ETHIOPIAN FOOD, MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY

Food Supplement Directive

June 2014

Contents

Preamble

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, THEREFOR, 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. 299/2006.

PART ONE
GENERAL

1. Short title

This directive may be cited as **"**Food Supplement Directive No. 23/2014.**"**

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. Registration requirement

In order to introduce food supplement in the Ethiopian market, the Authority shall register it after checking compliance with requirements provided from Article 7 to Article 10.

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

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) 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.

7. Administrative documents

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.

2) Required certificates

1) In order to acquire market authorization, an applicant shall submit Good Manufacturing Practice (GMP) and free sale certificates.
2) In appropriate circumstances, internationally accepted certification or certificate of quality management system may be accepted in lieu of GMP and free sale certificates.
3) The certificates presented under sub-article (1) of this article shall be dated, current and be original or authenticated by a competent authority.

8. Technical documents

1) Formulation, and manufacturing and packaging procedure

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

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) Analytical procedure;
c) Details of test method including procedures, analytical instruments and acceptance criteria; and
d) A certificate of analysis performed on the product. The analysis shall be from an external accredited laboratory for at least three batches of consecutive commercial sizes.

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 4 for accelerated stability data. Data for accelerated stability testing shall be at least for six months;
c) Minimum of three batch numbers and the batch type of at least two production sizes;
d) Manufacturing date;
e) Type and chemical nature of the packaging materials within which the study is conducted;
f) Analytical methods that will quantitatively measure the characteristic and chemical properties of each ingredients of product;
g) 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.
h) Summary of the study and storage recommendations based on the data generated.

9. Packaging and labeling requirements for finished product

1. The packaging materials shall be safe and suitable for its intended use, biodegradable, and able to safeguard the product's hygienic, safety, quality and food grade.
2. 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.
3. Label of a food supplement either directly or indirectly may not purport to prevent, diagnose, treat, cure or mitigate any disease.
4. 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.
5. Label shall clearly indicate pack size of unit pack.
6. 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 English language:

   a) Name of the product;
   b) Name and full address of the manufacturer, including country of origin;
   c) Identification of the product as "food supplement";
   d) List of ingredients;
   e) 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;
   f) Net content by weight for powdered products or volume for liquid;
   g) Date of manufacture and expiry, which shall indicate at least the month and year
   h) Where appropriate, the storage condition and shelf life of the product before and after opening and its reconstitution;
   i) Batch or lot number;
   j) Appropriate instruction for use or preparation;
   k) Required professional advice, if necessary; and
   l) Precautions and warnings, where necessary.

7. All ingredients on the label of the product shall be listed including:
   a) The source of the protein in the product;
   b) Except for single ingredient products, a list of ingredients with the corresponding quantities per specified unit of measure;
   c) If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used;
   d) Additives such as fillers, artificial colors, sweeteners, flavors, or binders by their specific names/E-numbers and qualified by words; and
   e) "Natural" or "artificial" in descending order in weight or volume.

PART THREE
CERTIFICATE OF COMPETENCE

10. Requirement for a certificate of competence

1) 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.
2) 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.
3) 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.
4) 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.
5) 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

1) The facility shall
   a) be self contained;
   b) be reasonably away from flood and swamp prone areas, offensive and waste disposal site;
   c) be locating in area where basic infrastructures including road, electricity and water are available;
   d) Be reasonably far from chemical manufacturing and storage areas.
2) 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

1) 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.
2) The store shall be constructed in such a way that it does not compromise the safety and quality of products.
3) The building shall be constructed with materials that do not affect the safety and quality of the product.
4) The storage room shall be constructed from stone, brick, or similar heat inhibiting materials.
5) The storage room shall be separate or separately enclosed.
6) 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.
7) Wall of the storage room shall be easily washable, free from cracks, and not convenient to harbor dirt.
8) Wall of the storage room shall be painted in white plastic paint or made out of ceramics or similar materials.
9) 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.

10) The ceiling shall be impermeable, smooth, easy to clean, light color, non porous, free of cracks and paint peels.
11) Doors and windows shall be able to prevent the entrance of dust, insects, rodents and other food contaminants.
12) Rooms shall be constructed in such a way to allow adequate air and light circulation.
13) 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

1) 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.
2) Depending on the climatic conditions of the area, there shall be ventilator or air conditioner.
3) Any materials in the store having contact with the regulated product shall not compromise the safety and quality of products.
4) An enclosed waste bin, necessary safety materials and working cloths shall be available.
5) Where products that need refrigerator for their storage, it shall have refrigerator or cooling equipments.

14. Professional requirement

1) 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.
2) The person who runs the business as technical personnel shall have at least bachelor's degree in food science and technology, food science and nutrition, food engineering, or pharmacy.

15. Responsibilities of the technical personnel

1) The appropriate technical personnel is responsible for any health related hazards caused by compromised safety and quality from the respective products.

2) A technical personnel is required to inform, any observed deviation from the original safety and quality to the owner.
3) If the owner of the business fails to take any corrective action in case where action is nessecery, the technical personnel shall have the obligation to inform the Authority.
4) 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.
5) 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

1) 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.
2) Notwithstanding to sub-article (1) of this article, certificate of competence may not be granted if

    a) there is no adequate and appropriate storage room;
    b) the walls and floor of the storage room are not easily washable;
    c) adequate lighting and ventilation is not available;
    d) the required technical personnel is not available; and
    e) depending on the nature of the product, there is no palate or shelf;
3) 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

1) Holder of a certificate of competence shall annually renew its certificate between "Hamle"1 and "Nehase" 30 of the Ethiopian budget year.
2) If the responsible person does not renew its certificate in accordance with sub-article (1) of this article, it shall renew the same with 50% increment penalty for each of the coming two months.
3) The certificate shall be deemed cancelled if the certificate is not renewed in accordance with sub-article (2) of this article.

PART FOUR
PRODUCT IMPORT, EXPORT AND WHOLESALE

21. Import requirement

1) In order to get port clearance, the following documents shall be required:
   a) Application letter;
   b) Copy of certificate of competency;
   c) Registration certificate;
   d) Health certificate;
   e) 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, physic-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 (1) (d) 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

1) Packaging and labeling of imported products shall be in accordance with the registration specification for finished products.
2) Any food supplement at the time of port clearance or release shall have at least 50 % of its total shelf life.
3) 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

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

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

PART FIVE
ADMINISTRATIVE MEASURES

25. Administrative measures and complaint handling

1) 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.
2) The person who is under administrative measure in accordance with sub-article (1) of this article may lodge complaint in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
3) Without prejudice to sub-article (1) 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 may be suspended from 1 to 6 months in one of the following condition:

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

4) the certificate of competence is in any manner transferred to third parties;
5) the Authority shall suspend certificate of competence for the same period if another appropriate organ suspends the institution from conducting its business activities; and
6) 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:

1) obtained its certificate of competence through fraudulent acts;
2) 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;
3) import, export, or distribute a product other than the product type the certificate of competence issued for;
4) possess or sale a product in any manner from any person having no certificate of competence;
5) acquire, possess, sale or distribute any unregistered, adulterated, counterfeited, damaged, expired, banned, unlabeled or unduly labeled product;
6) continuing operating its business by violating terms and conditions of any suspension measure;
7) is subjected to three or more suspension measures for similar faults listed under the suspension provision within three years;
8) is prohibited from doing its business by another appropriate government organ;
9) advertise its product for more than two times in contrary to food advertising directive; or
10) commits other comparable violations.

PART SIX
MISCELLANEOUS PROVISIONS

28. Pyramid sale prohibition

Appling 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

1) An importer shall only sell products to a wholesaler having valid certificate of competence from the Authority.
2) A wholesaler shall only sale products to pharmacy, drug store, and special shops having a certificate of competence from appropriate organ.
3) 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.
4) 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

1) 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.
2) Notwithstanding sub-article (1) 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.

33. Inapplicable and repealed laws

1) Any directive, which is inconsistent with this directive, shall not be applicable with respect to those matters provided for in this directive.
2) 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 11 October 2014.

Yehulu Denekew

Director General

Ethiopian Food, Medicine and Healthcare Administration and Control Authority

ANNEX-I

Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Application for Registration of supplementary food

1. Name of applicant organization _____
   Full address
   Region_____City_____Sub-city/Woreda_____
   House No._____ Phone No._____Fax/email_____
2. Name of the applicant individual _____
   Full address and responsibility of the individual
   Region_____City_____Sub-city/Woreda_____
   House No._____ Phone No._____Fax/email_____
   Applicant's responsibility in the organization_____

3. Name of the product to be registered _____
4. Type of the product _____
5. Color of the product _____
6. Presentation (Pack size, content) _____
7. Shelf life (in months) _____

8. Manufacturer information
   Name of the manufacturer_____
   Full address_____
   Plant address_____
   Postal address _____
   Phone number_____
   Fax number_____
   E-mail_____
   Website_____

9. List or annotate required documents or materials (attached with this form)
   _____

   _____

I HEREBY DECLARE THAT THE ABOVE STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF AND ATTACHED DOCUMENTS FURNISHED WITH THIS APPLICATION ARE GENUINE AND I UNDERSTAND IT MAY BE USED AS EVIDENCE FOR PENALTY UNDER ETHIOPIAN CRIMINAL LAW

Name of applicant individual signature and date

_____ _____

For official purpose

Application Number_____

Date of receipt _____

Registration Number_____

Registration Date_____

Office's Name and Signature_____

Date_____

ANNEX-II

የኢትዮጵያ የምግብ፣ የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለሥልጣን
Ethiopian Food, Medicine & Health Care Administration and Control Authority

Application Form for Certificate of Competence

1. Name of the organization _____
   Full address
   Region_____City_____Sub-city/Woreda_____
   House No._____ Phone No._____Fax/email_____

2. Full name of the owner/manager of the organization_____
   Adress
   Region_____City_____Sub-city/Woreda_____
   House No._____ Phone No._____Fax/email_____
3. Type of business

   Importer ☐ Wholesaler ☐ Exporter ☐

4. The type of product intended to hold----------

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5. Full name of technical personnel_____
   Education level_____
   (Attach copy of credentials: original credential must be presented during issuance of COC)

I hereby declare that the above statement is true to the best of my knowledge and belief and attached documents furnished with this application are genuine and I understand it may be used as evidence for penalty under the Ethiopian criminal law

Name of applicant individual signature and date

_____ _____

For official purpose

Application Number_____

Date of receipt _____

Office's Name and Signature_____

ANNEX-III

የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration and Control Authority

የብቃት ማረጋገጫ ምስክር ወረቀት ለመስጠት በተቆጣጣሪዎች የሚሞላ የኢንስፔክሽን ቅፅ

Inspection form to be filed by inspectors for issuing certificate of competence

A. Organization name product type

Address region _____ Zone/sub city _____ Woreda _____ city _____ Kebele _____ unique name of the place _____ telephone _____

B. Name of the organization owner/Representative _____

C. Name of technical personnel _____

ተቁ	**ዝርዝር መለኪያዎች Measuring criteria**	**የመመዘኛ ነጥብ Evaluation point**	**የተሰጠ ው ነጥብ Point given**
1.	**Environmental condition**	***21***	
1.1	**ድርጅቱ የተቋቋመበት ቦታ ለምግብ ብክለት ያለው ተጋላጭነት** Exposure of the Premises for potential contaminants	7	
	location of the premises related to residential	7	
1.2	**የመሰረተ ልማት ሁኔታ** Infrastructure	7	
2	***የህንፃው አሰራር ሁኔታ design and construction***	***45***	
2.1	**የህንጻው ከፍታ ከሚከማቸው ምግብ ጋር ያለው ተስማሚነት** Premises height from	2	
2.2	**ህንፃው የተገነባበት ማቴሪያል ሁኔታ** Type of building materials used	5	
2.3	**ድርጅቱ ከሚያከማቸው የምግብ መጠን አንፃር የክፍሎቹ ስፋት ሁኔታ** Adequacy of the storage room with respect to the amount of the product to be stored	4	
2.4	**የተለየ የምግብ ማከማቻ ክፍል፣የተበላሹ ምግቦች ማቆያ ቦታ፣ መፀዳጃና የእጅ መታጠቢያ ክፍል መኖሩ**		
2.5	Presence of rejected products storage area and quarantine area	5	
2.6	Presence and conditions of toilet and hand washing facilities	5	
2.7	**የህንፃው ግድግዳና ወለል ለማፅዳት ያለው ምቹነት** The suitability of Wall, floor and ceiling for washing	7	
2.8	**የማከማቻ ክፍሉ ጣሪያ የተሰራበት ማተሪያል መቀትና ከቀጥተኛ የፀሀይ ብርሃን የመከላከል አቅሙ** Capability of building materials, of ceiling, to protect the entrance of direct sun light and to regulate temperature	3	
2.9	**የህንፃው በርና መስኮት ምግብን ሊበክሉ ከሚችሉ ነገሮች የመከላከል አቅሙ** Capability of Doors and windows to protect the entrance of potential contaminants	4	
2.1.1	**በማከማቻ ክፍሉ ውስጥ ያለው የብርሃንና የአየር ዝውውር ሁኔታ** Condition of Lighting and ventilation of the storage room	7	

2.1.2	**የደረቅ ቆሻሻ አያያዝ ሁኔታ** Handling condition of solid and liquid waste	3	
3	***አስፈላጊ ግብአቶችና ቁሳቁሶች*** ***Necessary materials and equipments***	***31***	
3.1	**ምግቡን ለማስቀመጥ የሚያስችል በቂ መድርደሪያ ወይም ፓሌት መኖሩንና የማቴሪያሉ ዓይነትና የአቀማመጥ ሁኔታ** Availability of sufficient palates and/or shelves and manner of the order	10	
3.2	**ድርጅቱ የቅዝቃዜ ሰንሰለታቸው መጠበቅ የሚያስፈልጋቸው ምግቦች የሚያከማች ከሆነ ምግቡን ለማስቀመጥና ለማጓጓዝ የሚያስችል መሳሪያ መኖሩ** The presence of refrigerator if there are products which needs to keep their cold chain.	10	
3.3	**የመጀመሪያ ህክምና እርዳታ መስጫ መሳሪያ መኖሩን** Presence of first aid kit	2	
3.4	**የድንገተኛ እሳት አደጋ ማጥፊያ መሳሪያ መኖሩን** Presence of fire extinguisher	2	
3.5	**የምግብ ስርጭት መረጃ መያዣ ስርዓት መኖሩን** Presence of SOP	5	
3.6	**የሰራተኞች የደህንነት መጠበቂያ ማቴሪያሎች መኖራቸው** Presence of personal protective materials	2	
4	***Technical Personnel***	***3***	
4.2	**የጤና ምርመራ** Health Examination	3	
	ጠቅላላ Total	100	

Recommendation of the Authorized Officers _____
_____

Name of Authorized officers signature
1. _____ _____ date time
2. _____ _____ _____ _____
3. _____ _____

የሀላፊው አስተያየት Recommendation of Authorized person _____
Name _____ signature _____date _____ time _____

የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration and Control Authority

እዝል/Annex 2

የብቃት ማረጋገጫ ምስክር ወረቀት ለመስጠት በተቆጣጣሪዎች የሚሞላ የኢንስፔክሽን ቅፅ

Inspection form to be filed by inspectors for issuing certificate of competence

1. **የድርጅቱ ስም**_____**የምርቱ ዓይነት**_____
Organization's name Product type

አድራሻ
Address
ክልል_____**ዞን/ክ/ከተማ**_____**ወረዳ**_____**ከተማ**_____**ቀበሌ**_____
Region Zone/sub-city Woreda City Kebele
ስ.ቁ_____ **ኢ-ሜይል**_____ **የአካባቢው ልዩ መጠሪያ**_____
Telephone E-mail Unique name of the place

2. **የደርጅቱ ባለቤት / ተወካይ ስም**_____
Name of the organization owner/Representative
3. **የቴክኒካል ባለሙያ ስም**_____
Name of technical personnel

ተቁ	**ዝርዝር መለኪያዎች Measuring criteria**	**የመመዘኛ ነጥብ Maximum achievable point**	**የተሰጠው ነጥብ score**
	አካባቢያዊ ሁኔታዎች **Environmental condition**	***23***	
1.1	**ድርጅቱ የተቋቋመበት ቦታ ለብክለት ያለው ተጋላጭነት** Exposure of the premises for potential contaminants	10	
	ከመኖሪያ ቤት የተለየ መሆኑ Location of the premises related to residence	8	
1.2	**የመሰረተ ልማት ሁኔታ** Infrastructure	5	
2	***የህንፃው አሰራር ሁኔታ*** ***Design and construction***	***43***	
2.2	**ህንፃው የተገነባበት ማቴሪያል ሁኔታ** Types of building materials used	5	
2.3	**ድርጅቱ ከሚያከማቸው የምርት መጠን አንፃር የክፍሎቹ ስፋት ሁኔታ** Adequacy of the storage room with respect to the amount of the product to be stored	4	
2.4	**የተገለሉ ምርቶች ማቆያ ክፍል እና የተበላሹ ምርቶች ማቆያ ቦታ ሁኔታ** Conditions of rejected products storage area and quarantine area	5	
2.6	**መፀዳጃና የእጅ መታጠቢያ ክፍል ሁኔታ** Conditions of toilet and hand washing facilities	5	
2.7	**የህንፃው ግድግዳና ወለል ለማፅዳት ያለው ምቹነት** The suitability of wall, floor and ceiling for washing	7	
2.8	**የማከማቻ ክፍሉ ጣሪያ/ ኮርኒስ የተሰራበት ማቴሪያል መፀቀትና ከቀጥተኛ የፀሀይ ብርሃን የመከላከል አቅሙ**	3	

	Capability of building materials of the ceiling/ roof, to protect the entrance of direct sun light and to regulate temperature		
2.9	**የህንፃው በርና መስኮት ምርትን ሊበክሉ ከሚችሉ ነገሮች የመከላከል አቅሙ** Capability of doors and windows to protect the entrance of potential contaminants	4	
2.1.1	**በማከማቻ ክፍሉ ውስጥ ያለው የብርሃንና የአየር ዝውውር ሁኔታ** Condition of lighting and ventilation of the storage room	7	
2.1.2	**የደረቅ ቆሻሻ አያያዝ ሁኔታ** Handling condition of solid waste	3	
3	***አስፈላጊ ግብአቶችና ቁሳቁሶች*** ***Necessary materials and equipments***	***31***	
3.1	**ምርቱን ለማስቀመጥ የሚያስችል በቂ መድርደሪያ ወይም ፓሌት መኖሩ፣ የተሰራበት ቁስ ዓይነትና የአቀማመጥ ሁኔታ** Availability of sufficient palates and/or shelves, their material of construction and the manner of arrangement	10	
3.2	**ድርጅቱ የቅዝቃዜ ሰንሰለታቸው መጠበቅ የሚያስፈልጋቸው ተጨማሪ ምግቦች የሚያከማች ከሆነ እንደ ምርቱ መጠን ምርቱን ለማስቀመጥና ለማጓጓዝ የሚያስችል ማቀዝቀዣ መኖሩ** The presence of refrigerator proportional to the amount of the product if there are products which need to maintain their cold chain during storage and transportation.	10	
3.3	**የመጀመሪያ ህክምና እርዳታ መስጫ መሳሪያ መኖሩን** Presence of first aid kit	2	
3.4	**የድንገተኛ እሳት አደጋ ማጥፊያ መሳሪያ መኖሩን** Presence of fire extinguisher	2	
3.5	**የስርጭት መረጃ አያያዝ ስርዓት ሁኔታ** The condition of product distribution documentation system	5	
3.6	**የሰራተኞች የደህንነት መጠበቂያ ማቴሪያሎች መኖራቸው** Presence of personal protective device	2	
4	**የሰራተኞች የጤና ምርመራ ዉጤት** Health certificate of personnel	***3***	
	ጠቅላላ Total	100	

የኢንስፔክተሮች አስተያየት
Recommendation of the inspectors _____
_____

የኢንስፔክተሮች ስም	**ፊርማ**	**ቀን**	**ሰዓት**
Name of inspectors	signature	date	time
_____	_____		
_____	_____	_____	_____
_____	_____		

የሀላፊው አስተያየት
Recommendation of Authorized person _____

ስም **ፊርማ** **ቀን** **ሰዓት**
Name _____ signature _____date _____ time _____

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration and Control Authority

እዝል/Annex 4

በኢንስፔክሽን ወቅት የተገኙ ክፍተቶችን ለማሟላት ከድርጅቱ ጋር የሚገባ መተማመኛ ቅፅ

A Memorandum of understanding form for the gaps found during inspections

4. **የድርጅቱ ስም**_____**የምርቱ ዓይነት**_____
Organization's name product type

አድራሻ
Address
ክልል_____**ዞን/ክ/ከተማ**_____**ወረዳ**_____**ከተማ**_____**ቀበሌ**_____
Region Zone/sub city Woreda City Kebele
ስ.ቁ_____ **ኢ-ሜይል**_____ **የአካባቢው ልዩ መጠሪያ**_____
Telephone E-mail Unique name of the place

5. **የደርጅቱ ባለቤት / ተወካይ ስም**_____
Name of the organization owner/Representative
6. **የቴክኒካል ባለሙያ ስም**_____
Name of technical personnel

ተ.ቁ S.No	**በድርጅቱ ውስጥ የተገኙ ክፍተቶች** Gaps' identified	**በድርጅቱ መወሰድ ያለባቸው የማሰተካካያ እርምጃዎች** Corrective action that has to be taken	**የጊዜ ወሰን** Time frame to take corrective actions	**ምርመራ** Remark

የኢንስፔክተሮች ስም ፊርማ Name of inspectors signature 1. _____ _____ 2. _____ _____ 3. _____ _____ □□ Date _____	**የድርጅቱ ባለቤት/ ተወካይ ስምና ፊርማ** Name of the organization owner/Representative & signature _____ _____ **ቀን** Date _____

ማሳሰቢያ

- *ድርጅቱ የተቀመጠውን መስፈርት ከ 80% ፐርሰንት በላይ አሟልቶ ፍቃድ የሚሰጠው ከሆነ ጉድለቶችን ለማስተካከል ይህ የመተማመኛ ቅፅ በሶስት ኮፒ ተዘጋጅቶ 1 ኮፒ ለድርጅቱ የሚሰጥ 2ኛ ኮፒ ከድርጅቱ ፋይል ጋር ይያዛል፣3ኛ ኮፒ ለአንስፔክሽንና ሰርቬላንስ ዳይሬክቶሬት ለክትትል ይሰጣል፡፡*
- *ድርጅቱ መስፈርቱን ሳያሟላ ቀርቶ በድጋሚ ፈቃድ ለማውጣት የሚመለስ ከሆነ ይህ የመተማመኛ ቅፅ በሁለት ኮፒ ተዘጋጅቶ 1ኛ ኮፒ ለድርጅቱ የሚሰጥ 2ኛ ኮፒ ከድርጅቱ ፋይል ጋር ይያያዛል፡፡*
- *ድርጅቱ በገባው የመተማመኛ ሰነድ መሰረት ክፍተቶቹን በተቀመጠለት የጊዜ ገደብ ካላጋላ አግባብ ባለው ህግ መሰረት አስተዳዳራዊ እርምጃ ይወሰድበታል፡፡*

NB

- If the organization fulfills at least 80% of the criteria in this directive for getting certificate of competence; for taking corrective actions on slight deviation this memorandum of understanding form shall be prepared in three copies; 1 copy for organization, the other copy shall attached with the organization files and the third copy shall be given to inspection and surveillance directorate.
- If the organization does not comply with the requirements of this directive this memorandum of understanding form shall be prepared in two copies; 1 copy shall be given for the organization and the other copy shall be kept attached with the organization's file.
- If organization does not take a corrective action within the time frame specified on the memorandum of understanding the Authority may take administrative measure.

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration & Control Authority

Photo

እዝል/Annex 5

የብቃት ማረጋገጫ ምስክር ወረቀት
Certificate of Competence

ቁጥር _____
Ref.No
ቀን _____
Date

የድርጅቱ ስም _____**የንግድ ስራ ዓይነት**_____
Organization's Name Business type
የሚይዘው የምርት ዓይነት_____
Product Type
የድርጅቱ አድራሻ
Address of the organization
ክልል_____**ዞን/ክ/ከተማ** _____**ወረዳ**_____**ከተማ** _____
Region Sub city/Zone Woreda City
ቀበሌ_____ **የቤ/ቁጥር**_____**ስ/ቁጥር** _____**ፋክስ**_____
Kebele House no Telephone Fax

የድርጅቱ ባለቤት ሙሉ ስም _____
Owner's Full Name
አድራሻ /Address
ክልል_____**ዞን/ክ/ከተማ** _____**ወረዳ**_____**ከተማ** _____
Region Sub city/Zone Woreda City
ቀበሌ_____ **የቤ/ቁጥር**_____**ስ/ቁጥር** _____**ፋክስ**_____
Kebele House no Telephone Fax

ድርጅቱ ባለስልጣኑ ያወጣውን መስፈርቶች ማሟላቱ ስለተረጋገጠ በምግብ፣ በመድኃኒትና በጤና ክብካቤ አስተዳደርና ቁጥጥር አዋጅ 661/2002 **መሰረት ይህ የብቃት ማረጋገጫ ምስክር ወረቀት ተሰጥቷል፡፡**
This Certificate of Competence is issued upon fulfillment of requirements set by the Authority in accordance with Food, Medicine and Healthcare Administration and Control Proclamation No. 661/2009.

_____ _____
የሃላፊ ፊርማ **የተሰጠበት ቀን**
Signature of Authorized Person Date of Issue

ታድሷል Renewed 200___E.C/201___G.C **የደረሰኝ ቁጥር** _____ R/no **ፊርማ** _____ Signature	**ታድሷል** Renewed 200___E.C/201___G.C **የደረሰኝ ቁጥር** _____ R/no **ፊርማ** _____ Signature	**ታድሷል** Renewed 200___E.C/201___G.C **የደረሰኝ ቁጥር** _____ R/no **ፊርማ** _____ Signature

ማሳሰቢያ /Notice/
ይህ የብቃት ማረጋገጫ ምስክር ወረቀት በየአመቱ ካልታደሰ እንደተሰረዘ ይቆጠራል፡፡
This certificate of competence shall be considered cancelled unless renewed every year.
ድርጅቱ አግባብ ካላቸው ህጎችና መስፈርቶች ውጭ ሲሰራ ከተገኘ ይህ የብቃት ማረጋገጫ ምስክር ወረቀት ሊታገድ ወይም ሊሰረዝ ይችላል፡፡

This certificate of competence may be suspended or revoked if the organization is found in violation of appropriate laws & standards.

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration & Control Authority

እዝል/Annex 6

Application Form for Port Release

Date::_____
To: the Ethiopian Food, Medicine & Healthcare Administration & Control Authority
…… branch port of entry.
Importer Name: …….. Phone No: …… E-Mail:_____
Certificate of Competence Number._____
Full Name of Transit ……Phone No: ……. E-Mail:_____
The following product has been imported and is awaiting for inspection by your Authorized inspector. I request you to provide us your issuance of release certificate.
Bill of loading/airway bill: …… Date of Arrival: ……
Port of Entry: ……..
Country of Origin: …… Quantity: ……
Invoice Number: ……..…….
Food Consignment description: ……
Container IDs: …….. Container Location: ……
Our representative / transitor will be available at the time of inspection. Copies of all required documents are annexed along with this application.

_____
Name, signature, official seal and Designation

እዝል/Annex 7

Product Rejection Form

To, Customs and Revenue Authority Date: ……..
Types of product rejected: ……..
Commodity imported by: ……..
Consignment Number: ……..…. Invoice Number: …….…….
Country of Origin: …… Quantity: ……..

The above mentioned product was inspected by Dr/Mr./Mrs./Miss_____ the inspector of the Authority. The Authority requests you to reject this product and not to release it from this port of entry as the result(s) of the inspection analysis shows that the product does not conform to the specifications prescribed under the Food, Medicine and Healthcare administration proclamation No.661/2009 Article 5 Sub - Articles 2(g).

Yours Faithfully

Name of the inspector_____

Signature_____

Seal of the Authority

cc.
To inspection and enforcement Directorate
To inspection and surveillance directorate
To the owner of Product

እዝል/Annex 8

Port Entry-Exit Inspection Result Form

Importer name:-_____
Certificate of competence No:- _____
Port of Entry/Exit:- _____
AWB/BL:-_____
Invoice number:- _____
Declaration number:- _____

S.no	Description of products	Unit	Quantity	Name of manufacturer	Country of Origin	Bach /Lot. No.	Manufacturing Date	Expiry date	Remark

Result of inspection
Condition of the product

Storage and transportation _____
_____
Packaging and labeling _____
_____
Laboratory test result _____
Other requirements with the reference to regulation and guideline _____
(Sampling Technique): _____
_____
Laboratory test recommended? Yes …… No ……
_____
_____
Conclusion □ in view of inspection the quality of these product;
fully complies ☐ not complies ☐
General recommendation: _____
Name and signature of inspector
Name _____
Signature _____ Date of inspection _____ time _____

እዝል/Annex 9

Sampling Form

I/we name listed below the inspector (s) of Authority according to the mandate given under Article 5 Sub Article 2(d) of the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009 have taken the following sample for the purpose of laboratory analysis.

1	Name of the sample's owner	
2	Certificate of Competence No.	
3	Name and types of the sample	
4	Quantity	
5	Batch No.	
6	Expiry date	
7	Manufacturer Name	
8	Place of sampling	
9	Reasons of the sampling	

Name of Authorized inspectors organization

_____ signature _____
_____ signature _____
_____ signature _____

owners name /representative of the

name _____
signature _____
date _____time _____

Date of Sampling _____ time _____

The inspectors' coordinator recommendation

_____
_____

Inspectors' coordinator name

_____

Signature _____
Date _____

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration & Control Authority

እዝል/Annex 10

Sample Submission Form

To _____

According to the mandate given under Article 5 Sub Article 2(d) of the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009 the Authority have send the following sample for the purpose of laboratory analysis. Please, notify us the result of the examination/analysis.

1	Name and types of the sample	
2	Quantity	
3	Batch No.	
4	Manufacturing date	
5	Expiry date	
6	Country of Origin	
7	Sampling Date	
8	Reasons of the examination	
9	Type of the examination (e.g. microbiology, physicochemical, nutritional content, toxicology etc….)	

Authorized Officer

Full name _____

Signature _____

Date _____

እዝል/Annex 11

Memorandum of Understanding Form for a Quarantined Product

I/we name listed below the inspector (s) of Authority according to the mandate given under Article 5 Sub Article 2(e) of the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009 have quarantined the following this product until its safety and quality is proved.

Owner's Name _____ COC. No_____
Address
Region _____ Zone/Sub-City _____ Woreda _____ City _____ Kebele _____
Unique Name of the Place _____ telephone _____
Quarantine Food Address
Region _____ Zone/Sub-City _____ Woreda _____ City _____ Kebele _____
Unique Name of the Place _____ telephone _____

S.No	Types of Food	Bach/lot No.	manufacturing date	Expiry date	Name of the manufacturer	Country of origin	Quantity	Reasons of the quarantine

I the owner/possessor of this product my name is listed herein below confirmed that this product quarantined by the inspector(s) of the Authority will not be moved or used from its place until the investigation result is known.
Owner/Possessor Name_____ Signature _____ Date_____ time _____

Inspector(s) name who quarantined the product
Name
_____ signature ____
_____ signature _____
_____ signature _____
Date of quarantine _____ time _____

N.B
This form shall have three copies
1st copy shall be sent to inspection and surveillance
2nd copy shall file with the importer document and
3rd copy shall be kept in hand of inspector with the pad

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration and Control Authority

እዝል/Annex 12

ቀን _____
የመልቀቂያ ፍቃድ ቁጥር _____
Date Release Permit No.

በመግቢያና መውጫ በር የመልቀቂያ ማሳወቂያ ሰነድ
Entry-Exit Port Release Notification

ለ _____
To
ከዚህ በታች የተጠቀሰው ምግብ በምግብ፣ በመድኃኒትና በጤና ክብካቤ አስተዳደርና ቁጥጥር አዋጅ ቁጥር 661/2002 **እና ሌሎች አግባብነት ያላቸው ህጎች መስፈርት የሚያሟላ በመሆኑ ወደ ሀገር ውስጥ እንዲገባ/ ወደ ውጭ ሀገር እንዲወጣ ፈቃድ ተሰጥ~ል፡፡**
The food item specified hereunder has been approved to be Imported/Exported to/from the country in accordance with the requirements of the Food, Medicine & Healthcare Administration & Control Proclamation No. 661/2009 and other relevant laws.

1	**የድርጅቱ ስም** Name of the Organization	
2	**የመንገዣ ሰነድ ቁጥር** Bill of lading No.	
3	**ኢንቮይስ** Invoice No.	
4	**የዲክላራስዮን ቁጥር** Declaration number	
5	**የምግቡ ዓይነት** Type of food	
7	**ከኢንቮይሱ ውስጥ ወደ ሀገር እንዳይገባ/ከሀገር እንዳይወጣ የተከለከለ (ካለ)** Food not approved to be imported/exported from the invoce (if any)	

የምግብ ዓይነት (type of food)	**መለኪያ** (unit)	**መጠን** (Quantity)	**የምርት መለያ ቁጥር** (batch No)	**ምግቡ የተመረተበት** (Manf.date)	**የአምራቹ ድርጅት ስም** (Manufacturer)	**የተመረተበት ሀገር** (Country of origin)

የኢንሰፔክተር ሙሉ ስም_____
Name of aouthorised inspector
ፊርማ _____
Signiure
የተሰጠበት ቀን _____**አገልግሎት የሚያበቃበት ቀን** _____
Date of issuance Valid up to

ማህተም
Seal

ማሳሰቢያ፡
ይህ ፎርም በሶስት ኮፒ ተዘጋጅቶ ዋናው ለጉምሩክ 2ኛው ኮፒ ለድርጅቱ የሚሰጥ ሆኖ 3ኛው ኮፒ ከፓዱ ጋር የሚቀመጥ ይሆናል፡፡
This form shall have three copies the orginal sent to custom & revenue, the 2nd copy to the organization and the 3rd copy shall be kept along with the pad/

የኢትዮጵያ የምግብ፣ የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን
Ethiopian Food, Medicine & Healthcare Administration & Control Authority

Annex 13

Telephone: +251115522547
Fax: +251115521392
E-mail: regulatory@fmhaca.gov.et
Website- http://www.fmhaca.gov.et
P.O.Box - 5681
Addis Ababa - Ethiopia
Ref. No _____/_____/_____ Date: _____/____/_____

HEALTH CERTIFICATE

This is to certify that _____ Ltd, Address_____ Ethiopia is registered under certificate of competence No _____ in accordance with the Food, Medicine & Healthcare Administration & Control proclamation No. 661/2009 of Ethiopia, as a food _____. The food is inspected to ascertain compliance with the prescribed standard.

Permission is hereby granted to it for export of_____ Metric Tons of _____to _____ as here under shown.

	Name of food	Invoice Number	Batch no	Quantity (MT)	Values ($US)	remark
	Total					

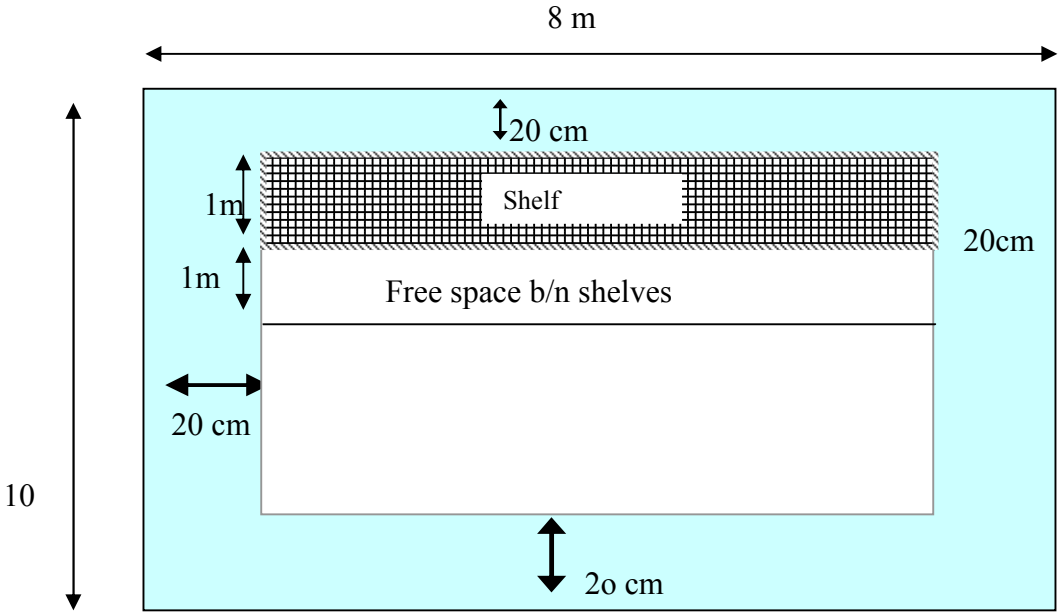
Please note that this Health Certificate is limited to this consignment only, and is Valid from Date _____/_____/_____ to Date____/____/_____.
Signed by:

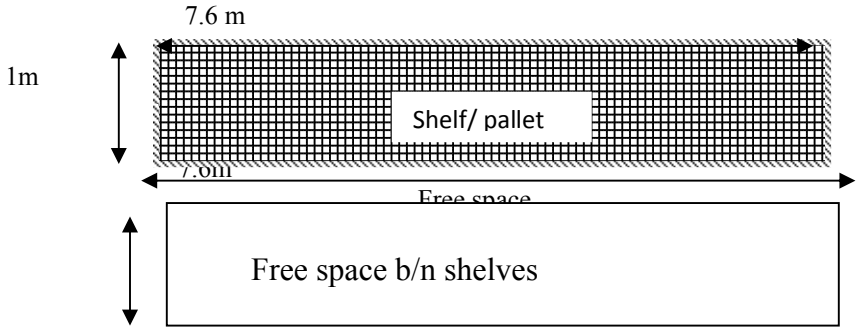
_____
Authorized person

Annex 14

A Model for Arrangement of Pallets or Shelves in Storage Room

Any food supplement business operator shall follow the following model arrangement of pallets or shelves in storage room





For example as shown on the above diagram if the area of the store room is 8 m by 10 m the total amount of pallets or shelves in the store room can determined according to the following calculation

Total Area = width*length
(Area $_1$) = 10m*8m
= $80m^2$

But as standard set the pallet or shelves in the store room shall be placed 50 cm away from the wall. So that if it is far 50 cm away from the wall in four direction /50cm*4 side/ the area occupied by the pallet or shelves shall be subtracted from the total area of the store room.
In this case:

$Area_2 = width_2 * length_2$

$= (width_1 - (50cm*2)) * (length_1 - (50cm*2))$

$= (10m - 1m) * (8m - 1m)$

$= 9\ m * 7\ m$

$= \underline{63\ m^2}$

Since the pallets or shelves shall be placed in the second area ($Area_2$) of the storage room, so the total number of pallets or shelves placed in the storage room will be:

$$\textit{No of shelves/ Pallets} = \frac{Area_2}{\textit{Area of shelves + Area of free space}}$$

$$= \frac{63m^2}{(1m*7.6m)+(1m*7.6m)}$$

$= \underline{4 \text{ shelves / pallets}}$

Therefore, the number of shelves/ pallets that can be placed in the storage room of area $80m^2$ shall not be more than four.

ANNEX 15

The table below lists some of the most common dietary ingredients with their recommended dietary allowance (RDA) values and acceptable maximum daily intake limits as a dietary supplement.

Name of Nutrient	**RDA**	**Acceptable maximum daily intake**
ACETYL CYSTEINE	250 mg	500 mg
BETA CAROTENE (PROVITAMIN A)	*	50,000 IU
BIOTIN	3µg	50-200 µg
BORON *	*	3 mg
CALCIUM	1000 mg. 1200 mg for pregnancy & lactation; & for adolescents between 11-24 yrs	1500mg
CHLORIDE	3400 mg	6800 mg
CHOLESTEROL	300mg	300mg
CHROMIUM	200 µg	600 µg of Glucose Tolerance Form (GTF
COPPER	2 mg	3 mg taken with Zinc at a 10:1 or

		15:1 ratio (Zinc: Copper)
DIETARY FIBRE	25g	50g
FLUORIDE	4 mg	8 mg
FOLATE (AS FOLIC ACID) - Vitamin B9	200 µg for men; 180 µg for women & 400 µg for pregnant women	800 µg
IODINE	150 µg	300 µg
IRON	Men-10mg, women-18mg, menopause Women-10mg. As a dietary supplement, inorganic iron (ferrous sulphate) which destroys Vitamin E should not be used. Organic iron (ferrous fumarate, ferrous citrate or ferrous gluconate) should be used.	36 mg
MANGANESE	2 mg	10 mg
MAGNESIUM	Men-350 mg, women-280mg, pregnant & lactating women-430mg	800 mg (Recommended with twice as much calcium)
MOLYBDENUM	75 µg	200 µg
PANTOTHENIC ACID	10mg	200 mg in a B complex supplement or up to 1000 mg

		in divided doses
PHOSPHORUS	1000 mg	1000 mg
POTASSIUM	2500mg	4000 mg. Athletes require up to 6000 mg because of heavy perspiration
PROTEIN (TOTAL PROTEIN)	56 g	112 g
SATURATED FATTY ACIDS	20g	40g
SELENIUM	400 µg	400 µg
SODIUM	600 mg	4800 mg
TOTAL CARBOHYDRATES	300g	600g
TOTAL FAT	65g	130g
VITAMIN A (RETINOL)	5000 IU. Pregnant women should not take over10,000IU of Vitamin A	10000-25000 IU
VITAMIN B12 (CYANOCOBALAMIN	6 µg	500-2000 µg
VITAMIN B2 (RIBOFLAVIN)	1.6 mg	25-100 mg
VITAMIN B3 (NIACIN/ NICOTINAMIDE)	20 mg	50-100 mg
VITAMIN B6 (PYRIDOXINE HCL)	2.0 mg	25-100 mg
VITAMIN BI (THIAMINE HCL)	1.5 mg. For pregnant & lactating	25-100 mg

	women 1.9 mg should be taken	
VITAMIN C (ASCORBIC ACID)	60 mg	1000-6000 mg
VITAMIN D3 (CHOLECALCIFEROL)	400 IU; (10.0 µg)	800 IU; (20.00 µg)
VITAMIN E (α- TOCOPHERYL ACETATE)	30 IU	400-1200 IU
VITAMIN K3 (MENADIONE)	80 µg for men, 65 µg for women	160 µg
ZINC	15 mg	30-50 mg (taken with a Zinc: Copper ratio of 10:1

- RDA value for this item has not been defined

It should be noted that the acceptable maximum daily allowance RDA shown above is not exhaustive and is bound to change from time to time according to acceptable standards.