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**THE ETHIOPIAN FOOD AND DRUG AUTHORITY**

**BABY FOOD CONTROL DIRECTIVE**

 **June/2021**

**Addis Ababa**

 **PREAMBLE**

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

**WHEREAS** considering the vulnerability of infants and the potential health risks including severe infections associated with inappropriate feeding practices, including the unnecessary and improper use of baby food;

**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 marketing of baby foods;

**WHEREAS it is necessary to** ensure and safeguard the right to life of children’s mentioned under the FDRE Constitution;

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

## PART –ONE

## GENERAL

## SHORTTITLE

This directive may be cited as “Baby Food Control Directive No.xxx/2021”

## DEFINITIONS

Without prejudice to the definitions provided under Proclamation No. 1112/2019 in this directive, unless the context requires otherwise:

1. **“Advertisement”** means every form of representation of a baby foods that includes, whether or not accompanied by or in association with spoken or written words, symbols, images, or elements whether in writing or sound and whether or not contained or issued in a publication for the purpose of promoting the sale or use of a Baby food means –
2. the display of notices, signs, or billboards; or
3. means of catalogues, price lists, labels, cards or other documents or material; or
4. the exhibition or distribution of promotional content through analogue or digital media including, but not limited to, cinematograph films, video recordings, audio recordings, images, digital storage devices stored or displayed on media of any form; or
5. means of radio, television, telephone, or in any other way in the country,
6. **apparatus”** means the whole or any part of a utensil or appliance used for collecting, preparing, storing, serving, delivery or taking of food and is designated by this Directive as a feeding product;
7. **“artificial feeding**” means feeding with any manufactured food product which replaces breast milk either partially or totally;
8. **Baby food:** means any food that is processed and suitable or represented as suitable for infants and young children which include infant formula, follow-up formula special formula, growing up formula, young child formula, complimentary food and ready-to-use therapeutic food; .
9. **“brand name”** means a name given by the manufacturer to a product or range of products;
10. **“bottle feeding”** means feeding liquid or semi-solid food from a feeding bottle;
11. “**complementary food**” means any food suitable or represented as suitable as an addition to breast milk, or follow-up formula for infants from the age of 6 months;
12. **“conflict of interest”** means a situation where there is a risk that a secondary interest of an organization or individual could influence, or could be perceived to influence, the independence, objectivity of professional judgement, or actions regarding the primary interest to protect the best interest of the child or undermine public trust in those individuals, organizations and their guidance and activities;
13. **“container”** means any form of packaging of a baby food baby food offered for sale as a retail unit, including wrappers;
14. **“cross-promotion”** also called brand crossover promotion or brand stretching is a form of marketing promotion where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding, shelving, and labeling of a product to closely resemble that of another (brand extension) and includes the use of similar brand names, packaging designs, labels, text, images, color schemes, symbols or slogans or other means for the purpose of promoting a product;
15. **“Feeding product”** means a device used to feed baby foods to infants and young children including feeding bottles, teats and dummy.
16. **“feeding bottle”** means a device represented to be used to feed liquids to infants and young children, composed of a teat and a receptacle to hold the liquid; it may have a locking ring to attach the teat to the container;
17. **“health care system”** means governmental, nongovernmental, or private institutions or organisations engaged, directly or indirectly, in childcare or health care for pregnant women, mothers, infants, young children, including conducting research, medical education, or any other services whether paid or unpaid, in relation to baby foods;
18. **“health worker**” means a person working in a component of such a health care system, whether professional or non-professional, whether for compensation of as a volunteer;
19. **“infant”** means a child from birth up to the age of 12 months;
20. **“marketing”** means promoting, distributing, selling, or advertising a baby food and feeding products including baby food and feeding products public relations and information services;
21. **“nutrition claim”** means any representation that states, suggests or implies that a baby food has particular nutritional properties including, but not limited to, the energy value and to the content of protein, fats, carbohydrates, sugars, as well as the content of vitamins and minerals, or any other nutrients.
22. **“promotion”** means any method directly or indirectly encouraging a person to purchase or use a baby food and feeding products ;
23. **“sample”** means a quantity of a baby food product presented for registration or laboratory test; or provided without cost for the purposes of providing them to parents or caregivers, directly or indirectly
24. **“Sponsorship**” means any financial or in-kind assistance to a person or a group of persons or an entity, whether public or private, and sponsor has a corresponding meaning.
25. **“supply”** means to provide to another person whether by means of sale or otherwise and whether or not for compensation of any sort;
26. **“Teat”** means the part of a feeding bottle from which the baby sucks liquid and is also referred to as a nipple.
27. **Therapeutic food: -** means foods designed for specific, usually nutritional, therapeutic purposes as a form of dietary supplement for children.
28. **“young child”** means a child from the age of 12 to 36 months;
29. **“Young child formula”** means an industrially formulated milk or milk-like product of animal or vegetable origin that is marketed or otherwise represented as suitable for feeding young children from 12 months of age. It is also referred to as “growing-up milk”, “formulated milk”, “toddler milk”, or drink/product for young children”.

## Scope of Application

This Directive shall be applicable on all manufactured locally and wholesaled cross regional, imported and exported baby foods.

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## PART -TWO

## REGISTRATION OF BABY FOOD

## General

1. Any baby food regulated under this directive shall be registered first by the Authority.
2. Any baby food registration certificate valid for five years.
3. The Authority shall issue certificate of registration for registered baby food upon ascertaining the fulfilment of requirements provided by the proclamation, this directive and other appropriate laws.
4. **Administrative documents**
	1. **An application for registration of baby food shall be in the following manner:**
5. 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 submitted via the Authority’s set registration platform
6. An applicant shall submit agency agreement, 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.
7. The Authority may require additional information or samples for clarification during evaluation of the product.
8. If the applicant fails to submit written responses for the information required under sub-article 1 (a) (b and 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 applicatio**n** shall be deemed to be withdrawn.
9. An applicant whose application is considered withdrawn in accordance with subarticle 1(d) of this article may lodge new registration application.
10. 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.
11. No application shall be accepted for registration if a manufacturer or distributor offers for sale skimmed, condensed, law fat or standard milk in powder or liquid form for infant formula.
12. **Agency agreement**
13. Any agency agreement that is made between the manufacturers or legally delegated supplier and the local agent responsible for import and distribute the products shall present:

Where the product is manufactured under contract, a written contract between the

Contract giver and acceptor, which clearly states the duties of each party, and an

agency agreement made between the contract giver and the local agent, should be

submitted

* 1. Where the manufacturer manufactures a product at two or more places, the agreement and responsibility of each party made between the manufacturers shall be submitted. In such a case the agency agreement between the local agent and the manufacturer shall be the site where the file is kept and the applicant for registration.
	2. The agreement shall be signed and sealed/stamped by both parties.
	3. The agent representing the manufacturer for importation of the product shall have a trade license issued by appropriate organ and certificate of competence issued by the Authority at the time of importation of the product.
	4. The agreement shall state that if any fraud or unsuspected and unacceptable adverse event occurs to the consumer under normal utilization, both parties will be responsible to collect the product from the community and are responsible to substantiate any adverse event.
	5. If the agreement between the manufacturer and local agent is canceled in any case the manufacturer shall inform the same to the Authority.
1. **Required certificates**
	1. 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.
	2. In appropriate circumstances, internationally accepted certification or certificate of Food Safety Management System (FSMS) may be accepted in lieu of GMP and HACCP.
	3. The certificates given by competent authority presented under sub-article (a) of thisarticle shall be dated, valid, and original or copy of the original authenticated byEthiopian Embassy.
	4. Notwithstanding what is provided under sub-article (a and c) of this article, a free salecertificate given by competent Authority shall be original and authenticated by Ethiopian Embassy.
	5. A certificate indicating the product is free from Bovine Spongiform Encephalopathy Transmissible Spongiform Encephalopathy (BSE/TSE) shall be presented , if the raw material is from animal source and contains (gelatin, magnesium stearate, lactose etc).
	6. In the case of local manufacturer COC and current audit inspection report is required.
2. **Technical documents**
3. **Formulation, manufacturing and packaging procedure**
4. Registration application shall be accompanied with qualitative andquantitative compositions data including names of all ingredients, additive,and its official reference.
5. 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);
6. **Data on method of analysis and specification of the finished product**

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

1. Specification of the finished product including test parameter and acceptable limits or

reference standard for test parameters.

1. The specification shall include physicochemical and microbiological test assay of ingredients of concern with safety and quality of the product;
2. Details of test method including procedures, analytical instruments and acceptance criteria;
3. The authority will conduct test consignment whenever required.
4. Certificate of analysis in accredited laboratory of the finished product at least for three consecutive commercial size batches.
5. A regulated product quality analysis result shall comply with the Ethiopian standard
6. In the absence of national standard Codex Alimentarious Standard or other relevant regional or international requirements accepted by the authority shall be acceptable
7. **Stability study report and shelf life assignment**

The applicant shall present relevant stability study report for both accelerated and real time based on the protocol.

The protocol shall indicate:

1. Brand or generic name of the product, if applicable;
2. The test condition shall mimic Ethiopian climatic conditions of zone 4a

(30±2ºC/65±5%RH for real time and 40±2ºC/75±5%RH for accelerated stability).

1. 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.
2. 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
3. Minimum of three batches and the batch type of at least two production sizes;
4. Manufacturing date;
5. Type and chemical nature of the packaging materials within which the study is conducted;
6. Analytical methods that will quantitatively measure the characteristic and chemical properties of each ingredients of product;
7. 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
8. Summary of the study and storage recommendations based on the data generated.
9. **Packaging and labeling requirements for finished product**
10. 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.

1. For approval of packaging material certification of analysis and specification (contact approval) shall be submitted;
2. Labels shall be in accordance with the provisions provided under part five of this \directive
3. **Onsite inspection**

The Authority may conduct on site GMP inspection on baby food manufacturing sites, as Appropriate

1. **Request sample for registration**
	1. If necessary the authority may request sample of registered product for laboratory testing.
	2. The Authority may accept Laboratory test result done by accredited laboratory.

**PART-THREE**

**Variation and re-registration**

1. **Notification of variation**
2. Where there is any variation on a registered baby food product after market authorization, the responsible person shall notify the Authority using the authority product registration platform of the variation before marketing the product with any variation,.
3. The Authority shall give response in three working days for notification made in regard to minor variation. Where the Authority fail to respond within three days the applicant may market the product with minor variation of application made.
4. The Authority shall give appropriate response regarding application for major variation within reasonable time. approve or decline where major variation
5. **Categories and Requirements for Variation Application**
6. For the implementation of sub-article (2) of article 10 `minor variation` means any change made in the product labeling and packaging in the manner that it doesn`t have any impact to the safety and quality of the product such as
7. Change in the logo of the company.
8. Change in Proprietary/Brand name
9. Change in the design or layout of the package without change in the content
10. Change in the color design of the package. However, the change should not affect the legibility of the label
11. Correction and/or statements of the label without any modification to the content of the message
12. For the implementation of sub-article (3) of article 10 `major variation` means any change made in the product, labeling and packging in the manner that it have any impact on the safety and quality of the product such as Change of Origin includes change of the country of origin or change of the manufacturing site.
	1. Changes in pack size with no change in package materials or specifications should consist of Samples of the actual product in the new pack size or the additional pack size.
	2. change in container-closure like a change from plastic bottle to glass
	3. Change in Ingredient(s) or Change in composition
	4. Change in shelf-life
	5. change in manufacturing/production process:
13. **Re-Registration Application**
14. An application for re-registration of registered baby product shall be made within 180 days before the due date with application form as indicated under annex I.
15. Registration shall be deemed revoked where applicant failed to apply for re-registration of registered product within period provided under article (1) of this article and an application after made after the given time shall be considered as a new applicant.
16. The application for re-registration shall consist of:

Free sale certificate (for imported product),

Current GMP certificate or HACCP or any other FSMS certificate,

A confirmatory letter that confirms no change is made to the condition for issuing the certificate registration under article (4) and (5) of this directive,

Samples of actual product with method of analysis if necessary.

Viii. Previous registration certificate

1. The authority shall collect the expired registration certificate and issue new registration certificate upon ascertaining fulfillment of required conditions for product

**PART FOUR**

**CERTIFICATE OF COMPETENCE**

1. **Manufacturing, import, export, or wholesale of baby food product**
	1. Any person who wants to engage in manufacturing, importing, exporting, or wholesale of a baby food product shall need to have a certificate of competence (COC) in accordance to applicable laws for certificate of competency.
	2. Any person wants to engage in import, export and wholesale of baby food product shall comply the requirements set in applicable laws for manufacturing, importing, exporting and wholesaling of food
2. **Storage, transportation and distribution**
3. Applicable safety standards shall be observed during storage, handling and transportation

 of products.

1. The storage room shall be clean, dry and free from pest rodent and any infestation.
2. Products in the storage room shall have information tag mentioning , type of product, status, and other information that describe the product.
3. Products shall be stored in an appropriate condition according to instructions placed on its label.
4. Products shall be stored in a way that it will not be exposed for direct sunlight, dust and moisture.
5. Products shall be stored separately from chemicals and other potential sources of contamination.
6. Deteriorated, expired, and damaged products shall be stored separately from products until disposal.
7. The product shall be distributed to legal traders.
8. The product shall be transported in a vehicle that shall not expose the product for contamination
9. All Product receiving and distribution information shall be documented.
10. Source of the product with full address
11. To which companies the product is distributed
12. Amount and type of product received or distributed

## PART FIVE

## PACKAGING AND LABELLING OF BABY FOOD

1. **Packaging requirements for baby food product**
2. The packaging material of baby food shall be made out of substances, which are safe and suitable for their intended use, and the product shall be packed in container which safeguards its hygienic, safety, quality and food grade.
3. If there is any research indicating prohibition of the packaging material, such condition shall be applicable.
4. **Labeling requirements for baby food product**
	1. Labelling requirements of baby food shall be in accordance to the national compulsory General Standards for Pre-packaged Foods Labelling (CES 73).
	2. 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.

* 1. 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.
	2. 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.
	3. The terms “humanized”, “materialized” or other comparable terms may not be used.
	4. 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 at least in Amharic or 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” in capital letters and indicated there under, the statement “Breastfeeding is the normal and optimal way to feed infants and young children. Breast milk is important for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses” in characters “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”;
3. A statement of the superiority of breast milk using letters with more than 12 font size
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;

1. Precautions and warnings, where necessary
2. Appropriate instruction for use or preparation;
3. Name and full address of the manufacturer, including country of origin;
4. List of ingredients;
5. Nutritional information declaring in numerical form the amount of nutrients presents in the product per portion of the product as recommended for daily consumption or amount per unit for single use;
6. Net content by weight for powdered products or volume for liquid;
7. Date of manufacture and expiry, which shall be indented and indicate at least the month and year; which the product is to be consumed, taking into account climatic and storage conditions;
8. The storage condition, and where appropriate, shelf life of the product before and after opening and its reconstitution;
9. Batch or lot number; and
10. Required professional advice, if necessary.
	1. 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.
	2. All ingredients on the label of the product shall be listed in accordance with the following sub-articles:-
11. The source of the protein in the product shall be identified and clearly shown on the label.
12. Except for single ingredient products, a list of ingredients shall be declared on the label.
13. If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used shall be declared.
14. Additives such as fillers, artificial colors, sweeteners, flavors, or binders shall be listed by their specific names/E-numbers and qualified by words.
15. “Natural” or “artificial” in descending order in weight or volume.
16. **Labelling requirements of baby food for infants and young children**
	1. A manufacturer or distributor shall not offer for sale or sell baby food for infants and young children if the labelling thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.
	2. A manufacturer or distributor shall not offer for sale or sell a baby food for infants and young children, unless the labelling thereto indicates in a clear, conspicuous and easily readable manner, in Amharic or English, the following particulars:
		* + 1. Instructions for appropriate preparation and use in words and in easily understood graphics;
				2. the age in numeric figures after which the product is recommended;
				3. a warning about the health risks of improper use, preparation or storage and of introducing the product prior to the recommended age; ‟a minimum font of 3 mm tall letters base based on the lower-case letter in bold red letters on a white background for packages with less than 200 cm square of available label space and large font in proportion to the size of larger packages.”
				4. “no less than one-third the size of the characters in the product name, and in no case less than 3mm in height in bold red letters on a white background”
				5. the list of ingredients and the declaration of nutritional value in accordance with relevant national standards or, in the absence of such standard, with the relevant Codex Alimentarius Standard;
				6. the required storage conditions both before and after opening, taking into account climatic conditions;
				7. The product category (whether infant, follow-up, growing up, complimentary food with age group, etc.)
				8. Contains the word, “WARNING” and indicated there under, the statement, “Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby’s health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup” in characters no less than one-third the size of the characters in the product name, and in no case less than 3mm in height and in bold red on a white background ;
				9. preparation instructions for infant or follow-up formula in powdered form that state that:
			1. powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
			2. it is necessary for formula to be prepared one feed at a time using water that has been boiled (to 100 °C) and then added to the powdered infant formula immediately or when the water is at least70°C, before feeding to the baby, cooled to body temperature; and
			3. any unused milk must be discarded immediately after every feed.
				1. includes a feeding chart in the preparation instructions, and
				2. in the case of follow-up formula, states that the product shall not be used for infants less than six months old or used as the sole source of nutrition of infants in characters “no less than one-third the size of the characters in the product name, and in no case less than 3mm in height”.
				3. A manufacturer or distributor shall not offer for sale or sell young child formula unless the container or label affixed thereto, in addition to the requirements of Subsections 17 and 18(2)(c) – (f), states that the product shall not be used to feed infants below 12 months or used as the sole source of nutrition for young children” in characters “no less than one-third the size of the characters in the product name, and in no case less than 3mm in height”
	3. A manufacturer or distributor shall not offer for sale or sell a baby food for infants and young children if the labelling thereto contains any health or nutrition claim or any representation that states or suggests that a relationship exists between the product or constitute thereof and health, including the physiological role of a nutrient in growth, development and normal functions of the body.
17. **Labelling of Ready-to-feed Therapeutic Food and Complementary Food Products**
18. Labelling requirements of ready-to feed therapeutic food and complimentary food product should be in accordance to the national compulsory standard CES 73-General Standards for Pre-packaged Foods Labelling. In addition to labelling requirements the following requirements mentioned in subsequent article should also be respected.
19. In addition to the requirements of Articles 17(2) and 17(3), a manufacturer or distributor shall not offer for sale or sell a ready-to-feed therapeutic food or a complementary food product if the container or label affixed thereto contains:
20. any text, image or other representation that suggests the suitability of the product for infants under six months including but not limited to references to development milestones clearly reached before six months, the use of pictures of infants appearing to be younger than six months;
21. any text, image or other representation of the product or is likely to undermine or discourage breastfeeding or create a belief that the product is equivalent or superior to breast milk;
	* + - 1. any text, image or representation that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared complementary foods;
				2. any recommendation to feed the product in a bottle or otherwise promote the use of bottle feeding;
				3. any endorsement, or anything that may be conveyed or construed as an endorsement by a health professional, an association of health professional or other body; and
				4. any element that allows for cross-promotion of any other baby food baby foods for infants and young children.
22. In addition to the requirements of Sub article (1), the label of a ready-to-feed therapeutic food or a complementary food product shall include:
	* + - 1. A statement in characters “no less than one-third the size of the characters in the product name, and in no case less than 3mm in height” on:
				2. the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
				3. the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
				4. instructions for preparation, storage, handling and use; and
				5. a feeding chart showing the appropriate ration/serving size consistent with guiding principles issued by the World Health Organization.
23. **Prohibitions related to labelling of skimmed or condensed milk**
24. Labelling requirements of skimmed or condensed milk feeding should be in accordance to the national compulsory standard CES 73General Standards for Pre-packaged Foods Labelling.
25. A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used to feed infants” in characters “no less than one-third the size of the characters in the product name, and in no case less than 3mm in height”
26. **Labelling of Low-Fat and Standard Milk**
27. Labelling requirements of law –fat and standard milk should be in accordance to the national compulsory standard CES 73 General Standards for Pre-packaged Foods Labelling.
28. A manufacturer or distributor shall not offer for sale or sell low-fat or standard milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used as an infant’s sole source of nourishment” in characters “no less than one-third the size of the characters in the product name, and in no case less than 3mm in height”

## PART SIX

## ADVERTISEMENT, PROMOTION AND SPONSORSHIP OF BABY FOOD

1. **General**

No person shall conduct direct or indirect advertisement, promotion and sponsorship activities of baby food and feeding product in a manner contrary to the provisions of this directive.

1. **Advertisement and Promotion of Infant formula**
2. Prohibition of direct and indirect advertising of infant formula introduced under Article 58 sub-article 4 of the Proclamation shall include the following.
3. Advertising through radio, television, internet or any communication means an infant formula product or business organization engaged in infant formula or showing or describing symbol, image, trade mark, logo or any description that has a representation of an infant formula product or the business organization engaged;
4. Communication through audio, visual or films, print, image or any means that transmits message about infant formula; writing, showing, describing or indicating infant formula product or business organization engaged in infant formula;
5. displaying any infant formula product or picture, sign, image or distinctive feature of an infant formula product at a retail outlet, public or work place or service;
6. announcing there is price discount for infant formula product;
7. showing or associating an infant formula product or brand name, emblem, trademark, logo or trade insignia or any other distinctive feature of an infant formula product or manufacturer, importer, wholesaler, exporter, agent of infant formula product while advertising or promoting other baby food or any other product or service;
8. providing a gift, with or without infant formula product, of any equipment or materials such as pens, calendars, posters, note pads, growth charts and toys or any other materials key ring, T-shirts, hats, or any other item with logo, symbol, name, or comparable message about infant formula product or manufacturer, importer, wholesaler, exporter, agent of infant formula product;
9. providing or distributing any material that has direct or indirect association with infant formula whether or not the material contains logo, mark or symbol of infant formula;
10. giving or providing financial or material gift in associating it with infant formula or manufacturer, importer, wholesaler, exporter, or agent of an infant formula product;
11. without prejudice to the exception provided under this directive, the supply of infant formula for free;
12. incentive promotions or loyalty schemes including redeemable coupons provided with the purchase of infant products;
13. sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts
14. sending message about infant formula or manufacturer, importer, wholesaler, exporter, agent, of infant formula product through mail, e-mail, phone number or any other communication means to targeted individuals or certain section of the community or for mass;
15. distributing information or education materials or performing educational services referring to infant formula,
16. Including any information in the labeling other than content of the product, address of the product manufacturer or importer or wholesaler or exporter or all together and instruction of use.
17. Including infant product, or its image, symbol, logo, name or any representation of such product or manufacturer, importer, wholesaler, exporter or agent of infant product while advertising any other product;
18. waiving or deferring payment through any means, or provide at lower than the set wholesale price where one exists, and in its absence, lower than 80 per cent of the retail price any quantity of an infant formula to a health professional, health care facility, or child care facility, or any other distributor;
19. Conducting any communication activities regarding infant formula through any communication method to individuals, section of community or to the general public.
20. Sponsorship Associated with Infant formula
	* 1. Any infant formula product manufacturer, importer, exporter, wholesaler or agent shall not sponsor any events to be broadcasted in a radio, television or internet, or any other media or covered with gazette or other print media or public contests or telephone counselling lines, campaigns or health professional association or health professional.
		2. Any infant formula product manufacturer, importer, exporter, wholesaler or agent shall not engage in any community support activities.
		3. Any infant formula product manufacturer, importer, exporter, wholesaler or agent which has another business may sponsor an event and engage in community support activities with such business where the name or trade name or trade mark or any other description or representation of this business has no association with the infant formula.
		4. Any infant formula product manufacturer, importer, exporter, wholesaler or agent shall not offer or give any gift, contribution, sponsorship, benefit, financial or otherwise such as fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences to a health worker.
		5. Notwithstanding letter (c) of this sub-article, any person engaged in infant formula product business shall not sponsor or provide support in any way to health institution or health professionals association.
21. A health professional or an association of health or child care professionals engaged in maternal and child health and care shall not –
22. Accept any gift, contribution, sponsorship, and benefit, financial or otherwise, of whatever value, from a manufacturer, importer, exporter, wholesaler or distributor of an infant formula.
23. Give samples of infant formula product to any person.
24. demonstrate the use of infant formula, except to individual mothers or members of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of infant formula, the costs of sustaining the supply of baby foods for six months and beyond as well as the other information required by Part VI.
25. Any person who in any way participates in the dissemination of infant formula product advertising, promotion and sponsorship activities and is in a position to control the activity shall stop or take all necessary measures to limit the accessibility of the prohibited dissemination or activity.
26. **Donation of infant formula**
	1. Any infant formula product manufacturer, importer, exporter, wholesaler or agent shall not make a donation of infant formula to any person.
	2. Notwithstanding sub-article (1) of this article a donation may be made in the following manner.
27. The donation is to be made for infant during emergency situation,
28. Permission obtained from the authority, and
29. No disclose made to public of such donation.
30. **Advertisement and promotion of baby food**
31. An advertisement and promotion of baby food other than infant formula shall be in the following manner.
32. Any advertisement of a baby food other than infant formula through radio, television, internet or any communication means shall state that breast feeding is the utmost benefit to the child and the product shall not substitute breast milk.
33. Any advertisement of a baby food other than infant formula shall not state that the product has medicinal claim.
34. Any advertisement of a baby food other than infant formula shall not be made in a manner that the product has association with infant formula.
35. Any person engaged in infant formula business may not advertise baby food other than infant formula if the product has the same brand or trade name or any identification with the infant formula.
36. Promotion of baby food excluding infant formula
37. Any person engaged in manufacturing, importing, exporting, wholesaling of baby food or representative of such business shall not promote baby food at health institution, health professional association or to health professional.
38. Any person engaged in manufacturing, importing, exporting, wholesaling of baby food or representative of such business shall not waive or deferring payment through any means, or provide at lower than the set wholesale price where one exists, and in its absence, lower than 80 per cent of the retail price, any quantity of a baby food and/or feeding product to a health professional, health care facility, or child care facility, or any other distributor.
39. Any person engaged in manufacturing, importing, exporting, wholesaling of baby food or representative of such business shall not distribute from or within a health care facility any equipment, services or materials such as pens, calendars, posters, note pads, growth charts and toys or any other materials which refer to or may promote the use of a baby food;
40. Sponsorship associated with baby food

1. Any person engaged in manufacturing, importing, exporting, wholesaling of baby food or representative of such business shall not offer or give any gift, contribution, sponsorship, benefit, financial or otherwise to a health worker, health professional association or health institution.
2. sponsor events, contests, telephone counseling lines, campaigns or programmes related to reproductive health, pregnancy, child birth, infant or young child feeding, child care, health or related topics;
3. A health professional or an association of health professionals shall not –
4. Accept any gift, contribution, sponsorship, and benefit, financial or otherwise, of whatever value, from a person engaged in a baby food business or his representative.
5. accept or give samples of baby food and/or feeding product to any person unless they are medically necessary and provided in sufficient quantities to ensure full nourishment for the entire infancy; or
6. demonstrate the use of baby food, except to individual mothers or members of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of baby food, the costs of sustaining the supply of baby foods for six months and beyond as well as the other information required by Part VI
7. donation of baby food

A donation of baby food other than infant formula shall be in the following manner.

1. Any person engaged in manufacturing, importing, exporting, wholesaling of baby food or representative of such business may donate, excluding infant formula, baby food.
2. The baby food to be donated in accordance to letter (a) shall need to be genuine product.
3. Donated product shall not be sold or used other than the purpose donation made.
4. **Information and education**
	* + 1. Written, audio, or visual concerning infant and young child feeding to inform or education pregnant women, mothers or family members shall not use any pictures or text that encourage artificial feeding and shall include clear information that describes the benefits and superiority of breastfeeding;
			2. There shall be no donations of informational or educational equipment or materials by baby food manufacturers, importer, export or distributors or representative
			3. The method used by a health care personnel during demonstrations for use of infant formula and follow-up formula shall be one-on-one in a secluded area and shall inform the infant's mother on the benefits and superiority of breastfeeding;
5. **Interaction with health care personnel**
6. Any interactions between a manufacturer, importer or distributor of breast-milk substitute or complimentary food product with any health care personnel worker shall strictly be limited to creating awareness about scientific and factual matters, providing samples for professional evaluation and research on the product.
7. A manufacturer, importer or distributor, who wishes to create awareness about the scientific and factual matters of the breast-milk substitute or complimentary food product, shall before commencing interactions with any health care personnel apply in writing to the Authority.
8. Any interactions between a manufacturer, importer or distributor ofbreast-milk substitute or complimentary food product and health care personnel for the purposes of professional evaluation of the product shall commence only after the approval of the Authority has been provided in writing.
9. Any health care personnel who wish to participate in any interaction with a manufacturer, importer or distributor of breast-milk substitute or complimentary food product for the purposes of professional evaluation or research on the product shall prepare a formal record of the interaction and submit it to the regulatory within 30 day following the interaction.
10. A manufacturer, importer or distributor of breast-milk substitute or complimentary food, during the interaction with health care personnel, shall not distribute any promotional material or items, distribute any samples of its product, or engage in other activities without the prior approval of the Authority.

**PART- SEVEN**

**ADMINISTRATIVE MEASURES**

1. **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 Proclamation No. 1112/2019 and 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.
2. **Warning letter**

Any person who violates requirements of this Directive which are not subject to suspension or revocation of certificate of competence or registration certificate may be subjected to written warning by the Authority.

1. **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:

1. If warning is given for two times and does not take any corrective actions accordingly;
2. sale, buy or distribute the product without knowledge of the technical personnel;
3. sell, buy or distribute a product not complying the requirements of this Directive
4. advertise or promote the products contrary to what is provided under this Directive;
5. Provided educational information that are prohibited under this Directive
6. Provide information or educates in a way that contravene the provisions of this directive
7. Sponsors events in a way that contravene the provisions of this Directive
8. the certificate of competence or registration certificate is in any manner transferred to third parties;
9. If the institution is suspended by another appropriate organ from business activities,
10. its certificate of competence shall be suspended for the same duration of time; and If comparable violation is committed.
11. **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.
1. **Returning certificate of competence**

The certificate of competence shall be returned within three working days if suspended, revoked,

And not renewed during the renewal period or termination of operation up on one's own will.

**PART EIGHT**

## MISCELLANEOUS

1. **APPROVAL OF INFORMATION**

Any broadcaster shall evaluate and conform the information delivered by its client or its representative is in line with the requirements of this Directive before broadcasting it..

1. **CONFLICT OF INTEREST SAFEGUARDS**
	1. Any health care personnel who has any interest whether pecuniary or business interest in any designated product or pre-packaged complementary food shall disclose the nature of interest to the Authority, on commencement of employment and as soon as the relevant facts have come to his or her knowledge.
	2. A disclosure of interest under this article shall be recorded by the Authority. A health care personnel having made such a disclosure shall not be present during any interactions under this Directive; and
	3. Any ambiguity in the meaning of this Directive should be interpreted in the manner that is most protective and in the best interests of the child.
2. **SERVICE FEE**

Any person who seeks regulatory service under this Directive may be required to pay applicable service fee in accordance with Rate of Service Fee Regulation No. 370/2015

1. **COOPERATION**
	1. Any broadcaster, publisher or any other concerned institution shall respect the obligation of this directive.
	2. Any advertiser, advertisement disseminator or broadcaster shall provide the copy of information which advertised, disseminated or broadcasted upon the request of the Authority inspector.
2. **REPEALED LAWS**
3. Revised Baby Food Control Directive No.40/2010 E.C” is repealed by this directive.
4. The provision of food Advertisement Directive pertaining to Infant formula, follow-up formula and young children is repealed by this Directive
5. **EFFECTIVE DATE**
6. This directive shall inter in to force on .../2021
7. Notwithstanding to sub-article(1) of this article, article( )regarding labelling and brand name shall come into effect at the twelve month from the date of adoption of this directive.

**Heran Gerba**

**Director General**

Ethiopian Food and Drug Authority

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## ANNEX I

## Marketing of Baby food for Infants and Young Children DirectiveNotice Number\_\_\_\_XXX

COMPLIANCE NOTICE

To:

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

Business address and contact:

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

This NOTICE is issued to inform you of non-compliance: (state provision of the Directive or Regulations that have allegedly been breached)

You are required within ........... days of the date of this notice to remedy the non-compliance and take the following action:

(1)

(2)

(3)

Failure to comply with this NOTICE within the specified time frame may result in court proceedings.

Signed: .................................................. Date: ................................. .

(Inspector)

## ANNEX II

## Marketing of Baby food for Infants and Young Children Directive Record of Authorisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date | Name of person giving authorisation | Name of person to whom of apparatus is issued. | No. and description of apparatus | Signature of authorised person/pharmacist |
|  |  |  |  |  |