



LEGAL NOTICE NO.....

**THE PBREAST MILK SUBSTITUTES (REGULATION AND CONROL)
ACT
(No.34 of 2012)**

**THE BREAST MILK SUBSTITUTES (REGULATION AND
CONTROL)(GENERAL) REGULATIONS, 2020**

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**THE BREAST MILK 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 responsible for matters relating to public health, makes the following Regulations—

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL)(GENERAL) REGULATIONS, 2020

Citation. **1.** These Regulations may be cited as the Breast Milk Substitutes (General) Regulations, 2020.

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

 “Act” means the Breast Milk Substitutes (Regulation and Control) Act;

 “cross-promotion” means a form of marketing promotion where customers of one product or service are targeted with the promotion of a related product;

 “donation” means a designated product or pre-packaged complementary food offered for charity or humanitarian aid;

 “donee” means the person or institution receiving the donation;

 “donor” means the person or institution making the donation;

 “KS CODEX STAN” means any Codex Standard that has been approved as the Kenya standards under the Standards Act;

 “KS EAS” means an East African Standard that has been approved as a Kenya standard under the Standards Act;

 “KS” means a Kenya Standard approved under the Standards Act; and

 “public analyst” means a health officer who examines,

reviews, evaluates, or conducts research of designated products and pre-packaged complementary food.

Guiding principles.

3. (1) The guiding principles for interpreting the Act and these Regulations, binds the authorised officers and all persons whenever any of them—

- (a) applies or interprets any provision of these Regulations;
- (b) are involved in the manufacture, distribution, study, or advising about the use of designated products or complementary foods or about breastfeeding; and
- (c) makes or implements public policy decisions.

(2) Without prejudice to the generality of sub-regulation (1), an authorised officer shall in the discharge of his or her functions under these Regulations, ensure that—

- (a) in the provision of nutrition services, the best interest of an infant and young child is protected;
- (b) initiation of breastfeeding of the infant is done within an hour of delivery and exclusive breastfeeding for a period of six months;
- (c) timely introduction of appropriate, adequate and safe complementary food with continued breastfeeding for a period of twenty-four (24) months and beyond;
- (d) where appropriate, breastmilk substitutes and pre-packaged complementary food shall be safe for the consumption of an infant and young child;
- (e) adequate and accurate information on breastfeeding and infant and young child feeding shall be available to the general public; and
- (f) interaction with manufacturers and distributors of designated products shall be done in the manner prescribed under the Act and these Regulations.

Objects.

4. The objects of these Regulations is to guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons understand that breast milk substitutes undermines breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children.

PART II—PROCEDURES RELATING TO THE USE OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD.

Production and packaging of designated and complementary food products.

5. The production, preparation and packaging of designated products and pre-packaged complementary food shall be in accordance with—

*Cap. 254,
Cap.242
and Cap. 496.*

- (a) the provisions of the Act, the Food, Drugs and Chemical Substances Act, the Public Health Act, the Standards Act and the Kenya Standards KSEAS 39 and any other written law; and
- (b) the Kenya standards for infant formula (KS EAS4), follow up formula (KS CODEX STAN 156), formulated pre-packaged complementary food for older infants and young children (KS-2515) and processed cereal based foods for infants and young children (KS EAS 72).

Registration.

6. Every manufacturer or importer of designated products shall register with the Nutrition and Dietetic Division, in the Ministry responsible for matters relating to health, by providing its physical address, telephone, website, and email contact information and declaring that the products it imports or distributes are subject to this Act and shall provide updated information within 30 days of these declared information changing.

Sampling and testing.

7. Sampling and testing of the designated products and pre-packaged complementary food shall be in accordance with the provisions of the Act, the Food, Drugs and Chemical Substances Act, the Public Health Act and the Standards Act and any other written law.

Complying with Regulations. **8.** A manufacturer, trader, importer and distributor shall not import, offer for sale or sell any designated product or pre-packaged complementary food if it does not comply with these Regulations, the Act and any other relevant written law.

Manufacturing, sell and expiry date. **9.** No person shall stock, distribute, sell or exhibit any food for infant and young child which does not have a manufacturing date, sell by date and an expiry date.

Use of alternative containers from the original. **10.** Any person who stocks, distributes, sells or exhibits a designated product or pre-packaged complementary food for use by infants or young children in an alternative container from the original containers shall hermetically seal and label the alternative container in accordance to the Act and any other written law.

Certificate of analysis. **11.** (1) An authorised officer may at any time, collect and submit to a public analyst a sample of a designated product or a pre-packaged complementary food product for analysis.

(2) The public analyst referred to under sub-regulation (1), shall upon analysis of the product, issue a certificate of analysis.

PART III—DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD.

Application to donate. **12.** (1) A person or institution who undertakes to make a donation of a designated product or pre-packaged complementary food product to a charitable children institution or social welfare institution under the Act or these Regulations shall make an application, in writing, to the Committee for approval.

(2) An application made under sub-regulation (1), shall be accompanied by a duly completed Form BMS 1 in the Schedule to these Regulations.

Restrictions to donations. **13.** (1) A person making a donation under the Act or these Regulations shall not advertise or publicize the making of such donation.

(2) The product being donated under sub-regulation (1), shall meet all the requirements of both the Kenyan and applicable international standard as prescribed in law and have at least fifty percent (50%) shelf life before expiry.

(3) The product being donated under sub-regulation (1), shall be in the original container with a clear label marked "Not for Sale".

(4) Donations of designated or pre-packaged complementary food products to charitable children institutions or social welfare institution, made under the Act and these Regulations shall be for the purpose for which they were donated.

(5) Without prejudice to the generality of sub-regulation (3), donations made to a charitable children institution or social welfare institution shall 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 or social welfare institution with prior written consent of the Committee.

Filing of returns.

14. (1) A person or institution making a donation under the Act and these Regulations shall within two weeks of making such donations, file returns with the Committee and the Director of Children Services, in Form BMS 2 in the Schedule to these Regulations.

(2) A donee upon receipt of the donations under the Act and these Regulations, shall within two weeks, file returns for use to the Committee in Form BMS 3 in the Schedule to these Regulations.

(3) A donee shall upon utilization of the donations under sub Regulation (1), file returns with the Committee in Form BMS 4 in Schedule to these Regulations indicating details of the number of children benefiting from the donations and the health outcomes of those recipients.

Application by charitable and social institutions.

15. A person of institution that wishes to apply for donation of a designated product or a pre-packaged complementary food product shall apply in writing to the committee for directions.

Use of donations.

16. (1) Donations of a designated product or a pre-packaged complementary food product shall be used only for purposes of benefiting infant and young children to optimal health outcomes of all recipients.

(2) No person shall, for the purpose of donating any

designated product or a pre-packaged complementary food product, without the written approval of the committee, directly donate or give to any person, institution or health facility any designated product or a pre-packaged complementary food product thereof.

PART IV—LABELLING OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD

Labelling of designated products and pre-packaged complementary food product.

17. (1) The label of a designated product or complementary food product, shall in addition to the provisions of the relevant written legislation or Kenya standard, contain the name, physical address, website address, email address and telephone number of the manufacturer, seller and, if imported to Kenya, contact information for the responsible importer.

(2) Notwithstanding sub-regulation (1), the label of a designated product or pre-packaged complementary food shall not refer to, promote or advertise any other designated product.

Prohibitions on labelling

18. A label or a container of a designated product or a pre-packaged complementary food shall not contain a photograph, drawing or other graphic representation other than for illustrating how the product is to be used.

Labelling of infant formula and follow-up formula.

19. (1) A person shall not offer for sale or sell infant formula and follow-up formula unless the container and the label affixed thereto, contains the following words expressed in English and Kiswahili language in bold and conspicuous characters in a prominent position and in not less than fifty percent (50%) of the size of the largest words on the label in red lettering on white background and not less than 3 mm in height based on the lower case "o" preceded by the word "WARNING" 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 potentially fatal diarrhea, lung infections and other illness. It is often difficult to resume breastfeeding after beginning to feed your baby breast milk substitutes."

(2) The label on any container of infant formula shall—

(a) not include words such as "maternalised"