

LEGAL NOTICE NO. ....

**THE BREASTMILK SUBSTITUTES (REGULATION AND  
CONTROL) ACT**  
*(No. 34 of 2012)*

**THE BREASTMILK SUBSTITUTES (REGULATION AND  
CONTROL) REGULATIONS, 2017**

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**THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) ACT**

*(No. 34 of 2012)*

**IN EXERCISE** of the powers conferred by section 28 of the Breast Milk Substitutes (Regulation and Control) Act, 2012, the Cabinet Secretary for Health makes the following Regulations—

**THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) REGULATIONS, 2017**

**PART I—PRELIMINARY**

Citation.                   **1.** These Regulations may be cited as the Breast Milk Substitutes (Regulation and Control) Regulations, 2017.

Interpretation.           **2.** In these Regulations, unless the context otherwise requires—

No. 34 of 2012.           "Act" means the Breast Milk Substitutes (Regulation and Control) Act, 2012;

"authorised officer" has the meaning assigned to it under section 11 of the Act;

"container" means any form of packaging of food for infants and young children and other designated products for sale, including wrappers;

"label" includes any tag, brand mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed or attached to a container of a designated product;

"maternalised" means infant formula processed in a manner that makes it similar to breast milk; and

"pacifier" means a rubber teat not attached to the bottle.

Application.

**3.** These Regulations apply to the marketing, and practices related thereto, of food for infants and young children and other designated products, when imported into, marketed, distributed, sold or manufactured in Kenya.

## **PART II—PROCEDURE FOR APPOINTMENT OF MEMBERS OF THE NATIONAL COMMITTEE**

Declaration of vacancy and application procedure.

**4.** (1) The Cabinet Secretary shall, by notice in the Gazette and at least two national newspapers of wide circulation, declare vacancies under section 4(2)(i) and (k) of the Act and request for applications.

(2) Any qualified person may make an application in accordance with the declaration made under paragraph (1) above:

Provided that application for nomination by the bodies representing the interests of private health institutions and non-governmental organisations under section 4(2)(i) of the Act shall be done within fourteen days of the notice.

(3) The bodies referred to under paragraph (2) above shall consider the applications, interview and shortlist at least three persons qualified for each position advertised.

(4) The names of the shortlisted persons under paragraph (3) above shall, within seven days from the date of short listing, be forwarded to the Cabinet Secretary who shall appoint, from among the shortlisted persons, members of the Committee in accordance with the provisions of the Act.

Establishment of sub-committees.

**5.** (1) When establishing sub-committees under section 4(8) of the Act, the Committee shall clearly indicate the terms of reference and procedures to be followed by such sub-committees.

(2) The membership of any sub-committee shall be made up of representatives of the various sectors of the

stakeholders represented on the Committee.

**PART III—MONITORING, INSPECTION AND  
STOCKING OF FOOD FOR INFANTS AND  
YOUNG CHILDREN**

Duties of  
authorised  
officers.

6. (1) An authorised officer shall implement these Regulations under the powers vested on him or her by the provisions of the Act.

(2) No authorised officer shall have any direct or indirect commercial interest in infant and young child feeding.

(3) An authorised officer in exercise of his or her duties under the Act and these Regulations shall investigate, observe and record information regarding the marketing practices of manufacturers and distributors at any points of sale, health care facilities, border posts and offices.

(4) Subject to the Act, an authorised officer may, for the purpose of monitoring violations of these Regulations enter any premises which are used for dealing in food for infants and young children or other designated products and may—

- a) require any person in the premises to furnish any information including documents in his or her possession as the authorised officer may require;
- b) caution the person on the premises regarding any violations of these Regulations;
- c) seize any goods or promotional materials or documents where the goods or promotional material or documents in question contravene these Regulations.

(5) An authorised person shall, after discharge of his or her duties under paragraph (1), submit a report in writing, in relation to his or her findings to the Committee.

(6) In any proceedings under these Regulations, a report

signed by an authorised officer shall be accepted as *prima facie* evidence of the facts stated therein.

(7) An authorised officer, acting in accordance with these Regulations, shall if required by any person, provide proof of his or her authority.

(8) The owner, occupier or person in charge of any premises entered by an authorised officer shall give to that authorised officer all reasonable assistance and shall furnish him or her with such information as the authorised officer may reasonably require.

(9) No person may obstruct or impede an authorized officer in the course of his or her performance of her duties.

(10) No person may knowingly make any false or misleading statement, either verbally or in writing, to any authorised officer engaged in carrying out his or her duties.

Conditions for stocking.

7. (1) No person shall stock, distribute, sell or exhibit any food for infants and young children which have expired or are beyond their shelf life.

(2) No person shall stock, distribute, sell or exhibit any food for infants and young children or other designated products which are not in their original containers.

(3) A container of food for infants and young children, for sale or distribution, shall be free from dents or any other form of damage and shall be kept—

- a) in a cool and dry place;
- b) at least 50cm from the floor; and
- c) in a hygienic manner.

#### **PART IV—DONATIONS OR DISTRIBUTION OF INFANT FOOD, ETHICAL INTERACTIONS, ETC.**

Donations or distribution of

8. (1) A person or institution willing to make donations

breast milk  
substitutes.

or distribution of breast milk substitutes or a complementary food product to charitable children institution under section 7 of the Act shall make an application in writing to the Cabinet Secretary for approval.

(2) The approval by the Cabinet Secretary referred to under paragraph (1) above shall be in writing following consultation with the Committee and the Director of Children services.

(3) In the event of a state of emergency, which may endanger the life and health of infant or young children, the Cabinet Secretary may approve the procurement of designated or complementary food products through the national emergency response framework and institutions.

(4) For the purposes of paragraph (3), a "state of emergency" includes the loss of a mother, natural calamity or exposure of breastfeeding mothers to an agent which may endanger the health of the child.

(5) Despite the provisions of paragraph (3), the Cabinet Secretary shall take necessary measures to ensure—

- a) the protection, promotion and support of optimal breastfeeding and to minimize the risk of artificial feeding; and
- b) where applicable, the quick rehabilitation of the health and nutritional status of breastfeeding mothers to enable the resumption of breastfeeding.

(6) Where the exceptional circumstances provided under these Regulations have been met to warrant donation or distribution of breast milk substitutes, the Cabinet Secretary shall take necessary measures to satisfy himself or herself that—

- a) the mother of the child has passed away or her health status makes it impossible for her to breastfeed;

- b) the father or the mother of the child does not have resources to enable him or her procure the breast milk;
- c) substitute or complementary food, as the case may be, or the parents are not known or accessible; or
- d) the facility or person taking care of the child does not have sufficient resources to procure the designated or complementary food product.

Prohibition on advertising donations.

**9.** Any person making a donation under section 7 of the Act shall not advertise or publicize or announce the making of such donation.

Filing donation returns.

**10.** Persons or institutions making donations under the Act and these Regulations shall be required to file, within one month of making such donations, returns with the Committee and the Director of Children Services, indicating details of the number of children benefiting from the donations and the health outcomes of those recipients.

Restrictions on use of donations.

**11.** Donations of breast milk substitutes or designated or complementary food products to charitable children institutions made under the Act and these Regulations shall only be used within the institution to which they are donated and shall not be distributed outside that institution unless further donated to another charitable children institution with prior written permission of the Cabinet Secretary in consultation with the Committee and the Director of Children Services.

Exceptions to prohibitions and ethical interaction.

**12.** (1) The prohibitions on advertisement and promotion of complementary food products to the general public shall not include promotional activities to support and encourage improved complimentary feeding practices, including the use of fortified complimentary food where these are appropriate:

Provided that—



- a) such promotional activities are carried out with the prior written approval of the Committee, under conditions to be provided by the Committee;
- b) such promotional activities shall not make any health or nutritional claims or promote specific brand names of products; and
- c) there shall be no cross-promotion of use of breast milk substitutes through the promotion of food for infant and young children.

(2) Ethical interaction envisaged under section 6(3) of the Act between the manufacturers or distributors and health workers shall be limited to the provision of information approved under these Regulations relating to designated and complementary food products and such information shall—

- a) be restricted to scientific and factual matters regarding the technical aspects and methods of use of the designated or complementary food product; and
- b) provide references to published and peer-reviewed studies to support any representation of claim that states or suggests that a relationship exists between the product or a constituent thereof, health, growth and development.

Professional inquiries.

**13.** (1) A health worker may, in course of discharge of his or her duties under the Act, raise technical questions regarding the use of breast milk substitutes, complimentary food product or designated food product with the manufacturers with written approval of the Committee.

(2) Every response by a manufacturer to professional inquiries under paragraph (1) shall be in writing and shall be copied to the Committee.

(3) General promotional literature of breast milk substitutes or complimentary food product or related

product shall not be supplied to a health worker in response to the questions raised under this regulation unless the literature contains answers to the questions.

Explanation of risks during demonstrations.

**14.** (1) Where demonstration for the use of a designated or complementary food product is permitted, such demonstration shall provide a detailed explanation of the risks of use of breast milk substitutes and a clear and appropriate information on all of the facts, including—

- a) the benefits and superiority of breastfeeding;
- b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for at least two years;
- c) how to prepare for and maintain exclusive breastfeeding including maternal nutrition;
- d) the negative effects which the introduction of artificial feeding has on lactation and how early introduction of complementary food product interferes with breastfeeding; and
- e) the difficulty of returning to breastfeeding after a period of artificial feeding.

(2) Further to the provisions under paragraph (1) above, the information provided during the demonstration shall include information on—

- a) the proper preparation and use of the product;
- b) the approximate financial cost of adequate feeding of an infant with the product;
- c) the health hazards of bottle feeding and the improper preparation of the product;
- d) how to feed an infant with an open cup;
- e) the importance of feeding infants with an open

cup;

- f) how complementary food can easily be prepared at home using local ingredients; and
- g) the fact that powdered infant formula is not a sterile product and needs to be prepared with water at a temperature of 70 degrees centigrade.

## **PART V—LABELLING, WARNING AND PREPARATION OF DESIGNATED PRODUCTS**

Labelling of  
designated  
products.

**15.** (1) Except to the extent otherwise provided for in the Act and these Regulations, every designated product shall be labelled in accordance with the labelling provisions of the Act and these Regulations.

(2) A label or a container of a designated product shall not contain a photograph, drawing or other graphic representation other than for illustrating methods of preparation but this shall not apply to complementary food unless otherwise specified.

(3) Labels of complementary food shall not include a photograph of an infant, and shall contain—

- a) the ingredients used;
- b) the composition and analysis of the product;
- c) the storage conditions required;
- d) the batch number and the date before which the product shall be consumed relevant to the climatic conditions of the country of consumption.

Instructions on  
labelling.

**16.** Containers or labels affixed to a designated product, other than a feeding bottle, teat or pacifier shall indicate in a clear, conspicuous and easily readable manner in English or Kiswahili language and easily understood graphics indicating—

- a) instructions for appropriate preparation and use;
- b) the age after which the product is recommended for use in numeric figures which in the case of complementary food, shall not be less than six months;
- c) a warning about the health risks of improper preparation and of using the product prior to the recommended age; and
- d) such other particulars as may be subsequently provided from time to time by the Committee.

Prohibition on labelling representations.

**17.** No container or label affixed to a designated product shall contain any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including psychological role of a nutrient in growth, development or normal functions of the body.

Labelling of infant formula and follow-up formula.

**18.** (1) A person shall not offer for sale or sell infant formula or follow-up formula unless the container or label affixed thereto, contains the following words in written and clear English or its translation in Kiswahili language—

- a) in bold and conspicuous characters in a prominent position and in not less than 50% of the size of the largest words on the label not less than 2mm in height preceded by the words "IMPORTANT NOTICE" in capital letters:

"Breast milk is best. Breast milk is ideal for the healthy growth and development of infants and young children. It protects against diarrhoea and other illness".

- b) in bold and conspicuous characters in a prominent position and in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the word

"WARNING" in capital letters:

"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 the cup".

(2) The label on any container of infant formula or follow-up formula shall—

- a) not include words such as "maternalised" or "humanised" or similar words or any comparison to breast milk;
- b) not use text that may tend to discourage breastfeeding;
- c) specify the source of protein; and
- d) in case of follow-up formula, state that the product shall not be used for infants for less than six months old.

Labelling directions for use of infant formula and follow-up formula.

**19.** Despite any other requirement in these Regulations with respect to containers or labels of infant formula or follow-up formula, labelling for infant or follow-up formula in powdered form shall in addition to including a feeding chart, state that—

- a) powdered formula may be contaminated with microorganisms during the manufacturing process or may become contaminated during preparation;
- b) it is necessary for formula to be prepared one feed at a time using water at above 70 degrees celsius; and
- c) any unused milk shall be discarded immediately

after every feed.

Labelling  
requirements  
for feeding  
bottles, etc.

**20.** A label, package or a container of a feeding bottle or teat shall indicate in a clear, conspicuous and easily readable manner in English or Kiswahili language—

- a) the following words in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the words "IMPORTANT NOTICE" in capital letters:

"Breast milk is best. Breast milk is ideal for the healthy growth and development of infants and young children. It protects against diarrhoea and other illness".

- b) the following words in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the word "WARNING" in capital letters:

"It is important for your baby's health that you follow the cleaning and sterilization instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast".

- c) instructions for cleaning and sterilization in words and graphics;
- d) a statement explaining that feeding with a cup is more hygienic than bottle feeding;
- e) a warning that children should not be left to self-feed for long periods of time because extended contact with sweetened liquids, including infant formula, may cause severe tooth decay; and
- f) the name and national address of the manufacturer or the distributor.

Labelling  
requirements

**21.** A label, package or a container of a pacifier shall

for pacifiers.

indicate in a clear, conspicuous and easily readable manner in English or Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the word "WARNING" in capital letters":

"Use of pacifier can interfere with breastfeeding".

## **PART VI— INFORMATION AND EDUCATIONAL MATERIALS**

Information and educational materials on infants and young children feeding.

**22.** (1) Notwithstanding any other provision of these Regulations, no person shall publish or cause or permit to be published or distributed any informational or educational material that relates to infant and young children feeding unless approved by the Committee.

(2) For the purposes of approval under paragraph (1), a person shall submit an application to the Committee and the Committee shall respond to the application within twenty one days of the receipt of the same.

(3) Before approving any application made in accordance with this regulation, the Committee shall satisfy itself that the content therein—

- a) is written in easily readable and understandable English or Kiswahili;
- b) does not make reference to any brand name or logo of any breast milk substitute, complementary food or designated product;
- c) does not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breast milk or to breastfeeding;
- d) does not include name or logo of any manufacturer or distributor of food for infants or young children;

- e) includes only factual and current information and is not presented in any picture that encourages bottle feeding or discourages breastfeeding; and
- f) complies with the provisions of the Act and these Regulations.

(4) Information or educational materials, whether written, audio or visual, electronic or otherwise, relating to infant and young children feeding shall clearly and conspicuously explain—

- a) the benefits and superiority of breastfeeding;
- b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years and beyond;
- c) how to initiate and maintain exclusive and sustained breastfeeding;
- d) why it is difficult to reverse a decision not to breastfeed;
- e) the importance of introducing complementary food from the age of six months;
- f) how and why any introduction of artificial feeding, the use of a feeding bottle or the early introduction of complementary food negatively affects breastfeeding; and
- g) the possibility of preparing complementary food at home using local ingredients.

Informational or educational materials on food for infants and young children.

**23.** (1) Where informational or educational material referred to in regulation 22 relates to feeding infants using breastfeeding substitutes or designated products, that information shall include—

- a) instructions for the proper preparation and use of the product;



- b) the approximate financial cost of adequate feeding of an infant with the product;
- c) the health hazard of bottle feeding and improper preparation of the product;
- d) how to feed infants with an open cup;
- e) the importance of feeding infants with an open cup; and
- f) the fact that powdered infant formula is not a sterile product and requires to be constituted with water of a temperature of not less than 70 degrees centigrade.

(2) Where the material referred to in regulation 22 includes the topic of infant feeding with complementary food, it shall explain—

- a) the health hazards of introducing complementary food too soon or too late; and
- b) that complementary food can easily be prepared at home using local ingredients.

## **PART VII—OFFENCES AND PENALTIES**

Offences and penalties.

**24.** (1) A person who contravenes the provisions of these Regulations commits an offence and is liable to a fine not exceeding one million shillings or a term of imprisonment not exceeding three years, or to both.

(2) Where an offence is committed by a body corporate or other association of individuals, a director, partner or any other person concerned in, or acting or purporting to act in the management of its affairs commits an offence unless that person proves that—

- a) the act or omission constituting the offence took place without his knowledge; or

b) he or she took reasonable steps to prevent the commission of the offence.

Made on the ....., 2017.

**CLEOPA K. MAILU,**  
*Cabinet Secretary for Health.*