



**Ethiopian Food, Medicine and Healthcare
Administration and Control Authority**

Food Supplement Directive

March, 2016

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Introduction

WHEREAS, it is necessary to ensure the safety, quality and presentation of food supplements;

WHEREAS, the nutritional intake from a diet may be insufficient and it may be recommended by health professional, consumers may consider their diet supplementation by vitamin, mineral and other forms of food supplements;

WHEREAS, considering the high concentration nature and its corresponding safety implications, it is important to put adequate regulatory mechanisms on food supplements in place;

WHEREAS, it is important that food supplements should pass through a registration process and business operators to have a certificate of competence before placing their products in the market;

NOW, THEREFORE, this directive is issued in accordance with Article 55 (3) of the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009, and Article 98 of the Food, Medicine and Healthcare Administration and Control regulation No. 299/2013.

PART ONE

GENERAL

1. Short title

This directive may be cited as “Food Supplement Directive No333/2020”

2. Definitions

Without prejudice to the definitions provided under Proclamation No. 661/2009, in this directive, unless the context otherwise requires:

- 1) “Food supplement” means a concentrated source of vitamin, mineral, amino acid, or other substance with nutritional or physiological effect, alone or in combination; prepared in dosage form and intended to supplement the normal diet;
- 2) “Health certificate” means a certificate issued by competent organ showing that the product is fit for human consumption or that meets the appropriate standards;
- 3) “Certificate of origin” means a document issued by a competent organ in the country in which the product is manufactured certifying where the product is manufactured;
- 4) "Good Manufacturing Practice (GMP)" means measures or practices undertaken to ensure that the process by which the food supplement manufactured or processed is of good quality and safe;
- 5) “Certificate of competence” means a work license issued for a person to carry out food supplement trade in accordance with this directive;
- 6) “Additives” means a substance, other than a typical ingredient, which is in accordance with appropriate standard or appropriately evaluated for safety and quality and is included in a product for a specific reason including colorant, stabilizer, sweetener, flavor ant, emulsifier, and preservative;
- 7) “Authority” means the Ethiopian Food, Medicine and Healthcare Administration and Control Authority;
- 8) “Free sale certificate” means a confirmatory letter issued by the national competent Authority which indicates the names of the product and explains whether the product is freely sold in country of origin or any other third countries;

- 9) “Ingredient” means any substance which is used in the manufacture or preparation of the food supplement;
- 10) “Label” means any tag, brand, and mark, pictorial or other descriptive matter, written, printed, stenciled, marked embossed or impressed on or attached to a packaging material of the product;
- 11) “Wholesaler” means a person who distributes food supplement in two or more regions.
- 12) “Marketing authorization” means an official confirmatory document issued by the Authority used for the distribution of the product in Ethiopia;
- 13) “Operation” means a business activity that includes import, export, wholesale or distribution of the product;
- 14) “Person” means any physical or juridical person.

3. Scope

This directive shall be applicable on import, export and wholesale of food supplement in Ethiopia.

4. Objectives

The objective of this directive shall be to:

- 1) Protect the public from health risks emerging out of unsafe and poor quality of food supplement; and
- 2) Protect the public from misleading practices in food supplement trade.

PART TWO

REGISTRATION

5. General requirement

In order to introduce food supplement in the Ethiopian market, the Authority shall register it after checking compliance with requirements provided from Article 6 to Article 9.

6. Administrative documents

6.1 Application for registration

- a) A dully-filled separate registration application shall be required for every product type and products with different ingredients or same products manufactured at different manufacturing sites. Application for the registration of products shall be made in accordance with ANNEX-I of this directive.
- b) An applicant shall submit actual sample of the proposed product, the primary and secondary packaging materials and labeling information together with the hard and/or electronic copy of registration file.
- c) The Authority may require additional information or samples for clarification during evaluation of the product.
- d) If the applicant fails to submit written responses for the information required under sub-article (1) (c) of this article within six months, or if the queries have been reissued for the third time and the applicant provided unsatisfactory responses, the application shall be deemed to be withdrawn.
- e) An applicant whose application is considered withdrawn in accordance with sub-article (1) (d) of this article may lodge new registration application.
- f) The entire registration file shall be in English or Amharic. Where original certificate are in other languages, copies shall be presented together with authenticated translation.

6.2 Required certificates

- a) In order to acquire market authorization, an applicant shall submit Good Manufacturing Practice (GMP) and free sale certificates.
- b) In appropriate circumstances, internationally accepted certification or certificate of quality management system may be accepted in lieu of GMP and free sale certificates.
- c) The certificates given by competent authority presented under sub-article (1) of this article shall be dated, valid, and original or copy of the original authenticated by Ethiopian Embassy.
- d) Notwithstanding what is provided under sub-article (1 and 3) of this article, a

free sale certificate given by competent Authority shall be original and authenticated by a Ethiopian Embassy.

- e) A certificate free from BSE/TSE shall be produced, if the raw material is from animal source and contains (gelatin, magnesium stearate, lactose etc).

7. Technical documents

7.1. Formulation and manufacturing and packaging procedure

- a) Qualitative and quantitative compositions data including names of all ingredients, source of ingredients, additive, and its official reference shall accompany registration application.
- b) The applicant shall also submit data on manufacturing, packaging and labeling procedure, including:
 - 1) specifications for all ingredients and packaging materials;
 - 2) flow chart and detailed description of the method of preparation mentioning the quality and quantity of the starting materials used, manufacturing formulae, critical process steps and manufacturing conditions, processing and packaging instructions;
 - 3) in-process quality control procedure and specification at each stage of manufacturing process;
 - 4) sample product completed batch-manufacturing record (BMR); and
 - 5) Final packaging and labeling procedures.

7.2. Data on method of analysis and specification of the finished product

The applicant shall provide the following documents along with the registration file:

- a) Specification of the finished product including test parameter, acceptable limits and reference for the parameters; the specification shall include physicochemical and microbiological test assay of ingredients of concern with safety and quality of the product;
- b) Details of test method including procedures, analytical instruments and acceptance criteria;
- c) Any food product shall be tested for every consignment;
- d) A certificate of analysis performed on the product. The analysis shall be from an

accredited laboratory for at least three batches of consecutive commercial size.

- e) A regulated product quality analysis result shall comply with the Ethiopian standard if any or Codex Alimentarius Standard or other relevant international requirements to be registered and marketed in Ethiopia.

7.3 Stability study report and shelf life assignment

The applicant shall present relevant stability study protocol, an accelerated and real time stability study report. The protocol shall indicate:

- a) Its brand or generic name, if applicable;
- b) The test condition shall mimic Ethiopian climatic conditions of zone 4a ($30\pm 2^{\circ}\text{C}/65\pm 5\%\text{RH}$ for real time and $40\pm 2^{\circ}\text{C}/75\pm 5\%\text{RH}$ for accelerated stability) for accelerated stability data. Data for accelerated stability testing shall be at least for six months;
- c) 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.
- d) The frequency of the test, for real time stability study is every 3 months in the first year, every six months in the second year and then annually until the end of shelf life. Data for accelerated stability testing shall be at least for six months.
- e) Minimum of three batch numbers and the batch type of at least two production sizes;
- f) Manufacturing date;
- g) Type and chemical nature of the packaging materials within which the study is conducted;
- h) Analytical methods that will quantitatively measure the characteristic and chemical properties of each ingredients of product;
- i) 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.
- j) Summary of the study and storage recommendations based on the data generated.

8. Packaging and labelling requirements for finished product

- a) The packaging materials shall be safe and suitable for its intended use, and able to safeguard the product's hygienic, safety, quality and food grade.

- b) Presentation and description of food supplements 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.
- c) Label of a food supplement either directly or indirectly may not purport to prevent, diagnose, treat, cure or mitigate any disease.
- d) The label of the food supplement shall contain all appropriate cautionary statement including side effects or risks of excessive intake, contraindications, any warning and precautions associated with the use of the product and instruction that the product shall be stored out of reach of children.
- e) Label shall clearly indicate pack size of unit pack.
- f) Label shall be affixed on every container of any food supplement bearing the following information in clearly legible and indelible letters at least in Amharic or Amharic and English language:
 - 1) Name of the product;
 - 2) Name and full address of the manufacturer, including country of origin;
 - 3) Identification of the product as “food supplement”;
 - 4) List of ingredients;
 - 5) Nutritional information declaring in numerical form the amount of nutrients present in the per portion of the product as recommended for daily consumption or amount per unit for single use;
 - 6) Net content by weight for powdered products or volume for liquid;
 - 7) Date of manufacture and expiry, which shall indicate at least the month and year
 - 8) Where appropriate, the storage condition and shelf life of the product before and after opening and its reconstitution;
 - 9) Batch or lot number;
 - 10) Appropriate instruction for use or preparation;
 - 11) Required professional advice, if necessary; and
 - 12) Precautions and warnings, where necessary.
- g) All ingredients on the label of the product shall be listed including:
 - 1) Except for single ingredient products, a list of ingredient product shall be declared on the label;
 - 2) If the ingredient is from animal or plant, scientific name of the plant and part of

- animal or plant used;
- 3) Additives such as fillers, artificial colors, sweeteners, flavors, or binders by their specific names/E-numbers and qualified by words; and
 - 4) “Natural” or “artificial” in descending order in weight or volume.

9. Notification of variation, validity of registration and requirement for re-registration

- a) 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.
- b) A product registered in accordance with this directive shall be valid for four years. The authorized person shall have the obligation to apply for re-registration within 120 days before the due date. Re-registration requirements shall include current GMP and free sale certificate, and a confirmatory letter that the method of manufacture or preparation is not changed.

PART THREE

CERTIFICATE OF COMPETENCE

10. Requirement for a certificate of competence

- a) Any person who wants to import, export, wholesale or distribution a food supplement under this directive shall apply for a certificate of competence in accordance with ANNEX-II.
- b) An exporter, importer, or distributor of regulated products applying for a certificate of competence under this directive shall fulfill minimum requirements in relation to location, building materials and work force as defined under this directive.
- c) Notwithstanding to sub-article (1) of this article, and depending on the nature of the product, other appropriate factors may be considered in granting a certificate of competence.
- d) In order to determine compliance with this directive, the Authority shall conduct an onsite inspection of the intended facility by at least two inspectors. If there is any required correction, the Authority may perform re-inspection free of charge. However, the Authority may only perform an inspection beyond the second time against payment of

required service fee.

- e) If the inspection result conducted under sub-article (4) of this article warrant granting of the certificate of competence, the Authority shall issue the same against payment of the prescribed service fee.

11. Location

- a) The facility shall
 - 1) be self contained;
 - 2) be reasonably away from flood and swamp prone areas, offensive and waste disposal site;
 - 3) be locating in area where basic infrastructures including road, electricity and water are available;
 - 4) Be reasonably far from chemical manufacturing and storage areas.
- b) The premise shall be free of conditions, which might lead to contamination including excessive dust, foul odors, smoke, pest and insect infestations, airborne microbial and chemical contaminants, and other similar conditions.

12. Design and construction

- a) The warehouse shall provide sufficient space for all activities carried out proportional to the amount of the products including a storage room, dispensing room, separate quarantine and rejected products storage room or area.
- b) The store shall be constructed in such a way that it does not compromise the safety and quality of products.
- c) The building shall be constructed with materials that do not affect the safety and quality of the product.
- d) The storage room shall be constructed from stone, brick, or similar heat inhibiting materials.
- e) The storage room shall be separate or separately enclosed.
- f) Floor of the storage room shall be made in cement, concrete, ceramic or similar materials, easily washable, free from cracks, be smooth and not convenient to harbor dirt and water.
- g) Wall of the storage room shall be easily washable, free from cracks, and not convenient

to harbor dirt.

- h) Wall of the storage room shall be painted in white plastic paint or made out of ceramics or similar materials.
- i) The roof shall be constructed from materials that do not allow the entry of direct sun light and which do not adversely affect the temperature of the room.
- j) The ceiling shall be impermeable, smooth, easy to clean, light color, non porous, free of cracks and paint peels.
- k) Doors and windows shall be able to prevent the entrance of dust, insects, rodents and other food contaminants.
- l) Rooms shall be constructed in such a way to allow adequate air and light (1000 lux for activities need naked eye, 250 lux for easy task and 200 lux for store man) circulation.
- m) There shall be a toilet with hand washing facility. The toilet shall be easily cleanable, well ventilated and not open directly to the store.

13. Materials and equipments

- a) Shelves or pallets shall be available in such a way that they are at least 20cm away from the floor, 50 cm from the walls and 30cm from the ceiling. Each shelf shall be placed 50 cm away from each other.
- b) Depending on the climatic conditions of the area, there shall be ventilator or air conditioner.
- c) Any materials in the store having contact with the regulated product shall not compromise the safety and quality of products.
- d) An enclosed waste bin, necessary safety materials and working cloths shall be available.
- e) Where products that need refrigerator for their storage, it shall have refrigerator or cooling equipments.

14. Professional requirement

- a) Any person engaged in import, export or distribution of regulated products under this directive must have an adequate number and appropriate technical and other personnel.
- b) The person who runs the business as technical personnel shall have at least bachelor's degree in food science and technology or applied human nutrition or public health nutrition or quality assurance and regulatory affairs or food science and nutrition or food

engineering, or pharmacy.

15. Responsibilities of the technical personnel

- a) The appropriate technical personnel are responsible for any health related hazards caused by compromised safety and quality from the respective products.
- b) A technical personnel is required to inform, any observed deviation from the original safety and quality to the owner.
- c) If the owner of the business fails to take any corrective action in case where action is necessary, the technical personnel shall have the obligation to inform the Authority.
- d) If the deviation believed to be an eminent and serious hazard to public health, the technical personnel shall inform to the Authority without awaiting the decision of the owner.
- e) Technical personnel shall facilitate on job training on food safety, and handling for other personnel.

16. Scoring and conditions for the denial of certificate of competence

- a) In order to grant a certificate of competence, an applicant shall fulfill at least 80% of set requirements as provided under ANNEX-III of this directive.
- b) Notwithstanding to sub-article (a) of this article, certificate of competence may not be granted if
 - 1) there is no adequate and appropriate storage room;
 - 2) the walls and floor of the storage room are not easily washable;
 - 3) adequate lighting and ventilation is not available;
 - 4) the required technical personnel is not available; and
 - 5) depending on the nature of the product, there is no palate or shelf;
- c) Where a certificate of competence is granted in accordance with sub-article (1) of this article with minor non-compliances, a memorandum of understanding in accordance with ANNEX-IV shall be signed between the inspectors and the applicant with a view to correct deficiencies and the applicant shall take the required corrective measures within the time period stipulated under the agreement.

17. Displaying certificate of competence

The responsible person shall put the original of the certificate of competence in a conspicuous and easily noticeable place by clients and regulatory officers.

18. Replacement of certificate of competence

If a certificate of competence is lost or damaged, the responsible person may request replacement by submitting a signed and dated application to the Authority.

19. Change of address and technical personnel

No person may change location and technical personnel of the facility without notifying and securing the permission from the Authority.

20. Renewal of certificate of competence

- a) A certificate of competence shall be renewed annually up on the confirmation of regulatory compliance through annual inspection, and payment of prescribed service fee.
- b) If the certificate of competence is not renewed in accordance with sub-article (a) of this article, it shall be renewed with 50% increment penalty for each of the coming two months.
- c) If the certificate of competence is not renewed in accordance with sub-article (b) of this article, the certificate of competence shall be considered invalid or cancelled.

PART FOUR

PRODUCT IMPORT, EXPORT AND WHOLESALE

21. Import requirement

- a) In order to get port clearance, the following documents shall be required:
 - 1) Application letter;
 - 2) Copy of certificate of competency;
 - 3) Registration certificate;
 - 4) Health certificate;
 - 5) Certificate of analysis containing, at least the date of analysis, name of organization

performing the analysis, certificate reference number, name of the product, batch or lot number, physico-chemical and microbiological test results.

- f) Invoice;
 - g) Packing list; and
 - h) Airway bill or bill of loading;
- 2) Copy of certified translation shall be presented where any original certificate is in language other than English or Amharic.
 - 3) Notwithstanding to sub-article (a) (4) of this article, where health certificate is not customary to be issued in the country of origin, such may be confirmed by the Authority from Embassy, consulate or appropriate government organ of the country of origin.
 - 4) Importation of a product sample may only be allowed for the purpose of product registration.
 - 5) Certificate of competence may not be required and the Authority may grant special permit where the product to be imported is used for scientific research, sample for registration, humanitarian aid, personal use which may not be of commercial size as determined by customs Authority.

22. Packaging and labeling

- a) Packaging and labeling of imported products shall be in accordance with the registration specification for finished products.
- b) Any food supplement at the time of port clearance or release shall have at least 50 % of its total shelf life.
- c) Depending on the purpose, the need and the time of use after entrance, the Authority may allow the import of products, with less than six months of time to expire.

23. Export

Depending on requirements of the country of destination and mandate of the Authority, the Authority may issue required regulatory documents to exporters.

24. Storage, transportation and distribution

- a) The responsible person shall observe applicable safety requirements during storage,
- b) handling and transportation of products

- c) Products shall be stored in an appropriate condition according to instructions placed on its label.
- d) Products shall be stored separately from chemicals and other potential sources of contamination.
- e) Deteriorated, expired, and damaged products shall be stored separately from products until disposal.

PART FIVE

ADMINISTRATIVE MEASURES

25. Administrative measures and complaint handling

- a) The Authority may take appropriate administrative measure against products, entities or individuals who violate requirements of this directive or other applicable laws in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure. The certificate of competence shall be returned within two working days if suspended, revoked, and not renewed during the renewal period or termination of operation up on one's own will.
- b) The person who is under administrative measure in accordance with sub-article (a) of this article may lodge complaint in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
- c) Without prejudice to sub-article (a) of this article, the following may be used as illustrative lists for suspension and revocation:

26. Suspension

Based on the severity of the violation, certificate of competence and/ or certificate of product registration and/ or professional license may be suspended from 1 to 6 months in one of the following condition:

- a) If warning is given for more than two times and does not take any corrective actions accordingly;
- b) sale, buy or distribute product without knowledge of the technical personnel;
- c) advertise the products in contrary to the Authority's food advertising directive;

- d) the certificate of competence is in any manner transferred to third parties;
- e) the Authority shall suspend certificate of competence for the same period if another appropriate organ suspends the institution from conducting its business activities; and
- f) If comparable violation is committed.

27. Revocation

Based on the nature and severity of the violation, certificate of competence may be revoked up to 2 years, if the person:

- a) obtained its certificate of competence through fraudulent acts;
- b) add or mix any substance to the product so as to increase its bulk or weight, or make it appear better or for any other similar purpose; and counterfeiting;
- c) import, export, or distribute a product other than the product type the certificate of competence issued for;
- d) possess or sale a product in any manner from any person having no certificate of competence;
- e) acquire, possess, sale or distribute any unregistered, adulterated, counterfeited, damaged, expired, banned, unlabeled or unduly labeled product;
- f) continuing operating its business by violating terms and conditions of any suspension measure;
- g) is subjected to three or more suspension measures for similar faults listed under the suspension provision within three years;
- h) is prohibited from doing its business by another appropriate government organ;
- i) advertise its product for more than two times in contrary to food advertising directive;
or
- j) Commits other comparable violations

PART SIX

MISCELLANEOUS PROVISIONS

28. Pyramid sale prohibition

Applying or attempting to apply a pyramid scheme of sale, based on the numbers of consumers, by announcing the guaranteeing of a reward, in cash or in kind, to a consumer

who purchases food supplement or makes financial contribution and where other consumer, through his salesmanship, purchase the food supplement or make financial contribution or enter in to the sales scheme shall be prohibited.

29. Supply chain and documentations

- a) An importer shall only sell products to a wholesaler having valid certificate of competence from the Authority.
- b) A wholesaler shall only sale products to pharmacy, drug store, and special shops having a certificate of competence from appropriate organ.
- c) Documents regarding import, export or wholesale activities, including full address of the buyer and the organization from whom the product is bought, invoices, receipts, stock and bin cards, and damaged, expired, or disposed products shall be kept at least for one year from expiry date of the product.
- d) Periodic report regarding imported, distributed, exported, damaged, expired or disposed products shall be made to the Authority every six months.

30. Public and media disclosure

- a) The Authority may only disclose administrative measure after 30 days of the final decision by the Authority or if the case is under complaint procedure after the final decision on the complaint.
- b) Notwithstanding sub-article (a) of this article, the Authority may publicize administrative measures where failure to publicize would result public health risk.

31. Advertisement

Food supplements may only be advertized in accordance with the Authority's Food Advertisement Directive.

32. 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 for Food, Medicine, Health Professional and Health Institutions Registration and

Licensing council of Ministers Regulation No.370/2015.”

33. Inapplicable and repealed laws

- a) Any directive, which is inconsistent with this directive, shall not be applicable with respect to those matters provided for in this directive.
- b) Food supplement import, export, wholesale and distribution directive No. 14/2013 is here by repealed.

34. Effective date

This directive shall enter into force on October 2015

Ethiopian Food, Medicine and Healthcare Administration and Control Authority