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 1in 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) Not withstanding 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"

or "humanised" or images that glorify or otherwise imply that feeding infants breast milk substitutes is natural or promotes cognitive, growth or other developmental goals;

(b) not contain any text, graphics or pictures 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 who are less than six months old.

Containers of designated and pre-packaged complementary food.

20. A label affixed to a container containing a designated product or pre-packaged complementary food, shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language and easily understood graphics indicating—

(a) instructions for appropriate preparation and use;

(b) the age range for which the product is recommended for use in numeric figures, in the case of complementary food, shall not be younger than six months;

(c) a warning about the health risks of improper preparation and of using the product before the recommended age; and

(d) such other particulars as may be subsequently provided from time to time by the Committee.

Labelling of formula in powdered form.

21. 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, indicate—

(a) that powdered formula may be contaminated during the manufacturing process or may become contaminated during preparation;

(b) that it is necessary for formula to be prepared one feed at a time using clean and safe water heated to at least seventy (70) degrees Celsius; and

(c) that any unused milk shall be discarded immediately after every feed.

Labelling requirements for feeding bottles.

22. A label, package or a container of a feeding bottle and the bottle itself shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 3 mm in height based on the lower case "o" preceded by the word "WARNING" in capital letters:

"Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against potentially fatal diarrhea, lung infections, and other illness".

Labelling requirements for teats.

23. (1) A label on a package or container of a teat shall not—

(a) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributer;

(b) contain words or images idealising the use of teats; and

(c) compare the act of suckling the teat to the action, motion or benefits of suckling human breast or physical properties of such human breast.

(2) A label, package or a container of a pacifier and the surface of the pacifier itself shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 3 mm in height preceded by the word "WARNING" in capital letters:

"Use of teats can interfere with breastfeeding."

Labelling requirements for pacifiers.

24. (1) A label on a package or container of a pacifier shall not—

(a) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributer;

(b) contain words or images idealizing the use of teats;

(c) compare the act of suckling the teat to the action, motion or benefits of suckling human breast or physical properties of such human breast.

(2) A label, package or a container of a pacifier and the surface of the pacifier itself shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 3 mm based in height based on the lower case "o" in red lettering on white background preceded by the word "WARNING" in capital letter:

"Use of pacifier can interfere with breastfeeding".

Particulars to be inscribed on container.

25. (1) No person shall sell, display for sale, consign or deliver any designated product or a pre-packaged complementary food product in a container, unless the container bears a label on which there appears—

(a) in English and Kiswahili languages, a true statement of the product as to the following matters—

(i) composition;
(ii) required storage condition;

(iii) manufacture date;

(iv) batch number;

(v) sell by date; and

(vi) expiry date.

(b) on a label marked on or securely attached to the container the following statement in red bold text against a white background;

"WARNING: Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against potentially fatal diarrhea, lung infections, and other illness".

(2) Any label affixed to any container of a designated product or a pre-packaged complementary food product as required under sub-regulation (1), shall bear directions for use in English and Kiswahili language and such adequate warnings against the health hazards of inappropriate preparation or use.

(3) The statement referred to in sub-regulation (1) shall—

(a) be clearly legible and shall appear conspicuously and in a permanent position on the label;

(b) specify the name of either the manufacturer, distributor, packer or labeller of the breast milk substitute or infant formula; and

(c) bear a physical address, website address, telephone number, and email address at which such person carries on business which shall be clearly shown in all notices, advertisements and other publications used by such person in connection with his business as dealer in the designated product or a pre-packaged complementary food product.

Warnings on nutrient.

26. A person shall not offer for sale or sell fluid milk, cereal and its products or bottled water, 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 and not less than 3 mm in height based on the lower case "o" in red

lettering on white background preceded by the word "WARNING" in capital letters:

"**WARNING**: NOT FIT FOR INFANTS: Breast milk is best for babies. It protects against diarrhea, pneumonia, lung infections, and other illness. Fluid milk, tap or bottled water, grain-based porridge, and other fluid and solid foods should not be used as breast milk substitutes during the first 6 months when breastfeeding should be infants' exclusive source of nutrition. Infant formula should only be used on the advice of a health professional. When these foods are used as complementary foods then continued breastfeeding is recommended for a period of upto 24 months and beyond."

PART V—INTERACTIONS BETWEEN MANUFACTURERS, DISTRIBUTORS AND HEALTH WORKERS.

Interactions.

27. (1) Any interactions between a manufacturer or distributor with any health worker shall strictly be limited—

(a) to creating awareness about scientific and factual matters on designated products and pre-packaged complementary food;

(b) to providing samples of designated products and pre-packaged complementary food for professional evaluation; and

(c) to providing samples of designated products and complementary foods for research on the product.

(2) The interactions between a manufacturer or distributor with any health worker referred to under sub-regulation (1), shall take place in a public venue approved by the Committee pursuant to a decision-making process consistent with the Fair Administrative Action Act, 2015.

No. 4 of 2015.

Creating awareness.

28. (1) Subject to section 6(3) of the Act, a manufacturer 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 worker apply in writing to the Committee for approval.

(2) An application made under sub-regulation (1), shall expressly provide for the following information—

(a) a sworn statement that the interaction does not imply an endorsement of the designated product or pre-packaged complementary food;

(b) a sworn statement that there is no existing relationship, collaboration or partnership or intended relationship, collaboration or partnership with the health worker;

(c) particulars of the health workers targeted for awareness;

(d) proposed public venue;

(e) sample of the designated product or pre-packaged complementary food to be used during the interaction;

(f) a certificate of analysis from a public analyst in Kenya;

(g) a detailed report on scientific findings and evidence based research on the benefits of the product;

(h) a peer-reviewed scientific information of the product;

(i) proof that the designated product or pre-packaged complementary food to be used during the interaction meets the national and international standards; and

(j) any other relevant document requested by the Committee.

(3) An applicant who is required to supply additional information under paragraph (j), shall do so within a period of 30 days from the date of the request.

Professional evaluation.

29. (1) Any interactions between a manufacturer or distributor and a health worker for the purposes of professional evaluation of a designated product or pre-packaged complementary food shall commence only after application to the Committee the approval of the Committee.

(2) Any health worker participating in the interaction under sub- regulation (1), shall—

(a) before commencing the interaction, seek written approval from the Committee; and

(b) state in writing that the interaction does not imply an endorsement of the designated product or pre-packaged complementary food and that there is no existing relationship, collaboration or partnership or intended relationship, collaboration or partnership with the manufacturer or distributor.

(3) The application referred to under sub-regulation (1) shall be accompanied by—

(a) an approved research protocol;

(b) an ethics approval from a competent and recognised authority responsible for research and innovation in Kenya issued pursuant to the Science, Technology and Innovation Act, 2013;

No. 28 of 2013.

(c) a certificate of analysis;

(d) proof of use in country of origin if the product is not made in Kenya;

(e) ethics approval from a competent authority if the product is originating outside of Kenya; and

(f) any other document the Committee may require.

Formal record.

30. Any health worker who wishes to participate in any interaction with a manufacturer or distributor, for the purposes of

professional evaluation, or research on a designated product or pre-packaged complementary food, shall prepare a formal record of the interaction and submit it to the Committee, within 30 days following the interaction.

Restrictions to interactions.

31. (1) A manufacturer or distributor during the interaction with a health worker shall not—

(a) distribute any promotional material or items;

(b) give misleading information prohibited under the Act;

(c) engage in activities that are not approved by the Committee;

(d) distribute any samples of designated or pre-packaged complementary food product;

(e) hold the event at an alternative venue not approved; and

(f) brand the venue in any way to promote infant formula.

Cross-promotion.

32. A manufacturer or distributor of a designated product or a pre-packaged complementary food shall not engage in cross-promotion.

Advertisement.

33. A person who makes a representation either directly or indirectly with an intention of promoting the sale or use of designated or pre-packaged complementary food product, either through—

(a) written publication, television or radio broadcast, film or electronic transmission, including the Internet, video or telephone;

(b) displays, signs, symbols, colours, billboards or notices; or

(c) exhibition of pictures or models;

commits an offence.

Demonstration for use of a pre-packaged complementary food product.

34. The method used by a health worker during demonstrations for use of complementary food product shall be either one-on-one or in a group and shall contain the following information—

(a) the benefits and superiority of breastfeeding;

(b) the value of exclusive breastfeeding for the first six months followed by sustained breastfeeding for at least 24 months and beyond;

(c) the proper preparation and use of the product;

(d) that use of cup or spoon feeding is safer than to bottle or spout feeding;

(e) the importance of feeding infants with an open cup and spoon; and

(f) how complementary food can easily be prepared at home using local ingredients.

Procedure for demonstration for use of infant and follow-up formula.

35. (1) The method used by a health worker during demonstrations for use of infant formula and follow-up formula shall be one-on-one in a secluded area and shall—

(a) be in the original container of manufacture;

(b) maintain hygiene;

(c) follow the manufacturer's instruction for preparation;

(d) issue the supplies in a plain packaging that conceals the brand name;

(e) declare whether the health facility is baby friendly; and

(f) make available the most recent document on demonstrations and their source.

(2) A health worker while conducting a demonstration under sub-regulation (1), shall inform the infant's mother on—

(a) the benefits and superiority of breastfeeding;

(b) how to initiate and sustain breastfeeding;

(c) the importance of periodic HIV/AIDS testing of parents, adherence to maternal Anti-Retroviral treatment and infant prophylaxis, early infant diagnosis, continued Anti-Retroviral treatment, and continued breastfeeding by mothers who are infected with HIV/AIDS;

(d) the value of exclusive breastfeeding for the first six months followed by sustained breastfeeding and introduction of nutritionally adequate and safe complementary foods for at least 24 months and beyond and optimal maternal nutrition;

(e) the difficulty of returning to breastfeeding after a period of artificial feeding;

(f) the approximate financial cost of adequate feeding of an infant with the product exclusively for six months and continued breastfeeding to 24 months and beyond;

(g) why it is difficult to return to breastfeeding after starting to feed babies breastmilk substitutes;

(h) the importance of not introducing complementary foods until after six months;

(i) the negative effects of artificial feeding on lactation and how early introduction of complementary food interferes with breastfeeding;

(j) instructions on proper preparation and use of the product;

(k) the potential health hazards of feeding bottles and cups with spouts;

(l) the importance of feeding an infant with an open cup and spoon; and

(m) how to feed an infant with an open cup and spoon.

Procedure for demonstrating proper complementary feeding.

36. (1) The method used by a health worker during demonstrations for complementary feeding for infants and young children aged 6-36 months—

(a) shall conceal brand name of the product;

(b) shall maintain hygiene; and

(c) follow the manufacturer's instruction for preparation.

(2) A health worker while conducting a demonstration under sub-regulation (1), shall inform the infant's mother on—

(a) the value of exclusive breastfeeding for the first six months followed by sustained breastfeeding and introduction of nutritionally

adequate and safe complementary foods for two years and beyond, and optimal maternal nutrition;

(b) the negative effects of artificial feeding on lactation and how mixed feeding interferes with breastfeeding;

(c) instructions on proper preparation and use of the product that emphasize home-prepared, use of locally available foods, suitability of the foods, nutrient-density, safe preparation, and safe feeding.

PART VI—INFORMATION, EDUCATION AND COMMUNICATION MATERIALS

Publication of information, education and communication materials.

37. (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 or communication material that relates to infant and young children feeding unless approved by the Committee.

(2) For the purposes of approval under sub-regulation (1), a person shall submit an application letter, together with a sample of the proposed material to be published or distributed containing any informational or educational or communication material that relates to infant and young children feeding.

(3) The Committee shall respond to the application made under sub-regulation (1) within twenty-one days of the receipt of the application, and may approve upon satisfaction that the information, education and communication materials comply to the provisions of regulation 38 of these Regulations.

Contents of information, education and communication materials.

38. The contents of the information, education and communication materials under these Regulations shall—

(a) be written in easily readable and understandable English or Kiswahili;

(b) not make reference to any brand

name or logo of any breast milk;

(c) substitute, pre-packaged complementary food or designated product;

(d) 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;

(e) not include name or logo of any manufacturer or distributor of food for infants or young children;

(f) include only factual, scientific and current information and is not presented in any picture that encourages bottle feeding or discourages breastfeeding;

(g) comply with the provisions of the Act and these Regulations;

(h) not include a photograph of an infant; and

(i) not include words or images that create the impression that the use of designated products are manufactured in accordance with the recommendation of a medical or dental practitioner or any other person registered under the Kenya medical practitioners and dentists board.

PART VII—ENFORCEMENT

Authorised persons.

39. An authorised officer may, in addition to the provisions of section 11 of the Act, include a health worker, custom officer, police officer or officers from the body responsible for Standards.

Inspection.

40. An authorised officer shall, subject to section 12 of the

Act, conduct an inspection in Form BMS 5 in the Schedule to these Regulations.

Access to breast milk substitutes.

41. A manufacturer or distributor, upon request, shall produce any prescribed designated product or pre-packaged complementary food to an authorised officer.

Seizures.

42.(1) Where an authorised officer finds any designated product or pre-packaged complementary food at any premises and the officer is satisfied, on reasonable grounds, that the goods are–

(a) prohibited goods; or

(b) not being sold by an authorised manufacturer, wholesaler, distributor or retailer of goods,

the officer may, without laying any information or obtaining any warrant, seize and remove those goods.

(2) Seizure of goods under these Regulations and Act by an authorized officer shall be in accordance to Form A and B provided for in the Schedule to these Regulations.

Conflict of Interest.

43.(1) A health worker who has any pecuniary or business interest, in any designated product or pre-packaged complementary food shall disclose the nature of the interest to the Committee, on commencement of employment and as soon as the relevant facts have come to his or her knowledge.

(2) A disclosure of interest under sub-regulation (1), shall be recorded by the Committee.

(3) A health worker having made such a disclosure shall not be present during any interactions under the Act.

General penalty.

44. A person who contravenes any of the provisions of these Regulations, shall be liable on to conviction, in accordance to the Act.

Spot fines.

45. A person who without lawful excuse the proof of which shall lie with him or her breaches any of these Regulations shall be liable, upon an inspection, by an inspector who attests to an honest belief and the balance of probability that such breach has been committed of an administrative monetary penalty of no more

than 20,000 Kenya Shillings.

Subsequent offences.

46. If a person is found to breach any provisions of these Regulations two or more times, the Cabinet Secretary responsible for public health may issue an order for a penalty to be issued in relation to each violation of the Regulations in respect of each unit sold in the case of labelling or distribution offenses or each person estimated to have been reached by advertising or promotional campaigns.

Review.

47. The Cabinet Secretary may from time to time review these Regulations for the better implementation of the Act.

SCHEDULE

(r. 12(2))

Form BMS 1

APPLICATION FOR DONATION

Donate Case No:.....Date:.....

TAKE NOTICE that I/We.....(Name of donor) of Identity/Registration No.:.....and Address.....seek consent to be allowed to make a donation to.....(Name of donee).

DESCRIPTION OF THE DONOR

Name:.....

Address:.....

Telephone:.....

Email:.....

Type of institution:.....

.....

Date of incorporation:.....

Reason for donation:.....

.....

.....

DESCRIPTION OF THE DONEE

Name:.....

Address.....

Telephone:.....

Email:.....

Types of institution:.....

Date of incorporation:.....

.....

DESCRIPTION OF THE DONATION

Name:.....

.....

Name of the manufacturer/dealer:……..……
Manufacturer date:……..……..… Batch No.:……
Sell by date:……...
Expiry date:……...
Quantity donated:……
…
Donor/Donee
Name: .....Name:.....
Signature:.....Signature:.....
Date:.....Date:.....

FORM BMS 2

(r. 14(1))

RETURNS FOR DONATION

Donate Case No:.....Date:.....

TAKE NOTICE that I/We.....(Name of donee) of Identity/Registration No.:.....and Address.....seek to make returns of products donated to us on the.....day of.....by.....(Name of donor).

DESCRIPTION OF THE DONOR

Name:.....

Address:.....

Telephone:.....

Email:.....

Type of institution:.....

Date of incorporation:.....

Reason for donation:.....

.....

.....

DESCRIPTION OF THE DONEE

Name:.....

Address.....

Telephone:.....

Email:.....

Types of institution:.....

....

Date of incorporation:.....

DESCRIPTION OF THE DONATION

Name:.....

.....

Name of the manufacturer/dealer:.....

Manufacturer date:..... Batch No.:.....

Sell by date:.....

Expiry date:.....

Quantity
donated:.....

Donee/Donor

Name: .....Name:.....

Signature:.....Signature:.....

Date: .....Date:.....

FORM BMS 3

(r. 14(2))

RETURNS FORUSE OF DONATION

Donate Case No:.....Date:.....

TAKE NOTICE that I/We.....(Name of donee) of Identity/Registration No.:.....and Address.....seek to make returns of products donated to us on the.....day of.....by.....(Name of donor).

DESCRIPTION OF THE DONOR

Name:.....

.....Address:.....

.....

Telephone:.....

.....Email:.....

.....

Type of institution:.....

..

Date of incorporation:.....

..

Reason for donation:.....

DESCRIPTION OF THE DONEE

Name:……

……

Address……

……..

Telephone:……

……..Email:……

……

Types of institution:……..……...

……

Date of incorporation:……..……

...

DESCRIPTION OF THE DONATION

Name:……

…..……

Name of the manufacturer/dealer:……..……..

Manufacturer date:……..…… .. Batch No.:……

Sell by date:……...

Expiry date:……

..

Quantity donated:……

FORM BMS 4

r.14(3)

RETURNS FORM

DESCRIPTION OF THE DONEE

Name:.....

.....

Address.....

.....

Telephone:.....

.....Email:.....

.....

Types of institution:.....

Date of incorporation:.....

DESCRIPTION OF THE DONATION

Name:.....

.....

Name of the manufacturer/dealer:.....

Manufacturer date:..... Batch No.:.....

Sell by date:.....

Expiry date:.....

.....

Quantity donated:.....

..

MODE OF USE

Beneficiaries:

Age bracket:

Number of beneficiaries:

Health outcomes:

I hereby declare that the above information is true.

Duly signed by:

Name:.....

Signature:.....

Date:.....

Form BMS 5

(r.40)

INSPECTION FORM

(To be used in case of inspection of 'articles' where the 'articles' are to be removed from the premises where they are seized).

To... *(Name and address of the vendor)*.....
.....
.....

Whereas I have reason to believe that the stock of goods detailed below which is/are at the premises of
.....
.
.....
.....
.....
.....
(Name of the premises or owner and address – physical and postal address)
Do not meet the provision(s) of Breast Milk Substitutes (Regulations and Control) Act.

DETAILS OF THE GOODS

Name of the manufacturer/distributor/importer/trader ....
....

Postal address..... ....
....

Physical location ....
..... .

Goods are marked/branded as follows..... ....
.....

Physical seal ....
.....

Description of goods ....
..... .

Manufacturer date:..... Batch No.:.....

Sell by date:.....

Expiry date:.....
.....

Quantity ....
....

Now therefore I ....
.....
an authorized officer under section 11 of Breast Milk Substitutes (Regulations and Control) Act, 2012 hereby inspects the said goods under section 12 and 13 of Breast Milk Substitutes (Regulations and Control) Act 2012.
Name of authorized officer
.....
Designation
..... .
Signature
.....
Date
.....
OFFICIAL RUBBER STAMP

Manufacturer/distributor/importer/trader/owner/person in possession of the goods
Name
.....
Designation
.....
Signature ..... Date
.....
WITNESS
Name
.....
Designation
.....
Signature
.....
To be filled in duplicate.

SEIZURE FORM A

(r. 42(2))

(To be used in case of seizure of 'articles' where the 'articles' are to be removed from the premises where they are seized).

To... *(Name and address of the vendor)*.....

.....

.....

.....

Whereas I have reason to believe that the stock of goods detailed below which is/are at the premises of

.....

.....

.....

(Name of the premises or owner and address – physical and postal address)

Do not meet the provision(s) of Breast Milk Substitutes (Regulations and Control) Act, 2012.

DETAILS OF THE GOODS

Name of the manufacturer/distributor/importer/trader

.....

Postal Address.....

.....

Physical location .....

.....

Goods are marked/branded as follows.....

.....

Physical seal .....

.....

Description of goods .....

.....

Manufacturer date:..... Batch No.:.....

Sell by date:.....

Expiry date:.....

.....

Quantity .....

.....

Now therefore I .....

.....

an authorized officer under section 11 of Breast Milk Substitutes (Regulations and Control) Act, 2012, hereby seize and detain the said goods under section 20 ofBreast Milk Substitutes (Regulations and Control) Act.

Name of authorized officer

.....

Designation

..... .

Signature

.....

Date

.....

OFFICIAL RUBBER STAMP

Manufacturer/distributor/importer/trader/owner/person in possession of the goods

Name

.....

Designation

.....

Signature ..... Date

.....

WITNESS

Name

.....

Designation

.....

Signature

.....

To be filled in duplicate.

SEIZURE FORM B

(r.42(2))

(To be used in case of seizure of 'articles' where the 'articles' are to be kept or stored in the premises where they are seized).

To... *(Name and address of the vendor)*.....
.....
.....
Whereas I have reason to believe that the stock of goods detailed below which is/are at the premises
of.....
....
.....
.....
(Name of the premises or owner and address – physical and postal address)
Do not meet the provision(s) of Breast Milk Substitutes (Regulations and Control) Act, 2012.
DETAILS OF THE GOODS.
Name of the manufacturer/distributor/importer/trader ....
....
Postal address..... ....
....
Physical location ....
..... .
Goods are marked/branded as follows..... ....
.....
Physical seal ....
.....
Description of goods ....
..... .
Manufacturer date:..... Batch No.:.....
Sell by date:.....
Expiry date:.....
.....
Quantity ....
....
Now therefore I ....
.....

an authorized officer under section 11 of Breast Milk Substitutes (Regulations and Control) Act, hereby seize and detain the said goods under section 20 of Breast Milk Substitutes (Regulations and Control) Actand direct you to keep the sealed stock in safe custody subject to such orders as maybe issued subsequently in relation there to.

Be it known to you that removal or alteration or interference in any way with the said article(s) without any authority is an offence under section 20, 21 and 22 of the Breast Milk Substitutes (Regulations and Control) Act.

Name of authorized officer

.....

Designation

..... .

Signature

.....

Date

.....

OFFICIAL RUBBER STAMP

Manufacturer/distributor/importer/trader/owner/person in possession of the goods

Name

.....

Designation

.....

Signature ..... Date

.....

WITNESS

Name

.....

Designation

.....

Signature

.....

To be filled in duplicate.

Made on the ....., 2020.

MUTAHI KAGWE
Cabinet Secretary for
Public Health.

EXPLANATORY MEMORANDUM ON COMPLIANCE TO THE PROVISIONS OF SECTION 5A OF THE STATUTORY INSTRUMENT ACT (NO 23 OF 2013) IN MAKING OF THE BREASTMILK SUBSTITUTE (GENERAL) REGULATIONS 2020

a) Statement of the proof and demonstration that sufficient public consultation was conducted

Noting the provisions of section 5A of the Statutory Instrument Act (No.23 of 2013), the Ministry of Health made adequate consultations with persons/firms who are likely to be affected by the proposed regulations, as highlighted below.

Regulations were subjected to public participation vide Public Notice published in MyGov on 13th August 2019 (copy attached) and www.mygov.go.ke for the Stakeholders' consultative forum on scheduled for 27th August 2019 at Afya Annex, room 406. Invitation was also done via email and department of health in the counties.

The draft regulations were posted online on Ministry of Health website www.health.go.ke and the Division of Nutrition and Dietetics website www.nutritionhealth.or.ke, and a call for written submissions to be sent via links provided in the website or to headnutrition.moh@gmail.com

Written submissions (attached) were received from the Kenya Association of Manufactures (KAM), Kenya Health Federation (KHF), and the Kenya Nutrition and Dietetics Institute (KNDI)

An External stakeholders' consultative forum on the draft BMS (Regulation and Control Act, 2012) was held on 27th August 2019 and was attended by 53 participants. Issues raised by KAM, KNDI and KHF through memoranda were discussed.

Following request from KAM for an opportunity to have a further consultation on the issues they had raised, a follow up meeting was held on 13th September 2019.

b) Statement of all consultations undertaken before the Regulations were made

The Regulations were made with consultation of the National Committee of Infant and Young Child Feeding (NCIYCF) established under the Breast Milk Substitutes (Regulation and Control) Act (No 34 of 2012).

The NCIYCF members enriched the Regulations making process given their varied expertise: knowledge in maternal, infant and young child feeding; inpatient and outpatient maternal and paediatric services; medical research; existing Kenya standards on infant formula, complementary foods and labeling of food products; experience in operations at national referral hospitals and medical training institutions; food safety and trade matters.

The regulation making process also involved active participation of the United Nations Agencies working on maternal, infant and young child feeding in Kenya, i.e., United Nations Children's Fund (UNICEF) and World Health Organization (WHO). Additionally, further

consultations were made with global experts on matters related to the WHO International Code of Marketing of Breastmilk Substitutes.

The process gained immensely from the experience and knowledge of one of the NCIYCF members on matters relating to Kenya and East Africa standards and Codex Alimentarius, and this ensured alignment to the existing legislations and regulations.

The drafting of the Regulations was carried by legal officers drawn from the Kenya Law Reform Commission and the legal unit at the Ministry of Health.

Internal stakeholders' consultative forum drawing participants from the departments in the Ministry of Health was held on 28th June 2019 to seek their views and build consensus on the provisions of the draft Regulations.

The Ministry also sought legal guidance and concurrence with the draft Regulations from the Attorney General.

c) Brief Explanation of the way consultation was carried out

The consultation process was governed by the following key principles: openness, access to information, visibility, transparency and accountability.

Several workshops were held to develop the draft regulations with participation of Ministry of Health, members of the National Committee of Infant and Young Child Feeding (NCIYCF), UNICEF, WHO, Legal experts (local and international), experts on matters of maternal, infant and young child feeding, trade and food standards.

Access to information was ensured by availing the draft Regulations at the Ministry of Health website www.health.go.ke and the Division of Nutrition and Dietetics website www.nutritionhealth.or.ke

Efforts were made to reach out to key stakeholders through public notice, email and hard copy invitation letters and through department of health in the counties, particularly for invitation to the External consultative forum that was held on 27th August 2019.

Inputs from stakeholders were taken into account and assessed by the team that was involved in the drafting and issues that were agreed upon to be included in the Regulations were incorporated.

An External stakeholders' consultative forum on the draft BMS (Regulation and Control Act, 2012) was held on 27th August 2019 to provide stakeholders with an opportunity to present their views and submissions.

On 10th June 22020, the Principal Secretary, Ministry of Health wrote to the Attorney General seeking legal guidance and concurrence with the draft Regulations.

d) and e) Outline of the Results of the Consultation and changes made

The results of the consultation and changes made to the draft Regulations as a result of the consultation is outlined in the matrix below.

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
1. Regulation 2 (Cross promotion) ***"Cross-promotion" means a form of marketing where customers of a product of service are targeted with promotion of a related product***	Discussions on definition of cross-promotion are still on-going at the CODEX There is no global position as at now that countries can adopt Proposal to put this regulation on hold until the process is concluded	a. According to Para 49 and 50 of 2019 CCNFSDU[1] report, the discussion was not on the **definition of cross promotion** rather on whether or not the term applies to a 'label or labelling'. Clause 9.6.4 of appendix III of the report put both 'Label & Labelling' in square brackets and not the term, 'cross promotion'. b. According to Para 24 to 28, of 2019 CCFL[2] report, the committee noted that the standard for follow-up formula did not have a definition for what 'cross promotion' though the request by CCNFSDU was related to the use of the words, 'label or labelling' in the phrase. WHO sought to clarify this as indicated in Para 27 of the report. The report concludes (Para 28) the committee decided to return the sentence "*Cross*	• Kenya law and regulation takes precedence over any regional standards and regulations. • The importance of recognizing the freedom of national governments even in the face of international and regional standards and regulations. • In good practice, standards exist for reference purposes in the development of regulation. • The term was discussed under a particular standard and the issue of concern was whether or not the resulting standard be out of the 'Mandate of Codex' as relates to IP & trade marks within WTO, TBT and TRIP. • MoH/KLRC Legal person will advise, while considering the independent

[1] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-40%252FREPORT%252FREP19_NFSDUe.pdf

[2] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-45%252FFinal%252520Report%252FREP19_FLe.pdf

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
		promotion between product categories is not permitted on the [label/ labelling] of the product" to CCNFSDU for further discussion based on the reservation the committee had. c. The commission's report of 2019[3], Para 84 (i) adopted the recommendation of CCFL and that discussion was referred back to CCNFSDU for further discussion/decision.	mandates for Codex and national Governments. • The World Trade Organization (WTO) agreement allows government to establish regulations to protect the health, safety of human, animal and environment provided they are notified. • It is also important to note there is no guidance/requirement that only the definitions in standards should be adopted in the regulations. In most cases definitions used in standards are limited to the interpretation of that particular standard and may not be applicable in other context. • **See Issue 17**
2.Regulation 8 (Stoking and expiry) ***No person shall stock, distribute, sell or exhibit any food for infant and young child which is expired. or whose declared date of expiry reads thirty(30) days before the declared date of expiry.***	This has potential to different interpretation Already, industry in self-regulation recalls expired products from stores to safeguard babies There is transferred liability from stockists to the manufacturer Let the stockists take liability Proposed R16[1] "*The label of a designated product shall be in accordance to East African standards and codex standards adopted by Kenya*"	It is true the standards address itself to expiry consistent to Cap 254	• Self-regulation by industry leaves a lot of room for improvement • The spirit of the 30 days was to have the products pulled out of shelve/not offered to sale 30 days before date of expiry in the spirit of protecting children from consuming expired products. A discussion on how to actualise this spirit will be explored. • It will not be harmful to have the statement as proposed by the industry.

[3] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-42%252FReport%252FREP19_CACe_Final.pdf

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
3. General labelling (R 16[1]	Industry is opposed to font size prescription in regulation. A previous attempt to abide by the prescribed size proved difficult to fit all the information required on labels posing challenges with space caused by larger fonts prescribed. KAM recognizes that the warning should still be legible but font size cannot be increased for all things. A presentation with current labels, one with prescribed font size and one with what industry proposes which was expected did not happen. There was only one which was poorly done as KAM did not interpret the proposed Regulation well KAM requested restraint from sharing/publicising the sample label presented as it contains a company name which needs to be protected as this was for demonstration by KAM.	The general provision as provided in regulation 16 (i) is consistent to Kenya Standards, Codex Standard for labelling and Cap 254 of the Laws of Kenya as it provides for the bare minimum of a label. The proposed text by industry is too general and would potentially introduce conflicts given that food labelling is an area which is emerging with new areas requiring standardization. Regulations should make specific normative reference to an existing standard and not make general requirement. Further, Kenya only implements Kenya Standards and hence reference to East Africa Standards and Codex standards is erroneous.	• A decision should be made on the font sizes given that BMS Act indicates that the CS will prescribe the font size. If the regulation for sizes is made, the standards will be revised to include the font size as will be required by the regulation. • Currently the Kenya Standards are silent on the font sizes but that does not take away the mandate given in law to the CS to prescribe font size. • This an area where engagement with the industry may be done to ensure practicability. • KAM to follow instructions and re-share the three labels as guided in regulation 16[1] as was agreed during BMS Regulations stakeholders meeting. This should be done soonest possible • Maintain the current statement as general as it is drafted in original text.
4. Regulation 17 (Prohibition on labelling)	KAM proposes revision of this regulations subsection 17 [1], [2] and [3] *(see appended KAM proposals)*	Kenya Standard for infant formula (KS EAS 4, clause 10.11.4) has similar wording to that of original draft regulation. According to BMS Act all products for the ages up to 24 months are considered BMS. This statement therefore applies to all that category. The law and regulation does not seek to regulate products beyond its scope.	• Maintain the text in the draft regulations.

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
5 Regulation 18[1] **Labelling of Infant Formula and Follow-up Formula** 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 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 and not less than 1.5mm in height 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 diarrhea and other illness".**	Delete and Replace the provisions of regulations 18 (1) as follows; 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 / or Kiswahili language in bold and conspicuous legible characters. In a prominent position in a manner that maximizes noticeability and legibility of the word: **'IMPORTANT NOTICE"** in capital letters. **"Breast milk is best. Breast milk is ideal for the healthy growth and development of infants and young children or a similar statement as to the superiority of breastfeeding or breast milk.** *Remove the health claim – "It protects against diarrhoea and other illness". Retain only the first part of proposed "IMPORTANT NOTICE"*	Research has revealed that breastfeeding protects infants against diarrhoea and other illness	• Maintain the text in the draft regulations.
6. Regulation 19 Languages in containers	KAM proposes that the Regulations align to the Kenya Standards noting that already, industry strives to meet international standards while complying with local laws. Proposal that any other requirements be captured in the existing standards	The Kenya Standards allows for both the use of either English or Kiswahili. In Tanzania, Kiswahili is a mandatory requirement.	• Recommendation accepted; We support the use of both languages. • Same as issue 5

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
	The use of both languages pose a challenge as there is so much more information already prescribed in existing labelling standards KAM proposes the use of English **'or'** Kiswahili, not **'and'**		
7. Regulation 20 (Constitution temperatures & Handling left over infant formula)	KAM recommends reference and harmonization to WHO/FAO recommendations giving options that allow for use of other viable hygienic preparation KAM proposed inclusion of recommendation to boil water to 100^{0}C then cool it to ambient temperatures as reconstituting with hot water (70^{0}C) interferes with the formulation and introduces risk of scalding.	In its effort to ensure infants are protected from E. Sakazakii, KS CAC/RCP 66:2008[4] section IX Para 5 requires appropriate information be provided to caregivers to avoid this contamination. CAC/RCP 66: 2008 and FAO/WHO. 2007[5],Safe preparation, storage and handling of powdered infant formula: guidelines both emphasize that preparation of formula should not be made by temperatures below 70^{0}C in home care. • KS EAS 4 does not prescribe temperatures of preparation but is currently scheduled for revision. However, it normatively refers to CAC RCP 66. • In many households in Kenya, water safety assurance may be a challenge and therefore the need for preparing formula with water at 70^{0}C to minimize chances of microbial contamination.	The Committee will further discuss and provide guidance on the water temperature.

[4] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B66-2008%252FCXP_066e.pdf

[5] https://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
		• At 70°C, most pathogenic micro-organisms are destroyed making the product relatively safe • This temperature controls for possible contamination of the product or contamination due to handling during preparation	
8. Regulation 21 (Languages in bottles) 9. Regulation 22 (2) (Labelling for teats) 10. Regulation 23[1] (Labelling for teats and pacifiers)	KAM advices that most traders of these products are importers and emphasized the need to engage this group.	There is no Kenya Standard for pacifiers	Maintain as in the draft regulations. The Kenya Standard for teats was developed before BMS Act was enacted, and hence the need to provide guidance in the regulations.
11. Regulation 23 (minimum information on containers)	Specialised products operate in a highly regulated industry because the consumer is highly vulnerable. This is achieved through; a. Legibility and information. (Presentation) b. Statutory instruments Act as a standard that all regulators must refer to in its development. c. Rights and liability for violations	There is no applicable Kenya Standard	Maintain as in the draft regulations.
12. Regulation 24 (Ethical interaction with health workers)	The general feeling of industry is that the issue of interactions in the Regulations has been over-belaboured	There is no applicable Kenya Standard Through this Regulation, the MoH seeks to control for 'conflict of interest' to protect infants	Maintain or revise the current text in the draft regulations considering KAM submissions

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
	KAM noted that regulating venue does not give rise to ethical interactions The industry already employing self-regulation and so sees no need for creating hurdles through regulations The proposed regulations do not include traders/importers who are major players KAM proposes that they are required t report annually for ease of trade noting that reports are more collaborative and empowering KAM noted that health care providers (HCP) are already regulated and therefore there is no need to have regulation targeting HCPs. KAM proposed adoption of the Pharma Industry where marketers' names are submitted upfront for approval In the event that Government upholds this Regulations which prescribe clearance by the committee, there is concerned about timelines for approvals/ rejection	MoH proposes that companies present an annual schedule of planned interaction sessions for approval	
13. Regulation 25 (Creating awareness)	KAM submitted that this regulation amounts to prohibition Regulations may include requiring industry to submit reports and penalizing false information/wrong doing	There is no applicable Kenya Standard MoH proposes that companies present an annual schedule of planned interaction/awareness creation sessions for approval	Maintain or revise the current text in the draft regulations considering KAM submissions

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
	In such an instance, KAM would support industries with guidelines for self-regulation Also supports access to information by consumers (constitutional right) who value information		
14. Regulation 26 Professional evaluation	KAM underscored the need to allow for self-regulation which supports the heavy liability that falls on industry in the case of legal matters rising. KAM indicated that regulation on professional evaluation is covered for in R 27 which is on research Following discussions, KAM requested that this be changed to read 'clinical validation' which MoH was going discuss further	There is no applicable Kenya Standard Professional evaluation is different from research and so needs to be regulated differently MoH proposes that companies present an annual schedule of planned professional evaluation activities to the committee for approval	Maintain or revise the current text in the draft regulations considering KAM submissions
15. Regulation 28 (Formal record)	According to KAM. the prohibitive aspect is the indication that the committee will approve which counters administrative law which dictates that the standards the committee uses to make the decision will be stipulated in regulation.	There is no applicable Kenya Standard MoH noted that research is already regulated by NACOSTI and that this regulations are supportive of the same for the bigger good and for checking on 'conflict of interest'	Maintain or revise the current text in the draft regulations considering KAM submissions
16. Regulation 29 (Restriction on interaction)	Manufacturers would like an opportunity to self-regulate as opposed to the strict prohibition approach to support their participation in informing health workers on products while enforcing the ethics.	There is no applicable Kenya Standard	Maintain or revise the current text in the draft regulations considering KAM submissions

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
17. Regulation on 'cross promotion'	Discussed in issue 1 above.	Discussed under issue 1.	However, the spirit of this regulation is consistent to the principle of labelling as indicated in clause 3.2 of KS EAS 38 (*Pre-packaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.*)
18. Regulation 32 (Advertisement)	KAM proposes deletion of the word 'indirectly' as it proposes liability on uncertain actions Also proposed replacing specific examples (displays, signs, bill-boards, notices) with 'outdoor displays'	There is no applicable Kenya Standard MoH reiterated that the term 'indirectly' is used in the mother Act and is interpreted thereof. The word 'indirectly' is also used in codex and therefore its use in the regulations is consistent with other related documents	Maintain the current text in the draft regulations.
19. Regulation 38 (Access to BMS)	KAM proposes that there is inclusion of the word 'in writing'	There is no applicable Kenya Standard MoH in response noted that the proposed regulation is consistent with other existing laws (CAP 254, 242)	Maintain the current text in the draft regulations.
20. Adherence to statutory instruments Act	KAM requested that there is consistency with the statutory instruments Act, 2013	There is no applicable Kenya Standard	MOH legal department will advise the committee for decision making

REPUBLIC OF KENYA

KNDI
Kenya Nutritionists & Dieticians Institute

Commodore Office Suites,
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Opposite Prestige Plaza
Kindaruma Road/Wood Avenue
Off Ring Road, Kilimani -
Nairobi, Kenya

P.O BOX 20436-00100,
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www.kndi.institute

Official Email:

Chief Executive Office

Cap 253B
An Act of Parliament to provide for the training, registration and licensing of nutritionists and dieticians; to provide for the regulation of the standards, and practice of the profession; to ensure their effective participation in matters relating to nutrition and dietetics, and for connected purposes
[Act No. 18 of 2007, L.N. 130/2008.]

KNDI/CEO/MOH/03/09/19(1)

Tuesday, September 03, 2019

THE CHAIRPERSON
National Committee on IYCF
Ministry of Health
P.O. Box 30016–00100, Nairobi, Kenya

***ATTENTION*: DIRECTOR NUTRITION SERVICES AND SECRETARY TO THE COMMITTEE**

Dear Sir/Madam,

RE: MEMORANDUM FOR DRAFT REGULATION ON Cap 34

KNDI has read the draft regulations and is of the following opinions:

1. The Breast Milk Substitute Act (Regulation and Control) is already a regulation that can be implemented in its current state before additional regulations.
2. The committee should translate the current ongoing draft into comprehensive SOPs to be implemented by an officer appointed by the CS to operationalize the Act as guided by the committee.
3. Any additional regulation should take the format of general legal provisions which can allow for further SOPs.

In general, it is in our considered opinion that the document being discussed as draft regulations fits well under Standard Operating Procedures (SOPs) that may only require the Cabinet Secretary to authorize upon recommendation by the committee as stipulated under section 5 (1) of Cap 34. The committee spearheading this process should be made aware that there is need to have clear difference between regulation and SOPs. The former is a legislative tool for governance while the latter is an operational tool for day to day execution. Some finer details would require operational execution on day to day basis yet the committee only has provisions within the Act that establishes it to have quarterly meetings.

Recommendation
Proper implementation of Breastmilk Substitute (Regulation and Control) Act Cap 34 should have a secretariat within MOH to be headed by an authorized officer appointed by the Cabinet Secretary for purposes of implementing the Act. Such an officer shall implement operations based on SOPs developed by the committee and approved by the Cabinet Secretary. (**Note: the committee members are individuals with other responsibilities within their respective institutions whose interests they are representing and will have no time to sit on day to day basis**). *See detailed memorandum* (Attached)

Thank you.

Dr. David Omondi Okeyo (**MSc, PhD, MPH, RPHNS**)
CHIEF EXECUTIVE OFFICER

Copy to:
Cabinet Secretary, Ministry of Health
KNDI Chairperson

Annex1: DETAILED MEMORANDUM ATTACHMENT: Draft Regulation: The Breastmilk Substitutes (Regulation and Control) Act, Cap 34.

Kenya Nutritionists and Dieticians Institute (KNDI) created by Nutritionists and Dieticians Act, No. 18 of 2007 (cap 253b) has a mandate to regulate the standards and practice of nutrition and dietetics in Kenya and is keen on effective service delivery of nutrition and dietetics to Kenyans particularly those that touch on nutrition sensitive and specific issues like breastfeeding and complementary feeding.

It has come to the realization of the institute that the draft regulations have reached public participation stage and is almost being finalized for gazettement when many matters are still not cleared at critical stakeholder phase. As an institution created by a statute which gives its Council authority and powers to handle all matters of nutrition and dietetics in Kenya, we wish to submit a memorandum which conveys short-falls both in the content, process and spirit behind Cap 34 as follows:

A. SHORT-FALLS IN THE CONTENT

1. It is important for the committee to realize that Breast Milk (Regulation and Control) Act was established as a service Act following WHO Code of Practice and not as a Body Corporate and therefore the Act itself is a service *Regulation and Control* legal framework.
2. Due to (1) above, additional regulation can only strengthen the superior Act 9CAP 34) by consensus on what is the real gap that pose potential risks that other laws and standards fail to address. The institute has noted that, the entire regulation does not recognize the Nutritionists and Dieticians Act No. 18, 2017 whose Council has the following functions:

    a. Determine and set a framework for the professional practice of nutritionists and dieticians
    b. Set and enforce standards of professional practice and ethics on nutrition and dietetics
    c. Enforce a programme of quality assurance for the nutrition and dietetics profession
    d. Research into and provide public education on nutrition and dietetics
    e. Maintain the competence of members by updating their knowledge through publication and conduct of continuing professional education

f. Provide training for nutritionists and dieticians
g. Design programmes and methods for sensitization on suitable dietary and nutritional habits; and
h. Perform such other function as may be necessary for the proper administration of this Act.

These functions cannot be ignored in the implementation of cap 34 as certain provisions of the current draft regulations may duplicate some provisions already being undertaken under Cap 245B implementation framework.

3. **Part II - Procedures relating to the use of designated and pre-packaged complementary food.**

The Institute's management in consultation with a few professionals are of the view that this part fits well under standard operating procedures and should not form content of regulations.

4. **Part III – Donations of designated products and pre-packaged complementary food.**
    a. The process of seeking to donate products under Part III is a sole responsibility of the cabinet secretary or his/ her representative through a delegated authority. This power cannot be delegated to a committee with just advisory role. Delegation can be done to an officer who has full time responsibility in office for that purpose. These powers are provided for under Section 7 of Cap 34 and strictly refer to the Cabinet Secretary or his/her representative unless the drafters are amending the law.
    b. The applications for such approvals can only be made to an appointed authorized officer who is full time in office to undertake this exercise with clear job description. **It shall be the responsibility of the committee to develop SOPs for such an officer**. This will allow the CS to exercise her powers as designated officer to hire and fire an effective officer.
    c. Sections 12, 13, 14, 15 are just more SOPs for day to day operations and should be expunged from this draft to the correct document.

5. **Part IV Labelling of Designated Products and Pre-Packaged Complementary Food**
    a. Section 16. There are already other regulations on appropriate labeling of food products with well-informed expertise. Specific details with regard to Cap 34 should be detailed under SOPs. The details in 16 (i) are inadequate with the recommended standards of labelling and should be left to various existing regulatory authorities. For example, *KNDI is developing a comprehensive standard way of labelling food products with nutrition claims under Section 36(2) of the Act and Section 6(i) and 13(j) of the Amendment sections within the Health laws (Amendment Act).* This is a compressive food labeling regulation that should apply for all the foods including complimentary food product. Any addition required for enforcement as proposed by this committee can only be executed through SOPs.
    b. Under 16 (2) and 17 of draft regulation the matter is already being addressed within the mother Act (cap 34) within the provisions of Section 9. This is already complete regulation and can only be operationalized through details SOPs for day to day operations.
    c. The contents of Section 18–23 are SOPs, not regulations. Remember, SOPs are supposed to operationalize regulation.

Part V: Interaction between Manufacturers, Distributors and Health Workers.

6. Interaction between a manufacturer and health workers can take place beyond the Kenyan Boundaries and therefore should have no bottle neck as long us ethical interaction is assured. Some interactions do not necessarily take place physically and could be online beyond Kenyan Boundaries. This section has no legal meaning and more of a barrier than regulation. It cannot even qualify to be part of SOPs.
7. Take note that manufactures also have a right for legal trade and are some of the support systems for UHC especially on access to complimentary foods by high risk groups of children that cannot breastfeed and so each case should be treated on its own under SOPs than regulations criminalize key players.
8. From section 24 – 27 areas in the draft regulation where committee makes approval should be changed to "an authorized officer appointed

by the Cabinet Secretary' to spearhead the day to day implementation of the Act.

Note: **The spirit of this regulation should be geared towards bringing sanity in business with an aim of promoting breastfeeding. The intention should not be geared towards blocking manufacturers from conducting a healthy and ethical business. Malnutrition can be caused by both poor breastfeeding practices and marketing of substitute on equal magnitude. Short-term programming objectives by partners should not inform public legal protections.**

B. SHORT-FALLS IN THE PROCESS

(a) It has come to the realization of the institute that a committee was constituted without notification of representation under Section 4 (2), Paragraph (h). This committee expresses with finality to have completed draft regulations with adequate consultation with critical stakeholders, yet a key stakeholder like KNDI has been left out in the process. What was the intention of not including KNDI in the committee?

(b) The matter on breastfeeding is a nutrition specific matter for Kenyans and would require participation of KNDI council as a critical stakeholder. The process therefore was ultra-vires to CAP 235B which necessitated inclusion of the chairperson or his/her representative under Section 4 (2), Paragraph (h) of Cap 34. This implies that the committee outrightly undermined the role of Paragraph (h) above.

Compiled and submitted by:

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CHIEF EXECUTIVE OFFICER

Copy to:
Cabinet Secretary, Ministry of Health
KNDI Chairperson

MINISTY OF HEALTH

REPORT OF BMS ACT, 2012 (GENERAL) REGULATIONS STAKEHOLDERS MEETING

PUBLIC PARTICIPATION FORUM

27TH AUGUST 2019

HELD AT AFYA ANNEXE 4TH FLOOR, ROOM 406

1. Introduction

The meeting began at 9.30 am with a word of prayer and an interactive introduction followed by welcoming remarks by the Head-Division of nutrition and dietetics. The meeting was chaired by – Dr. Mohamed Sheikh, Head of Department of Family Health.

Organizations present were Department of Legislations and Regulations, Division of Nutrition & Dietetics, Kenya Law Reform Commission, Kenya Association of Manufacturers (KAM), Kenya Nutritionists and Dieticians Institute (KNDI), members of public, members of the National Committee on Infant and Young Child Feeding (NCIYCF), members of the Maternal Infant and Young child Nutrition Technical Working Group (MIYCN TWG) including UNICEF, Save the Children, Nutrition and Health Programme plus (NHP plus), Action against Hunger (ACF), Kenyatta National Hospital (KNH) and National AIDS & STI Control Programme (NASCOP).

In her opening remarks, the Head Division of Nutrition & Dietetics appreciated all participants for attending the meeting whose Public notice was published in MyGov on 13th August 2019. She welcomed all to participate in this noble process of developing BMS Act, 2012 Regulations. The highlights of her remarks were:

- The Ministry of Health has drafted the regulations (accessible at the ministry website for public to comment).
- The Constitution of Kenya requires any law making process to include public participation.
- The Cabinet Secretary (CS) in consultation with the NCIYCF has been granted the powers to make Regulations in section 28 of the BMS Act in particular – the wording, size, procedure, and any other thing required for the implementation of the Act.
- The draft regulations prescribe how implementation of certain sections of the Act should be accomplished.
- The purpose of the stakeholder meeting is to collect the views, oral and written memorandum on the draft BMS Regulation

2. Agenda

Below find appended the program for the stakeholders meeting.

Agenda_BMS regulations _stakeh

3. Presentation of the Draft BMS Act (General) Regulations

The Kenya Law Reform Commission representative took participants through the provisions of the draft BMS Act (General) Regulations and thereafter participants were requested to table their submissions.

BMS final-version 3.pdf

4. Stakeholders' Submissions

4.1 Kenya Association of Manufacturers (KAM)

KAM had submitted written memorandum to the ministry before the meeting. However, they were requested to present the highlight of the memorandum. Upon request, KAM was granted a follow up meeting to comprehensively present their submission at a date to be communicated. The following is a summary of KAM submission:

1. Regulations will be a Barrier to Trade –the requirements in the Labelling section are deviating from the East African Standards (EAS) on labelling for the EAC market.
2. Some of specific clause industry wanted changed/deleted saying they are injurious to industry and hindrance to business include;
    a. Definition of "cross-promotion" as it is already a discussion at codex.
    b. Reference to codex and EAS in the Regulations. There should be no deviation from the East African standards especially on how they relate in labelling.
    c. Committee approval stage should be clearly documented on the time it takes to approve and/or reject.
    d. Investigations procedure should be clearly stipulated
    e. Proposed that importers should also be subjected to the Regulations in addition to manufacturers and distributors
    f. Labelling
        i. Discussions on how to put out information clearly using prescribed font 50% (or 25%) without distorting the meaning
        ii. Requirement to have the label in English and Kiswahili
        iii. Need to include 'date of manufacture' alongside expiry date
    g. Seizure of products – the provision in the Regulations permitting Authorized Officers to access entry without a court order
    h. Applicability of the recommended temperature (70°C) for water used in the preparation of the BMS at
    i. Not to sell products 30 days to expiry date.

Below are section specific inputs for consideration.

REGULATION NO.	ISSUES RAISED
Regulation 16 (2)	For the statement on relevant standards, quote specific standard. These regulations should be harmonized with other relevant standards
Regulation 17	Should be specific especially on the logo and pictures The requirement to have labels in English and Kiswahili should be English AND/OR Kiswahili.
Regulation 18	Language; English and or Kiswahili to be for Kenyan people and to be left open for the rest of the countries The word "WARNING" to be replaced with "IMPORTANT NOTICE" Conspicuous word to be removed because it is wrongly used Use the text as it is captured in the East African Standards
Regulation 19 (d)	Creates uncertainty – it should comply with the standards or be – delete
Regulation 20(a)	Labelling – Appears as if it is the only option but there are other options Preparation of feed at 70 degrees can scold the caregiver. The risks have been addressed by instructions on boiling of water and cooling to room temp
Regulation 22	Labeling of teats and bottles to be reconsidered
Regulation 20,22,23	Provision be provided for according to the standards
Regulation 23	There should be detailed understanding of consumer protection rights Harmonize with constitution regulation 6
Regulation 24	Application must meet with provisions of Article 47 Is a duplication of labeling standards
Regulation 25-30	Should be deleted
Regulation 39	Seizure of products by Authorized persons without court order is not acceptable
Regulation 40	Should be aligned with section 16
Regulation 40 2(d)	To be deleted
Regulation 33	Review

4.2 Submissions from the Members of Public

SECTION/REGULATION	ISSUES ARISING
Interpretation	Explain fully on the interpretations e.g. child, toddler and young person
Part IV	Do not use the word **may** instead use the word **shall**. Be specific and certain Instead of **Health worker,** use **Health officer** Explain enforcement
Regulation 22	"conspicuous" – The word conspicuous is used wrongly, another word should be used instead
Regulation 23	On the designated product the manufacturing date must appear
Regulation 38	Should not use the word request, it should be "upon demand" Specify the offence and do not generalize.

5. WAYFORWARD

1. KAM to send revised memorandum by close of business Monday 2nd September 2019
2. To avoid face-off between the ministry and the industry, the chair ruled that the submissions in the memorandum received from KAM be analyzed by the technical team who will in turn provide response to all comments in the memorandum.
3. Drafting team to meet on Thursday 12th Sept 2019 to review the memorandum submitted by stakeholders and comments collected during stakeholders meeting.
4. Drafting team and KAM representatives to hold a meeting to discuss KAM submission at length at a date to be communicated in due course.

The meeting adjourned at 12noon.