



**Ethiopian Food, Medicine and Health Care
Administration and Control Authority**

**Infant Formula and Follow-up Formula
Directive**

March, 2016

Contents

Introduction.....	4
PART ONE.....	5
GENERAL.....	5
1. Short title.....	5
2. Definitions.....	5
3. Scope.....	7
4. Objectives.....	7
PART TWO.....	7
REGISTRATION.....	7
5. General requirement for registration.....	7
6. Administrative documents.....	7
7. Technical documents.....	9
8. Packaging and labeling requirements for finished product.....	11
9. Notification of variation and re-registration.....	12
PART THREE.....	13
CERTIFICATE OF COMPETENCE.....	13
10. Requirement for a certificate of competence.....	13
11. Location.....	13
12. Design and construction.....	14
13. Materials and equipments.....	14
14. Professional requirement.....	15
15. Responsibilities of the Technical Personnel.....	15
16. Scoring and conditions for the denial of certificate of competence.....	16
17. Displaying certificate of competence.....	16
18. Replacement of certificate of competence.....	16
19. Change of address and technical personnel.....	16
20. Renewal of the certificate of competence.....	17
PART FOUR.....	18
PRODUCT IMPORT, EXPORT AND WHOLESALE.....	18
21. Import requirement.....	18
22. Packaging and labeling.....	18
23. Export.....	19
24. Storage, transportation and distribution.....	19
PART FIVE.....	20
ADMINISTRATIVE MEASURES.....	20
25. Administrative measures and complaint handling.....	20
26. Suspension.....	20
27. Revocation.....	21
28. Returning certificate of competence.....	21
PART SIX.....	22
MISCELLANEOUS PROVISIONS.....	22
29. Supply chain and documentations.....	22
30. Public and media disclosure.....	22
31. Advertisement.....	22

32. Service fee..... 23
33. Inapplicable and repealed laws 23
34. Effective date 23

Introduction

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.299/2013.

PART ONE

GENERAL

1. Short title

This directive may be cited as “Infant Formula and Follow-up Formula Directive No.30/2016”

2. Definitions

Without prejudice to the definitions provided under Proclamation No. 661/2009 and Regulation No.299/2013, in this directive, unless the context otherwise requires:

1. “Complementary food” means any food formulated industrially as suitable or represented as suitable as an addition to breast milk, infant formula or follow up formula for infants from the age of six months up to the age of 24 months;
2. “Infant ” means a child from birth up to the age of 12 months;
3. “Infant formula” means breast milk substitute formulated industrially in accordance with the applicable standards to satisfy the normal nutritional requirements of infants up to six months of age and adapted to their physiological characteristics;
4. “Young children” means a children from the age of 12 months up to the age of three years (36 months);
5. “Follow-up formula” means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with the appropriate standards 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;
6. “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;
7. “Appropriate standard” means a product standard set in the Ethiopian standard, if any or CODEX Alimentarius or other international standards;
8. “Label” means any tag, brand, mark, pictorial, or other descriptive matter, written, printed, stenciled, marked, embossed, or impressed on,or attached or otherwise appearing to, a container of any infant-formula, complementary food, follow-up formula and

special formula which is printed or affixed to a packing material which provides the necessary information about a food and includes an insert;

9. "Container" means any form of packaging of products for sale as a normal retail unit including wrappers;
10. "Product" means any regulated item under this directive including infant formula, follow-up formula, special formula;
11. "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;
12. "Certificate of competence" means a work license issued for a person to carry out product trade in accordance with standards set;
13. "Health certificate" means a certificate issued by competent authority showing that the product is fit for human consumption or that meets appropriate standards;
14. "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, flavorant, emulsifier, and preservative;
15. "Wholesaler" means a person who distributes products in more than one region;
16. "Food Safety Management System" means the assurance that food in the food chain needs to demonstrate its ability to control food safety hazards to ensure that food is safe for human consumption.
17. "Manufacturer" means a company producing food by involving operations in the preparation of a food product, from receipt of materials, through processing, packaging, and labelling and intended to sale for more than one regional state or foreign markets
18. "Market" means to promote, distribute, sell, or advertise infant, follow-up, complementary or special formula and includes product public relations and information service
19. "Authority" means the Ethiopian Food, Medicine and Health Care Administration and Control Authority;
20. "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;

21. “Hazardous Analysis Critical Control Point (HACCP)” means a system, which identifies, evaluates and controls hazards which are significant for product safety;
22. “Market authorization” means an official document issued by the Authority for the purpose of marketing or free distribution of the product in Ethiopia;
23. “Sample” means a single or small quantity of infant, follow-up, complementary or special formula or bottles, teats or pacifiers without cost.
24. “Person” means any physical or juridical person;

3. Scope

This directive shall be applicable on all imported, exported and locally manufactured complementary foods, infant formulas, special formulas, and follow-up formulas.

4. Objectives

The objectives of this directive shall be to:

- 1) Protect infants and young children from health risks emerging out of unsafe or sub standard products;
- 2) Take regulatory measures in safeguarding breast feeding; and
- 3) Control the packaging and labeling information of regulated products under this directive.

PART TWO

REGISTRATION

5. General requirement for registration

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

6. 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 submitted in English or Amharic. Where original certificate are in other languages, copies shall be presented together with authenticated translation.
 - g) No application will accepted for registration if a manufacturer or distributor shall offer for sale skimmed, condensed, low fat or standard milk in powder or liquid form for infants.

2) Required certificates

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

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

7. Technical documents

7.1 Formulation, 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 and detailed description of the method of preparation mentioning the quality and quantity of the starting materials used, manufacturing formulae, critical process steps and manufacturing conditions, processing and packaging instructions;
 - 3) In-process quality control procedure and specification at each stage of manufacturing process and;
 - 4) sample product completed batch-manufacturing record (BMR);

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

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

- a) Specification of the finished product including test parameter and acceptable limits or reference standard for test parameters. The specification shall include physicochemical and microbiological test assay of ingredients of concern with safety and quality of the product;
- b) Details of test method including procedures, analytical instruments and acceptance criteria;
- c) The authority will conduct test consignment whenever required.
- d) Certificate of analysis in accredited laboratory of the finished product at least for three consecutive commercial size batches.
- e) A regulated product quality analysis result shall comply with the Ethiopian standard if

any or Codex Alimentarius Standard or other relevant international requirements to be registered and marketed in Ethiopia.

7.3 Stability study report and shelf life assignment

The applicant shall present relevant stability study protocol 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 4a ($30\pm 2^{\circ}\text{C}/65\pm 5\%\text{RH}$ for real time and $40\pm 2^{\circ}\text{C}/75\pm 5\%\text{RH}$ for accelerated stability).
- c) Stability study report for at least 6 months of accelerated and 12 months of real time (actual storage condition) and if the company claims for shelf life of more than 12 months, while performing accelerated stability study for 6 months and a real time stability study for 12 months, they need to provide a justification with a commitment letter.
- d) The frequency of the test should be every 3 months in the first year, every six months in the second year and then annually until the end of shelf life. Data for accelerated stability testing shall be at least for six months and real time
- e) Minimum of three batches and the batch type of at least two production sizes;
- f) Manufacturing date;
- g) Type and chemical nature of the packaging materials within which the study is conducted;
- h) Analytical methods that will quantitatively measure the characteristic and chemical properties of each ingredients of product;
- i) Initial and 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
- j) Summary of the study and storage recommendations based on the data generated.

8. Packaging and labeling requirements for finished product

- a) 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.
- b) Labels shall not discourage breast feeding in any manner and shall be designed to provide the necessary information about the appropriate use of the product.
- c) Any products shall 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.
- d) 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.
- e) The terms “humanized”, “materialized” or other comparable terms may not be used.
- f) 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 Amharic and English:
 - 1) Name of the product; and its identification as “infant formula”, “complementary food”, or ‘follow-up formula’ or its equivalent;
 - 2) The words “Important Notice” or its equivalence;
 - 3) A statement of the superiority of breast milk;
 - 4) 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;
 - 5) Precautions and warnings, where necessary;
 - 6) Appropriate instruction for use or preparation;
 - 7) Name and full address of the manufacturer, including country of origin;
 - 8) List of ingredients;
 - 9) 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;
 - 10) Net content by weight for powdered products or volume for liquid;
 - 11) Date of manufacture and expiry, which shall be indented and indicate at least the month and year;
 - 12) The storage condition, and where appropriate, shelf life of the product before and

- after opening and its reconstitution;
- 13) Batch or lot number; and
 - 14) Required professional advice, if necessary.
- g) 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.
 - h) All ingredients on the label of the product shall be listed in accordance with the following sub-articles:
 - 1) The source of the protein in the product shall be clearly shown on the label.
 - 2) Except for single ingredient products, a list of ingredients shall be declared on the label with the corresponding quantities per specified unit of measure.
 - 3) If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used shall be declared.
 - 4) Additives such as fillers, artificial colors, sweeteners, flavors, or binders shall be listed by their specific names/E-numbers and qualified by words.
 - 5) “Natural” or “artificial” in descending order in weight or volume.

9. Notification of variation and re-registration

- a) Where there is any variation on a registered product after market authorization, the responsible person shall notify the Authority of the variation before marketing the product with variation.
- b) 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 or HACCP or FSMS certificate, and a confirmatory letter that the method of manufacture or preparation is not changed.

PART THREE

CERTIFICATE OF COMPETENCE

10. Requirement for a certificate of competence

- a) Any person wants to import, export, or wholesale a regulated product under this directive shall apply for a certificate of competence in accordance with ANNEX-II.
- b) An exporter, importer, or wholesale of regulated products applying for a certificate of competence under this directive shall fulfill minimum requirements in relation to location, design and construction, building materials and manpower as defined under this directive.
- c) Notwithstanding to sub-article (a) of this article, and depending on the nature of the product, other appropriate factors may be considered in granting a certificate of competence.
- d) In order to determine compliance with this directive, the Authority shall conduct an onsite inspection of the intended facility by at least two inspectors.
- e) 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.
- f) If the inspection result conducted under sub-article (4) of this article warrant granting of the certificate of competence, the Authority shall issue the same against payment of the prescribed service fee.

11. Location

- a) The facility shall
 - 1) Be self-contained;
 - 2) be reasonably away from flood and swamp prone areas, offensive and waste disposal site;
 - 3) be locating in area where basic infrastructures including road, electricity, water and telecommunication are available;
 - 4) be reasonably far from chemical manufacturing and storage areas.
- b) The premise shall be free of conditions which might lead to contamination including

excessive dust, foul odors, smoke, pest and insect infestations, airborne microbial and chemical contaminants, and other similar conditions.

12. Design and construction

- a) The 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.
- b) The store shall be constructed in such a way that it does not compromise the safety and quality of products.
- c) The storage room shall be separate or separately residence.
- d) 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
- e) Wall of the storage room shall be easily washable, free from cracks, and not convenient to harbor dirt.
- f) Wall of the storage room shall be painted in white plastic paint or made out of ceramics or similar materials.
- g) 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.
- h) The ceiling shall be impermeable, smooth, easy to clean, light color, non porous, free of cracks and paint peels.
- i) Doors and windows shall be able to prevent the entrance of dust, insects, rodents and other food contaminants.
- j) Rooms shall construct in such a way to allow adequate air and light circulation.
- k) There shall be a toilet with hand washing facility. The toilet shall be easily cleanable, well ventilated and not open directly to the store.

13. Materials and equipments

- a) Shelves or 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.
- b) Depending on the climatic conditions of the area there shall be ventilator or

air conditioner.

- c) Any materials in the store having contact with the regulated product shall not compromise the safety and quality of products.
- d) An enclosed waste bin, fire extinguisher, first aid kit, necessary safety materials and working cloths shall be available.
- e) Where products that need refrigerator for their storage, it shall have refrigerator or cooling equipments.

14. Professional requirement

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

15. Responsibilities of the Technical Personnel

- a) The appropriate technical personnel is responsible for any health related hazards caused by compromised safety and quality from the respective products.
- b) A technical personnel is required to inform, any observed deviation from the original safety and quality, to the owner.
- c) If the owner of the business fails to take any corrective action in case where action is necessary, the technical personnel shall have the obligation to inform the Authority.
- d) If the deviation believed to be an eminent and serious hazard to the public health, the technical personnel shall inform to the authority without awaiting the decision of the owner.
- e) Technical personnel shall facilitate on job training on food safety, and handling for other personnel.
- f) The technical personnel shall keep the invoices and other records regarding to the sale of the product and shall report to the authority annually.
- g) The technical personnel shall follow up the distribution channel (chain) of the product to

the market.

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

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

17. Displaying certificate of competence

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

18. 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.

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 the certificate of competence

- a) A certificate of competence shall be renewed annually up on the confirmation of regulatory compliance through annual inspection, and payment of prescribed service fee.
- b) If the certificate of competence is not renewed in accordance with sub-article (1) of this article, it shall be renewed with 50% increment penalty for each of the coming two months.
- c) If the certificate of competence is not renewed in accordance with sub-article (2) of this article, the certificate of competence shall be considered invalid or cancelled.

PART FOUR

PRODUCT IMPORT, EXPORT AND WHOLESALE

21. Import requirement

- a) In order to get port clearance, the following documents shall be required:
 - 1) Application letter;
 - 2) Copy of certificate of competency;
 - 3) Registration certificate;
 - 4) Health certificate;
 - 5) Certificate of analysis containing, at least the date of analysis, name of organization performing the analysis, certificate reference number, name of the product, batch or lot number, physic-chemical and microbiological test results.
 - 6) Invoice;
 - 7) Packing list; and
 - 8) Airway bill or bill of loading;
- b) Where any original certificate is in language other than English or Amharic, copies shall be presented together with certified translation.
- c) Notwithstanding to sub-article (a) (4) of this article, where health certificate is not customary to be issued in the country of origin, such may be confirmed by the Authority from Embassy, consulate or appropriate government organ of the country of origin.
- d) Importation of a product sample may only be allowed for the purpose of product registration.
- e) Certificate of competence may not be required and the Authority may grant special permit where the product to be imported is used for scientific research, sample for registration, humanitarian aid, personal use which may not be of commercial size as determined by customs Authority.

22. Packaging and labeling

- a) Packaging and labeling of imported products shall be in accordance with the registration specification for finished products.

- b) Upon the issuance of import certificate after the inspection of the product by authority inspectors, if the shelf-life of the food is less than 9 months, the remaining shelf-life of the food shall be 6 months and above.
- c) Upon the issuance of import certificate after the inspection by the authority inspectors, if the shelf-life of the food is more than 9 months, the remaining shelf-life of the food shall be 50% and above.
- d) 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, required regulatory documents may be issued by the Authority to exporters.

24. Storage, transportation and distribution

- a) Applicable safety standards shall be observed during storage, handling and transportation of products.
- b) Products shall be stored in an appropriate condition according to instructions placed on its label.
- c) Products shall be stored separately from chemicals and other potential sources of contamination.
- d) Deteriorated, expired, and damaged products shall be stored separately from products until disposal.

PART FIVE

ADMINISTRATIVE MEASURES

25. Administrative measures and complaint handling

- a) 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.
- b) The person against whose product or whom an administrative measure is taken in accordance with sub-article (a) of this article may lodge complaint in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
- c) 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.
- d) Without prejudice to sub-article (a) of this article, the following may be used as illustrative lists for suspension and revocation:

26. Suspension

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

- a) If warning is given for more than two times and does not take any corrective actions accordingly;
- b) sale, buy or distribute product without knowledge of the technical personnel;
- c) advertise the products;
- d) the certificate of competence is in any manner transferred to third parties;
- e) 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
- f) If comparable violation is committed.

27. Revocation

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

- a) obtained its certificate of competence through fraudulent acts;
- b) possess or sale a product in any manner from any person having no certificate of competence;
- c) 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;
- d) import, export, or distribute a product other than the product type the certificate of competence issued for;
- e) possess, sale or distribute any unregistered, adulterated, counterfeited, damaged, expired, banned, unlabeled or unduly labeled product;
- f) intentionally acquire a product from unlawful sources or intentionally sale to or distribute those products to a person having no certificate of competence;
- g) without having contractual agreement with the manufacturer, sales products by repacking, or relabeling the pre-packed products;
- h) continue operating its business by violating terms and conditions of any suspension measure;
- i) is subjected to three or more suspension measures for similar faults listed under the suspension provision within three years;
- j) is prohibited from doing its business by another appropriate government organ;
- k) advertise its product for more than two times in contrary to applicable laws;
- l) impedes the work of inspector; or
- m) Commits other comparable violations.

28. 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

29. Supply chain and documentations

- a) An importer may only sell products to a wholesaler or retailers having valid certificate of competence from the appropriate organ.
- b) 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.
- c) A wholesaler may only sale follow up formula to retailers having a certificate of competence from any appropriate organ.
- d) 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.
- e) 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.
- f) Periodic report regarding imported, distributed, exported, damaged, expired or disposed products shall be made to the Authority every six months.

30. Public and media disclosure

- a) 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.
- b) Notwithstanding sub-article (a) of this article, the Authority may publicize administrative measures where failure to publicize would result public health risk.

31. Advertisement

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

32. Service fee

Any person who seeks regulatory service under this directive may be required to pay applicable service fee to the Authority according to the “Rate of Service Fees for Food, Medicine, Health Professional and Health Institutions Registration and Licensing council of Ministers Regulation No.370/2015.”

33. Inapplicable and repealed laws

- 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.

34. Effective date

This directive shall enter into force on March/ 2016.

Ethiopian Food, Medicine and Healthcare Administration and Control Authority