Ethiopian Food, Medicine and Health Care Administration and Control Authority

Infant Formula and Follow-up Formula Directive

June 2014

Contents

Preamble

WHEREAS, considering the vulnerability of infants and the potential health risks including severe infections associated with unsafe or poor quality infant formula, special formula and follow-up formulas;

WHEREAS, following the national attention afforded to the promotion and protection of infants and child health, it is found essential to adequately regulate the safety quality, and promotion of infant, follow-up and special formulas;

WHEREAS, that the encouragement and protection of breastfeeding is an important part of the health, nutrition and other social measures require to promote healthy growth and development of infants and young children ; and that breastfeeding is an important aspect of primary health care;

WHEREAS, it is found essential to require infant formula, special formula and follow-up formulas to pass through a registration process, have market authorization and the person involved in trading these products to have a certificate of competence before products are made available to the public;

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.299/2014.

PART ONE
GENERAL

1. Short title

This directive may be cited as “Infant Formula and Follow-up Formula Directive No 335/2020

2. Definitions

Without prejudice to the definitions provided under Proclamation No. 661/2009 and Regulation No.299/2014, in this directive, unless the context otherwise requires:

1) “Infant formula” means breast milk substitute formulated industrially in accordance with applicable standards to satisfy the normal nutritional requirements of infants up to six months of age and adapted to their physiological characteristics;
2) “Follow-up formula” means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with the appropriate standard for follow-up formula and marketed or otherwise represented as suitable for feeding infants and young children from the sixth month on up to three year of age;
3) “Special formula” means a type of infant formula specially processed or formulated to satisfy the special nutritional requirements of infants starting from birth and during the first six months with specific disorders, diseases or medical conditions;
4) “Appropriate standard” means a product standard set in the Ethiopian or CODEX Alimentarius standard;
5) “Label” means any tag, brand, mark, pictorial, or other descriptive matter, written, printed, stenciled, marked, embossed, or impressed on, or attached to, a container of any infant-formula, complementary food, follow-up formula and special formula;
6) “Container” means any form of packaging of products for sale as a normal retail unit including wrappers;

7) “Product” means any regulated item under this directive including infant formula, follow-up formula, special formula;

8) "Good manufacturing practice" means measures or practices undertaken to ensure that the process by which infant, follow-up, or special formula is manufactured or processed is of good quality and safe;

9) “Certificate of competence” means a work license issued for a person to carry out product trade in accordance with standards set;

10) “Health certificate” means a certificate issued by competent authority showing that the product is fit for human consumption or that meets appropriate standards;

11) “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;

12) “Wholesaler” means a person who distributes products in more than one region;

13) “ Manufacturer” means a manufacturer producing product intended to sale for more than one regional states or foreign markets;

14) **“**Authority” means the Ethiopian Food, Medicine and Healthcare Administration and Control Authority;

15) “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;

16) “Hazardous Analysis Critical Control Point (HACCP)” means a system, which identifies, evaluates and controls hazards which are significant for product safety;

17) “Market authorization” means an official document issued by the Authority for the purpose of marketing or free distribution of the product in Ethiopia;

18) “Person” means any physical or juridical person;

3. Scope

This directive shall be applicable on all import, export, and wholesale trade of infant formula, special formula, and follow-up formula.

4. Objectives

The objectives of this directive shall be to:

1) protect infants and young children from health risks emerging out of unsafe or poor quality this products;
2) take regulatory measures in safeguarding breast feeding; and
3) control the packaging, labeling information and advertisement of regulated products under this directive.

PART TWO
REGISTRATION

5. Registration requirement

Any product regulated under this directive and to be marketed in Ethiopia shall be registered by the Authority after satisfying requirements provided under Article 7 to Article 10.

6. Notification of variation and 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 product with variation.
2) A product registered in accordance with the preceding article 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 HACCP 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 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 submitted 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 a registration certificate, an applicant shall submit Good Manufacturing Practice (GMP), Hazard Analysis Critical Control Point (HACCP), or ISO 22000.2005, 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 HACCP.

3) The certificates presented under sub-article (1) of this article shall be dated, current and authenticated copy.

8. Technical documents

1) Formulation, and manufacturing and packaging procedure

a) Registration application shall be accompanied with qualitative and quantitative compositions data including names of all ingredients, additive, and its official reference.

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) Certificate of analysis in external laboratory of the finished product at least for three consecutive commercial size batches.

3) Stability study report and shelf life assignment

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

a) Brand or generic name of the product, if applicable;
b) The test condition shall mimic Ethiopian climatic conditions of zone 4 for accelerated and real time 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 all subsequent results of chemical, physical and microbiological test results. 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; and
h) Summary of the study and storage recommendations based on the data generated.

9. Packaging and labeling requirements for finished product

1) The packaging material shall be made out of substances, which are safe and suitable for their intended use, and the product shall be packed in container which will safeguard its hygienic, safety, quality and food grade.
2) Labels may not discourage breast feeding in any manner and shall be designed to provide the necessary information about the appropriate use of the product.
3) Any products may not be described or presented on any label or in any labeling in a manner that is false, misleading or discouraging breastfeeding or is likely to create an erroneous impression regarding its character in any respect.

4) Neither the container nor the label shall have pictures of the infants or other pictures or texts, which may idealize the use of the product.
5) The terms “humanized”, “maternalised” or other comparable terms may not be used.
6) The immediate container of the product shall be affixed or written on with a label bearing the following particulars in clearly legible, clear, conspicuous and indelible letters at least in Amharic or in Amharic and English:

    a) Name of the product; and its identification as “infant formula”, “complementary food”, or ‘follow-up formula’ or its equivalent;
    b) The words “Important Notice” or its equivalence;
    c) A statement of the superiority of breast milk;
    d) A statement that the product should be used only on the advice of a health professional as to the need for its use and the proper method of use;
    e) Precautions and warnings, where necessary;
    f) Appropriate instruction for use or preparation;
    g) Name and full address of the manufacturer, including country of origin;
    h) List of ingredients;
    i) Nutritional information declaring in numerical form the amount of nutrients present in the product per portion of the product as recommended for daily consumption or amount per unit for single use;
    j) Net content by weight for powdered products or volume for liquid;
    k) Date of manufacture and expiry, which shall be indented and indicate at least the month and year;
    l) The storage condition, and where appropriate, shelf life of the product before and after opening and its reconstitution;
    m) Batch or lot number; and
    n) Required professional advice, if necessary.

7) A statement “Breast milk is the best food for your baby” or a comparable statement regarding the superiority of breastfeeding or breast milk shall be provided.
8) All ingredients on the label of the product shall be listed in accordance with the following sub-articles:

a) The source of the protein in the product shall be clearly shown on the label.
b) Except for single ingredient products, a list of ingredients shall be declared on the label 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 shall be declared.
d) Additives such as fillers, artificial colors, sweeteners, flavors, or binders shall be listed by their specific names/E-numbers and qualified by words.
e) "Natural" or "artificial" in descending order in weight or volume.

10. Quality analysis result

A regulated product quality analysis result shall comply with the Ethiopian or Codex Alimentarius Standard requirement to be registered and marketed in Ethiopia.

PART THREE
CERTIFICATE OF COMPETENCE

11. Requirement for a certificate of competence

1) Any person wants to import, export, or wholesale a regulated product 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 manpower 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. Where inspection

results find out one or more set requirements to be corrected, re-inspection may be carried out free of charge. However, an inspection beyond the second time may only be made against payment of service fee required by the Authority.

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.

12. 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, water and telecommunication 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.

13. Design and construction

1) The store 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 storage room shall be separate or separately residence.
4) 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.

5) Wall of the storage room shall be easily washable, free from cracks, and not convenient to harbor dirt.
6) Wall of the storage room shall be painted in white plastic paint or made out of ceramics or similar materials.
7) 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.
8) The ceiling shall be impermeable, smooth, easy to clean, light color, non porous, free of cracks and paint peels.
9) Doors and windows shall be able to prevent the entrance of dust, insects, rodents and other food contaminants.
10) Rooms shall constructed in such a way to allow adequate air and light circulation.
11) There shall be a toilet with hand washing facility. The toilet shall be easily cleanable, well ventilated and not open directly to the store.

14. Materials and equipments

1) Shelves or pallet shall be available in such a way that they are at least 20cm away from the floor, 50 cm 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, fire extinguisher, first aid kit, 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.

15. Professional requirement

1) Any person engaged in import, export or distribution of regulated products under this directive shall 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 and food engineering.

16. 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 necessary, the technical personnel shall have the obligation to inform the Authority.
4) If the deviation believed to be an eminent and serious hazard to the 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.
6) The technical personnel shall keep the invoices and other records regarding to the sale of the product and shall report to the authority annually.
7) The technical personnel shall follow up the distribution channel of the product to the market.

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

1) In order to be granted with 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.

18. Displaying certificate of competence

Original of the certificate of competence shall be placed in a conspicuous place where it can be easily seen by clients and regulatory officers.

19. Replacement of certificate of competence

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

20. 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.

21. Renewal of the certificate of competence

1) A certificate of competence shall be renewed between "Hamle"1 and "Nehase" 30 of the Ethiopian calendar up on the confirmation of regulatory compliance through annual inspection, and payment of prescribed service fee.
2) If the certificate of competence is not renewed in accordance with sub-article (1) of this article, it shall be renewed with 50% increment penalty for each of the coming two months.

3) If the certificate of competence is not renewed in accordance with sub-article (2) of this article, the certificate of competence shall be considered cancelled.

PART FOUR
PRODUCT IMPORT, EXPORT AND WHOLESALE

22. 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) Where any original certificate is in language other than English or Amharic, copies shall be presented together with certified translation.
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.

23. Packaging and labeling

1) Packaging and labeling of imported products shall be in accordance with the registration specification for finished products.
2) Any product, at the time of release, shall have more than six months of time to expire if its total shelf life is nine months, and more than 50 % of its total shelf life if the shelf life is more than nine months.
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.

24. Export

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

25. Storage, transportation and distribution

1) Applicable safety standards shall be observed 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

26. Administrative measures and complaint handling

1) Products, entities or individuals who violate requirements of this directive or other applicable laws may be subjected to appropriate administrative measure in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
2) The person against whose product or whom an administrative measure is taken 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) Complaints may be submitted by the licensee, owner of the business or a duly authorized agent of the owner or licensee. The complaint shall be submitted within 30 days from the time when administrative measure is taken.
4) Without prejudice to sub-article (1) of this article, the following may be used as illustrative lists for suspension and revocation:

27. 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;
4) the certificate of competence is in any manner transferred to third parties;
5) If the institution is suspended by another appropriate organ from business activities, its certificate of competence shall be suspended for the same duration of time; and
6) If comparable violation is committed.

28. Revocation

Based on the 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) possess or sale a product in any manner from any person having no certificate of competence;
3) 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;
4) import, export, or distribute a product other than the product type the certificate of competence issued for;
5) possess, sale or distribute any unregistered, adulterated, counterfeited, damaged, expired, banned, unlabeled or unduly labeled product;
6) intentionally acquire a product from unlawful sources or intentionally sale to or distribute those products to a person having no certificate of competence;
7) without having contractual agreement with the manufacturer, sales products by repacking, or relabeling the pre-packed products;
8) continue operating its business by violating terms and conditions of any suspension measure;
9) is subjected to three or more suspension measures for similar faults listed under the suspension provision within three years;
10) is prohibited from doing its business by another appropriate government organ;
11) advertise its product for more than two times in contrary to applicable laws;
12) impedes the work of inspector; or
13) commits other comparable violations.

29. Returning certificate of competence

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.

PART SIX

MISCELLANEOUS PROVISIONS

30. Supply chain and documentations

1) An importer may only sell products to a wholesaler or retailers having valid certificate of competence from the appropriate organ.
2) A wholesaler may only sale infant and special formula to health institutions, special shop and super marketer having a certificate of competence from the appropriate organ.
3) A wholesaler may only sale follow up formula to retailers having a certificate of competence from any appropriate organ.
4) The business operator shall keep the full address of the organization to whom the product is sold and the organization from whom the product is bought.
5) Documents regarding import, export or wholesale activities, including invoices, receipts, stock and bin cards, and damaged, expired, or disposed products shall be kept for one year after expired date of the products in appropriately and supplied to the Authority when required.
6) Periodic report regarding imported, distributed, exported, damaged, expired or disposed products shall be made to the Authority every six months.

31. Public and media disclosure

1) Disclosure of administrative measure shall only be allowed 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.

32. Advertisement

Infant, follow up and Special Nutritional Formula may only be advertized in accordance with the Authority's Food Advertisement Directive.

33. Service fee

Any person who seeks regulatory service under this directive may be required to pay applicable service fee to the Authority.

34. 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) "Infant Formula, Follow-up Formula and Formulas for Special Nutritional Purpose Regulatory Directive No. 13/2013" is hereby repealed.

35. 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

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 ባለልጣን
Ethiopian Food, Medicine & Health Care Administration and Control Authority

Application Form for Certificate of Competence

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

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

Importer ☐ Wholesaler ☐ Exporter ☐

5. The type of product intended to hold

Infant formula ☐ Follow-up formula ☐ Special formula ☐

Complementary Food ☐

6. 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 መውቀትና 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 _____

ANNEX-IV

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

AMemorandum of Understanding
የመተማመኛ ቅፅ

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 / ተወካ ስም**_____
   Name of the organization owner/Representative
3. **የቴክኒካል ባለሙያ ስም**_____
   Name of technical personnel

ተ.ቁ S.No	**በድርጅቱ ውስጥ የተገኙ ክፍተቶች** Gaps' identified	**በድርጅቱ መወሰድ ያለባቸው የማስተካካያ 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. _____ _____ **ቀን** Date _____	**የድርጅቱ ባለቤት/ ተወካይ ስምና ፊርማ** Name of the organization owner/Representative & signature _____ _____ **ቀን** Date _____

<u>ማሳሰቢያ</u>

- *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 ሲአንስፔክሽንና ሰርቪላንስ ዳይሬክቶሬት ለክትትል ይሰጣል።*
- *ድርጅቱ መስፈርቱን ሳያሟላ ቀርቶ በድጋሚ ፈቃድ ለማውጣት የሚመለስ ከሆነ ይህ የመተማመኛ ቅፅ በሁለት ኮፒ ተዘጋጅቶ 1ኛ ኮፒ ለድርጅቱ የሚሰጥ2ኛ ኮፒ ከድርጅቱ ፋይል ጋር ይያያዛል።*
- *ድርጅቱ በገባው የመተማመኛ ሰነድ መሰረት ክፍተቶቹን በተቀመጠለት የጊዜ ገደብ ካላጣላ አግባብ ባለው ህግ መሰረት አስተዳዳራዊ እርምጃ ይወሰድበታል።*

<u>NB</u>

- *If organization comply at least 80% of the directive criteria for getting certificate of competence for taking corrective actions on 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 file.*
- *If organization does not take a corrective action within the time frame specified on the memorandum of understanding the Authority may take the administrative measure.*

ANNEX-V

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

Photo

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

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/

1. **ይህ የብቃት ማረጋገጫ ምስክር ወረቀት በየአመቱ ካልታደሰ እንደተሰረዘ ይቆጠራል፡፡**
   This certificate of competence shall be considered cancelled unless renewed every year.
2. **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.

ANNEX-VI

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

Application Form for Port Release

Date: _____

To: The Ethiopian Food, Medicine & Healthcare Administration & Control Authority
_____ branch port of entry.

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

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

3. Certificate of competence number_____
4. Full Name of transit _____Phone No: _____
   E-Mail:_____

The following product has been imported and is waiting for inspection by the Authority's inspector. I hereby request a 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.

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

_____ _____

ANNEX-VII

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

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).

Sincerely

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

ANNEX-VIII

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

Port Entry-Exit Inspection Result Form

1. Importer name:-_____
2. Certificate of competence No:- _____
3. Port of Entry/Exit:- _____
4. AWB/BL:-_____
5. Invoice number:- _____
6. 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;

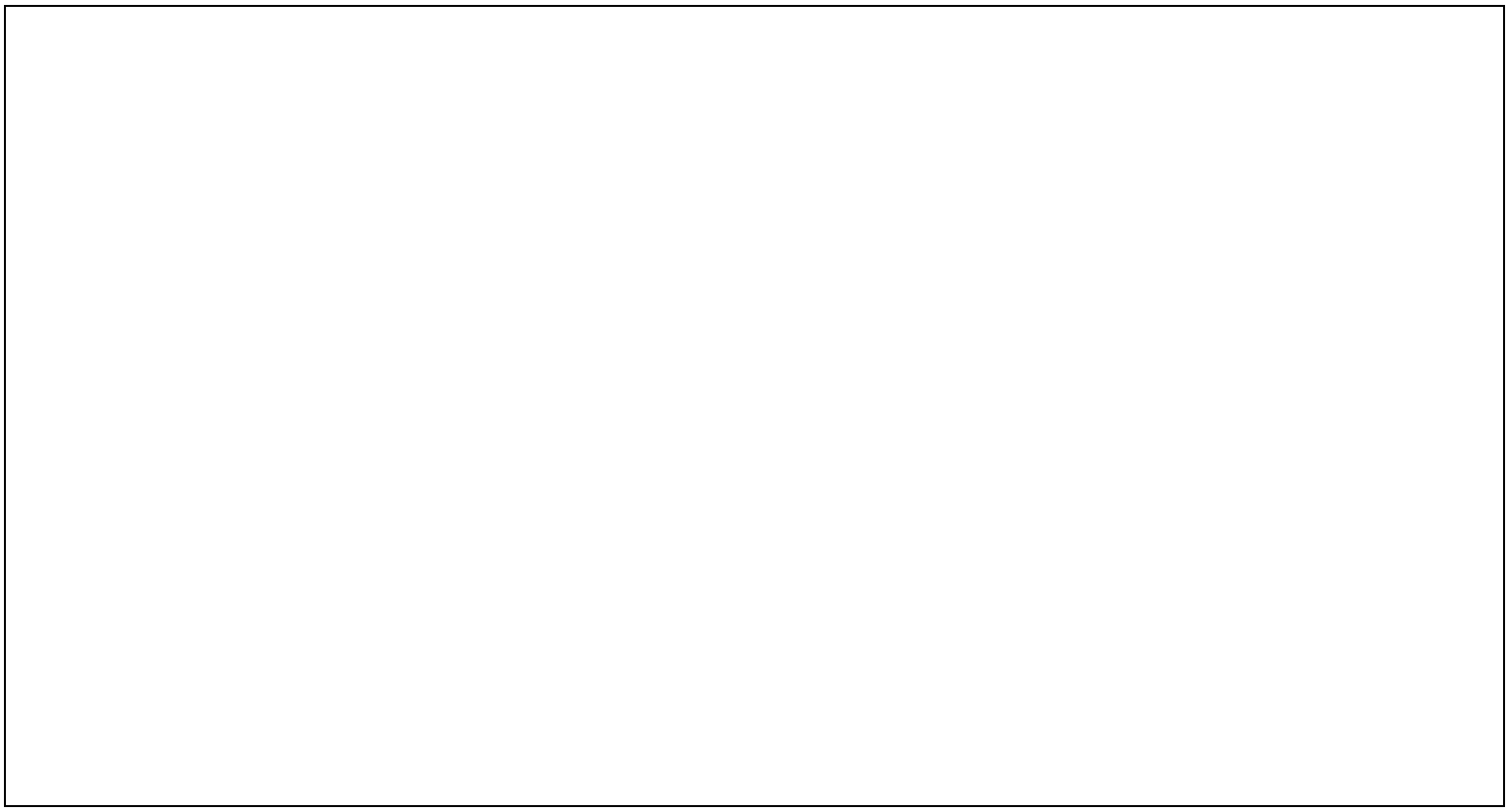
fully complies ☐ not complies ☐

General recommendation: _____

Name and signature of inspector

Name _____

Signature _____ Date of inspection _____ time _____



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

Sampling Form

I/we, listed below inspector (s) of Authority mandated in accordance with Article 5 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 owners name /representative of the organization

_____ signature _____ name _____
_____ signature _____ signature _____
_____ 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

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 _____

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

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.

1. Owner's Name _____ COC. No_____
   Address
   Region _____ Zone/Sub-City _____ Woreda _____ City _____ Kebele _____
   Unique Name of the Place _____ telephone _____
2. 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
1. _____ signature ____
2. _____ signature _____
3. _____ 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

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)

የኢንስፔክተር 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

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 _____, Address_____ Ethiopia is registered under certificate of competence No _____ in accordance with the Food, Medicine and Healthcare Administration and 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					

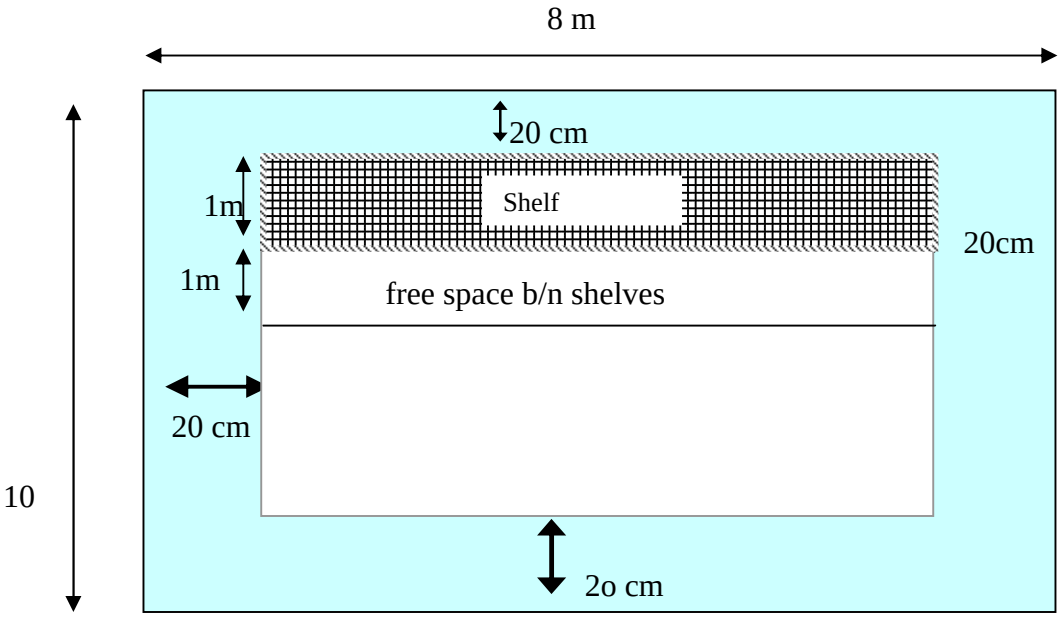
Please note that this Health Certificate is limited to this consignment only, and is Valid from Date _____/_____/_____ to Date____/____/_____.

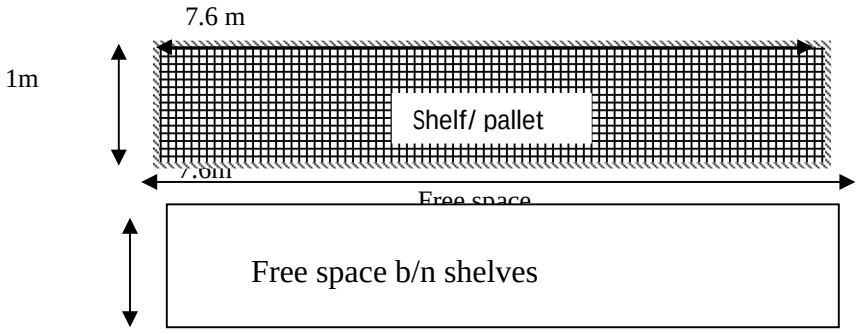
Signed by:

_____
Authorized person

በምግብ ማከማቻ ክፍል የምግብ መደርደሪያ ወይም ፓሌት አቀማመጥ ሞዴል

ማንኛውም የምግብ ንግድ ድርጅት ለምግብ ማከማቻ የሚያዘጋጀው ክፍል ውስጥ ሊያኖራቸው የሚገባ የመደርደሪያ ወይም ፓሌት አቀማመጥ እንደሚከተለው መሆን አለበት





በአንድ የምግብ ማከማቻ ክፍል ሊኖሩ የሚችሉ የምግብ መደርደሪያ ወይም ፓሌት ብዛት ከዚህ በታች በተቀመጠው ስሌት መሰረት ማወቅ ይቻላል፡፡

ለምሳሌ በስእሉ ላይ እንደተቀመጠው የመጋዘኑ ስፋት 10ሜትር በ 8 ሜትር የሆነ ማከማቻ ክፍል ሊኖሩ የሚችሉ መደርደሪያዎች ወይም ፓሌቶች ለማወቅ እንደሚከተለው ይሆናል፡፡

Total Area = width*length

(Area $_1$) = 10m*8m

= $80m^2$

ይሁን እንጂ በተቀመጠው መስፈርት መሰረት አንድ የምግብ መደርደሪያ ወይም ፓሌት ሊቀመጥ የሚችለው ከማከማቻ ክፍሉ ግድግዳ ቢያንስ 20 ሴሜ ርቆ መቀመጥ አለበት፡፡

በዚህ መሰረት ከግድግዳው በኣራቱ አቅጣጫ ያለው /20cm*4 side/ ስፋት ከጠቅላላ የመጋዘኑ ስፋት መቀነስ አለበት፡፡

በዚህ መሰረት

$Area_2 = width_2 * length_2$

$= (width_1 - (20cm*2)) * (length_1 - (20cm*2))$

$= (10cm - 0.4m) * (8m - 0.4m)$

$= 9.6m * 7.6m$

$= \underline{\mathbf{72.96m^2}}$

ስለዚህ የምግብ መደርደሪያዎቹ በውሰጠኛው ስፋት (Area $_2$) ላይ ብቻ ናቸው ሊቀመጡ የሚችሉ፡፡

በዚህ መሰረት በማከማቻ ክፍሉ በ Area $_2$ ላይ ሊኖሩ የሚችሉ የመደርደሪያ ብዛት ለማወቅ

$$\textit{No of shelves/ Pallets} = \frac{\textit{Area}_2}{\textit{Area of shelves + Area of free space}}$$

$$= \frac{72.96m^2}{(1m*7.6m)+(1m*7.6m)}$$

$= \underline{\mathbf{4.8 \text{ shelves / pallets}}}$

ከላይ በተገለጸው ምሳሌ መሰረት በ $80m^2$ ስፋት ያለው መጋዘን ሊኖሩ የሚችሉ (1m width & 7.6m length ያላቸው ሸልፎች) የሸልፍ ብዛት 5 ሼልፎች ብቻ ይሆናሉ ማለት ነው፡፡