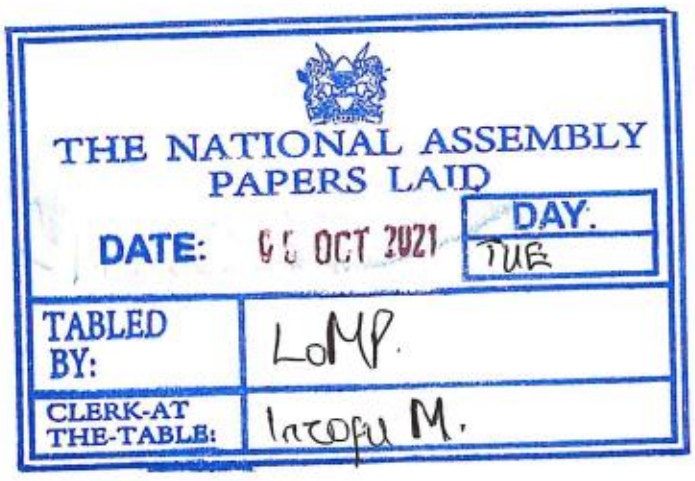
TABLE OF CONTENTS



No.1

MINISTRY OF HEALTH

OFFICE OF THE DIRECTOR GENERAL

INTERNAL MEMO

THE NATIONAL ASSEMBLY
PAPERS LAID
DATE: 05 OCT 2021
DAY: TUE
TABLED BY: LoMP.
CLERK-AT THE-TABLE: Inzofu M.

FROM : Ag. Director General

TO : Head of Directorates
Head of Departments
Head of Divisions/Units

DATE : 18th June, 2019

REF : **MOH/NDU/MEMO/Vol.1/71(a)**

RE: INVITATION TO A CONSULTATIVE MEETING FOR BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) ACT.

Breastfeeding is the single-most effective intervention for child survival, growth and development. Exclusive breastfeeding for the first 6months of the child's life and continued breastfeeding upto 2 years and beyond combined with appropriate complementary feeding after 6 months saves 13 percent and 9 percent of child deaths respectively.

In realization of this huge potential, Kenya committed to protecting, promoting and supporting breastfeeding by signing to the World Health Assembly *Innocenti Declaration in 1983* that called member countries to come up with local legislations to give effect to the CODE of Marketing of Breast Milk Substitutes to protect, promote and support breastfeeding. In 2012, the Kenya Breast Milk Substitutes (Regulation and Control) Act, was enacted and the next agenda was to develop regulation to operationalize the BMS Act. The draft BMS regulations are ready for stakeholder participation. A meeting has been organized to sensitize stakeholders within the Ministry of Health and obtain their inputs before subjecting the drat to public participation.

The purpose of this memo therefore, is to invite you and staff under you, to a Stakeholders' Consultative Meeting to be held on 28th June, 2019 at **Afya Annex (NASCOP), KNH Grounds, 3rd Floor, Room 302 starting 9.00 a.m. to 1.00 p.m.**

For more information, contact Caroline Kathiari on Phone No.0721285074, Email: carolarimi@yahoo.co.uk

Dr. J. Wekesa Masasabi
Ag. DIRECTOR GENERAL FOR HEALTH

Copy to: Principal Secretary

No. 2

MINISTRY OF HEALTH

REPORT OF THE INTERNAL STAKEHOLDERS' CONSULTATIVE FORUM ON THE DRAFT BREAST MILK SUBSTITUTES (GENERAL) REGULATIONS

28th JUNE 2019

AFYA ANNEX BUILDING, 3RD FLOOR ROOM 302

REPORT OF THE INTERNAL STAKEHOLDERS CONSULTATIVE FORUM ON THE DRAFT BMS ACT REGULATIONS, 28th JUNE 2019 AT AFYA ANNEXE

The meeting began at 9.30 a.m with a word of prayer and an interactive introduction followed by welcoming remarks mentioning about the meeting agenda.

AGENDA

Time	Activity	Responsibility
9.00-9.30	Arrival and Registration	NDU
9.30-9.40	Welcome remarks introduction	Head of DFH-Dr. Sheikh
9.40-10.00	Overview of MIYCN programme	MOH –NDU - Carol
10.00-10.20	Background & road map on BMS ACT, 2012 and	Head NDU - Veronica
10.20-12.00	Health Break	
10.50-12.00	Presentation on the BMS general regulations	Annette
12.00-12.50	Plenary	MOH
12.50-1.00	Way forward & next steps	Head-NDU
	Closing remarks	

List of participants

No.	Name	ORGANIZATION	TELEPHONE
1.	Pam Malebe	IBFAN	0722720816
2.	Evan Juma	MOH-CHDU	0727402142
3.	Allan Barasa	MOH-FSU	0733458769
4.	Wanzala Violet	MOH-CHDU	0726425843
5.	Mary Jullienne	MOH-CHDU	0757166067
6.	Grace Ndegwa	MOH-DSQARK	0724707693
7.	Shadrack Oiye	IYCF Committee	0722759449
8.	Veronica Kirogo	MOH-NDU	0721434443
9	Peris Mbugua	MOH-DNCD	0724991561
10	Faith Gitahi	KNH	0722653619
11	Laura Kiige	UNICEF-KCO	0704871117
12	Peter Ngwatu	KPA	0722775942
13	Michael Gichangi	MOH –OSU	0733343012
14.	Agnes Ngina	MOH-CHDU	0721586203
15	Margret Muli	NASCOP	0724084729
16.	Omwoyo Annette	KLRS	0700484811
17.	Elias Kirimi	MOH-NDU	0728835035
18.	Martha Kemunto	MOH-NDU	0722995388
19.	Rose Wambu	MOH-NDU	0723269091
20.	Caroline K. Kathiari	MOH-NDU	0721285074

BACKGROUND AND ROADMAP OF BMS ACT 2012 AND REGULATIONS

The benefits of breastfeeding were highlighted; Breastfeeding improves the survival, health, and development of all children and therefore important in a child life. In 1983, the 34th World Health Assembly adopted the International Code of Marketing of Breast Milk Substitutes and informed that there was:

- Inappropriate and unethical marketing of breast milk substitutes
- Many infants getting malnourished or dying from consumption of contaminated or diluted breast milk substitutes
- The Code recognized that health workers, women, and families are susceptible to direct and indirect BMS marketing strategies.
- It consists of 11 articles outlining the responsibilities of governments, health-care systems, and workers, and of the companies that market or manufacture breast milk substitutes.
- The code depends on national legislation, monitoring, and enforcement for its effectiveness thus the reason behind the journey of BMS ACT 2012.

BMS Act, 2012

- The journey of drafting a national legislation started in 1983 when the ministry of health drafted the 1st Breastmilk Substitutes Bill after Kenya became a signatory to the *Innocenti Declaration.*
- In 2012, BMS Act was enacted and Kenya was ranked 4th among 51 countries in the *World Breastfeeding Trends Initiative* report on the implementation of the Code.

Draft BMS (General) Regulation

A presentation was made on the draft BMS (General) regulation.

Development of the BMS Regulations

- The development of the Regulations spearheaded by the National Committee on Infant and Young Child Feeding (NCIYCF) commenced in 2012.
- During a review workshop held in October 2018, significant gaps in the content were identified and it was recommended the regulations be redrafted with technical support from legal drafters.
- Re-drafting workshop was held on 21st to 25th January 2019 and a revised draft BMS regulations was produced.
- The revised draft BMS was circulated to internal stakeholders via email to obtain their input in May 2019.
- However, since no comments have been received to date, the need for an internal stakeholders consultative meeting was conceived.

Inputs on the draft from the participants

1. **Preliminary**

   (Clause 3) Guiding principles has significant changes

   Recommendation: Should be reviewed to strengthen the BMS Act.

   Initiation of breastfeeding with 1 hr of delivery – How practical will it be? – Should strengthen the Act.

2. **Part II – Use of Designated products and pre-packed complementary food.**
   (Clause 4) Production - Pre-packed has not been defined strongly in the BMS Act.
   (Clause 7) Importation – Are the offenses reasonable? (3 yrs imprisonment section 27)
   Recommendation: in order to strengthen the act – Ban manufacturer for 5 yrs.

3. **Part III – Donations of designated products and Pre-packed complementary food.**
   (Clause 11) Application to Donate – There are significant changes in donations
   - No guidance for donation for NGOs, it MUST be clear in regulations (make it an offense).
   - The donor to sign an MOU with KEMSA
   - NGO cannot be allowed to donate directly.
   - Give provisions for donations (volume because of dumping)
   - MUST provide guidelines to donations during emergencies – Strengthen it
   - Who receives the donations? –The donor must receive an approval by the committee or CS
   - Change the Act and show functions and list what is to be donated
   - Be specific to BMS Act (donations) on the functions

   (Clause 12) –Restrictions to donations
   -Have approval from committee for its suitability.
   - Meet international and Kenya regulations
   - No pre-packing on donations – MUST be on their original containers
   -All donations must be labeled as donations **("Not for Sale")**
   -(12 -4) – is not in the BMS Act it should be added.

   (Clause 13) – Filing returns
   - The form is not tallying with the act – BMS 2
   - Strengthen Form BMS 4

4. **Part IV – Labeling of Designated Products and pre-packed complementary food.**
   (Clause 20 a) – Delete the microorganism during manufacturers and strengthen the clause.

5. **Part V- Interaction between manufacturers, distributors and Health Workers**
   (Clause 24) - Interactions
   - Information of inserts- Cross promotion - Provide for both
   -

6. **Part VII- Enforcement.**
   - Define who is a community health worker before being added in the Act

NB: The BMS Act, 2012 needs to be reviewed since it is defective)

Way Forward

1. Option A. The committee to pay a courtesy call to the AG to consult on possibility of amendments of the BMS Act as statutory miscellaneous amendment Bill so as to enable implementation of the BMS General Regulation.
2. Option B. Write to the Law Reform Advisory asking for their advice – the act prescribes parliament approval of the BMS Regulations

3. Identify stakeholders for public participation.
4. Ensure that list of participants and their signatures is captured
5. Option C. Amend the entire Act.
6. Consultative forum for external stakeholders to be held by 31st August 2019.

Acknowledgement
The activity was supported by ACF for teas and Lunch at a cost of KSH 15,500.

No. 3

ACTIVITY: DRAFT BMS REGULATION INTERNAL STAKEHOLDERS FORUM

DATE : 28th June 2019

VENUE : AFYA ANNEXE 3RD FLR RM 302

ATTENDANCE LIST

NO	NAME	ORGANIZATION	TELEPHONE	ID NUMBER	EMAIL ADDRESS	SIGN
1.	Pam Malebe	IBFAN	0722720516	1893446	jmalebe n e yahoo.com	
2.	Evans Juma	MOH CHDU	0727402142	32736177	omallama @gmail.com	
3.	Allan Baraza	MOH-FSU	0733458769	13576473	wasilwa@gmail.com	
4.	Wanzala Violet	MoH/CHDU	0726425843	34300789	VioletKinyi625@gmail.com	
5.	Mary Julianne	MOH/CHDU	0757166600-7	34307950	mary.Nienne@gmail.com	
6.	Grace Ndegwa	MOH - DSOHH	0724716928	22716381	gkamau@gmail.com	
7.	Shadrack Diye	MCF Committee Member	0727-754764	13644014	Diyeshad@gmail.com	

8.	Veronica Kirogo	MOH-NDU	0721434443	10119115	VKirogo@yahoo.com	
9.	Pens Mbugua	MOH - BNCS	0724 991561	21729368	katoniOA@gmail.com	
10.	Faith Gitahi	KNH	0722653619	1209027	faithgitahi@gmail.com	
11.	Laura Kuga	UNICEF NCO	0704871117	12710201	lkuga@unicef.org	
12.	Peter Ngwatu	KPA	0727159442	11057922	pngwatu@yahoo.com	
13.	Michael Gichangi	MOH-OSV	0733343012 0721572109	7635625	gichangi55@yahoo.com	
14.	Agnes Ngina	MOH-CHDU	0721586203	6294506	agnes.gakuhu@gmail.com	
15.	Margaret MULI	NASCOP	0729084729	22871016	Margaretmmuli@gmail.com	

Verified by:

MOH OFFICER: Doe Wambu Sign: _____ Date: 28/06/2019

ACF STAFF: Mary Kimani Sign: _____ Date: 28/06/2019

ACTION AGAINST HUNGER

ACTIVITY: DRAFT BMS REGULATION INTERNAL STAKEHOLDERS FORUM

DATE : 28th June 2019

VENUE : AFYA ANNEXE 3RD FLR RM 302

ATTENDANCE LIST

NO	NAME	ORGANIZATION	TELEPHONE	ID NUMBER	EMAIL ADDRESS	SIGN
1.	Omwolo Annette	KLRC	0700484811	24599015	annette.omwoyo@gmail.com	
2.	ELIAS KIRIMI	MOH - NAU	0728355085	27731060	eliaskirimi7@gmail.com	
3.	MARTHA KEMUNTO	MOH - NDU	0729957888	13607675	marthaw@nndk.go.ke	
4.	Rose Wambu	MoH - NDU	0723269091	0718582	wangeth@gmail.com	
5.	Caroline K. Kathiari	MOH-NDU	0721285071	14412021	Carolkimu@yahoo.com	
6.						
7.						

ACTION AGAINST

THE REPUBLIC OF KENYA

MINISTRY OF HEALTH

IMPORTANT PUBLIC NOTICE

Stakeholders' Consultative Forum on the Draft BMS (Regulation and Control Act, 2012) Regulations

The Breast Milk Substitutes (Regulation and Control) Act, 2012 provides for appropriate marketing and distribution of breast milk substitutes and hence supports safe and adequate nutrition for infants through promotion of breastfeeding and proper use of breast milk substitutes, were necessary and for connected purposes.

The Government through the Ministry of Health has committed to implement and oversee the process of adoption of the legislation and has consequently developed regulations to guide implementation and monitoring of adherence and/or violation.

In the spirit of public participation as envisaged in the Constitution, the Ministry of Health has convened a stakeholders meeting to discuss the Draft Regulations and invites the relevant stakeholders to attend the meeting which will be held on 27th August, 2019 at AFYA Annex (NASCOP) Room 406 starting 8:00 a.m.

The Draft Regulations can be accessed on **www.health.go.ke** or **www.nutritionhealth.or.ke**, Views and comments may be sent via email through the link on the website. Alternatively you can write to: The Head, DFH-DN&D, Ministry of Health, **headnutrition.moh@gmail.com** **P.O. Box 30016-00100,** Nairobi by **20th August, 2019.**

MINISTRY OF HEALTH

OFFICE OF THE DIRECTOR GENERAL FOR HEALTH

Telephone: Nairobi 254-020-2717077
Fax: 254-2719008
Email: dghealth2019@gmail.com

AFYA HOUSE
CATHEDRAL ROAD
P. O. Box 30016-00100
NAIROBI

When replying please quote:

Ref: MOH/ADM/1/1/2

23rd July, 2019

_____

_____

_____

RE: STAKEHOLDER'S CONSULTATIVE MEETING ON THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) ACT, 2012 REGULATIONS

Breastfeeding is the single-most effective intervention for child survival, growth and development. Exclusive breastfeeding for the first 6 months of the child's life and continued breastfeeding upto 2 years and beyond combined with appropriate complementary feeding after 6 months saves 13 percent and 9 percent of child deaths respectively.

In realization of this huge potential, Kenya committed to protecting, promoting and supporting breastfeeding by signing to the World Health Assembly Innocenti Declaration in 1983 that called member countries to come up with local legislations to give effect to the CODE of Marketing of Breast milk Substitutes to protect, promote and support breastfeeding. In 2012, the Kenya BreastMilk Substitutes (Regulation and Control) Act, 2012 was enacted. In order to operationalize the BMS Act, Draft BMS regulations have been developed and are ready for stakeholder participation.

The purpose of this letter therefore is to invite you to the stakeholders consultative meeting to be held on **27th August,2019** at **Afya Annex (NASCOP), KNH grounds, 4th floor, room 406** starting **8.00 am.**

Thank you for the continued collaboration.

Dr. J. Wekesa Masasabi
DIRECTOR GENERAL FOR HEALTH

Legal Notice No.....

THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) ACT

(No. 34 of 2012)

Arrangement of clauses

Part I- Preliminary

Part II- Procedures Relating to the Use of Designated Products and Pre-packaged Complementary Foods.

Part III- Donations of designated products and Pre-Packaged Complementary Food.

Part IV: Labelling of Designated Products and Pre-packaged Complementary Food.

Part V- Interactions between Manufacturers, Distributors and Health Workers

Part VI- Enforcement

THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) ACT

(No. 34 of 2012)

IN EXERCISE of the powers conferred by section 28 of the Breast Milk Substitutes (Regulation and Control) Act, 2012, the Cabinet Secretary responsible for matters relating to public health, makes the following Regulations–

THE BREASTMILK SUBSTITUTES (GENERAL) REGULATIONS, 2019

Part I- Preliminary	
Citation	**1.** These regulations may be cited as the Breastmilk Substitutes (General) Regulations, 2019.
Interpretation	**2.** In these Regulations, unless the context otherwise requires– "Act" means the Breastmilk Substitutes (Regulation And Control) Act; "Authorised officers" means a person appointed under the Act. "Committee" means the National Committee on Infant and Young Child feeding established under section 4 of the Act; "Cabinet Secretary" means the Cabinet Secretary for the time being responsible for matters relating to public health; "Cross-promotion" means a form of marketing where customers of a product or service are targeted with promotion of a related product; "donation" means a designated product or pre-packaged complementary food offered for charity or humanitarian aid; "designated product" has the meaning assigned to it under the Act; "donee" means the person or institution receiving the donation; "donor" means the person or institution making the donation; "health worker" has the meaning assigning to it under the Act; "KS CODEX STAN" means 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 the provision of breastfeeding services under these Regulations, binds the authorised officers and all persons whenever any of them– (a) applies or interprets any provision of these Regulations; and (b) makes or implements public policy decisions. (2) Without prejudice to 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 (6) months; (c) timely introduction of appropriate pre-packaged complementary food with continued breastfeeding for a period of two (2) years or 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 breastmilk substitutes and pre-packaged complementary food shall be done in the manner prescribed under the Act and these regulations.
Part II- Procedures Relating to the Use of Designated Products and Pre-packaged Complementary Food.	
Production.	**4. (1)** The production, preparation and packaging of designated products and pre-packaged complementary food shall be in accordance with the

Cap. 254, 242 and 496.	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.
Sampling and Testing. Cap. 254, 242 and 496.	**5.** 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.
Packaging.	**6.** The designated products and the pre-packaged complementary food shall be packaged in accordance with the Act, the relevant written laws, 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).
Importation.	**7.** (1) A manufacturer or distributor shall not import, offer for sale or sell any designated product or the pre-packaged complementary food if it does not comply with these Regulations, the Act and any other relevant written law. (2) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.
Stocking.	**8.** (1) 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. (2) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.
Use of Alternative containers from the original.	**9.** Any person who stocks, distribute, sell or exhibit 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.	**10.** (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.	**11.** (1) A person or institution who undertakes to make a donation of a designated product or a 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 one (1) shall be accompanied by a duly completed **Form BMS 1** in the first schedule to these Regulations.
Restrictions to Donations.	**12.** (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 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 made under the Act and these Regulations shall be for the purpose for which they were donated. (5) Without prejudice to sub Regulation (3), donations made to a charitable children 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 institution with prior written consent of the Committee.

Filing of Returns.	**13.** (1) A Person or institution making donations 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 the prescribed **Form BMS 2** in the first schedule to these Regulations. (2) A donee upon receipt of the donations under this Act and these Regulations shall within two weeks file returns for use to the Committee in the prescribed **Form BMS 3** in the first Schedule to these Regulations. (3) A donee shall upon utilization of the donations under sub Regulation (1) file returns with the Committee in the prescribed **Form BMS 4** in first 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.	**14.** A charitable or social institution who 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.
Uses of Donations.	**15.**(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 authority 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. (3) A person who contravenes the provisions of sub Regulation (1) and (2), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.
Part IV: Labelling of Designated Products and Pre-Packaged Complementary Food.	
Labelling of Designated Products and Pre-packaged Complementary Food.	**16.** (1) The label of a designated product shall in addition to the provisions of the relevant written legislation or Kenya standard, contain the name, address and telephone number of the manufacturer, importer or seller. (2) Not withstanding sub regulation (1), the label of a designated product and pre-packaged complementary food shall not refer to, promote or advertise any other designated product.
Prohibitions on labelling.	**17.** 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.	**18.(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 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". (2) The label on any container of infant formula shall— (a) not include words such as "maternalised" or "humanised" or similar words or any comparison to breast milk; (b) not use of text, graphics/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.	**19.** 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 after which the product is recommended for use in numeric figures, in the case of complementary food, shall not be less than six months; (c) a warning about the health risks of improper preparation and of using the product before to 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	**20.** 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 on it, indicate that– (a) powdered formula may be contaminated during the manufacturing process or may become contaminated during preparation;

	(b) it is necessary for formula to be prepared one feed at a time using clean and safe water of at least seventy (70) degrees Celsius; and (c) any unused milk shall be discarded immediately after every feed.
Labelling Requirements for feeding bottles.	**21.** A label, package or a container of a feeding bottle 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 1.5mm in height preceded by the words "IMPORTANT NOTICE" in capital letters: "Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against diarrhea and other illness".
Labelling Requirements for teats.	**22 (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; (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 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 1.5mm in height preceded by the word "WARNING" in capital letters": "Use of teats can interfere with breastfeeding".
Labelling Requirements for teats and pacifier.	**23 (1)** A label on a package or container of a pacifier shall not; (d) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributer; (e) contain words or images idealising the use of teats; (f) 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 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 1.5mm in height preceded by the word "WARNING" in capital letters": "Use of pacifier can interfere with breastfeeding".

Particulars to be inscribed on container	**23 (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, that is- (i) composition; (ii) required storage condition; (iii) batch number; and (iv) expiry date; (b) on a label marked on or securely attached to the container the following statement- "Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It protects against diarrhea and other illness". (2) Any label affixed to any container of a designated product or a pre-packaged complementary food product as required under subsection (1) of this section 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 subsection (1) of this section 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 an 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.
Part V- Interactions between Manufacturers, Distributors and Health Workers	
Interactions.	**24.(1)** Any interactions between a manufacturer or distributor with any health worker shall strictly be limited to–

	(a) creating awareness about scientific and factual matters on designated products and pre-packaged complementary food; (b) providing samples of designated products and pre-packaged complementary food for professional evaluation; and (c) providing samples of designated products and complementary foods for research of 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.
Creating Awareness.	**25.** (1) Subject to section 6 (3) (a) 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 of 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.
Professional evaluation.	**26.** (1) Any interactions between a manufacturer or distributor and a health worker for purposes of professional evaluation of a designated product or pre-packaged complementary food shall commence after 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.
Research of Product.	**27.** (1) A health worker who intends to carry out research on a designated product or pre-packaged complementary food and intends to request for samples from a manufacturer or distributor shall apply in writing to the Committee. (2) The application referred to under sub Regulation (1), shall be accompanied by– (a) an approved research protocol; (b) an ethical approval from a competent and recognised authority in Kenya; (c) a certificate of analysis; (d) proof of use in country of origin if the product is not made in Kenya; (e) ethical approval from a competent authority if the product is originating outside of Kenya; and (f) any other document the Committee may require.
Formal Record.	**28. (1)** Any health worker who wishes to participate in any interaction with a manufacturer or distributor, for 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 to the Committee on request. (2) The formal record referred to in sub Regulation (1) shall contain such information as may be directed by the Committee.
Restrictions to Interactions.	**29.** (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 as prohibited by the Breastfeeding Act; (c) engage in activities without the approval of the Committee;

	(d) distribute any samples of designated or pre-packaged complementary food product; (e) hold promotional activity at an alternative venue not approved; and (f) brand the venue in any way to promote infant formula.
Cross-Promotion.	**30.** (1) A manufacturer or distributor of a designated product or a pre-packaged complementary food shall not engage in cross-promotion. (2) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.
Information Inserts.	**31.** (1) A manufacturer or distributor of a designated product or a pre-packaged complementary food, shall not insert any other information, beyond the scope of the packaged product for purposes of consumer information or education. (2) A manufacturer or distributor of a designated product or a pre-packaged complementary food, shall not collaborate with another manufacturer or distributor of any other product other than a designated product or a pre-packaged complementary food, to insert any other information, beyond the scope of the packaged product for purposes of consumer information or education. (3) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.
Advertisement.	**32.** 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 and shall be liable to prosecution in accordance with section 27 of the Act.
Demonstration for use of a pre-packaged complementary food product.	**33.** The method used by a health worker during demonstrations for use of pre-packaged 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 two years; (c) the proper preparation and use of the product; (d) the importance of feeding infants with an open cup and spoon; and (e) how pre-packaged complementary food can easily be prepared at home using local ingredients.
Procedure for demonstration for use of infant and follow-up formula	**34. (1)** The method used by a health worker during demonstrations for use of infant formula shall be one-on-one in a secluded area and shall– (a) be in the original container of manufacture; (b) conceal the brand name; (c) maintain hygiene; and (d) 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 benefits and superiority of breastfeeding; (b) the value of exclusive breastfeeding for the first six months followed by sustained breastfeeding for at least two years and optimal maternal nutrition; (c) the difficulty of returning to breastfeeding after a period of artificial feeding. (d) the negative effects of artificial feeding on lactation and how early introduction of pre-packaged complementary food interferes with breastfeeding; (e) instructions on proper preparation and use of the product; (f) the approximate financial cost of adequate feeding of an infant with the product; (g) the health hazards of bottle feeding (h) the importance of feeding an infant with an open cup and spoon; and (i) how to feed an infant with an open cup and spoon.
Part VI- Enforcement	
Authorised Persons	**35.** In addition to Section 11 of the Act, an authorised officer may include a health worker, custom officer, police officer or officers from the body responsible for Standards.

Inspection.	**36.** An Authorised officer, shall subject to section 12 of the Act, conduct an inspection in the prescribed **Form 5** in the first Schedule to these Regulations.
Confidential Information.	**37.** (1) An officer who divulges confidential information obtained during the course of investigations conducted under these Regulations, the Act or any other law commits an offence. (2) Despite sub Regulation (1), this Regulation does not apply to information that is– (a) given as evidence in proceedings taken under the Act or any other law relating to consumer protection; (b) given by the authorised officer as part of a report; (c) prepared for the purpose of an investigation; or (d) a matter of public record or is otherwise in the public domain. (3) A person who contravenes the provisions of this Regulation, commits an offence and shall be liable to prosecution in accordance to section 27 of the Act.
Access to Breasmilk substitutes.	**38.** A manufacturer or distributor, upon request shall produce any prescribed designated product or pre-packaged complementary food to an authorised officer
Seizures.	**39. (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; and (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 prescribed in the Schedule to these Regulations.
Conflict of Interest.	**40.** (1)A health worker who has any interest whether pecuniary or business interest in any designated product or pre-packaged complementary food shall disclose the nature of interest to the Committee, on commencement of employment and as soon as the relevant facts have come to his or her knowledge in accordance with the Public Officers Ethics Act, No. 4 of 2003.

	(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.

FIRST SCHEDULE

Forms

Form BMS 1
Application for Donation

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.:**.....
Expiry Date:.....
Quantity Donated:.....

DONOR
Name:
Signature:
Date:

DONEE
Name:
Signature:
Date:

FORM BMS 2

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.:**……

Expiry Date:……...

Quantity Donated:……

DONEE
Name:
Signature:
Date:

DONOR
Name:
Signature:
Date:

FORM BMS 3

RETURNS FOR USE 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.:**.....

Expiry Date:.....

Quantity Donated:.....

FORM BMS 4

DESCRIPTION OF THE DONEE

(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 .....

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 of 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.

Form BMS 4

SEIZURE FORM B

(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.

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.....

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) ACT and 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.

Name:.....

Address.....

Telephone:..... .....

Email:.....

Types Of Institution:.....

Date Of Incorporation:.....

DESCRIPTION OF THE DONATION

Name:.....

Name Of The Manufacturer/Dealer:.....

Manufacturer Date:..... **Batch No.:**.....

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

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.....

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.

KENYA ASSOCIATION OF MANUFACTURERS
Driving Global Competitiveness
60 YEARS OF ADDING VALUE

Our Ref: KAM/10/10/mb/jw/PW/2019

2nd September, 2019

The Head of Nutrition
DFH-DN&D
Ministry of Health
Afya Annex (NASCOP), Kenyatta Hospital
P.O Box 30016 - 00100
NAIROBI

Dear Sir/Madam,

RE: SUBMISSION OF KAM REVISED MEMORANDUM ON THE DRAFT BREAST MILK SUBSTITUTES (REGULATION AND CONTROL ACT 2012) REGULATION 2019

The Kenya Association of Manufacturers (KAM) presents its compliments and appreciates the continued support.

Following the call for memorandum published in the daily newspapers on the Draft Breast milk Substitutes (Regulation and Control Act 2012) Regulation and the Stakeholders Consultative Forum held on the 27th August 2019 at Afya Annex (NASCOP) we wish to;

1. Submit our revised Memorandum as per the Forum discussions agreeing to the extension of the submission timeline to the 2nd September 2019, close of business.
2. Request for your prompt feedback on a date and time as agreed at the Forum, to afford further consultation to industry players due to, the limited time at the said Forum for industry to adequately comment on the Regulations. This is also on the basis that industry players are directly affected by the proposed Regulations.

The purpose of this letter is to re-submit the revised Kenya Association of Manufacturers Memorandum on the proposed Draft Breast milk Substitutes (Regulation and Control Act 2012) Regulation, 2019 and request for a meeting to discuss our member's proposals adequately. We propose to have the meeting on the 10th September 2019 at 10:00 am at your offices or on a suitable date and time.

P.O. Box 30225 - 00100 Nairobi, Kenya
Website: www.kam.co.ke
Email: info@kam.co.ke
Location: 15 Mwanzi Road, Opposite Westgate Shopping Mall
Westlands, Nairobi

Tel: +254 20 2324817/8; 020 8155531/2, 020 2166657
Mobile: +254 722 201368, 0706 612384
Chairman: Sachen Gudka, **CEO:** Phyllis Wakiaga

Feedback should be communicated to us via our physical address and advance feedback email to ceo@kam.co.ke on mobile +254 721 303335/+254 723 443363.

Your early feedback will be appreciated.

Yours sincerely,

Phyllis Wakiaga
CHIEF EXECUTIVE

Cc:
Sicily K. Kariuki (Mrs.), EGH, MBS, CBS
Cabinet Secretary
Ministry of Health
Afya House, Cathedral Road
P.O. Box 30016–00100
NAIROBI, KENYA

KENYA ASSOCIATION OF MANUFACTURERS

MEMORANDUM ON THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL ACT, 2012) REGULATIONS 2019

Submitted to

SICILY K. KARIUKI (EGH, MBS, CBS), CABINET SECRETARY, THE MINISTRY OF HEALTH, NUTRITIONAL HEALTH DEPARTMENT

By

PHYLLIS WAKIAGA, THE CHIEF EXECUTIVE, KENYA ASSOCIATION OF MANUFACTURERS (KAM)

AUGUST 2019

1.0 INTRODUCTION

About KAM

Kenya Association of Manufacturers (KAM) is the leading business membership organization in East Africa that plays a key advocacy role on behalf of manufacturers in Kenya and in the region through her strong linkages with all sectors of the economy. KAM has over 950 members and represents over 40% of Kenya's manufacturing value add industries.

KAM represented Kenya's manufacturing sector interests in the East Africa Trade integration process through the design, ratification and implementation of the Customs Union, and the Common Market Protocol. The integration process in East Africa has been successful with Kenya Playing a critical role. The EAC region integration is expected to spur the manufacturing sector enhancing intra-EAC trade in value added products and thus grow the economies of the region.

About the Nutrition and Food Sub Sector

The Association has a membership of manufacturers of breast milk substitutes which include infant milk and food substitutes aimed at providing substitutes to infants and young children. The businesses are under the food and beverage sector.

The Association recognizes and promotes the need to improve the health and nutrition of infants and young children. This includes promotion of conducive working environment for mothers to promote breast feeding. In addition, Industry players recognize that the products produced are targeted as substitutes in cases only where a mother is ill and unable to breast feed on their own or through assistance to express the breast milk. Such substitutes are permitted in Kenya under laws such as the Breast Milk Substitutes (Regulation and Control) Act, 2012, the Kenyan Guidelines on Essential New Born Care, among others.

Manufacturers under the Association continue to support the country in delivering its international obligations to the **International Code of Marketing of Breast-milk Substitutes by the World Health Organization**. This is in recognition of the role that manufacturers and distributors of breast-milk substitutes have in relation to infant feeding, and in the promotion of the Code and its proper implementation.

2.0 PROPOSED AMENDMENTS TO THE BREAST MILK SUBSTITUTES (REGULATIONS AND CONTROL ACT 2012), REGULATIONS 2019

In response to the call for public participation on the afore-referenced Regulation, we propose the following amendments to be considered before the Regulation is enacted. In summary our proposals require;

1. Recognition of the existing regulator provisions and standards of product development and labelling of breast substitute products. In Kenya this is provided for under standards developed and adopted at the East African Community level and also CODEX standards. This will ensure compliance, adhere to Kenya's obligations at the EAC level on Standards, and also limit market access distortions.
2. Review the proposed provision of limiting interactions with health professionals. This is on the basis that the provisions will affect proper use and prescription of milk substitutes, disregard the existing regulatory system in place to govern ethics of health professionals, and will limit industries extended responsibility of ensuring awareness creation of their products to ensure proper prescription and their use as well as minimize social and economic liability placed on the industry on market failures.
3. Review jointly with industry the provisions on the suitable legibility of product information. This will ensure it meets requirements of the Kenyan adopted standards and minimize distortion of information on products leading to miss-information.
4. Compliance with the Statutory Instruments Act of 2013 due to the direct impact to businesses and also cost implication to the industry.
5. Review the provisions to ensure adherence to the requirements of limitation of human rights and freedoms under the Kenya Constitution.

KENYA ASSOCIATION OF MANUFACTURERS (KAM) PROPOSALS TO THE BREAST MILK SUBSTITUTES (REGULATIONS AND CONTROL ACT 2012), REGULATIONS 2019			
	Part I		
No	**Provision/Issue**	**KAM Proposal**	**Justification for proposals**
1.	**Regulation 2** **In these Regulations, unless the context otherwise requires–** "Cross-promotion" means a form of marketing where customers of a product or service are targeted with promotion of a related product;	**Delete this definition of cross promotion.**	We propose deletion of the definition of cross promotion. This is on the basis that there is no definite and clear definition of the same in the country and even globally. There are currently ongoing discussions on the definition of cross promotion by the Codex Alimentarius Commission level. The term cross promotion was introduced at Codex Committee for Nutrition and Food for Special Dietary Uses (CCNFSDU) as part of labelling provisions for Follow up formula. It was presented to Codex Committee on Food Labeling (CCFL) in May 2019 and was referred back to CCNFSDU. It was again discussed an Codex Alimentarius Commission (CAC) in July 2019. Was not approved and was referred back to CCNFSDU. The discussions have therefore not been concluded on the terms and definition of cross promotion. It would be premature for the country to adopt a definition in the national regulations which may not be aligned with international best practice. We therefore propose to suspend the term until an agreed position is reached on the same.
	Part II- Procedures Relating to the Use of Designated Products and Pre-packaged Complementary Food		
2.	**Regulation 8** **Stocking** No person shall stock, distribute, sell or exhibit any food for infant	**1) Delete "or whose declared date of expiry reads thirty (30) days before the declared date of expiry" to read as follows**	The provisions as proposed will lead to ambiguity and thereby affect effective implementation. This is especially the words used stating "or whose declared date of expiry reads thirty (30) days before the declared date of expiry".

	and young child which is expired or whose declared date of expiry reads thirty (30) days before the declared date of expiry.	***8. (1) No person shall stock, distribute, sell or exhibit any food for infant and young child which is expired.***	The EAC Standards similarly prohibits stocking, distributing, selling or exhibiting any infant food. It does not include the said additional words. We propose the alignment of the provisions in this Regulation with the EAC Standards on the same.
	Part IV: Labelling of Designated Products and Pre-Packaged Complementary Food		
3.	**Regulation 16** **Labelling of Designated Products and Pre-packaged Complementary Food** 16. (1) The label of a designated product shall in addition to the provisions of the relevant written legislation or Kenya standard, contain the name, address and telephone number of the manufacturer, importer or seller.	**Delete the proposed provisions of regulation 16 (1) and replace with the following:** ***16 (1) The label of a designated product shall be in accordance to East African Standards and Codex Standards adopted by Kenya.***	Article 9 on labelling of the International Code of Marketing of Breast-milk Substitutes by the World Health Organization, the EAC standards and Codex standards provides a clear framework for regulating of labels. The Code provides that Labels should be designed to provide the necessary information about the appropriate use of the product. The proposed provisions has included only a few of the required information and left out the other requirements. This will affect implementation and cause confusion in the market. There is need to ensure that the labelling requirements under the regulations must be harmonized with the Kenya and EAC Standards as well as the WHO Code on the same. This will promote compliance and mitigate any misunderstanding on different norms governing the same subject matter. Deviation from already developed standards adopted within the EAC will also distort trade market and can lead to denial of access to markets as well as Kenya being reported to be violating the acceptable standards. In the event that Kenya wishes to deviate from the existing standards, the due process must be followed to ensure the same.
4.	**Regulation 17** **Prohibitions on labelling**	Delete and replace regulation 17 as follows;	Regulation 17 should be revised to align with WHO Code and KS EAS 4 of 2013. Any deviation from this will cause

	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.	***17(1) Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula.*** ***17(2) Label of sweetened condensed milk, powdered milk and liquid milk, not intended for infant feeding, must bear a statement indicating that they are not Breast Milk Substitutes*** ***17(3) Other related products e.g. porridge meant for general population should message the message that they are not complimentary products suitable for feeding infants below 36 months.***	confusion within the market due to conflicting provisions and as result cause non-compliance. In the event of deviation from existing agreed standards, the due process. The current wording in the regulations does not provide enough clarity on pictures/illustrations that are prohibited. Trademarks (including images or graphic representations) are used on labels by manufacturers to allow consumers to distinguish their products from those of competitors. The prohibition should be reviewed to focus on representations that expressly show infants or mothers. To protect infants from unsuitable feeding options, a statement should be included on labels of other unsuitable milks to guide mothers/parents on their unsuitability for infant feeding The provisions need to be harmonized with the current agreed standard in use in Kenya ie. KS EAS 4 of 2013. The limitation of other images on the products is prohibitive to brand owners and focus should be made on representations that expressly display breastfeeding. Trademarks (including images or graphic representations) are necessary on labels by manufacturers to allow consumers to distinguish their products from those of competitors.
5.	**Regulations 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	**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***	To align with the text of KS EAS 4, 2013. EAS 38 (labelling standard) 7.2.1 states that "the language shall be English and/or any other official language used in the importing East African Partner state" The labels are multilingual as products are supplied to many countries e.g. EAC English for Kenya, Kiswahili for Tanzania and French for Rwanda/Burundi hence large text as prescribed will not fit on the labels. The overall impact would be severe limitations on

	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".	***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.***	production and supply, where we may not justify a dedicated label. Ultimately, production efficiency will be compromised to possible levels of discontinuation and closure Regarding the size of the characters on the labeling, we recommend to remove the wording "not less than fifty percent (50%) of the size of the largest words on the label and not less than 1.5mm in height". Maintaining the wording size is not practical and will result in labels that cannot fit all requirements. The regulatory requirement for labelling is long such that large text as prescribed will not fit on labels. These include; Brand name, common name, nutritional composition table, ingredient list, allergen statements, Net weight, Name and address of manufacturer, country of origin, preparation instructions, manufacturing date, expiry date, batch code, Breast feeding notices, safe preparation notices among others. Challenges will be faced in implementing the proposed font sizes regulation due to varied product standards such the inclusion of nutritional requirements. With regard to limiting the languages, the labels included on packaging are destined for many markets which some are multilingual such as within the EAC, English for Kenya, and Swahili for Tanzania and French for Rwanda hence the text will not fit on the labels. The overall impact would have a severe impact on the production, on supply, including for our specific imported range where the volumes of sales may not justify a dedicated labelling. Ultimately, the risk is that some products (especially the imported ones) may be discontinued in the

			Kenyan market. The overall impact would have a severe impact on the production, on supply, including for our specific imported range where the volumes of sales may not justify a dedicated labelling. Ultimately, the risk is that some SKUs (especially the imported ones) may be discontinued in the Kenyan market. Regarding the size of the characters on the labeling, we recommend to remove the wording "not less than fifty percent (50%) of the size of the largest words on the label and not less than 1.5mm in height". Maintaining the wording is not practical and will result in labels that cannot fit all requirements. Moreover, this also will impact the imported range (as explained above)
6.	**Regulation 19** **Containers of designated and pre-packaged complementary food** A label affixed to a container containing a designated product or prepackaged 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 after which the	**1) Addition of the word "or" to read as follows;** **English and or Kiswahili** **19 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/ or Swahili language.	The provisions should be aligned and harmonized with Kenya Standards. Regulation 19(d) be removed as it creates regulatory uncertainty and will impact on production and supply. Manufacturers invest a lot in specific labeling which meet international best practices and comply with specific local laws. Having other particulars added from time to time will require changes that manufacturers will not be able to timely adapt to. Instead, we recommend that the specific requirements should be listed and captured in a standard.

	product is recommended for use in numeric figures, in the case of complementary food, shall not be less than six months; (c) a warning about the health risks of improper preparation and of using the product before to the recommended age; and (d) such other particulars as may be subsequently provided from time to time by the Committee.		
7.	**Regulation 20** **Labelling of Formula in Powdered form** 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 on it, indicate that– (a) powdered formula may be contaminated during the manufacturing process or may become contaminated during preparation; (b) it is necessary for formula to be prepared one feed at a time using clean and safe water of at least seventy (70) degrees Celsius; and (c) any unused milk shall be	**Delete the clause and replace with the EAC adopted Standards on the same to read as follows;**	We propose harmonization of the regulations with WHO/FAO recommendations which include recommendations for use of other viable hygienic preparation methods where there is high level of confidence in the safety of the product e.g. food safety management systems and certifications and where there are heat sensitive nutrients in the product. See extract below: CAC/RCP 66 – 2008 Code of Hygienic Practice for Powdered formulae for infants and young children – has provision for alternatives to the use of water at 70ºC. Proposed statement would be to recommend using previously boiled water, cooled down to ambient temperature for preparations and fed to babies. Products in powder form shall be reconstituted with water that safe or has been rendered safe by previous boiling for preparation. Refer to KS EAS 4, 2013. Delete this clause as this requirement is not practical due to risk of burning/scalding during preparation; practically mothers will need to buy thermometers to measure the water temperature at home.

	discarded immediately after every feed.		Additionally this has a direct effect on heat-sensitive nutrients e.g. heat-labile vitamins e.g. vitamin C, live culture, etc. that will be destroyed/denatured hence by hot water, compromising the nutritional value of the product. The authorities should only permit products that are safe and compliant to consumers. In Kenya, safety is already regulated via mandatory requirement to provide Food Safety Management system certification (ISO 22000/FSSC 22000) before putting products on the market. (Refer to the enclosed said document on food safety). The proposal on the temperatures will cause liability to manufacturers in the event of any scalding from using the product. The provisions should be reviewed in line with manufacturers' proposals on product use and which is reflected in the adopted EAC standards.
8.	**Regulation 21** **Labelling Requirements for feeding bottles** A label, package or a container of a feeding bottle 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 1.5mm in height preceded by the words "IMPORTANT NOTICE" in capital letters: "Breastfeeding is best. Breastfeeding is ideal for the	**1) Addition of the word "or" to read English and/or Kiswahili** **2) Replace the provisions of the proposed regulation 21 with the following;** *A label, package or a container of a feeding bottle shall indicate in a clear, conspicuous and easily readable manner in English* ***and/ or*** *Kiswahili language.* **3) Delete the word "it protects against diarrhea and other illness"** **4) Delete the wording "not less than fifty percent (50%) of the size of the largest words on the label and not**	The proposed provisions to include limitation of size and height of the fonts on products will be challenging to implement. This is because the text of 50% and a height of 1.5 mm will be too large to fit on the label. We propose the provisions to be aligned with Kenya Standards on labeling. The labels are multilingual as products are supplied to many countries e.g. EAC English for Kenya, Uganda, Kiswahili for Tanzania. There is need to align the provisions with the existing Kenya Standards.

	healthy growth and development of infants and young children. It protects against diarrhea and other illness".	**less than 1.5mm in height".** **5) Addition of the paragraph "Or a similar statement as to the superiority of breast feeding or breast milk" and "in bold and conspicuous characters in a prominent position, in a manner that maximizes noticeability and legibility of the word "Importance Notice" in capital letters;** **to read 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.***	
9.	**Regulation 22** **Labelling Requirements for teats**	**1) Delete and Replace the proposed provisions of regulation 22 (2) with the following paragraph;**	The proposed provisions should be aligned to Kenya standard on feeding bottles and teats which are as per our proposed recommendation.

	22 (2) A label, package or a container of a pacifier 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 1.5mm in height preceded by the word "WARNING" in capital letters": "Use of teats can interfere with breastfeeding".	***The label of the teat shall indicate in a clear, conspicuous and easily readable manner in English and/ or Kiswahili language.***	
10.	**Regulation 23 (1) Labelling Requirements for teats and pacifier** 23 (1) A label on a package or container of a pacifier shall not; (d) show any graphic representation other than for illustrating cleaning, the logo of manufacturer or distributer; (e) contain words or images idealising the use of teats; (f) 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 shall indicate in a clear, conspicuous and easily readable manner in English and Kiswahili language the following	**1) Delete and replace the proposed provisions of regulation 23 (1) as follows;** ***A label, of a pacifier shall indicate in a clear, conspicuous and easily readable manner in English and/ or Kiswahili language and conspicuous legible character and in a prominent position in a manner that maximizes noticeability and legibility of the word 'IMPORTANT NOTICE" in capital letters.***	The proposals should be aligned to Kenya standard on feeding bottles and teats which are as per our proposed recommendation.

	words in not less than 50% of the size of the largest words on the label not less than 1.5mm in height preceded by the word "WARNING" in capital letters": "Use of pacifier can interfere with breastfeeding".		
11.	**Regulation 23** **Particulars to be inscribed on container** 23 (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, that is- (i) composition; (ii) required storage condition; (iii) batch number; and (iv) expiry date; (b) on a label marked on or securely attached to the container the following statement- "Breastfeeding is best. Breastfeeding is ideal for the healthy growth and development of infants and young children. It	**1) Delete provisions of regulation 23 (1) or align it the Kenya adopted standards on labelling.** **2) Addition of the word "or" to regulation 23 (1) (a)** **to read as follows;** ***A label, of a pacifier shall indicate in a clear, legible and easily readable manner in English and/ or Kiswahili language.***	The proposed provisions should be aligned to Kenya standard on feeding bottles and teats which are as per our proposed recommendation.

	protects against diarrhoea and other illness". (2) Any label affixed to any container of a designated product or a pre-packaged. Complementary food product as required under subsection (1) of this section 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 subsection (1) of this section 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 an 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.		
	Part V- Interactions between Manufacturers, Distributors and Health Workers		
12.	**Regulation 24 (2)**	**Delete 24 (2) on ethical interactions of**	We propose deletion of the provisions on the following

	Interactions (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.	**medical representatives and health professionals to align the provisions to the WHO Code on marketing which permits dissemination of information to health professionals on breast milk substitutes.**	basis: • Article 6.2 on health care systems in the WHO Code on Breast Milk permits the dissemination of information to health professionals. Sub Article 6.5 provides that feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use. To ensure proper use of the products, manufacturers have a role to play to ensure that information on their products is shared with care givers. Failure by manufacturers to support health workers may lead to miss information and which burden will be ultimately be attributed to the manufacturers. In the event that a product is prescribed wrongly then liability falls on manufacturers. • Sub article 7.5 of the WHO Code provides that manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient. The proposed provisions present the following challenges; (i) **Approval process:** The process of approval by the Committee has not been set out. This will affect the rights to fair administrative action under Article 47 of the Constitution of Kenya, 2010 which provides

			that *every person has the right to administrative action that is expeditious, efficient, lawful, reasonable and procedurally fair*. The process of approval should have; - clear timelines for the application process; when to expect feedback from the Committee on approval; - in the event that the Committee does not approve the procedure for rejection which should involve, - Inclusion of grounds for when a rejection can occur clearly stipulated; - Reasons for rejection requirement provided and timelines for the same; - Provisions for an appeal process which should be clearly stated. The Committee cannot be the body responsible for the Appeal and a separate independent and impartial body should be established to ensure a fair administrative process. (ii) **Single approval systems:** Due to the nature of businesses, single approval of venues will be difficult unless it is annual approval or the Committee works with strict timelines for feedback. (iii) **Capacity and constitution of the Committee:** The Constitution of the said Committee as is does not work on a full time and permanent basis. This is likely to cause delays. (iv) **Constitution of the Committee:** The composition of the Committee does not have the representative body of manufacturers represented and participation despite being key stakeholders in the process and their critical role. This may likely lead to bias in decision making in comparison to a Committee that has presence of representation of

			manufacturers and private sector. (v) **Limitation of rights under the Constitution 2010:** Limiting interactions with public health professionals will infringe on constitutional rights and freedoms which include **freedom of association under Article 36; consumer protection rights under Article 46 and rights to access information under Article 35 of the Constitution, 2010.** The procedure for limiting such rights are safeguarded under the Constitution and which requires any such limits and restrictions in the Bill of Rights to only be limited by law. In this case, the Act should have stipulated such limitations and restrictions for all the rights mentioned which seek to be limited in addition to stating the other requirements of Article 24 of the Constitution.
13.	**Regulations 25** **Creating Awareness** (1) Subject to section 6 (3) (a) 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	**1) Delete Regulation 25 providing for the process of interactions for purposes of awareness creation on scientific and factual matters on breast milk substitutes.**	**Internal best practice on interactions** There is need for the country to follow international norms for ethical marketing of health care products which promote creation of awareness such as in the pharmaceuticals, and nutrition products. **Existing Institutional health professional governance systems and ethical codes of conduct** Industry recognizes the need that led to limiting direct marketing to consumers and the public. However when it comes to ethical interactions with healthcare professionals, this can be regulated due to the organized regulatory system for health professions guided by their ethical codes of conduct in prescribing products. In Kenya the health care professionals have a well-structured governance framework to monitor and hold accountable their ethical responsibilities and this should be utilized as part of self-regulation of such a sector. Awareness through health professionals is the only viable option to ensure enhanced

	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 of 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.		awareness on use of such infant products for industry players due to existing regulatory frameworks for the professionals. The proposal to have the Committee under the Act approve processes will present challenges for the sector. One of the key challenges is the constitution and operations of the Committee to implement this functions effectively and in a manner that adheres to the right to fair administrative action. The Breast milk substitutes Act, 2012 under Section 6 (3) a, b, c, allows the ethical interaction between industry and healthcare professionals. Sub Section 6 (3) c goes further to recognize consumer rights under Article 46 (1) (b). We propose deletion of provisions of the proposed regulations based on the following; • The proposals under proposed regulation 25 (2) (b) in the regulations to introduce a bureaucratic process which involves sworn statements to aver no relationships and we propose deletion of the provisions. • 25 (2) (c) proposes provisions which will affect the health professional privacy and is proposed to be deleted. • Delete (d) since it violates constitutional provisions on freedom of association • 25 (2) (f) to be deleted since it is a requirement by another Government agency in order to avoid duplication of roles within Government. The certificate of analysis are already part of product regulatory approval process carried out by the Kenya Bureau of Standards (KEBS) and Ministry of Health before products are released into the market.

			• 25 (2) (g) to (j) to be deleted since the provisions are already a requirement of product regulatory approval/registration process. This will avoid duplication of existing function by another Government regulatory agency. The proposed regulations provisions under this part will be unique to Kenya and is not aligned with international practices and norms. **Importance of awareness creation on milk substitutes** The importance for awareness by industry players to health professionals is critical to ensure; • The products they produce are used and prescribed in a correct manner to ensure safe use for infants and young children; • The extended responsibility by industry players to create awareness and capacity building arguments government's efforts on awareness in the country. This is recognition of the limited resources that all Governments are faced with, especially in African economies. • Manage liability to Industry players who will and continue to receive the highest liability for failures in the market which are largely caused by lack of information on breast substitutes in the market.
14.	**Regulation 26** **Professional evaluation** 26 (1) Any interactions between a manufacturer or distributor and a health worker for purposes of professional evaluation of a designated product or pre-packaged complementary food shall commence after the	**1) Delete regulation 26 that seeks to limit interactions.**	There is need to promote Health professionals to receive information and capacity-building to be able to advise patients accordingly.

	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.		
15.	**Regulation 28** **Formal Record** (1) Any health worker who wishes to participate in any interaction with a manufacturer or distributor, for 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 to the Committee on request. (2) The formal record referred to in sub Regulation (1) shall contain such information as may	**1) Delete the word "professional evaluation"; and** **2) Replace the provisions of regulation 28 with the following provisions;** ***"Any health worker who seeks to participate in any interaction with a manufacturer or distributor, for purposes of research on a designated product or pre-packaged complementary food, shall prepare a formal record of the interaction and submit to the Ethical Scientific Committee".***	We propose deletion of the words "professional evaluation on the basis that it does not require the Committee's approval. Scientific Research is approved by Ethical committee Kenya. Restriction of interactions with health workers will affect efforts to promote scientific research and other collaborations with the industry.

	be directed by the Committee.		
16.	**Regulation 29** **Restrictions to Interactions** 29 (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 as prohibited by the Breastfeeding Act; (c) engage in activities without the approval of the Committee; (d) distribute any samples of designated or pre-packaged complementary food product; (e) hold promotional activity at an alternative venue not approved; and (f) brand the venue in any way to promote infant formula.	**1) Delete provisions of Regulation 29 on restrictions to interactions.**	We propose the following changes; • Delete the proposed provisions to limit interactions under regulation 29 (1). This is on the basis that the Breast milk substitute Act, section 6 (2) (e). • Regulation 29 (1) delete (c and e) refer to comments on clause 25 regarding violation of constitutional rights on freedom of association and consumer rights to product information. • Delete 29 (1) (d) contradicts with proposed provisions of regulation 24 (1) (b) and the BMS Act 6 (3) (b). • Delete 29 (1) (f) as the scientific content of the meeting is very specific to the product and targeted to the healthcare professionals. Restriction of interactions for industry players and we propose for its removal based on the following grounds; • International norms of marketing ethical products (medicines and infant nutrition products) which is globally done via interactions with health professionals. Kenya would be a unique country where industry is required to seek a committee's approval to engage health professionals, and through a very bureaucratic process. • Kenya would also be a unique country where health professionals have to seek a committee's approval to interact with industry for information sharing for the sake of the consumers. Health professionals already have their codes of conduct which regulates the way they do their work. Health professionals deserve their independence to conduct their professional work and make decisions regarding

			their patients • Limiting interactions with health professionals will also deny them opportunity for trainings that are facilitated by industry covering areas of interest, such as pediatric nutrition, complementary feeding, among others. • The Industry recognizes the need for limiting interactions between manufacturer or distributor and mothers and general public. Proposals to extend the limitation to health professionals will infringe on Article 46 (1) of the Constitution that provides consumers with right to access information necessary for them to gain full benefits of goods and services. • Industry representatives are charged with responsibility of ensuring ethical sharing of factual scientific information about their products. This is to equip healthcare professionals with the right information so that they are able to assist consumers in making the right choice when they have ascertained existence of a need. • The interaction with healthcare professionals contributes to nutrition knowledge accumulation by healthcare professionals. This is a critical industry contribution to capability building of human resources for health under the current Governments' Big Four priority on Universal Health Coverage.
17.	**Regulation 30** **Cross promotion** **30 (1) A manufacturer or** distributor of a designated product or a prepackaged complementary food shall not engage in cross-promotion.	**1) Delete Regulation 30 of the regulations**	We propose deletion of the definition of cross promotion. This is on the basis that there is no definite and clear definition of the same in the country and even globally. There are currently ongoing discussions on the definition of cross promotion by the Codex Alimentarius Commission level. The term cross promotion was introduced at Codex

	(2) A person who contravenes the provisions of sub Regulation (1), commits an offence and shall be liable to prosecution in accordance with Section 27 of the Act.		Committee for Nutrition and Food for Special Dietary Uses (CCNFSDU) as part of labelling provisions for Follow up formula. It was presented to Codex Committee on Food Labeling (CCFL) in May 2019 and was referred back to CCNFSDU. It was again discussed an Codex Alimentarius Commission (CAC) in July 2019. Was not approved and was referred back to CCNFSDU. The discussions have therefore not been concluded on the terms and definition of cross promotion. It would be premature for the country to adopt a definition in the national regulations which may not be aligned with international best practice. We therefore propose to suspend the term until an agreed position is reached on the same.
18.	**Regulation 32** **Advertisement** 32 (1) 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 and shall be	**1) Delete the words "or indirectly" in the first paragraph of regulation 32 (1).** **2) Replace the words "displays, signs, symbols, colours, billboards or notices" under regulation 32 1 (b) with "outdoor displays";** **To read as follows;** **Regulation 32 A person who makes a representation to the public 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 local internet,**	The use of the word "indirectly" proposes liability on an uncertain action which cannot be defined. We propose the deletion of the word so as to remain with the word "directly" which is avoid ambiguity. The proposal to delete regulation 32 (1) b is to ensure clarity to support implementation. Inclusion of the words displays, signs, symbols, colours, billboards or notices is too general; or re is need to define what symbols and colours entail to avoid ambiguity which will affect compliance.

	liable to prosecution in accordance with section 27 of the Act.	**video or telephone;** **(b) displays, billboards or notices; or** **(c) exhibition of pictures or models;** **Commits an offence and shall be liable to prosecution in accordance with section 27 of the Act.**	
19.	**Regulation 38** **Access to Breast milk substitutes** 38 A manufacturer or distributor, upon request shall produce any prescribed designated product or pre-packaged complementary food to an authorized officer.	**1) Addition of the word "writing: before the words "request in" to read as follows;** ***A manufacturer or distributor, upon request in writing shall produce any prescribed designated product or pre-packaged complementary food to an authorized officer.***	There is need to ensure the request is in writing for official purposes.
20.	**Adherence to the Statutory Instruments Act provisions**	**We propose for the Ministry to;** **i. Comply with the provisions of the Statutory Instruments Act of 2013;** **ii. Undertake development of a regulatory impact statement as per the requirement of the Statutory Instruments Act of 2013 on the basis that the Regulations have a direct impact to industry players and also will impose costs to implement the same on businesses.** **The assessment of the costs and benefits shall include an assessment of the economic,**	**Key relevant provisions of the Act** The Government enacted the Statutory Instruments Act of 2013 to provide for the making, scrutiny, publication and operation of statutory instruments and for matters connected therewith. The law provides for the development of the following documents; **(i) Regulatory impact statement**: The Ministry responsible is required to prepare for the statutory instrument a regulatory impact statement. **(ii) Consultation before making statutory instruments:** Before a regulation-making authority makes a statutory instrument, and in particular where the proposed statutory instrument is likely to—(a) have a direct, or a substantial indirect effect on business; or (b) restrict competition; The regulation-making authority shall make

		environmental and social impact and the likely administration and compliance costs including resource allocation costs.	appropriate consultations with person who are likely to be affected by the proposed instrument. In determining whether any consultation that was undertaken is appropriate, the regulation making authority shall have regard to any relevant matter, including the extent to which the consultation— (a) drew on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument; and (b) ensured that persons likely to be affected by the proposed statutory instrument had an adequate opportunity to comment on its proposed content **Impact of the Regulations on industry players** We wish to bring to your attention the following to note based on the provisions of the Statutory Instruments Act; (i) Manufacturers of Breast Milk Substitutes are directly affected by the proposed Regulations and Act. (ii) If a proposed statutory instrument is likely to impose significant costs on the community or a part of the community, the regulation making authority shall, prior to making the statutory instrument, prepare a regulatory impact statement about the instrument. The contents of regulatory impact statements are provided for under the law and must be considered.

Kenya Healthcare Federation
The Health Sector Board for KEPSA

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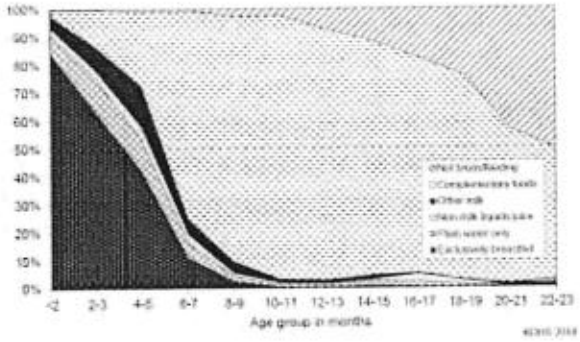
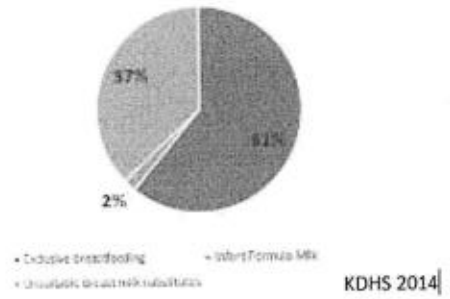
KHF Position on Breast Milk Substitute (Regulation and Control Act 2012) Regulations 2019

Introduction

Kenya Healthcare Federation (KHF) is the health sector board of the Kenya Private Sector Alliance (KEPSA). The Federation promotes strategic public-private partnerships toward achieving national access to quality healthcare and is dedicated to engaging the government and all relevant stakeholders in achieving quality healthcare by maximizing the contribution of the private sector. Industry commits to fully supporting exclusive breast-feeding for the first six months and continued breast-feeding alongside suitable breastmilk substitutes as recommended by WHO Code. There have also been tremendous efforts to abide by the BMS Act in its current form pending the regulations to implement it.

Infant feeding practices by age





KDHS 2014

Exclusive breast-feeding rate stands at 61% (KDHS 2014) while infant formula usage is 2%. There is therefore need for concerted efforts to address the close to 37% unsuitable breast milk substitutes responsible for malnutrition

Anaemia	54%
Stunting	26%
Under 5's Mortality	52/1000 births
Low Birth Weight	8%

Proposed amendments to the breast milk substitute (regulation and control Act 2012) regulations 2019

Article 25: Requirement that industry applies in writing to committee whenever it intends to create awareness about scientific and factual matters of the breastmilk substitutes with healthcare professionals, including submissions of sworn affidavits

Requested consideration

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- International regulations, norms and best practice (Refer to article 7.2 of WHO Code on marketing breast milk substitutes) provide for ethical interaction for purposes of creating awareness to healthcare professionals.
- Article 46 (b) of the constitution guarantees consumer access to information with respect to informed decision making. Restricting industry from engaging healthcare professionals will disempower them from supporting consumers and thereby infringing on this right.
- This has potential to provide grounds for endless wait for approval (or lack thereof)

Article 26: Requirement that health care professional participating in interaction with industry, must before commencing such interaction, seek written approval from MoH committee.

Requested considerations

- Healthcare professionals already operate within the international code of professional ethics with some even having their own local guidelines aligned to international regulations, norms and best practices.
- This amounts to double regulation and limitation of freedom to exercise professional ethics.

Infringes on Health professionals' freedom of Association as enshrined in article 36 of Kenya constitution. There is no such restriction around the world and this is unique to Kenya, not aligned to it.

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THE REPUBLIC OF KENYA

MINISTRY OF HEALTH

IMPORTANT PUBLIC NOTICE

Stakeholders' Consultative Forum on the Draft BMS (Regulation and Control Act, 2012) Regulations

The Breast Milk Substitutes (Regulation and Control) Act, 2012 provides for appropriate marketing and distribution of breast milk substitutes and hence supports safe and adequate nutrition for infants through promotion of breastfeeding and proper use of breast milk substitutes, where necessary and for connected purposes.

The Government through the Ministry of Health has committed to implement and oversee the process of adoption of the legislation and has consequently developed regulations to guide implementation and monitoring of adherance and/or violation.

In the spirit of public participation as envisaged in the Constitution, the Ministry of Health has convened a stakeholders meeting to discuss the Draft Regulations and invites the relevant stakeholders to attend the meeting which will be held on 27th August, 2019 at AFYA Annex (NSCDP) Room 406 starting 8:00 a.m.

The Draft Regulations can be accessed on **www.health.go.ke** **www.nutritionhealth.or.ke**. Views and comments may be sent via email through the link on the website. Alternatively you can write to: The Head, DFH-DN&O, Ministry of Health, **headnutrition.moh@gmail.c** **P.O. Box 30016-00100,** Nairobi by **20th August, 2019.**

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.

ACTIVITY : STAKEHOLDERS FORUM FOR REGULATIONS FOR THE BMS ACT, 2012
DATE : 27TH AUGUST 2019
VENUE : AFYA ANNEXE RM 406

ATTENDANCE LIST

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ACTIVITY : STAKEHOLDERS FORUM FOR REGULATIONS FOR THE BMS ACT, 2012
DATE : 27TH AUGUST 2019
VENUE : AFYA ANNEXE RM 406

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ACTIVITY : STAKEHOLDERS FORUM FOR REGULATIONS FOR THE BMS ACT, 2012
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ISO 9001:2015 Certified

ACTIVITY : STAKEHOLDERS FORUM FOR REGULATIONS FOR THE BMS ACT, 2012
DATE : 27TH AUGUST 2019
VENUE : AFYA ANNEXE RM 406

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ACTIVITY : STAKEHOLDERS FORUM FOR REGULATIONS FOR THE BMS ACT, 2012
DATE : 27TH AUGUST 2019
VENUE : AFYA ANNEXE RM 406

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ACTIVITY : STAKEHOLDERS FORUM FOR REGULATIONS FOR THE BMS ACT, 2012
DATE : 27TH AUGUST 2019
VENUE : AFYA ANNEXE RM 406

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ACTIVITY : STAKEHOLDERS FORUM FOR REGULATIONS FOR THE BMS ACT, 2012
DATE : 27TH AUGUST 2019
VENUE : AFYA ANNEXE RM 406

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53.	Prof NJUATI	KEMRI-UNIVERSITY	0722235323	ruth-njuati2003@yahoo.com	
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55.					
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57.					
58.					

ACTIVITY: MEETING TO REVIEW THE PUBLIC COMMENTS FOR THE BMS REGULATIONS

DATE : 13TH SEPTEMBER 2019

VENUE : AFYA ANNEXE 3RD FLR RM 306

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13.	Peter Mwtua	KEBS	0720834424	16470239	MWtua@kebs.org	
14.	JAMES NJIRU	Save the Children	0720551062	13332335	James.Njiru@savethechildren.org	
15.	AUCH RONALD	MOH - LEGAL	0795701275	35758218	ronnieauch20@gmail.com	

Verified by:

MOH OFFICER: Caroline K. Kathiar Sign: _____ Date: 13/9/2019

ACF STAFF: Mary Kimani Sign: _____ Date: 13/9/2019

ACTIVITY: MEETING TO REVIEW THE PUBLIC COMMENTS FOR THE BMS REGULATIONS

DATE : 13TH SEPTEMBER 2019

VENUE : AFYA ANNEXE 3RD FLR RM 306

ATTENDANCE LIST

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7.						

No. 14

MINISTRY OF HEALTH

OFFICE OF THE PRINCIPAL SECRETARY

Telephone: +254-2-2717077
E-mail: pshealthke@gmail.com
When replying please quote:

AFYA HOUSE,
CATHEDRAL ROAD
P.O. Box 30016 – 00100,
NAIROBI

Ref: MOH/ADM/1/1/2

Date: 10th June 2020

Kennedy Ogeto, CBS
Solicitor General
P.O Box 40012-00100
NAIROBI

Dear Kennedy,

RE: FINAL DRAFT BREAST MILK SUBSTITUTE (GENERAL) REGULATIONS, 2020

Kenya has made tremendous improvement in promoting, protecting and supporting breastfeeding in the past decades. This has been achieved through appropriate practices such as early introduction of breastfeeding immediately after birth, exclusive breastfeeding for the first six months and continued breastfeeding up to 2 years. However, inappropriate marketing and distribution of Breast Milk Substitutes continues to undermine these gains.

The Breast Milk Substitutes (Regulations and Control) Act. No. 34 of 2012 was enacted to provide for appropriate marketing and distribution of breast milk substitutes. The Act also gives the Cabinet secretary for Health powers in consultation with the National committee on Infant and Young Child Feeding to make Regulations prescribing how implementation of certain sections of the Act should be accomplished.

Subsequently, the Ministry of Health jointly with the National committee on Infant and Young Child Feeding, the Kenya Law Reform Commission and stakeholders has drafted the Breast Milk Substitutes (General) Regulations. The Regulations have been subjected to both internal and external stakeholder's validation.

The purpose of this letter is to request you to review the draft Breast Milk Substitute (General) Regulations (attached) and clearance if in concurrence for tabling in the National Assembly.

Yours sincerely,

Susan Mochache, CBS
PRINCIPAL SECRETARY

Copy to: Cabinet Secretary for Health

No. 15

OFFICE OF THE ATTORNEY-GENERAL
&
DEPARTMENT OF JUSTICE

Our Ref: 119/2/42

20th November, 2020

Principal Secretary
Ministry of Public Health
Afya House
NAIROBI

20 NOV 2020

RE: THE BREASTMILK SUBSTITUTES (GENERAL) REGULATIONS, 2020

Reference is made to your letter under Ref No. MOH/ADM/1/1/2 dated the 10th June, 2020 requesting this Office to review the said Regulations. As requested, we have reviewed the same and through this letter we hereby forward them for your concurrence noting the following:

1. We shall require the signed original and two copies of the Regulations for publication. Further to this, we enclose herewith an annotated version of the draft Regulations indicating the exact alterations made to the Regulations which should accompany the final draft.

2. The definitions of "Cabinet Secretary", "complementary food product", "designated product", "health worker" and "health facility" appearing in regulation 2 have been deleted. These terms are already defined in section 2 of the Act negating the need to have them defined in the Regulations.

3. Regulation 5(1) has also been altered by deleting the words: "where a conflict among these standards arise generally, these regulations shall prevail over the other is more protective of the children." We gather that most of these standards are anchored in the relevant Acts of Parliament of which subsidiary legislation cannot override them.

4. Once published, section 11 of the Statutory Instrument Act (No. 23 of 2013) requires the responsible Cabinet Secretary to ensure that a copy of the Regulations is

23 NOV 2020

transmitted to the Clerk of the National Assembly within seven (7) days of publication for parliamentary scrutiny. In this regard, we wish to draw your attention to the provisions of section 5A of the said Act which requires that the Regulations are accompanied by-

(a) statement on the proof and demonstration that sufficient public consultation was conducted;

(b) a brief statement of all the consultations undertaken before the Regulations were made;

(c) a brief statement of the way the consultation was carried out;

(d) an outline of the results of the consultation; and

(e) a brief explanation of any changes made to the legislation as a result of the consultation.

5. In view of the timeframe between publication and submission of the Regulations as indicated, it is imperative that all the necessary documentation be ready before submission of the Regulations for publication.

Please be advised accordingly.

FRED MWACHI
DEPUTY CHIEF PARLIAMENTARY COUNSEL
FOR: ATTORNEY-GENERAL

Copies to:

Hon. Attorney-General

Solicitor-General

Legal Notice No.....

The Breast Milk Substitutes (General) Regulations, 2020.

Arrangement of clauses

Clause

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 (General) Regulations, 2020

Part I- Preliminary

Citation.

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

Interpretation.

2. In these Regulations, unless the context otherwise require—
"Act" means the Breastmilk Substitutes (Regulation and Control) Act;

"advertisement or promotion" has the meaning as expressed in subsection 6 (2) of the Act;

"authorised officer" means a person appointed under the Act;

"breast milk substitute" has the meaning assigned to it under section 2 of the Act;

"Committee" means the National Committee on Infant and Young Child feeding established under section 4 of the Act;

"Cabinet Secretary" means the Cabinet Secretary responsible for matters relating to public health;

"complementary food products" means, in addition to the products listed in the Act, any food suitable as or presented as a suitable complement to breastmilk, for infants from the age of six months up to the age of 36 months;

"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;

"designated product" has the meaning assigned to it under section 2 of the Act;

"donee" means the person or institution receiving the donation;

"donor" means the person or institution making the donation;

"health worker" has the meaning assigned to it under section 2 of the Act;

"health facility" has the meaning assigned to it under section 2 of the Health Act;

"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, breast milk 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 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.

Cap. 254, 242 and 496.

5. (1) The production, preparation and packaging of 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, the Standards Act and the Kenya Standards KSEAS 39 and any other written law, where a conflict among these standards arise generally, these Regulations shall prevail unless the other is more protective of children.

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

Sampling and testing.

6. 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

Cap. 254, 242 and 496.

Act, the Public Health Act and the Standards Act and any other written law.

Packaging.

7. The designated products and the pre-packaged complementary food shall be packaged in accordance with the Act, the relevant written laws, 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).

Importation.

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.

Stocking.

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 the prescribed 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 the prescribed 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 the prescribed 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.

Uses 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 breastmilk 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, indicating that—

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

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

(c) 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 letters": "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. (1) 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 to—

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

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

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

No. 4 of 2015.

(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.

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 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.

Research of product.

30. (1) A health worker who intends to carry out research on a designated product or pre-packaged complementary food and intends to request samples from a manufacturer or distributor shall apply in writing to the Committee.

(2) The application referred to under sub-Regulation (1), shall be accompanied by—

(a) an approved research protocol;

28 of 2013.

(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;

(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.

31. (1) 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.

(2) The formal record referred to in sub Regulation (1), shall contain such information as may be directed by the Committee.

Restrictions to interactions.

32. (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 without the approval of 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.

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

Information inserts.

34. (1) A manufacturer or distributor of a designated product or a pre-packaged complementary food, shall not insert any other

information, beyond the scope of what is prescribed for packaged product.

(2) A manufacturer or distributor of a designated product or a pre-packaged complementary food, shall not collaborate with another manufacturer or distributor of any other product beyond the scope of the packaged product for purposes of consumer information or education.

Advertisement.

35. 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.

36. 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.

37. (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 breast milk 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.

37. (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

Information, Education and Communication Materials.

38. (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 paragraph (1), a person shall submit an application letter, together with a sample of the proposed material be published or distributed containing any informational or educational or communication material that relates to infant and young children feeding.

Contents.

39. The contents of the information, education and communication materials under this 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) includes only factual, scientific and current information and is not presented in any picture that encourages bottle feeding or discourages breastfeeding; and
(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.

Response

40. The Committee shall respond to the application within twenty-one (21) days of the receipt of the application, upon satisfaction that the information, education and communication materials materials comply to the provisions of Regulation 39 of these Regulations.

Part VII-Enforcement

Authorised persons.

41. 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.

42. An authorised officer, shall subject to section 12 of the Act, conduct an inspection in the prescribed Form BMS 5 in the Schedule to these Regulations.

Access to breast milk substitutes.

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

Seizures.

44. (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 prescribed in the Schedule to these Regulations.

Conflict of Interest.

45. (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.

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

Spot fines.

47. 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.

48. 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.

49. (1) The Cabinet Secretary may from time to time review these Regulations for the better implementation of the Act.

(2) Despite the generality of sub Regulation (1), these Regulations are exempted from the provisions of paragraph 21(1)(b) of the Statutory Instruments Act.

SCHEDULE

r. 11(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

Name: .....

Signature:.....

Date:.....

Donee

Name:.....

Signature:.....

Date:.....

r. 13(1)

FORM BMS 2

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
Name: .....
Signature:.....
Date: .....

Donor
Name:.....
Signature:.....
Date:.....

r. 13(2)

FORM BMS 3
RETURNS FOR USE 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:……

r. 13(3)

FORM BMS 4

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:.....

r. 42(2)

SEIZURE FORM A

(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 of 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.

r. 42(2)

SEIZURE FORM B

(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) Act and 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.

r. 39.

Form BMS 5
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.

Explanatory Memorandum to the Breast milk Substitutes (General) Regulations, 2019

The Breast milk Substitutes (General) Regulations, 2019 are made pursuant to section 28 of the Breast milk Substitutes (Regulation and Control) Act, 2012, by the Cabinet Secretary responsible for matters relating to public health.

Part I provides for the preliminary matters such as citation, interpretation and the guiding principles. Some of the terms defined under clause 2 includes "Cross-promotion" to mean a form of marketing promotion where customers of one product or service are targeted with promotion of a related product. Clause 3 of the Regulations provides for the guiding principles which includes the requirement to ensure that the best interest of an infant and young child is protected; initiation of breastfeeding of the infant to be done within an hour of delivery and exclusive breastfeeding for a period of six months and timely introduction of appropriate complementary food with continued breastfeeding for a period of 24 months and beyond.

Part II of the Regulations provides for procedures relating to the use of designated products and pre-packaged complementary food. These include, Production, Sampling and Testing, Packaging, Importation, Stocking, Use of Alternative containers from the original, as well as the issuance of a certificate of analysis for sampled foods. Clause 6 provides that designated products and the pre-packaged complementary food shall be packaged in accordance with the Act, the relevant written laws, 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).

Part III of the Regulations provides for the manner of making donations of designated products and Pre-Packaged Complementary Foods. These shall include the requirement to make an application to the Committee, restrictions to donations, filing of returns as well as application by charitable and social institutions and the uses of donations. Clause 11 provides that , a person or institution who undertakes to make a donation of a designated product or a 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.

Part IV of the Regulations provides for the manner of Labelling of Designated Products and Pre-packaged Complementary Food, Prohibitions on Labelling, Labelling of Infant Formula and Follow up Formula, Containers of Designated and Pre-Packaged Complementary Food,

Labelling of Formula in Powdered Form, Labelling Requirements for Feeding Bottles, Labelling Requirements for Teats, Labelling Requirements for Teats and Pacifiers, Particulars to be Inscribed on Container as well as Warning on Nutrients.

Clause 18 provides that 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 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."

Part V provides for interactions between manufacturers, distributors and health Workers. These includes, creating awareness, professional evaluation, research of product, formal records, restrictions to interactions, cross-promotion, informational inserts, advertisement, demonstration for use of a Pre-packaged complementary food product, procedure for demonstration for use of infant and follow-up formula, procedure for demonstrating proper complementary feeding. Clause 34 prohibits any direct or indirect representation with an intention of promoting the sale or use of designated or pre-packaged complementary food product.

Part VI of these Regulations provides for enforcement through, the authorised persons, inspection, access to breast milk substitutes, seizures as well as the imposition of a general penalty and spot fines. It also provides for the review of the Regulations by exempting them from the provisions of the Statutory instruments Act. Clause 44 provides that 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 Kenyan Shillings.

Dated this.....2020

Mutahi Kagwe, EGH

Cabinet Secretary

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

ARRANGEMENT OF REGULATIONS

Regulation

PART 1—PRELIMINARY

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

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

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

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—

(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

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

(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

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.

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.

On 10th June 2020, the Principal Secretary, Ministry of Health wrote to the Attorney General (AG) seeking legal guidance and concurrence on the draft Regulations. The AG through a letter date 20th November 2020, advised the Ministry to publish the Regulations and transmit the same to the National Assembly.

The Ministry notified the World Trade Organization (WTO) on the proposed BMS regulations on 22nd December 2020. Comments from two member states namely the United States and Switzerland were received in February 2021. Additionally, KAM even though not a WTO member state and the Embassy of the United States of America submitted written comments to the Cabinet Secretary.

A consultative meeting on the proposed Regulations was held on 5th February 2021 with the Committee on Delegated Legislation of the National Assembly. The committee directed that the Ministry conducts a regulatory impact assessment of the proposed instrument.

The draft responses to the comments from the United States and Switzerland were presented to the National Technical Barriers to Trade (TBT) committee on 10th March 2021, for onward transmission to WTO.

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.

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.

The Ministry also sought legal guidance and concurrence with the draft Regulations from the Attorney General (AG). The AG cleared the regulations for publication in the Kenya Gazette and transmission to the National Assembly.

On 22nd December 2020, MOH notified the World Trade Organization (WTO) on the proposed regulations. Comments were received from the United States of America Government and Switzerland Government. Additionally, the Embassy of the United States of America, KAM, Cereal Millers Association and Water Bottle Association of Kenya submitted their comments.

A consultative meeting with the Committee on delegated legislations of the National Assembly was held on 5th February 2021.

The MOH response to comments received following WTO notification were presented to the National Technical Barriers to Trade (TBT) committee on 10th March 2021 and later transmitted to the WTO.

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.

Following request by the Kenya Association of Manufacturers (KAM) for another consultation, a meeting was held on 13th September 2019 where KAM presented their comprehensive memorandum and key issues were discussed.

On 10th June 2020, the Principal Secretary, Ministry of Health wrote to the Attorney General seeking legal guidance and concurrence with the draft Regulations. The AG advised the Regulations to be published and additionally be transmited to the National Assembly.

The Ministry notified the World Trade Organization (WTO) on the proposed BMS regulations on 22nd December 2020. Comments from two member states namely the United States and Switzerland were received in February 2021. Additionally, the Embassy of the United States of America, KAM, Cereal Millers Association and Water Bottle Association of Kenya submitted their comments.

A consultative meeting with the Committee on delegated legislations of the National Assembly was held on 5th February 2021. The committee advised MOH to carry out regulatory impact assessment to be submitted together with the proposed regulations to the National Assembly.

The draft responses to the comments from the KAM, United States of America and Switzerland were presented to the National Technical Barriers to Trade (TBT) committee on 10th March 2021, and thereafter submitted to the WTO.

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.

i. Changes made after stakeholders' consultations and subsequent meeting with KAM held on 27th August 2019 and 13th September 2019 respectively.

Clause/Regulations	KAM submission	MOH Response	Justification
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	Retain the difinition Codex standards often follow national practice, not lead them. The consensus on the definition at the World Health Assembly is a prudent basis for Kenya's regulatory definition. Regulation of cross promotion is important in controlling unethical promotions & advertising.	The clause is maintained with the following justifications. • Kenya law and regulation takes precedence over any regional standards and regulations. • The term cross promotion is used as defined by WHO technical guidance documents. It is important in controlling unethical promotions & advertising. • 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'. • According to Para 24 to 28, of 2019 CCFL[2] report, the committee noted that the standard

[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	KAM submission	MOH Response	Justification
			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 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. • 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.
2.R [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*"	The clause was revised to read: *No person shall stock, distribute, sell or exhibit any food for infant and young child which does not have a manufacturing date and an expiry date.*	• Two dates will be required i.e. manufacturing and expiry date. • Manufacturing date is used at the point of importation and this is very important for the country- the law requires that products have at least 75% expiry date during importation. • Expiry date is for purposes of harmonization with internal laws; Cap 254 emphasizes expiry date for purposes of Food Safety and Hygiene.

[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	KAM submission	MOH Response	Justification
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.	Maintain the section	KAM was given an opportunity to present to the committee an artwork sample to demonstrate that the font size as proposed would be a challenge to implement. The presentation did not come up with designed label to justify their concern but rather they presented a superimposed artwork of an existing label
4. Regulation 17 (Prohibition on labelling)	KAM proposes revision of this regulations subsection 17 [1], [2] and [3] *(see appended KAM proposals)*	Maintain the text in the draft regulations.	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.

Clause/Regulations	KAM submission	MOH Response	Justification
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"*	Maintain the text in the draft regulations.	• Research has revealed that breastfeeding protects infants against diarrhea and other illness

Clause/Regulations	KAM submission	MOH Response	Justification
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 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'**	The comment was adopted to allow for use of either Kiswahili and/or English	This was considered for consistency with Cap 254 and the EAC protocol The Kenya Standards allows for both the use of either English or Kiswahili. In Tanzania, Kiswahili is a mandatory requirement. • Same as issue 5
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°C then cool it to ambient temperatures as reconstituting with hot water (70°C) interferes with the formulation and introduces risk of scalding.	The requirement was maintained at 70° C	The committee reviewed UNICEF, WHO and CDC guidance on the same. It was noted that maintaining water temperatures above 70° C protects babies from E. Sakazakii and Salmonella. It was noted that some formulas would contain some nutrients that would be denatured at this temperature. However, the risk of denaturing nutrient is less compared to the risk of exposing the infants and young children to E. Sakazakii or Salmonella. In its effort to ensure infants are protected from E. Sakazakii, KS CAC/RCP 66:2008[4] section IX Para 5

[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

Clause/Regulations	KAM submission	MOH Response	Justification
			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°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°C to minimize chances of microbial contamination. • 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

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

Clause/Regulations	KAM submission	MOH Response	Justification
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.	Maintain as in the draft regulations.	Engagement and notification of the regulations will be made.
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	Maintain as in the draft regulations.	There is no applicable Kenya Standard and hence the regulation The regulation are coming in to address the existing regulatory gaps
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 KAM noted that regulating venue does not give rise to ethical interactions	Maintained the section	The notification of venue will guide the inspectors/monitors if they need to investigate or confirm activities are in compliance to the Act. Documented evidence of continued violation of the Act and the code is indication of nonexistence or inadequate of self-regulation The section includes all players i.e manufacturer and distributors which include traders' importers etc.

Clause/Regulations	KAM submission	MOH Response	Justification
	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		There will be binding procedures governing timelines related to receipt, acknowledgement and decision by the committee on request for venue

Clause/Regulations	KAM submission	MOH Response	Justification
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 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	Maintain the section	The section does not prohibit rather it provides guidance on how awareness by the industry should be approved and conducted
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	Maintain 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	Regulation provided for minimum requirements which any stakeholder may use for self-regulation if they deem fit
15. Regulation 28 (Formal record)	According to KAM. the prohibitive aspect is the indication that the committee will approve	Maintain	The section does not provide any prohibitive act. The clause is only requiring information and no approval is envisaged in the section

Clause/Regulations	KAM submission	MOH Response	Justification
	which counters administrative law which dictates that the standards the committee uses to make the decision will be stipulated in regulation.		
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.	Maintain	Documented evidence of continued violation of the Act and the code is indication of nonexistence or inadequate of self-regulation
17. Regulation on 'cross promotion'	Discussed in issue 1 above.	Discussed under issue 1.	Discussed under issue 1.
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'	Maintain	The objective to regulate all persons and media involved in advertisement given that advertisement is prohibited in the Act itself.
19. Regulation 38 (Access to BMS)	KAM proposes that there is inclusion of the word 'in writing'	Maintain	MoH in response noted that the proposed regulation is consistent with other existing laws (CAP 254, 242)

Clause/Regulations	KAM submission	MOH Response	Justification
20. Adherence to statutory instruments Act	KAM requested that there is consistency with the statutory instruments Act, 2013	The drafting are done in compliance of the Statutory Instruments Act and other obligations such as WTO/TBT agreements	

ii. Changes made after comments on the proposed regulations were received from the United States of America government and Government of Switzerland, following Kenya's notification to the WTO on 22nd December 2020.

Responses to concerns raised by the United States of America

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
PART II – PROCEDURES RELATING TO THE USE OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD			
5. (a) & (b): International Standards:	The document "The Breast Milk substitutes (Regulation and Control) (General) Regulations, 2020" references 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)." We request confirmation that these standards were developed considering, and are in harmony with, the following Codex Standards: Codex Guidelines on Nutrition, Labeling (CAC/GL-1985), Codex General Guidelines on Claims (CAC/GL 1979),	The codex standards were used as the reference documents during the development of the corresponding Kenyan standards, which are adopted from the harmonized East African standards.	The objective of the regulations is to contribute to prevention of deceptive practices and protection of human health and safety by regulating the marketing/advertising or promotion of BMS products as well as donation and interaction of health workers with distributors/manufacturers among others. The standards do not address these aspects as recommended under the WHO International Code for

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
	Codex Standard for Vitamin and Mineral Food Supplements (CAC/GL 55-2005), Codex Guidelines on Formulated Complementary Foods for Older, Infant formula and formulas for special medical purposes intended for infants (CODEX STAN 72-1981, Standard for Labelling of Claims for Foods for Special Medical Purposes (CODEX STAN 181-1991), Formula Foods for Use in Very Low Energy Diets for Weight Reduction (CODEX STAN203-1995),General Standard for Bottled/Packaged Drinking Waters (CODEX STAN 227-2001), Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981).		marketing of breastmilk substitute to which Kenya has committed to implement in its entirety.
9. Manufacturing, sell, and expiry date:	To provide the justification for requiring products to have three dates on the label: a "manufacturing date, sell by date and an expiry date." The Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985	Kenya accepts to revise section 9 and requirement for two dates i.e. Manufacture date and Expiry date	Manufacturing date is used at the point of importation and this is very important for the country- the law requires that products have less than 75% expiry date during importation. Expiry date is for purposes of harmonization with internal laws; Cap 254 emphasizes expiry date for purposes of Food Safety and Hygiene.
10.Use of alternative containers from the original	Please clarify how Kenya will promote food safety and hygiene, prevent product contamination and adulteration, and prevent consumer misinformation by allowing re-packaging of these products in alternative containers? How will Kenya ensure that any re-packaging will remain consistent with international standards?	These provision allows for bulk importation and packaging in retail unit, a practice which is already happening	This provision will ensure continuity in business. Food quality and safety is assured through the implementation of existing national regulations and standards.
11.(1) Certificate of analysis:	Please confirm that this provision indicates routine monitoring and verification of product characteristics and does not indicate that each product must be accompanied by a certificate of analysis. Please clarify the frequency and method of inspection for products under the scope of this provision.	The certificate of analysis referred to in this section is issued after sampling and analysis by authorized officers. Note: It is not carried out by the	This is for purposes of routine monitoring. The government inspectors collect samples and send to government recognized analysts for analysis and issuance of certificate of analysis for decision making.

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
		manufacturers or distributors.	The frequency is as need arises as guided by the existing routine monitoring and verification framework s for the country.
PART III – DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOODS			
13.2 Labelling of Donations	The United States recommends that Kenya eliminate the provisions of this proposed regulation pertaining to the "shelf life" of donated products. Has Kenya considered that these products are not packed just-in-time when donations are needed and how these proposed measures could impact response to an emergency necessitating the mass feeding of infants or young children?	This is important to ensure the products going to charitable homes do not have short expiry because they may keep them for long. This will also protect against dumping.	The expiry date requirement of 50% has been brought down from the normal 75% that applies for the other imported food products for general household use. This is also consistent with government policies on donated food products.
17.(1) Labeling of designated products and pre-packaged complementary food product:	Please provide the justification for requiring website, email address, and telephone number of the manufacturer, seller, and importer on the label. We note that Article 4.4 of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985 (Rev. 1-1991)) only requires the name and address of the manufacturer, seller, and importer.	Kenya has accepted to amend this requirement to have: **name, physical address** and **contacts** where contacts could be either be **website, email address or telephone)**	Most of the BMS designated products are imported hence this information is required for traceability. The requirements are also provided for in the existing national legislations.
18 Prohibition on Labeling:	The United States suggests using the language found in the Codex Standard for Infant Formula (Codex Stan 72-1981) which states that labels should not discourage breastfeeding nor contain pictures of infants and women, or any other picture which idealizes infant formula	Kenya considered the statement in the standards and found them not sufficient enough to underscore the importance of breast feeding and therefore not effective or appropriate to achieve Kenya's objective.	Based on Article 9.2 of the International Code of marketing of BMS, the government has developed this statement to emphasize on the superiority of breast feeding. This message is consistently communicated during promotion of breast feeding and has contributed to improvement in the rated of exclusive breast feeding from 31% in 2008/9 to 62 % in 2014.

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
19.(1) Labeling of infant formula and follow-up formula: The	United States supports using the specific language for infant formula found in Article 9.6.1(b) of the Codex Standard for Infant Formula and Formula for Special Medical Purposes for Infants: "Breast milk is the best food for your baby". The United States also suggests that Kenya include language that identifies which products should be given to infants in situations where human milk is not available.	**Same as 18 above**	Same as justification under 18 above in that the Codex language would not be effective or appropriate to achieve Kenya's objective.
21.(a) & (b): Labelling of formula in powdered form	The manufacturing and safe handling characteristics of specific products within the scope of this regulation can vary considerably. The United States suggests that Kenya include information about the health hazards of inappropriate preparation, storage and use, rather than requiring general statements on containers that indicate a product may be contaminated during the manufacturing process or during preparation. Such recommendations may conflict with product-specific instructions and thus inadvertently undermine safe use.	**Maintain clause**	Evidence shows that contamination of food including powder formula can happen at any level from manufacturing to transportation to handling and consumption. This aims to educate the consumers as provided for in article 46 (1) (b) of the Constitution of Kenya.
25.(1) (a) & (b) Particulars to be inscribed on container:	The United States notes its previous comments on Part II 9. on the use of expiration dates. Additionally, has Kenya considered whether the proposed warning statement on complementary foods may prevent them from being used appropriately? The United States notes that at about age 6 months, infants should be introduced to nutrient-dense, developmentally appropriate foods to complement human milk or infant formula feedings.	**Maintain clause**	The consideration of appropriate complementary feeding was considered and there are other guidelines and policies in the country addressing this to complement the regulations.
26.Warnings on nutrients:	The United States appreciates Kenya's desire to ensure that infants and young children receive nutrition appropriate to their stage of development. However, the proposed inclusion of warning statements on a broad range of fluid milk, cereal, and bottled water products could create significant barriers to trade in these products. The public consumes many of these products. Has Kenya considered whether the proposed statement may lead to consumer confusion and prevent their use even in appropriate	Kenya has considered this comments and taking into consideration '22' and '25' has decided to DELETE the entire clause 26 from the regulations	The intent is covered in other clauses of the regulations.

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
	contexts? Has Kenya considered whether the proposed warning statement would deter the use of bottled water products in the preparation of powdered breast milk substitutes in situations where they are needed as the sole source of potable water? If Kenya implements this requirement, we ask for clarification on: the exact scope of products subject to the requirement, if the requirement will apply to both domestically produced and imported products, and if any required statements were developed with consideration to the Codex General Standards for Bottled/Packaged Drinking Waters (CODEX STAN 227-2001) and Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981).		
32. Cross-promotion:	Can Kenya explain the need for this provision? We note that in section Part IV 17.2 Kenya specifies, "the label of a designated product or prepackaged complementary food shall not refer to, promote or advertise any other designated product". This appears to adequately cover the concept of cross-promotion.	**Maintain clause**	Section Part IV 17.2 refers to the label of a designated product or complementary food promoting another designated product while 32 covers general cross promotion in the context of designated products and complementary foods. The two types of cross promotion are of interest to Kenya based on the marketing methods in the country.
33.Advertisement:	Please clarify whether the restriction on promotion of sale or use would extend to the manufacturing companies' ability to use logos and trademarks on their websites.	**Maintain clause**	This is not a restriction on the use of the companies' logos and trademarks as stipulated in the Kenya Trade Marks Act.
PART VII – ENFORCEMENT			
40. Inspections:	Please clarify the frequency and method of inspection for products under the scope of this proposal that are imported into Kenya	Routine inspection for both imported and locally produced products is carried out	This is a routine inspection for all designated products whether imported or locally manufactured.

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
		in accordance with national legislations or based on complaints as the case may be.	The inspection is done routinely for purposes of compliance to the BMS Act,2012

Responses to comments raised by the Governments of Switzerland

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
PART I – PRELIMINARY			
Interpretation Cross promotion (2)	Switzerland considers this definition should be removed as the term is currently not defined internationally and it is not aligned with the Codex discussions in the frame of the revision of the Codex Standard for follow-on formula. Indeed "Cross-promotion" was discussed at CODEX Committee for Nutrition and Foods for Special Dietary Uses (CCNFSDU 41) in December 2019 and it has been concluded not to use the term "Cross-promotion" to avoid confusion.	The term cross promotion is used as defined by WHO technical guidance documents. It is important in controlling unethical promotions & advertising	Codex standards often follow national practice, not lead them. The consensus on the definition at the World Health Assembly is a prudent basis for Kenya's regulatory definition. Kenya will consider constructive suggestions to revise the proposed definition provided they do not propose to abandon the regulatory objective.
Objects (4)	Switzerland notes the information provided in this paragraph undermines the legitimacy of breast milk substitutes and is not scientifically founded nor in line with international standards, including the WHO International Code of Marketing of Breast-Milk Substitutes. When mothers are unable to breastfeed or choose not to, a safe and nutritious alternative is required. In this context, scientifically developed breast-milk substitutes are the only recognized and proven alternative to breastmilk for infants as acknowledged by the WHO International Code of Marketing of Breast-Milk Substitutes. In its introduction, the WHO Code acknowledges that "there is legitimate market for infant formula [...] these products should accordingly, be made accessible to those who need them [...]".	**Maintain the paragraph**	Section 4 does not prohibit the sale of breast-milk substitutes, it only prohibits the promotion of these products and prohibits their sale if they fail to meet labelling, compositional, and other related requirements. This provision is consistent with WHO guidance, generally, and, in particular, World Health Assembly (WHA) resolution of 2016 that calls on countries to implement the WHO *Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young*

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
	Switzerland recommends a revision of this paragraph according to the objective to protect and promote breastfeeding and not undermining breast milk substitutes.		*Children* to further protect breastfeeding, prevent obesity and chronic disease, and promote a healthy diet. In addition, the guidance aims to ensure that caregivers receive clear and accurate information on feeding. WHO developed the guidance as a response to a growing body of evidence that shows that the promotion of BMS and some commercial foods for infants and young children undermines progress on optimal infant and young child feeding.
Manufacturing, sell, and expiry date (9)	Having these three dates on the same products will increase the misunderstanding and misuse of date marking. A clear and unique date marking would be better understood by the consumer and could reduce food waste.	Kenya accepts to revise section 9 and requirement for two dates i.e. Manufacture date and Expiry date	Manufacturing date is used at the point of importation and this is very important for the country; the law requires that products have at least 75% of time remaining before the expiry date at the time of importation. Expiry date is for purposes of harmonization with internal laws; *Food, Drugs and Chemical Substances Act, Cap 254* requires the reporting the expiry date for purposes of food safety and hygiene by the consumer.
Use of alternative containers from the original (10)	Switzerland considers this practice should not be allowed from a safety perspective, due to the risk of re-contamination, risk of adulteration, losing product integrity and proper information. In case the Codex General Principles of Food Hygiene (CXC 1-1969) is not followed, such a practice could affect the health of the infant and young children. Moreover, the use of alternative containers raises questions over responsibility aspect as well as accountability if the person	This provision allows for bulk importation and packaging in retail unit, a practice which is already happening	This provision will ensure continuity in business. Food quality and safety is assured through the implementation of existing national regulations and standards.

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
	who put the product in the alternative container does not represent the Food Business Operator of the original product.		
PART III – DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOODS			
Restrictions on Donations (13.2)	Switzerland believes that there should not be a prescribed period of shelf life before expiration for donation as this would be restrictive and not viable to be implemented. It needs to be noted that the products within the scope of the regulation should generally provide for a "Best- Before Date" or "Best Quality-Before Date" in accordance with (ii) the respective Codex Standard above (Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)). Such products should do not have any 'expiry date' and it would be difficult to define what 50% of the expiry date are. This requirement may result in addition in an increase in food waste which is not in line with Sustainable Development Goal Target 12.3 which seeks to halve global food waste at retail and consumer levels by 2030. Switzerland also notes that considering that the current draft Regulation proposed by Kenya is not aligned with international standards, products will not be able to meet "both Kenyan and applicable International Standards".	This is important to ensure the products going to charitable homes do not have short expiry because they may keep them for long. This will also protect against dumping.	The expiry date requirement of 50% has been brought down from the normal 75% that applies for the other imported food products for general household use. This is also consistent with government policies on donated food products.
Labeling of designated products and pre-packaged complementary food product (17.1)	This requirement goes beyond what is indicated in the Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), which requires in its point 4.4 only 'The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food' to be declared. Switzerland considers that this text should be aligned with Codex requirements.	Kenya has considered this comment and decided to amend this requirement to have: **name, physical address** and **contacts** where contacts could be either be **website, email address or telephone)**	Most of the BMS designated products are imported hence this information is required for traceability.

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
Prohibition on Labeling (18)	Switzerland notes that this requirement goes beyond what is indicated in the Codex Standard for Infant Formula (CXS 72-1981), which already states that labels should not discourage breastfeeding and does not allow pictures of infants and woman nor any other picture or text which idealizes the use of infant formula. Therefore, the proposed provision should be redrafted accordingly in order to be aligned with the Codex Standard for Infant Formula (CXS 72-1981). Graphic representation for easy identification of the products and for illustrating methods of preparation should be permitted. For mothers who cannot or choose not to breastfeed, infant formula is the only suitable breast milk substitute recognized as appropriate by the WHO.	Kenya considered the statement in the standards and found them not sufficient enough to underscore the importance of breast feeding and therefore not effective or appropriate to achieve Kenya's objective.	Based on Article 9.2 of the *International Code of Marketing of Breast-milk Substitute*, the government has developed this statement to emphasize on the superiority of breast feeding. This message is consistently communicated during promotion of breast feeding and has contributed to improvement in the rated of exclusive breast feeding from 31% in 2008/9 to 62 % in 2014. Switzerland did not identify any use of images that are not used for promotional purposes and the use of which would not interfere with providing mandatory information on labels. The use of company logos, provided they do not idealize artificial breast-milk substitutes may be used.
Labeling of infant formula and follow-up formula (19.1)	Switzerland notes that the draft provisions established by this article are not aligned with the labelling requirements established by Codex Standard for Infant Formula (CXS 72-1981) and the Codex Standard for Follow-up formula (CXS 156-1987), including the draft version currently under discussion/revision by CCNFSDU.	**Kenya proposed to retain section 19.(1)**	Same as justification under 18 above and the overview above the table in that Codex language would not be effective or appropriate to achieve Kenya's objective.
Labelling of formula in powdered form (21(a) (b))	This labelling requirement could arouse fears in consumers and will go against the general principles of labelling standards in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) that says: "3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect."	**Maintain clause**	Evidence shows that contamination of food including powder formula can happen at any level from manufacturing to transportation to handling and consumption. This aims to educate the consumers as provided for in article 46 (1) (b) of the Constitution of Kenya.

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
	Switzerland suggest that this part should be replaced by a piece of information calling to follow carefully instructions of use, as otherwise improper preparation can make the baby ill. With regard to point b) on formula preparation, bottle preparation and instructions for use should refer to the Code of Hygienic practice developed and adopted by Codex (Code of Hygienic Practice for powdered formulae for infants and young children (CXG 66-2008)) which provides for a range of risk management options in preparation and handling of bottles including alternatives to the 70°C recommended by WHO in 2008, and to CXS 72-1981 and CXS 156-1987. In addition, such details, in principle, should fall under national standards rather than a national code.		This risk is widely recognized in the scientific literature, but it has not been brought to the attention of Kenyan consumers. The labelling instructions are for the benefit of consumers who do not have laboratory equipment or expertise to judge the microbiological equivalence of alternative risk management approaches not the equipment to sustain them.
PART V: INTERACTIONS BETWEEN MANUFACTURERS, DISTRIBUTORS AND HEALTH WORKERS			
Cross-promotion (32)	Industry should enable parents and caregivers to easily rely on the same family of products as the child grows. Expert use of text, images and colors should support the goal of providing distinctly labelled products, specifically to avoid the risk of consumer confusion between infant formula, Follow Up Formula, and Food for Special Medical Purposes ("FSMP"). Adding to strict restrictions may lead to consumer confusion in identifying safe, legitimate, nutritious products for young children. It could have the unintended consequence of depriving mothers and caregivers of the necessary information to make appropriate nutrition decisions for their young children. Switzerland considers that the adoption of such restrictions are incompatible with the established rules for international trade and could result in trade impediments. Such restrictions would be considered more trade restrictive than necessary to meet the legitimate objective of protecting human health and increase	**Maintain clause**	The intend of this section is to restrict promotion of designated products through products outside the scope of designated products such as complementary foods. The suitable age of for consumption of the product meets the objective of reducing consumer confusion. Linking one product to another using, symbols, colour-coding or other means serves a prohibited promotional objective.

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
	breastfeeding rates (contrary to Article 2.2 of the TBT Agreement).		

Responses to comments raised by KAM/WBAK/CMA

Article in the BMS with comment	KAM/WBAK/CMA submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification	Article in the BMS with comment
26.Warnings on nutrients:	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 3mm 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 diarrhoea, pneumonia, lung infections, and other infections. 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 up to 24 months and beyond."	Delete proposed provisions of regulation 26 on warning nutrients requiring warnings on bottled water, grain-based porridge, and other fluid and solid foods should not be used as breast milk substitutes	Kenya has considered this comments and taking into consideration and accepted to Delete the entire clause 26 from the regulations	The intent is covered in other clauses of the regulations.