Good Manufacturing Practice (GMP) of the manufacturer, or internationally accepted certification or certificate of food safety management system; and
4. Free sale certificates that contain list of the product and state that the product is sold in the country of origin or third country.
5. Certificate of analysis
6. Certificate that indicate the packaging material is food grade.

**Technical documents**Composition or Formulation, manufacturing and packaging procedure1. Qualitative and quantitative compositions data including names of all ingredients, raw materials, source of ingredients, additive, and its official reference shall accompany registration application.
2. The applicant shall also submit data on manufacturing, packaging and labeling procedure, including:
	1. specifications for all ingredients and packaging materials;
	2. flow chart, flow chart detailed description, critical process steps;
	3. manufacturing procedure including fortificant usage procedure,
	4. in-process quality control procedure and specification;
	5. Final packaging and labeling instruction.

Data on method of analysis and specification of the finished productThe applicant shall provide the following documents along with the registration file:1. Finished product specification as indicated in the standard including nutritional facts, physicochemical, microbiological test, safety parameters, acceptable limits and reference for the parameters,
2. Details of test methodand acceptance criteria;

Stability study report and shelf life assignmentThe applicant shall present relevant stability study protocol, an accelerated and real time stability study report. The report shall indicate:1. Its brand or generic name, if applicable;
2. The test condition shall mimic Ethiopian climatic conditions of zone 4a (30±2ºC/65±5%RH for real time and 40±2ºC/75±5%RH for accelerated stability) for accelerated stability data.
3. Stability study report for at least 6 months of accelerated and 12 months of real time (actual storage condition) and justification for claimed shelf life.
4. Stability study shall be undertaken on minimum of three batch numbers and the batch type of at least two production sizes.
5. Type and chemical nature of the packaging materials within which the study is conducted.
6. Analytical methods that quantitatively measures the characteristic and chemical properties of each ingredients of product.
7. Initial and subsequent results of chemical, physical and microbiological test result. The frequency of testing shall be every 3-month including the initial for the first year and every 6-month for the second year and every year thereafter, until the shelf life is determined.
8. Summary of the study and storage recommendations based on the data generated.

Packaging and labelling requirements for fortified food and fortificant1. The packaging materials shall be food grade, safe, suitable for its intended use, not light transparent, and able to safeguard the product’s hygienic.
2. Presentation and description of fortified food on any label or in any labeling shall not be false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
3. Label shall clearly indicate pack size of unit pack.
4. Label shall be affixed on every primary packaging of any fortified food and fortificant bearing the following information in clearly legible and indelible letters at least in Amharic and/or English language:
5. Name of the product;
6. Name and full address of the manufacturer, including country of origin;
7. list of ingredients;
8. for fortified food, the name and amount of fortificant available
9. Net content by weight for solid products or volume for liquid;
10. Date of manufacture and shelf life, which shall indicate at least the month and year
11. The storage condition and, where appropriate, shelf life of the product before and after opening and its reconstitution;
12. Batch or lot number;
13. National standard mark and fortification logo.And registration number
14. Appropriate instruction for use or preparation for fortified food and fortificant products;
15. Actual sample of the packaging material.

**Onsite inspection and Laboratory Test**After dossier evaluation is completed and found acceptable, the Authority may conduct onsite inspection to evaluate the good manufacturing practice of the manufacturer and laboratory test on sample product.**Issuing Market Authorization**1. The authority shall issue certificate of market authorization where the applicant fulfilled the requirements of dossier evaluation, good manufacturing practice and sample laboratory test in accordance with this directive.
2. Market authorization issued under sub-article 1 of this article shall be valid for five years.

**Market Authorization certificate content**The certificate of market authorization shall have the information in accordance with Annex I of this directive. **Notification of variation**1. Where there is any variation on a registered product after market authorization, the responsible person shall notify the Authority of the variation before marketing the new product with variation.
2. The market authorization holder shall not market the product registered unless approval is given by the authority.
3. For the applicability of this article, ``major variation`` mean a change made on the registered product or manufacturer and that affects the product safety and quality including, but not limited to, change on:
	* 1. manufacturing site;
		2. pack size.
		3. container and closer
		4. ingredient other than main ingredient
		5. shelf life;
		6. production process;
		7. composition;
		8. quality control process or specification, or
4. For the applicability of this article, ``minor variation`` means changes made on registered product or manufacturer and that do not have effect on safety and quality of the registered product, such as change in the logo of the company, change on proprietory or brand name, change in the color, design or layout of the package without changing the content and affecting the legibility of the label, changing the secondary package or correction of statements of the label without any modification to the content of the message
5. **Requirements for major variation**
	* 1. Application for Change of Origin

Where there is change made on the country of origin or the manufacturing site, the market authorization holder shall notify the authority and submit:-1. Good Manufacturing Practice and Free sale certificate as indicated under article 5 of this directive
2. Accelerated stability study data demonstrating compatibility with the previously approved product, and commitment to continue the real time stability study in accordance with article 3 of this directive.
3. Where the shelf life of the product is beyond one year, the results of the on-going stability study should be submitted every 6 month until the final shelf-life is determined.
4. Sample of packaging and labeling.
5. Sample of actual product.
6. Statement confirming that product composition, manufacturing process and quality control standard is not changed and where there is change, the new data on each of these components should be submitted.
	* 1. Change of pack Size

Applications for changes in pack size with no change in package materials or specificationsshould consist of:-1. Samples of the actual product in the new pack size or the additional pack size.* + 1. Application for change in Container-Closure

Where there is a change made to container-closure such as a change from plastic bottle to glass bottle, the market authorization holder shall submit:1. Packaging material specification,
2. A statement from the manufacturer stating the reasons (s) for the change,
3. Accelerated stability data demonstrating compatibility with the previously approved product, and commitment to continue the stability study under normal recommended storage conditions.
4. The results of the on-going stability study should be submitted every 6 month until the final shelf-life is determined.
5. Sample of actual product
	* 1. Change in Ingredient other than main ingredient

Where there is a change made on ingredient other than main ingredients of the products, the market authorization holder shall submit:* + 1. Good manufacturing practice or internationally accepted certification or certificate of food safety management system, and free sale certificate.
		2. Data on composition as indicated under article 3(1) of this directive.
		3. Specification and analytical procedure as indicated under article 3(2)
		4. Accelerated stability data of the product and commitment to continue the stability study under normal recommended storage conditions should be submitted. The results of the on-going stability study should also be submitted every 6 month until the final shelf-life is determined.
		5. Stability data required under this sub-article (d) may waived where the change made doesn`t affect the shelf life of the product and justification with evidence produced.
		6. A statement and justification confirming that the product safety and quality are not affected or certificate of analysis.
		7. Sample of actual product.
		8. Where there is change on main ingredient of the product, the application shall be made as a new product.
		9. Application for change on shelf-life

Where a change made on the shelf-life, the market authorization holder shall submit:* 1. Requirements provided under article 9 sub-article 4 (a)-(h) of this directive (requirement related to shelf life).
	2. A real time stability study data as provided under article of this directive 3(3).
	3. Labeling with current shelf life.
		1. Change in the Production Process

Where a change made on reported production process, the market authorization holder shall submit, * 1. Data on manufacturing and packaging procedure as required under article 7(1) of this directive (flow chart, manufacturing process, in process quality control, critical control point..).
	2. Finished product specification with certificate of analysis
	3. Sample of actual product.
		1. Change on the quality control process or specifications

Where a change is made on the quality control method, both in-process and finished product quality control, the market authorization holder shall submit: * + 1. The new quality specifications and control methods.
		2. Sample of actual product.
1. **Requirement for minor variation**

A market authorization holder shall submit the following to the Authority.1. Confirmation letter that indicates the variation made and the change has no effect on safety and quality of the product.
2. Sample of actual product
3. **Approval of variation**
	* + 1. The Authority shall review variation made and approve where requirements are fulfilled and re-issue market authorization.
			2. The Authority may reject variation made or request further amendment.
4. **Re-registration**
5. The market authorization holder should apply for re-registration within 120 days before the due date.
6. The following requirements shall be fulfilled for re-registration of fortified food and fortificant.
7. Valid, dated, original or authenticated copy of current good manufacturing practice or internationally accepted certification or certificate of food safety management system;
8. Valid, dated, original or authenticated copy of free sale certificates that contain list of the product and state that the product is sold in the country of origin or third country.
9. A confirmatory letter that the method of manufacturing and preparation is not changed.
10. Finished product specification and certificate of analysis conducted by the accredited laboratory.
11. Samples of packaging materials or a statement from the manufacturer confirming that the type of packaging materials and the labels are identical to the one submitted during the time of previous registration.
12. Samples of actual product with method of analysis, where certificate of analysis conducted by the accredited laboratory is not submitted.
13. Unless exempted, onsite good manufacturing practice shall be conducted.
14. Certificate of competency for local manufacturer.
15. Authenticated representation letter shall be required where the application made through representative. Agency agreement shall be required where the registration application made by a local agent.
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| 1. **Certificate of competency**
	1. Certificate of competency shall be required to manufacture, import or wholesale fortified food or fortificant.
	2. Certificate of competency shall be issued and governed for manufacturing, and importing and wholesale fortified food or fortificant in accordance with pre-licensing for food manufacturer directive, and food import and wholesale directive respectively.
2. Market Authorization number
3. The primary package of fortified food and fortificant shall bear the market authorization number given by the authority.
4. Notwithstanding sub-article 1 of this article the market authorization number may place on secondary package where the primary package has no sufficient space and the authority permits.

 **Administrative measure****MISCELLANEOUS**1. **Service fee**

Any person who seeks regulatory service under this directive may be required to pay applicable service fee to the Authority according to the “Rate of Service Fees”set by the regulation. 1. **Inapplicable and repealed laws**

Any directive, which is inconsistent with this directive, shall not be applicable with respect to those matters provided for in this directive. 1. **Effective date**
2. This directive shall enter into force on xxxxxxxx 2023
3. Notwithstanding sub-article (1) of this article, new applicant and those manufacturers who have been operating before the issuance of this directive, need to fulfill the requirement of this Directive from theeffective date of this directive

**HeranGerba****Ethiopian Food and Drug Authority****Director General** |

Annex I

Content of certificate of market Authorization

1. Product name;
2. General appearance of the product;
3. Pack size;
4. Types of packaging material,
5. Ingredient list for chemical product;
6. Shelf life of the product;
7. Name and address of manufacturer;
8. Name and address of agent or importer; (For import product)
9. Name and address of license holder;
10. validity date of the certificate;
11. certificate
12. Type of registration; and
13. Date issue and reference number of the certificate