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MOH/ADM/1/1/106

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REPUBLIC OF KENYA

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.

RE: THE BREASTMILK SUBSTITUTES (GENERAL) REGULATIONS, 2020

Reference is made to your letter under Ref No: MOH/ADM/i/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 products", "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 unless 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

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DEPARTMENT OF JUSTICE
CO-OPERATIVE BANK HOUSE, HAILLE SELLASIE AVENUEP.O. Box 56057-00200, Nairobi-Kenya TEL: Nairobi 2224029/ 2240337
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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

Committee on Technical Barriers to Trade

Original:

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** KENYA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Health **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above**: Ministry of Health, Afya House, Cathedral Road, P.O. Box:30016–00100, Nairobi, Kenya. Telephone: +254-20-2717077 Email: ps@health.go.ke; pshealthke@gmail.com; headnutrition.moh@gmail.com ,directorphke@gmail.com
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], OTHER:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Milk and milk products (ICS:67.100)
5.	**Title, number of pages and language(s) of the notified document:** The Breast Milk substitutes (Regulation and Control) (General) Regulations, 2020 (38 page(s), in English)
6.	**Description of content:** The Objects of this regulations is to guide persons who 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. This regulation also provides for production, preparation and packaging of designated products and pre-packaged complementary foods and shall be in accordance with the; (a) provisions of the Act, the Food, Drugs and Chemical Substances Act, the Public Health Act and the Kenya Standard KS EAS 39 and any other written Laws and; (b) the Kenya Standards for Infant formula (KSEAS 4), 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).
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety Quality requirements

8.	**Relevant documents:** N/A	
9.	**Proposed date of adoption:** **Proposed date of entry into force:**	March 2021 Upon declaration as mandatory by the relevant Cabinet Secretary
10.	**Final date for comments:** 18th February 2020	
11.	**Text available from: National enquiry point [X], or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:** Kenya Bureau of Standards (KEBS) P.O. Box: 54974-00200, Nairobi, Kenya Tel: +(254) 020 605 490 +(254) 020 605 506 +(254) 020 694 8258 Fax: +(254) 020 609 660 +(254) 020 609 665 E-mail: info@kebs.org Website: http://www.kebs.org	

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.

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Legal Notice No.....

THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) ACT

(No. 34 of 2012)

Arrangement of clauses

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

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:

(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.

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.

THE BREASTMILK (GENERAL) REGULATIONS, 2020

Feedback of concurrence to the BMS (General) Regulations, 2020

Item	Response	Date/Duration	Means of Verification
No. 1, 2, 3	The National Committee on Infant and Young Child Feeding (NCIYCF), MOH-Division of Nutrition and Dietetics and the technical team is in concurrence.	25th November 2020	• Minutes
No. 4 a) *Statement of proof and demonstration that sufficient public participation was done*	• As required by the Kenya constitution, 2010, the draft BMS Regulations were subjected to public participation vide Public Notice published in the daily Nation of 13th August 2019 and www.mygov.go.ke for the open forum scheduled for 27th August 2019 at Afya Annex, room 406. • The draft regulations were posted online on www.health.go.ke and www.nutritionhealth.or.ke • External stakeholders consultative forum on the draft BMS (Regulation and Control Act, 2012) to discuss the draft Regulations • Issues raised by Kenya Association of Manufactures (KAM), Kenya Nutritionists and Dieticians Institute (KNDI) and Kenya Private Sector Alliance (KEPSA) through memoranda were discussed during a consultative meeting		• Public notice • Online platforms by date • KAM Memorandum with responses
No. 4 b) *A brief statement of all the consultations undertaken before the regulations were made*	• According to BMS Act Article **(4) The Cabinet Secretary shall, by regulations, prescribe the manner in which the activities specified in clause (3) shall be conducted,** MOH-DND in collaboration with NCIYCF members with technical support from WHO and UNICEF engaged in drafting of the BMS Regulations MOH with active particition of the NCIYCF held various consultative meetings at different levels including; 1) Internal stakeholders consultative forum to sensitize and build	28th June 2019	• Agenda • Participants lists

	consensus on the provisions of the draft Regulations 2)External stakeholders consultative forum on the draft BMS (Regulation and Control Act, 2012) to discuss the draft Regulations 3) Follow up meeting with Kenya association of manufacturers(KAM) on submitted memorandum 3) Workshop to incorporate feedback from stakeholders 4) Meeting for validation of the final draft of the BMS Regulations	 27th August 2019 13th September 2019 25th – 29th November 2019 4th February 2020	• Public Notice • Invitation letter • Reports of consultative meetings
4. *c) A brief statement of the way the consultation was carried out*	In line with part b), all activities were done in collaboration with the different stakeholders through correspondence, consultations, meetings and workshops		
4. d) *Outline the results of the consultation*	The following are the results of the consultations; 1. Matrix of issues raised with corresponding responses 2. Draft BMS Regulations with issues amicably incorporated		
4. e) *A brief explanation of any changes made to the Legislation as a result of the consultation*	Following the various consultative forums indicated above, there were several changes agreed upon and adopted in the draft BMS Regulations		
5.	All necessary documents are available and ready for submission		

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

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.

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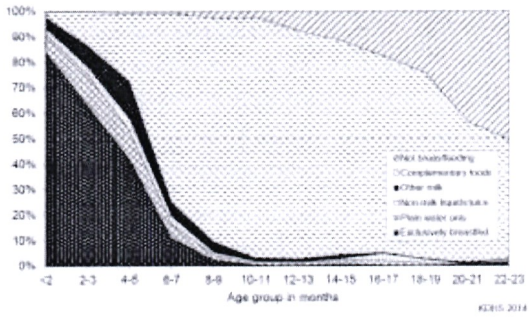
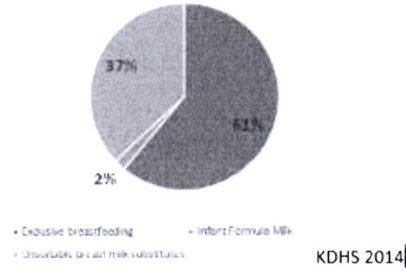
KHF Position on Breast Milk Substitute (Regulation and Control Act 2012) Regulations 2019

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.

www.mygov.go.ke

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 (NSCOP) 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 email through the link on the website. Alternatively you can write to: Head, DFH-DN&D, Ministry of Health, **headnutrition.moh@gmail.c** **P.O. Box 30016-00100,** Nairobi by **20th August, 2019.**

Legal Notice No.....

The Breast Milk Substitutes (General) Regulations, 2020.

Arrangement of clauses

Clause

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

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.

(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.

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 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.

No. 23 of 2013.

(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

No. 12

MINISTRY OF HEALTH

REPORT OF MEETING HELD TO DISCUSS KENYA ASSOCIATION OF MANUFACTURERS MEMORANDUM ON THE DRAFT BREASTMILK SUBSTITUTE (GENERAL) REGULATIONS

DATE: 13th September 2019
VENUE: AFYA ANNEX, ROOM 306

Annexures

1. Invitation letter for the internal stakeholders' consultative meeting.
2. Report of the internal stakeholders' consultative meeting held on 28th June 2019.
3. Attendance list of Internal Stakeholders' consultative meeting held on 28th June 2019.
4. Public Notice for External Stakeholders' consultative forum published in MyGov on 13th August 2019.
5. Invitation Letter for External Stakeholders' consultative forum.
6. Zero Draft Breast Milk Substitute Act circulated for public participation.
7. Written submission by the Kenya Association of Manufacturers (KAM).
8. Written submission by the Kenya Healthcare Federation.
9. Written submission by the Kenya Nutritionists and Dieticians Institute.
10. Report of the External Stakeholder consultative forum held on 27th August 2019.
11. Attendance list of External Stakeholder consultative forum held on 27th August 2019.
12. Report of the consultative meeting with KAM held on 13th September 2019.
13. Attendance list of the consultative meeting with KAM held on 13th September 2019.
14. Letter Ref No. MOH/ADM/1/1/2 dated 10th June 2020 from the Principal Secretary, Ministry of Health to the Solicitor General, seeking legal guidance on the draft BMS regulation.
15. Attorney General Letter Ref. 119/2/42 dated 20th November 2020 providing feedback to the Principal Secretary, Ministry of Health, on the proposed BMS Regulations, 2020.
16. World Trade Organization Notification.

Preamble
Following the BMS Act (General) Regulations' stakeholders' forum in fulfilment of the constitutional requirement to subject all legislation to public participation, and where KAM representatives requested an opportunity to present their submissions to the NCIYCF, this meeting was convened.

The chairperson called the meeting to order at 9.10 am followed by prayer and self-introduction of all members present. In her opening remarks, the chairperson noted that:

- marketing of replacement feeds should be without taking away the benefits of breast feeding from the population.
- breastfeeding greatly benefits a child as it contains growth factors, supports development of stimulation, introduction of healthy bacteria and on the whole the development of bonds.
- It was appreciated that BMS manufacturers play a role infant nutrition as there may be instances where replacement milk may be needed.
- the goal of all persons represented in the room is one – promotion of survival of children of this country.

PRESENTATIONS

KAM position:

Data from Kenya Demographic Health Survey on breastfeeding shows room for improvement.

KAM recognizes that breast milk is primary and critical to infant health and nutrition and emphasizes on compliance to MoH guidance for supporting breastfeeding efforts in Kenya.

The Food and Beverage sector in KAM emphasizes self-regulation where the industry monitors the International code of marketing and breastfeeding standards globally. The industry has greatly complied to various legislations that protect, promote and support breastfeeding such as establishment of breast feeding room, provision of flexible periods for nursing employees and extension of maternity leave, through self-regulation.

Further, it is noted that unsuitable breastfeeding substitutes has 30% of the market share. Examples cow's milk packaged deceitfully and is in shelves in supermarkets leading to the belief that it is a suitable breast milk substitute. KAM recommends that a notice of unsuitability be included on the packaging.

There is a huge opportunity for multi-stakeholder partnership with the ministry to address unsuitable alternatives in market. It is important the partnership is done in a conducive environment and that is ethically sound.

KAM Memorandum on the draft BMS Act (General) Regulations, 2019:

In opening remarks, KAM notes that the industry is focused on the gap that consists the women who cannot breastfeed. Further, the industry recognises the standards and

regulations that exist in Kenya. This effort is reinforced by agencies and reporting standards that are enforced by the ministry.

The presenter underscored the importance of abiding to regionally and globally harmonized processes. The industry abides to the regionally and globally harmonized standards and therefore any proposed changes e.g. labelling should follow laid down notification procedures.

Deliberations and way forward

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

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

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

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
		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. c. The commission's report of 2019[3], Para 84 (i) adopted the recommendation of CCFL and that discussion was referred back to CCNFSDU for further discussion/decision.	trade marks within WTO, TBT and TRIP. • MoH/KLRC Legal person will advise, while considering the independent mandates for Codex and national Governments. • The World Trade Organization (WTO) agreement allows government to establish regulations to protect the health, safety of human, animal and environment provided they are notified. • It is also important to note there is no guidance/requirement that only the definitions in standards should be adopted in the regulations. In most cases definitions used in standards are limited to the interpretation of that particular standard and may not be applicable in other context. • **See Issue 17**
2.Regulation 8 (Stoking and expiry) ***No person shall stock, distribute, sell or exhibit any food for***	This has potential to different interpretation Already, industry in self-regulation recalls expired products from stores to	It is true the standards address itself to expiry consistent to Cap 254	• Self-regulation by industry leaves a lot of room for improvement • The spirit of the 30 days was to have the products pulled out of shelve/not offered to sale 30 days before date of expiry in the spirit of

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

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
infant and young child which is expired. or whose declared date of expiry reads thirty(30) days before the declared date of expiry.	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"*		protecting children from consuming expired products. A discussion on how to actualise this spirit will be explored. • It will not be harmful to have the statement as proposed by the industry.
3. 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	The general provision as provided in regulation 16 (i) is consistent to Kenya Standards, Codex Standard for labelling and Cap 254 of the Laws of Kenya as it provides for the bare minimum of a label. The proposed text by industry is too general and would potentially introduce conflicts given that food labelling is an area which is emerging with new areas requiring standardization. Regulations should make specific normative reference to an existing standard and not make general requirement. Further, Kenya	• A decision should be made on the font sizes given that BMS Act indicates that the CS will prescribe the font size. If the regulation for sizes is made, the standards will be revised to include the font size as will be required by the regulation. • Currently the Kenya Standards are silent on the font sizes but that does not take away the mandate given in law to the CS to prescribe font size. • This an area where engagement with the industry may be done to ensure practicability. • KAM to follow instructions and re-share the three labels as guided in regulation 16[1] as was agreed

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
	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.	only implements Kenya Standards and hence reference to East Africa Standards and Codex standards is erroneous.	during BMS Regulations stakeholders meeting. This should be done soonest possible • Maintain the current statement as general as it is drafted in original text.
4. Regulation 17 (Prohibition on labelling)	KAM proposes revision of this regulations subsection 17 [1], [2] and [3] *(see appended KAM proposals)*	Kenya Standard for infant formula (KS EAS 4, clause 10.11.4) has similar wording to that of original draft regulation. According to BMS Act all products for the ages up to 24 months are considered BMS. This statement therefore applies to all that category. The law and regulation does not seek to regulate products beyond its scope.	• Maintain the text in the draft regulations.
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	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.	Research has revealed that breastfeeding protects infants against diarrhoea and other illness	• Maintain the text in the draft regulations.

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
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".**	**"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"*		
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 Kenya Standards allows for both the use of either English or Kiswahili. In Tanzania, Kiswahili is a mandatory requirement.	• Recommendation accepted; We support the use of both languages. • Same as issue 5
7. Regulation 20	KAM recommends reference and	In its effort to ensure infants are	The Committee will further discuss and

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
(Constitution temperatures & Handling left over infant formula)	harmonization to WHO/FAO recommendations giving options that allow for use of other viable hygienic preparation KAM proposed inclusion of recommendation to boil water to 100^{0}C then cool it to ambient temperatures as reconstituting with hot water (70^{0}C) interferes with the formulation and introduces risk of scalding.	protected from E. Sakazakii, KS CAC/RCP 66:2008[4] section IX Para 5 requires appropriate information be provided to caregivers to avoid this contamination. CAC/RCP 66: 2008 and FAO/WHO. 2007[5],Safe preparation, storage and handling of powdered infant formula: guidelines both emphasize that preparation of formula should not be made by temperatures below 70^{0}C in home care. • KS EAS 4 does not prescribe temperatures of preparation but is currently scheduled for revision. However, it normatively refers to CAC RCP 66. • In many households in Kenya, water safety assurance may be a challenge and therefore the need for preparing formula with water at 70^{0}C to minimize chances of microbial contamination. • At 70^{0}C, most pathogenic micro-organisms are destroyed making the product relatively safe	provide guidance on the water temperature.

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

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

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
		• This temperature controls for possible contamination of the product or contamination due to handling during preparation	
8. Regulation 21 (Languages in bottles) 9. Regulation 22 (2) (Labelling for teats) 10. Regulation 23[1] (Labelling for teats and pacifiers)	KAM advices that most traders of these products are importers and emphasized the need to engage this group.	There is no Kenya Standard for pacifiers	Maintain as in the draft regulations. The Kenya Standard for teats was developed before BMS Act was enacted, and hence the need to provide guidance in the regulations.
11. Regulation 23 (minimum information on containers)	Specialised products operate in a highly regulated industry because the consumer is highly vulnerable. This is achieved through; a. Legibility and information. (Presentation) b. Statutory instruments Act as a standard that all regulators must refer to in its development. c. Rights and liability for violations	There is no applicable Kenya Standard	Maintain as in the draft regulations.
12. Regulation 24 (Ethical interaction with health	The general feeling of industry is that the issue of interactions in the	There is no applicable Kenya Standard Through this Regulation, the MoH	Maintain or revise the current text in the draft regulations considering KAM

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
workers)	Regulations has been over-belaboured KAM noted that regulating venue does not give rise to ethical interactions The industry already employing self-regulation and so sees no need for creating hurdles through regulations The proposed regulations do not include traders/importers who are major players KAM proposes that they are required t report annually for ease of trade noting that reports are more collaborative and empowering KAM noted that health care providers (HCP) are already regulated and therefore there is no need to have regulation targeting HCPs. KAM proposed adoption of the Pharma Industry where marketers' names are submitted upfront for approval In the event that Government upholds this Regulations which prescribe clearance by the committee, there is concerned about timelines for	seeks to control for 'conflict of interest' to protect infants MoH proposes that companies present an annual schedule of planned interaction sessions for approval	submissions

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
	approvals/ rejection		
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	There is no applicable Kenya Standard MoH proposes that companies present an annual schedule of planned interaction/awareness creation sessions for approval	Maintain or revise the current text in the draft regulations considering KAM submissions
14. Regulation 26 Professional evaluation	KAM underscored the need to allow for self-regulation which supports the heavy liability that falls on industry in the case of legal matters rising. KAM indicated that regulation on professional evaluation is covered for in R 27 which is on research Following discussions, KAM requested that this be changed to read 'clinical validation' which MoH was going discuss further	There is no applicable Kenya Standard Professional evaluation is different from research and so needs to be regulated differently MoH proposes that companies present an annual schedule of planned professional evaluation activities to the committee for approval	Maintain or revise the current text in the draft regulations considering KAM submissions

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
15. Regulation 28 (Formal record)	According to KAM. the prohibitive aspect is the indication that the committee will approve which counters administrative law which dictates that the standards the committee uses to make the decision will be stipulated in regulation.	There is no applicable Kenya Standard MoH noted that research is already regulated by NACOSTI and that this regulations are supportive of the same for the bigger good and for checking on 'conflict of interest'	Maintain or revise the current text in the draft regulations considering KAM submissions
16. Regulation 29 (Restriction on interaction)	Manufacturers would like an opportunity to self-regulate as opposed to the strict prohibition approach to support their participation in informing health workers on products while enforcing the ethics.	There is no applicable Kenya Standard	Maintain or revise the current text in the draft regulations considering KAM submissions
17. Regulation on 'cross promotion'	Discussed in issue 1 above.	Discussed under issue 1.	However, the spirit of this regulation is consistent to the principle of labelling as indicated in clause 3.2 of KS EAS 38 (*Pre-packaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.*)

Clause/Regulations Proposal	KAM proposals/discussions	Position from standards/MOH (NCIYCF)	Advice/Action/Way forward
18. Regulation 32 (Advertisement)	KAM proposes deletion of the word 'indirectly' as it proposes liability on uncertain actions Also proposed replacing specific examples (displays, signs, bill-boards, notices) with 'outdoor displays'	There is no applicable Kenya Standard MoH reiterated that the term 'indirectly' is used in the mother Act and is interpreted thereof. The word 'indirectly' is also used in codex and therefore its use in the regulations is consistent with other related documents	Maintain the current text in the draft regulations.
19. Regulation 38 (Access to BMS)	KAM proposes that there is inclusion of the word 'in writing'	There is no applicable Kenya Standard MoH in response noted that the proposed regulation is consistent with other existing laws (CAP 254, 242)	Maintain the current text in the draft regulations.
20. Adherence to statutory instruments Act	KAM requested that there is consistency with the statutory instruments Act, 2013	There is no applicable Kenya Standard	MOH legal department will advise the committee for decision making

Closing remarks

In making final remarks, the representative from KAM promised to re-share the sample label (current, recommended, proposed) by 18th September 2019.

MOH was requested to consider holding additional public participation fora in other regions. However, members were informed that there are no plans for other public engagement since public participation was held in August 2019 meeting whose notification was published in the local newspaper, as required by law.

There was also a request to invite industry to a validation forum as required by constitution in demonstrating willingness to be open and to engage.

Finally, KAM appreciated MOH for calling of public participation and reiterated that the food industry is ready to cooperate and collaborate for the bigger good of the children of this country.

The chairperson of the committee in closing appreciated everyone for attending the meeting and for the inputs that came through. She further noted that the committee is committed to acting in the best interest of the children of Kenya and will continue to represent Government well in this space. She hoped that the process of publishing the BMS (General) Regulations is successfully concluded in the near future to support enforcement of the law.

The meeting finally adjourned at 1310 hours

Annexes:

1. List of participants *(attached)*
2. Draft BMS Act (General) Regulations, 2019
3. KAM Memorandum on BMS (General) Regulations

No. 14

MINISTRY OF HEALTH

OFFICE OF THE PRINCIPAL SECRETARY

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When replying please quote:

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CATHEDRAL ROAD
P.O. Box 30016 – 00100,
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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

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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15.	AUCHI RONALD	MOH - LEGAL	0795701275	35758218	ronnieauch20@gmail.com	

Verified by:

MOH OFFICER: Caroline V. Kathuri 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

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