REPUBLIC OF KENYA

THE NATIONAL ASSEMBLY

TWELFTH PARLIAMENT- FIFTH SESSION (2021)

COMMITTEE ON DELEGATED LEGISLATION

REPORT ON THE CONSIDERATION OF THE BREAST MILK SUBSTITUTES (REGULATIONS AND CONTROLS) (GENERAL) REGULATIONS, 2021

(Legal Notice No. 184 of 2021)

THE NATIONAL ASSEMBLY
PAPERS LAID
DATE: 10 NOV 2021
DAY. WEDNES

TABLED BY:	Member, Committee on Delegated Legislation
CLERK-AT THE-TABLE:	Finlay Muniu

NOVEMBER, 2021

The Directorate of Audit, Appropriations & other Select Committees
The National Assembly,
Parliament Buildings,
NAIROBI.

Approved for tabling
10/11/2021
DS

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ABBREVIATIONS

KAM	Kenya Association of Manufactures
BMS	Breast Milk Substitutes
LN	Legal Notice
MOH	Ministry of Health
RMA	Regulatory Making Authority
SO	Standing Order
WHO	World Health Organisation
WTO	World Trade Organisation

CHAIRPERSON'S FOREWORD

The Cabinet Secretary for Health, in exercise of the powers conferred by section 28 of the Breast Milk Substitutes (Regulation and Control) Act, (*No. 34 of 2012*), made the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021. The Regulations were made *vide LN No. 184 of 2021,* published in the Gazette on the 27th August 2021.

The purposes and objects of the Regulations is to give full effect to the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021, more particularly, the Regulations seek to:-

(i) reduce preventable infant and young child illness and deaths through protection, promotion and support of optimal breastfeeding and complementary feeding and proper use of breast milk substitutes ,where necessary;
(ii) promote and protect the breast interests of an infant and young child and
(iii) guide the ethical interactions of manufacturers with health workers, the manner in which donations are used or received, demonstration on use, development of informational and educational communication materials and labeling of BMS and other designed products.

Pursuant to section 16 of the Statutory Instruments Act, the Committee ,in response to a request by the regulation making Authority, held a prepublication scrutiny meeting with Ministry of Health on the 5th of February, 2020 at Baraza Conference Room at the Whitesands Resort Mombasa, in which the following issues emerged -

(a) The committee was informed that, public participation was undertaken in accordance with the Constitution through various stakeholders' meetings including consultations with Kenya Association of Manufacturers, Kenya Health Federation, Kenya Nutritionist and Dieticians Institute.
(b) It was noted, that regulation 26 requires that the labelling of breast milk substitutes products to specifically lay out the exact words in English and Kiswahili language in bold and in a prominent position on the container.
(c) The Committee was informed that some of the already existing samples are from foreign countries and are written in foreign languages e.g., Saudi Arabian products being written in Arabic.
(d) The Committee brought to the attention of the Cabinet Administrative Secretary that section 28 of the BMS Act empowers the National Assembly to cause amendments to be made to the regulations once the Regulations are laid before the House.

The committee held a further meeting with Kenya Association of Manufacturers (KAM) on the 23rd of March, 2021 who raised concerns against the regulations being published in the manner presented , particularly citing the following grounds -

1) That there was lack of public consultation on the provisions under regulation 26. Further that the Act only focuses on milk products and does not provide for the regulation of items such as bottled water, cereals and porridge;
2) That an impact assessment has not been carried out which is in contravention with the Statutory Instruments Act that requires conducting of regulatory impact assessment due to the nature of the regulations.

3) That if the regulations are published in their current nature, it would greatly affect investments, economic, employment contribution to the country.
4) That product labelling provisions are extremely restrictive and will negatively affect the industry.
5) That the definition of the term "cross-petition" used in the regulations ought to be reviewed. And amended.

Consequently, KAM proposed to the Ministry of Health certain amendments to the Regulations of which recommendations were suggested and forwarded to the Committee as contained in the memorandum forwarded to the National Assembly and partly adopted by the Committee and incorporated in this Report.

The Committee scrutinised the Legal Notice No.184 of 2021 in light of its conformity to the Constitution, the Breast Milk Substitutes (Regulation and Control) Act, (*No. 34 of 2012),* the Interpretation and General Provisions Act (*Cap 2*) and the Statutory Instruments Act (*No. 23 of 2013*) which regulate the making, scrutiny and publication of the instrument and made various observations -

Statutory Timelines – The Regulations were published in the gazette on the 27th August 2021, *vide* Legal Notice No 184 of 2021, submitted to the Clerk of National Assembly on 5th October, 2021 and laid in the House on 6th October, 2021 being within the requisite statutory timelines under section 11(1) of the Statutory Instruments Act.

Public participation – According to the Explanatory Memorandum submitted to the Committee and the presentations made by the Ministry of Health during the meetings, the Ministry demonstrated that consultations were undertaken with key stakeholders while preparing the Regulations and their input considered before finalization of these Regulations. Some of the key stakeholders indicated to have been consulted are the Ministry of Health, Members of the National Committee of Infant and Young Child Feeding (NCIYCF), UNICEF, WHO, legal experts (local and international) and experts on matters of maternal, infant and young child feeding, trade and food standards. The Ministry has attached an Explanatory memorandum with a schedule of stakeholders they met during their public participation exercises.

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

Regulatory Impact Statement - Following the resolution and directions of the Committee during the prepublication scrutiny meeting, and pursuant to section 6 of the Statutory Instruments Act, a Regulatory Impact Assessment was conducted and a Regulatory Impact Statement presented alongside the Regulations, as they are likely to impose significant costs on the community or a part of the community.

Having examined the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021 published vide (*Legal Notice No, 184 of 2021* in line with the Constitution, the Interpretations and General Provisions Act (*Cap 2*), the Statutory Instruments Act, 2013

(*No. 23 of 2013*), the Breast Milk Substitutes (Regulation and Control) Act, (*No. 34 of 2012),* pursuant to which they are made, the Committee resolved that the **House approves the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021,** published *vide* (*Legal Notice No, 184 of 2021) w*ith the exception of the provisions set out in the schedule hereunder, which the Committee proposes to be amended pursuant to Section 28 (5) of the Breast Milk Substitutes (Regulations and Controls) Act, 2012.

I wish to most sincerely thank the Speaker and the Office of the Clerk of the National Assembly for the invaluable support accorded to the Committee in the discharge of its mandate.

On behalf of the Members of the Select Committee on Delegated Legislation and pursuant to Standing Order 210 (4) (b) ,it is my pleasure and duty to present to the House, the Committee's **Report on the Consideration of the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021 (LN No 184 *of 2021.*)**

HON. WILLIAM KASSAIT KAMKET, M.P.

1. PREFACE

1.1 Establishment and Mandate of the Committee

1. The Select Committee on Delegated Legislation is established pursuant to ***Standing Order No. 210*** and is mandated to scrutinize statutory instruments submitted to the National Assembly for consideration. The Committee is expected to consider in respect of any statutory instrument, conformity with the Constitution, the Act pursuant to which it is made or other relevant written laws and the Standing Orders.
2. The Committee, during scrutiny is guided by the principles of good governance, rule of law and in particular considers whether the statutory instrument -

    a) is in accordance with the provisions of the Constitution, the Act pursuant to which it is made or other relevant written laws;
    b) infringes on fundamental rights and freedoms of the public;
    c) contains a matter which in the option of the Committee should more properly be dealt with in an Act of the Parliament;
    d) contains imposition of taxation;
    e) directly or indirectly bars the jurisdiction of the court;
    f) gives retrospective effect to any of the provision in respect to which the Constitution does not expressly give any such power;
    g) it involves expenditure from the consolidated fund or other public revenues;
    h) is defective in its drafting or for any reason form or part of the statutory instrument calls for any elucidation;
    i) appears to make some unusual or unexpected use of the power conferred by the Constitution or the Act pursuant to which it is made;
    j) appears to have had unjustifiable delay in its publication or laying before Parliament;
    k) makes rights, liberties or obligations unduly dependent upon non-renewable decisions;
    l) makes rights, liberties or obligations unduly dependent insufficiently defined administrative powers;
    m) inappropriately delegates legislative powers;
    n) imposes a fine, imprisonment or other penalty without express authority having been provided for in the enabling legislation;
    o) appears for any reason to infringe on the rule of law;
    p) inadequately subjects the exercise of legislative power to Parliamentary scrutiny; and
    q) accords to any other reason that the Committee considers fit to examine.

1.2 Committee Membership

3. The Committee membership comprises –

The Hon. William Kassait Kamket, M.P. (Chairperson)
Tiaty Constituency
KANU

The Hon. Muriuki Njagagua, M.P. (Vice Chairperson)
Mbeere North Constituency
Jubilee Party

COMMITTEE MEMBERS

The Hon. Waihenya Ndirangu, M.P.
Roysambu Constituency
Jubilee Party

The Hon. Ronald Tonui, M.P.
Bomet Central Constituency
Jubilee Party

The Hon. William Cheptumo, M.P.
Baringo North Constituency
Jubilee Party

The Hon. William Kamoti, M.P.
Rabai Constituency
Orange Democratic Movement

The Hon. Cecily Mbarire, MGH, M.P.
Nominated
Jubilee Party

The Hon. Martha Wangari, M.P.
Gilgil Constituency
Jubilee Party

The Hon. Alice Wahome, M.P.
Kandara Constituency
Jubilee Party

The Hon. Gideon Mulyungi, M.P.
Mwingi Constituency
Wiper Democratic Movement – Kenya

The Hon. Robert Mbui, M.P.
Kathiani Constituency
Wiper Democratic Movement - Kenya

The Hon. (Dr.) Wilberforce Oundo, M.P.
Funyula Constituency
Orange Democratic Movement

The Hon. Daniel Maanzo, M.P.
Makueni Constituency
Wiper Democratic Movement -Kenya

The Hon. George G. Murugara, M.P.
Tharaka Constituency
Democratic Party

The Hon. Timothy Wanyonyi, M.P.
Westlands Constituency
Orange Democratic Movement

The Hon. Jennifer Shamalla, M.P.
Nominated
Jubilee Party

The Hon. Munene Wambugu, M.P.
Kirinyaga Central Constituency
Jubilee Party

The Hon. Patrick Mariru, M.P.
Laikipia West Constituency
Jubilee Party

The Hon. Sammy Seroney, M.P.
Nominated

The Hon. Robert Gichimu, M.P.
Gichugu Constituency
Jubilee Party

Wiper Democratic Movement – Kenya
The Hon. Tindi Mwale, M.P.
Butere Constituency
Amani National Congress

The Hon. Edith Nyenze, M.P.
Kitui West Constituency
Wiper Democratic Movement – Kenya

The Hon. Abdi Koropu Tepo, M.P.
Isiolo South Constituency
Kenya Patriots Party

1.3 Committee Secretariat

4. The secretariat facilitating the Committee comprises -

Mr. Mohamed Jimale
Clerk Assistant II (Team Leader)

Ms. Ruth Mwihaki Gakuya
Clerk Assistant II

Mr. Dima Dima
Principal Legal Counsel

Mr. Josphat Motonu
Fiscal Analyst I

Ms. Fiona Musili
Research Assitant II

Ms. Noelle Chelangat
Media Relations Officer II

Mr. Anthony Wamae
Serjeant at Arms

Mr. Charles Ayari
Superitendent of Electronics

Mr. Muriithi Theuri
Parliamentary Intern

2. CONSIDERATION OF THE BREAST MILK SUBSTITUTES (REGULATIONS AND CONTROLS) (GENERAL) REGULATIONS, 2021 (LN. NO. 184 OF 2021)

2.1 Introduction

5. The Cabinet Secretary in the Ministry of Health, in exercise of the powers conferred by section 28 of the Breast Milk Substitutes (Regulation and Control) Act, (*No. 34 of 2012*), made the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021 *vide LN No. 184 of 2021* of 27th August, 2021.

2.2 Purposes and objects of the Regulations

6. The purposes and objects of the Regulations are to give full effect to the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021. Particularly, the Regulations seek to:-

1. Reduce preventable infant and young child illness and deaths through protection, promotion and support of optimal breastfeeding and complementary feeding and proper use of breast milk substitutes where necessary.
2. Promote and protect the breast interests of an infant and young child in the following ways -
   (i) Initiation if breastfeeding of the infant done within an hour of birth and promotion, protection and support of an inclusive breastfeeding for the first six months of life.
   (ii) Timely introduction of appropriate adequate and safe complementary food with continued breastfeeding for a period of 24 hours months or beyond.
   (iii) Where necessary bread milk substitute and prepackaged complementary food shall be safe for the consumption by an infant or young child; and
   (iv) Adequate and accurate information on breastfeeding and infant and young child feeding shall be available to the public.
3. Guide the ethical interactions of manufacturers with health workers, the manner in which donations are used or received, demonstration on use, development of informational and educational communication materials and labeling of BMS and other designed products.

2.3 Conferment with Regulation Making Authority

7. The Committee, pursuant to section 16 of the Statutory Instruments Act, and in response to a request by the Ministry of Health, held a prepublication scrutiny meeting on the 5th February, 2020 in Mombasa County in which the following concerns were raised –

a) **Public participation** - the committee was informed that public participation was undertaken in accordance with the Articles 10 and 118 of the Constitution and sections 5, 5A and the schedule to the Statutory Instruments Act, through various stakeholders' meetings including consultations with Kenya Association of Manufacturers, Kenya Health Federation, Kenya Nutritionist and Dieticians Institute.

b) **Support of mothers in the process - t**he Committee was informed that the Ministry had introduced certain programmes to ensure that breastfeeding mothers are taken care of through Counselling where mothers are given sufficient information on Breast Milk Nutrition.

c) **Quality assurance and standards** - the Committee was assured that the Ministry of Health has been able to come up with the required standards, which are considered safe for use in the Kenyan market.

d) **Delay in preparation of the Regulations** - the Committee noted that the Breast Milk Substitutes (Regulation and Control) Act was enacted in 2012 yet the proposed regulations were still in draft form. The Ministry responded that development of the regulations had been an ongoing process since the enactment of the Act and involved engaging with the private sector, some of whom were opposed to some provisions of the regulations.

e) **Ethics revolving around the regulations** - the Committee raised concerns on the ethics behind the selling of the breast milk substitutes by the various players in the industry. In response, the Ministry reiterated that Part V of the Regulations spells out the manner of interaction between manufacturers, distributors, and health workers and that regulation 31 specifically limits this interaction by outlining what is prohibited during the interactions.

f) **Regulatory Impact Statement (RIS)** - the Committee noted that issues concerning breastmilk substitutes affect the better part of the community especially mothers and children in all families hence the Ministry is required to conduct a regulatory impact assessment and attach a Regulatory Impact Statement as required under section 6 of the Statutory Instruments Act since it is apparent that the Regulations are likely to impose significant costs on the community or a part of the community.

g) **Labelling of BMS products** - on the labelling of the breast milk substitutes products, it was noted that regulation 26 specifically lays out the exact words in English and Kiswahili language in bold and in a prominent position on the container.

h) The Committee was informed that some of the already existing samples are from foreign countries and are written in foreign languages e.g., Saudi Arabian products being written in Arabic.

i) The Committee brought to the attention of the CAS that section 28 of the BMS Act empowers the National Assembly to cause the regulations to be amended where it was deemed proper so to do.

8. The Committee, pursuant to section 16 of the Statutory Instruments Act, held a further meeting with representatives from the Kenya Association of Manufacturers (KAM) on 23rd March, 2021 in which the following issues were raised –

(i) **Lack of public consultation on new provisions under Regulation 26:** KAM raised concerns on the omission to include the provisions to regulate bottled water, cereals and porridge under the regulations. They further reiterated that the newly introduced provisions under Regulation 26 were not previously included in the draft Breast milk Substitutes Control Regulations 2020. The Committee noted that as indicated by the ministry, the Act does not provide for regulation of such items and that the focus is on milk products.

(ii) **Non-compliance with the Statutory Instruments Act, 2013:** The Act mandates the conducting of a regulatory impact assessment on the Regulations due to its economic impact to businesses. According to KAM, the impact assessment had not been carried out despite escalation to the World Trade Organization for approval.

(iii) **Economic impact:** KAM further contended that the Regulations would greatly affect investments, economic contribution and employment contribution to the country.

(iv) The Committee was informed that product-labelling provisions are extremely restrictive and will negatively affect the Industry despite being an approved and lawful product in the Country.

(v) KAM in their presentation to the Committee was opposed to inclusion of cross-promotion terminology in product scope.

9. The Committee further held a joint meeting with the Regulation making Authorities and the Kenya Association of Manufacturers (KAM) in the Mini Chamber, County Hall, Parliament Buildings, where the following issues were raised.

2.4 Submission from the Ministry of Health

10. The Chief Administrative Secretary, in the Ministry of Health Dr. Rashid A. Aman, informed the Committee that -

a) The Ministry had held extensive consultations with all relevant stakeholders, including the Kenya Association of Manufacturers (KAM), in accordance with the Constitution and the Statutory Instruments Act, 2013. That KAM in particular, had been given numerous forums to address their concerns on the Regulations and this included communication from KAM either directly to the Cabinet Secretary, Ministry of Health or through the Cabinet Secretary, Ministry of Industrialization, Trade and Enterprise Development.

b) The Ministry has adopted a number of issues raised by KAM including deletion of Regulation 26 (i.e. requirement to have similar labelling in bottled water) of the original draft and review of regulation on temperature guidelines.

c) However, there are some recommendations, which were not adopted as proposed by KAM and adequate justification provided. KAM never responded on the Justification provided by the Ministry. Further, the Memorandum submitted by KAM is the same one previously submitted.

d) According to the Ministry, the statement by KAM that the Regulations will drive them out of the market was unsubstantiated. They indicated to the Committee that the purpose of the Regulations is not to ban the sale or use of Breast Milk Substitutes but to regulate the same and that granted that the Breast Milk Substitutes Act has been in force since 2012, the statement that the Regulations will drive them out of the market was misleading.

e) During the meeting with KAM, the Committee observed that some of the representatives that accompanied KAM were representing foreign multinationals.

f) The Ministry reiterated that they had notified the World Trade Organization Technical Barriers to Trade Committee (WTOTBT) in Geneva on the draft Regulations as required by the TBT Agreement and received comments from various member states including the USA, Switzerland and the EU. The Ministry stated that KAM, though un-procedural, also submitted their memorandum to the WTO TBT Committee. In the National TBT Committee meeting, KAM, once again, submitted their memorandum and the Ministry responded adequately.

g) According to the Ministry issues of safety and quality were not subject matter to the regulations as there were already existing Regulations in the health sector addressing issues of safety and quality.

h) In responding In response to KAM contentions that the term of "public venue" be defined , the ministry was of the opinion that the definition of "public place" has been provided in the Public Order Act,

i) While KAM raised the concerns on labeling of the products according to the Ministry, the provisions on labelling are in line with how all other products are dealt with.

2.5 Submission from Kenya Association of Manufacturers

11. KAM highlighted the following issues in the regulations and informed committee that no consensus was reached in addressing their concerns during the stakeholder engagements on the regulations -

1) **Transition Period**

12. The regulations does not stipulate a transition period hence, once they are approved and passed by the National Assembly as a law they become effective immediately and all products in the market will be rendered non-compliant. Recalling the products off the shelf will lead to widespread stock outs and caregivers will not be able to access products for their babies. Manufacturers will also incur losses due write offs.

Proposed amendment – a transition period of 24 months be provided to cater for products on shelf, and on transit and depletion of packaging materials.

2) **Interactions with Health Care Professionals**

13. To KAM, the requirements in regulation 27 (2) (a) (b) are ambiguous as one can only create awareness of a product that they would normally endorse, and that there may exist a personal relation between a medical delegate creating awareness of a designated product to the targeted healthcare professional and matters that touch an a relationship should not be a deterrent for such interaction.

Proposed amendment -

i. Delete regulation 27 (2) (a) and (b) and a definition of the particulars of the healthcare worker (27 (2) (c) be provided to ensure this requirement will not lead to infringement of the Data Protection Act.

ii. Proposed the definition of "public venue", that regulation (27 (2) (1d)- refers to prohibition of meetings in a "public venue" hence it may be imperative to provide a definition of a "public place" to avoid misinterpretation

iii. 27 (2) (f) A certificate of analysis from an accredited lab to be submitted to avoid additional costs of analysis for already certified products.

iv. It may be important to provide the timelines for feedback and approval in accordance to the Fair Administrative Action Act, 2015.

v. That, the definition for cross promotion is subject to misinterpretation as it may impact, product logos, branding, colour schemes which are IP rights and proper placements of products on shelf's for hygiene and safety and should therefore be reviewed to reduce Ambiguity and infringement on intellectual property rights and trademark rights on its application scope in the Kenyan market.

vi. That, the ministry ought to address product distinction through labelling and align with text in existing standards as this is in line with Kenya standard KS EAS 4 the Infant formula specification Section 10.11.5

vii. That, under regulation 18, the statement as is, implies that the manufacturer's logo is prohibited on the label and should therefore be rephrased to align with existing KS EAS 4 standard. The mmanufacturer's corporate logo illustration should also be part of the label for identification of the product.

viii. That the regulation be amended to provide that the label shall have no pictures photographs, drawings, or any other graphics which represent infants and/or women other than illustrating methods of preparations. The label shall not idealize the use of the designated product.

14. In regulation 19 (1) it was proposed that the word "**Warning**" be replaced with the words "**Important Notice**" and include 'or an equivalent statement' at the end to provide flexibility where a similar statement has been provided with sufficient meaning and the provisions be maintained as per the harmonized EAC Standards 10.11.3.

Further that -

a. they should delete regulation 37 (b) since the purpose of engaging the health professional is to create awareness about the product, which should include the brand name
b. according tom the ministry , the purpose of engaging the health professional is to create awareness about the product, which should include the brand name and producer.
c. they ought to provide clarity on the restriction under regulation 37 (c).

3. COMMITTEE OBSERVATIONS

15. Following comprehensive scrutiny of the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021, the Committee made the following observations:–

3.1 Statutory Timelines

16. Section 28 of the Act provides for further statutory timelines over and above the timeliness stipulated under the Statutory Instruments Act. The Regulations were tabled on the 21st October, 2021. The House went on recess on 21st October, 2021 being sixteen days after the date on which they were tabled and when time stopped running. The House resumed its sittings on 8th November, 2021 (and has five (5) more days within which to reach a resolution) hence the time lapses on Saturday the 13th November, 2021.

17. THAT, the Regulations were published in the gazette on the 27th August, 2021, *vide* Legal Notice No 184 of 2021, submitted to the Clerk of the National Assembly on 5th October, 2021 and laid in the House on 6th October, 2021 being within the requisite statutory timelines under section 11(1) of the Statutory Instruments Act.

3.2 Consultation / Public participation

18. According to the Explanatory Memorandum submitted to the Committee and the presentations made by the Ministry during the meetings, the Ministry demonstrated that consultations were done while preparing the Regulations, with key stakeholders whose input were considered before finalization of these Regulations. Some of the key stakeholders indicated to have been consulted are Ministry of Health, members of the National Committee of Infant and Young Child Feeding (NCIYCF), UNICEF, WHO, legal experts (local and international) and experts on matters of maternal, infant and young child feeding, trade and food standards.

19. The Ministry has attached an Explanatory Memorandum with a schedule of persons with whom they met during their public participation exercises.

20. Efforts were made to reach out to stakeholders through public notice, email and hardcopy invitation letters and through the Departments of Health in the counties.

21. Following a request by the Kenya Association of Manufacturers (KAM) for another consultation session, a meeting was held on 13th September 2019 where KAM presented their comprehensive memorandum and key issues were raised.
22. On 10th January 2020, the Principal Secretary, Ministry of Health wrote to the Attorney General (AG) seeking legal guidance and concurrence on the draft regulations. Further that the AG through a letter dated 20th November 2020, advised the Ministry to publish the regulations and transmit the same to the National Assembly.
23. The Ministry notified the World Trade Organization on the proposed BMS regulations and comments from two member states (United States of America and Switzerland) were received. Inputs from stakeholders were taken into account and assessed by the team that was involved in the drafting of the regulations and issues that were agreed upon to be included in the Regulations were incorporated.
24. Summary of the issues raised by stakeholders and MOH responses has been attached.

3.3 Regulatory Impact Statement

25. Following the resolution and directions of the Committee during the prepublication scrutiny meeting, and pursuant to section 6 of the Statutory Instruments Act, a Regulatory Impact Assessment was conducted and a Regulatory Impact Statement presented alongside the Regulations as they are likely to impose significant costs on the community or a part of the community.

4. COMMITTEE RECOMMENDATION

26. Having examined the conformity of the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021 published *vide* (*Legal Notice No, 184 of 2021,* with the Constitution, the Interpretations and General Provisions Act (*Cap 2*), the Statutory Instruments Act, 2013 (*No. 23 of 2013*), pursuant to which they are made, **the Committee recommends that the House approves the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021,** published *vide* (*Legal Notice No, 184 of 2021) w*ith amendments to Regulations 1, 2 and 27(1).

5. SCHEDULE: PROVISIONS OF THE REGULATIONS PROPOSED FOR AMENDMENT

PROVISION OF THE REGULATION	PROPOSED AMENDMENTS	JUSTIFICATION
Regulation 1 ***"These Regulations may be cited as the Breast Milk Substitutes (General) Regulations, 2021."***	These Regulations may be cited as the Breast Milk Substitutes (General) Regulations, 2021 and shall come into force on 30th of May, 2022	The Committee recommends to the House to adopt the proposed amendment to provide for a commencement date in Regulation 1 to be 30th May, 2022 being six months after date on which this House approves the Regulation.
Regulation 2 ***"Interpretation"***	Insert the following definition immediately after	To make it clear and certain what amounts to a public venue within the meaning of

	the definition of the word "public analyst" "public venue" means any venue to which for the time being the public or any section of the public are entitled or permitted to have access whether on payment or otherwise, and, in relation to any meeting to be held in the future, includes any venue which will, on the occasion and for the purpose of such meeting, be a public venue	the Regulation and in respect to where manufacturers and other stakeholders may meet for purposes of this Regulation.
Regulation 27 (1) Creating awareness (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 complementary food product, shall before commencing interactions with any health worker apply in writing to the Committee for approval."***	Insert the following sub regulation immediately after (sub regulation)1 (1 A) the committee shall upon receiving an application under (sub regulation 1)1 consider the application and respond to the applicant within 14 days	To provide for a timeline in within which a manufacturer who has applied for approval to create awareness about scientific and factual matters may expect to receive response from the National Committee on Infant and Young Child Feeding

For **Signed**..... **Date**...10/11/2021.....

THE HON. WILLIAM KASSAIT KAMKET, M.P.
(CHAIRPERSON)

6. ANNEXURES

1. **Adoption List**
2. **Legal Notice Number (*L.N. No. 184 of 2021*)**
3. **Committee Minutes**
4. **Submission by the Ministry of Health**
5. **Submission by the Kenya Association of Manufactures**

COMMITTEE ON DELEGATED LEGISLATION

ADOPTION LIST

Adoption of the Report on the Consideration of the Breast Milk Substitutes (Regulation and Control) (General) Regulations, 2021 (*Legal Notice Number* 184 of 2021).

We, the undersigned, hereby affix our signatures to this Report to affirm our approval:
DATE: 10TH, NOV, 2021 **VENUE:** 2ND FLOOR, CONTINENTAL HOUSE.

	HON. MEMBER	SIGNATURE
1.	Hon. Kassait Kamket, MP (Chairperson)	
2.	Hon. Muriuki Njagagua, MP (Vice Chairperson)	
3.	Hon. Isaac Waihenya Ndirangu, MP	
4.	Hon. Cecily Mbarire, MP	
5.	Hon. Alice Wahome, MP	
6.	Hon. Daniel Maanzo, MP	
7.	Hon. Robert Mbui, MP	
8.	Hon. Martha Wangari, MP	
9.	Hon. Ronald Kiprotich Tonui, MP	
10.	Hon. Timothy Wanyonyi, MP	
11.	Hon. William Kamoti, MP	
12.	Hon. Gideon Mulyungi, MP	
13.	Hon. George Gitonga Murugara, MP	
14.	Hon. Jennifer Shamalla, MP	
15.	Hon. Munene Wambugu, MP	
16.	Hon. Patrick Kariuki Mariru, MP	
17.	Hon. (Dr.) Wilberforce Oundo, MP	
18.	Hon. Abdi K. Tepo, MP	
19.	Hon. Edith Nyenze, MP	
20.	Hon. Robert Githinji Gichimu, MP	
21.	Hon. Sammy Seroney, MP	
22.	Hon. Tindi Mwale, MP	
23.	Hon. William Cheptumo, M.P	

MINUTES OF THE 67TH SITTING OF THE COMMITTEE ON DELEGATED LEGISLATION HELD ON MONDAY, 8TH NOVEMBER, 2021 AT 2.00 P.M. IN THE MINI CHAMBERS, PARLIAMENT BUILDINGS

PRESENT

1. **The Hon. Kassait Kamket, M.P.** - **Chairperson**
2. The Hon. Daniel Maanzo, M.P.
3. The Hon. George Murugara, M.P.
4. The Hon. Abdi Tepo, M.P.
5. The Hon. Robert Gichimu, M.P.
6. The Hon. Munene Wambugu, M.P.
7. The Hon. Jennifer Shamalla, M.P.
8. The Hon. Edith Nyenze, M.P *(Virtual attendance)*
9. The Hon. Sammy Seroney, M.P. *(Virtual attendance)*

ABSENT WITH APOLOGY

1. **The Hon. Muriuki Njagagua, M.P.** - **Vice Chairperson**
2. The Hon. Patrick Mariru, M.P.
3. The Hon. Robert Mbui, M.P.
4. The Hon. Cecily Mbarire, MGH, M.P.
5. The Hon. Waihenya Ndirangu, M.P.
6. The Hon. Martha Wangari, M.P.
7. The Hon. Alice Wahome, M.P.
8. The Hon. Gideon Mulyungi, M.P.
9. The Hon. Kamoti Mwamkale, M.P.
10. The Hon. Timothy Wanyonyi, M.P
11. The Hon. (Dr.) Wilberforce Oundo, M.P.
12. The Hon. Ronald Tonui, M.P.
13. The Hon. Nicholas Tindi Mwale, M.P.
14. The Hon. William Cheptumo, M.P

IN-ATTENDANCE

National Assembly Secretariat

1.	Mr. Mohamed Jimale	-	Clerk Assistant II
2.	Ms. Ruth M. Gakuya	-	Clerk Assistant II
3.	Mr. Wilson Dima Dima	-	Principal Legal Counsel
4.	Mr. Charles Ayari	-	Superintendent of Electronics (Audio)
5.	Mr. Eugene Luteshi	-	ICT
6.	Mr. Mohamed Said	-	Serjeant-at-Arms
7.	Mr. Mureithi Theuri	-	Intern
8.	Mr. Lumumba Kilama	-	Pupil
9.	Ms. Dorothy Kandie	-	Pupil

Ministry of Health

1. Dr. Rashid A. Aman - Chief Administrative Secretary
2. Ms. Rose Wambu - Manager, Maternal, Infant, and Young Child Nutrition (MIYCN).
3. Ms. Ruth Nduati - Chair, Maternal, Infant, And Young Child Nutrition (MIYCN) Committee
4. Ms. Veronica Kirogo - Director of Nutrition
5. Ms. Terry Rotich - Senior State Counsel Ministry of Health
6. Dr. Martin Chabi Joseph - Nutrition Child & Adolescent Health -(WHO)
7. Mr. Patrick Cordia - Chief of Nutrition UNICEF Kenya
8. Ms. Sahara S. Ali - Principal Public Health Officer
9. Ms. Vivian N. Mboga - Parliamentary Liaison Officer.

Kenya Association of Manufacturers

1. Ms. Miriam Bomett - Deputy Head, Policy Research and Advocacy
2. Mr. George Kiongo - Country Head, DANONE
3. Ms. Brenda Werema - Science Support, DANONE – KAM Member
4. Mr. Ngentu M. Njeru - East Arica Managing Director Nestle, KAM Member
5. Mr. James Ojiambo - Regulatory Affairs Nestle Kenya - KAM
6. Ms. Teresia Waithaka - Corporate Communication Manger, Nestle - KAM Member
7. Mr. Noel N. Okwach - Legal Counsel, Kenya Association Of Manufacturers (KAM)
8. Mr. Austine Mwinzi - Sectors Officer , Kenya Association of Manufacturers
9. Mr. Lydia Luther - Legal Counsel, Kenya Association of Manufacturers
10. Mr. Malcolm Mwangi - Legal Support, Kenya Association of Manufacturers

MIN.NO. /NA/CDL/2021/293 PRAYER AND PRELIMINARIES

The Chairperson called the meeting to order at 2.25 a.m. with the Prayer. A round of self-introductions was then conducted before proceeding with the business of the day.

He then informed the meeting that the Committee had previously engaged with the Ministry of Health on the Breast Milk Substitutes (Regulation and Control) Regulations while in draft form in a meeting held 5th February, 2020 and with the Kenya Association of Manufacturers on 23rd March, 2021 respectively. He pointed out that during the said meetings, various proposals were made by the Committee which had been incorporated in the published regulations.

However, the Kenya Association of Manufacturers raised concerns vide a letter dated 28th September, 2021 that the industry proposals were not taken into account before publications. He said that KAM Members are raising concerns that if the Regulations are approved in its current format would have a negative impact on the sub sector.

The Chairman reiterated the objective of the meeting was therefore to address any outstanding issues in the Regulations before House approval.

He highlighted that the regulations had a strict timelines, having been tabled on 6th October, 2021 and with the House resuming its sittings on 8th November, 2021, the Committee and the House had until Thursday 11th November, 2021 to reach a resolution on the regulations. The Chairman pointed out that Section 28 (5) mandates the Committee to propose amendments to the Regulations. ***"If a resolution is passed by the National Assembly within twenty one days on which it next sits after the regulation is laid before it that the regulation be annulled or amended in a specific manner, the regulation shall thenceforth be void or amended as resolved by the Assembly.***

He thereafter directed that the given that the timelines left the Committee can then only listen to the parties on the issues under dispute or approve the Regulations subject to amendments as shall be resolved by the Committee.

He then invited the Ministry of Health and the Kenya Association of Manufacturers to make their presentations.

MIN.NO. /NA/CDL/2021/294 CONFIRMATION OF MINUTES

Minutes of the previous sittings were read and confirmed as follows –

Minutes of the 53rd sitting held on Tuesday, 28th September, 2021 at 8.00 a.m. were confirmed as a true record of the proceedings having been proposed by Hon. Robert Gichimu, M.P and seconded by the Hon. Abdi Tepo , M.P.

Minutes of the 54th sitting held on Tuesday 29th September, 2021 at 10.00 a.m. were confirmed as a true record of the proceedings having been proposed by Hon. Abdi Tepo, M.P and seconded by the Hon. Robert Gichimu , M.P.

Minutes of the 55th sitting held on Tuesday, 5th October, 2021 at 7.30 a.m. were confirmed as a true record of the proceedings having been proposed by the Hon. Robert Gichimu, M.P and seconded by the Hon. Daniel Maanzo M.P.

MIN.NO. /NA/CDL/2021/295 MATTERS ARISING

There were no matters arising.

MIN.NO. /NA/CDL/2021/ 296 ADOPTION OF REPORT

The Committee considered and unanimously adopted the Committee Report on the **annulment** of the Environmental Management and Coordination (Impact Assessment and Audit) (Amendment) Regulations, 2016 (*Legal Notice No. 149 of 2016*) having been proposed by the Hon. Abdi Tepo, M.P. and Seconded by the Hon. Robert Gichimu, M.P.

MIN.NO. /NA/CDL/2021/ 297 CONSIDERATION OF THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021 (*LEGAL NOTICE NO.184 OF 2021*).

Submission from the Ministry of Health

Dr. Rashid A. Aman, Chief Administrative Secretary, Ministry of Health informed the Committee that -

1. The Ministry had held extensive consultations with all relevant stakeholders, including the Kenya Association of Manufacturers (KAM), in accordance with the Constitution and the Statutory Instruments Act, 2013. KAM in particular, had been given numerous forums to address their concerns on the Regulations and this included communication from KAM either directly to the CS, Ministry of Health or through the CS, Ministry of Industrialization and Trade.
2. The Ministry has adopted a number of issues raised by KAM including deletion of Regulation 26 (i.e. requirement to have similar labelling in bottled water) of the original draft and review of regulation on temperature guidelines.
3. However, there are some recommendations which were not adopted as proposed by KAM and adequate justification provided. KAM never responded on the Justification provided by the Ministry. Further the Memorandum submitted by KAM is the same one submitted repeatedly.
4. The statement by KAM that the Regulations will drive them out of the market was not true. The purpose of the Regulations is not to ban the sale or use of Breast Milk Substitutes but to regulate the same. Given that the Breast Milk Substitutes Act has been in force since 2012, the statement that the Regulations will drive them out of the market is untrue.
5. During one of the meetings with KAM, it was observed that the representatives from KAM were representing foreign multinationals.
6. The Ministry also notified the World Trade Organization Technical Barriers to Trade Committee (WTOTBT) in Geneva on the draft Regulations as required by the TBT Agreement and received comments from various member states including the USA, Switzerland and the EU. KAM, though un-procedural, also submitted their memorandum to the WTO TBT Committee. In the National TBT Committee meeting, KAM, once again, submitted their memorandum and the Ministry responded adequately.
7. Safety and quality requirements are not the subject of these Regulations because there are already existing Regulations addressing on issues of safety and quality.
8. The definition of public place has been provided in the Public Order Act,
9. That the regulations provisions on labelling are in line with how all other products are dealt with.

Submission from the Kenya Association of Manufacturers

Ms. Mirriam Bomett, Deputy Head, Policy Research and Advocacy, representing the CEO KAM, highlighted the following issues in the regulations and informed committee that no consensus was reached in addressing them during the stakeholder engagements on the regulations:-

1. **Transition Period**

The regulations don't stipulate a transition period hence, once they are approved and passed by the National Assembly as a law they become effective immediately and all products in the market will be rendered non-compliant. Recalling the products off the shelf will lead to widespread stock outs

and caregivers will not be able to access products for their babies. Manufacturers will also incur losses due write offs.

Proposed amendment – a transition period of 24 months be provided to cater for products on shelf, and on transit and depletion of packaging materials.

2. **Interactions with Health Care Professionals**

The requirements in article 27 (2) (a) (b) are ambiguous as one can only create awareness of a product that they would normally endorse. Secondly, there may exist a personal relation between a medical delegate creating awareness of a designated product to the targeted healthcare professional. Such a relationship should not be a deterrent for such interaction.

Proposed amendment -

i. Delete article 27 (2) (a) and (b) and a definition of the particulars of the healthcare worker (27 (2) (c) be provided to ensure this requirement will not lead to infringement of the Data Protection Act.
ii. Proposed public venue (27 (2) (1d)- provide a definition of a "public place" to avoid misinterpretation
iii. 27 (2) (f) A certificate of analysis from an accredited lab to be submitted to avoid additional costs of analysis for already certified products.
iv. Provide the timelines for feedback and approval of this application as per the Fair Administrative Action Act, 2015.

3. **Cross- promotion**

The definition for cross promotion is subject to misinterpretation as it may impact, product logos, branding, colour schemes which are IP rights and proper placements of products on shelf's for hygiene and safety and should therefore be reviewed to reduce Ambiguity and infringement on intellectual property rights and trademark rights on its application scope in the Kenyan market.

Proposed amendment –

i. Address product distinction through labelling and align with text in existing standards as this is in line with Kenya standard KS EAS 4 the Infant formula specification Section 10.11.5
ii. Proposed definition: "Cross-promotion" also called brand crossover promotion or brand stretching) is a form of marketing promotion where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding, and labelling of a product to closely resemble that of another (brand extension). In this context, it can also refer to use of promotional activities for one product and/or promotion of that product in particular settings to promote another product".

4. **Labelling**

a. Under article 18, the statement as is, implies that the manufacturer's logo is prohibited on the label and should therefore be rephrased to align with existing KS EAS 4 standard. The mmanufacturer's corporate logo illustration should also be part of the label for identification of the product.

Proposed amendment –

The label shall have no pictures photographs, drawings, or any other graphics which represent infants and/or women other than illustrating methods of preparations. The label shall not idealize the use of the designated product.

a. In article 19 (1) replace the word "**Warning**" with "**Important Notice**" and include 'or an equivalent statement' at the end to provide flexibility where a similar statement has been provided with sufficient meaning and the provisions be maintained as per the harmonized EAC Standards 10.11.3.
b. Delete 37 (b) since the purpose of engaging the health professional is to create awareness about the product, which should include the brand name
c. Delete 37(e) Purpose of engaging the health professional is to create awareness about the product, which should include the brand name and producer.
d. Provide clarity on the restriction under 37 (c)

Committee Observation

The Committee made the following observations:-

(1) Statutory Timelines

The Regulations were published in the gazette on the 27th August, 2021, *vide* Legal Notice No 184 of 2021, submitted to the Clerk, National Assembly on 5th October, 2021 and laid in the House on 6th October, 2021 being within the requisite statutory timelines under section 11(1) of the Statutory Instruments Act.

(2) Public participation

According to the Explanatory Memorandum submitted to the Committee and the presentations made by the Ministry of Health during the meetings, the Ministry further demonstrated that consultations were done while preparing the Regulations, with key stakeholders whose input were considered before finalization of these Regulations. Some of the key stakeholders indicated to have been consulted are Ministry of Health, members of the National Committee of Infant and Young Child Feeding (NCIYCF), UNICEF, WHO, legal experts (local and international) and experts on matters of maternal, infant and young child feeding, trade and food standards. The Ministry has attached an Explanatory memorandum with a schedule of persons with whom they met during their public participation exercises. Following a request by the Kenya Association of Manufacturers (KAM) for another consultation session, a meeting was held on 13th September 2019 where KAM presented their comprehensive memorandum and key issues were raised.

The Kenya Association of Manufacturers (KAM) had however raised some genuine concerns on the regulations as published, as they were likely to have a negative impact on the industry if implemented as published.

(3) Regulatory Impact Statement

Pursuant to section 6 of the Statutory Instruments Act, a Regulatory Impact Assessment was conducted and a Regulatory Impact Statement presented alongside the Regulations as they are likely to impose significant costs on the community or a part of the community.

Committee Resolution

Having examined the conformity of the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021 published *vide* (*Legal Notice No, 184 of 2021,* with the Constitution, the Interpretations and General Provisions Act (*Cap 2*), the Statutory Instruments Act, 2013 (*No. 23 of 2013*), pursuant to which they are made, **the Committee recommends that the House approves the Breast Milk Substitutes (Regulations and Controls) (General) Regulations, 2021,** published *vide* (*Legal Notice No, 184 of 2021) w*ith the exception of the provisions set out in the schedule hereunder, which the Committee proposes amendment pursuant to Section 28 (5) of the Breast Milk Substitutes (Regulations and Controls) Act, 2012 as per the schedule hereunder -

SCHEDULE: PROVISIONS OF THE REGULATIONS PROPOSED FOR AMENDMENT

PROVISION OF THE REGULATION	**PROPOSED AMENDMENTS**	**JUSTIFICATION**
Regulation 1 ***"These Regulations may be cited as the Breast Milk Substitutes (General) Regulations, 2021."***	These Regulations may be cited as the Breast Milk Substitutes (General) Regulations, 2021 and shall come into force on 30th of May, 2022	The Committee recommends to the House to adopt the proposed amendment to provide for a commencement date in Regulation 1 to be 30th May, 2022 being six months after date on which this House approves the Regulation.
Regulation 2 ***"Interpretation"***	Insert the following definition immediately after the definition of the word "public analyst" "public venue" means any venue to which for the time being the public or any section of the public are entitled or permitted to have access whether on payment or otherwise, and, in relation to any meeting to be held in the future, includes any venue which will, on the occasion and for the purpose of such meeting, be a public venue	To make it clear and certain what amounts to a public venue within the meaning of the Regulation and in respect to where manufacturers and other stakeholders may meet for purposes of this Regulation.
Regulation 27 (1) Creating awareness (1)		To provide for a timeline in within which a manufacturer who has applied for approval

"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 complementary food product, shall before commencing interactions with any health worker apply in writing to the Committee for approval."	Insert the following sub regulation immediately after (sub regulation)1 (1 A) the committee shall upon receiving an application under (sub regulation 1)1 consider the application and respond to the applicant within 14 days	to create awareness about scientific and factual matters may expect to receive response from the National Committee on Infant and Young Child Feeding

MIN.NO. /NA/CDL/2021/298 ADJOURNMENT

There being no other business the meeting was adjourned at 4.45 p.m. Next meeting will be held on Wednesday 10th November, 2021 at 9.00 a.m.

Signed..... **Date**10/11/2021.....

HON. KASSAIT KAMKET, M.P.
(CHAIRPERSON)

MINUTES OF THE 18TH SITTING OF THE COMMITTEE ON DELEGATED LEGISLATION HELD ON TUESDAY, 23RD MARCH, 2021 AT 10.00 A.M. IN THE COMMITTEE ROOM 9, MAIN PARLIAMENT BUILDINGS

PRESENT

1. The Hon. Muriuki Njagagua, M.P. - Vice Chairperson
2. The Hon. Waihenya Ndirangu, M.P. *(Virtual Attendance)*
3. The Hon. Cecily Mbarire, MGH, M.P.
4. The Hon. Martha Wangari, M.P. *(Virtual Attendance)*
5. The Hon. Abdi Tepo, M.P.
6. The Hon. Edith Nyenze, M.P
7. The Hon. George Murugara, M.P.
8. The Hon. Gideon Mulyungi, M.P. *(Virtual Attendance)*
9. The Hon. Jennifer Shamalla, M.P.
10. The Hon. Munene Wambugu, M.P.
11. The Hon. Robert Gichimu, M.P.
12. The Hon. Sammy Seroney, M.P. *(Virtual Attendance)*

ABSENT WITH APOLOGY

1. The Hon. Kassait Kamket, M.P. - Chairperson
2. The Hon. William Cheptumo, M.P
3. The Hon. Alice Wahome, M.P.
4. The Hon. Ronald Tonui, M.P.
5. The Hon. Kamoti Mwamkale, M.P
6. The Hon. Daniel Maanzo, M.P.
7. The Hon. Robert Mbui, M.P.
8. The Hon. Timothy Wanyonyi, M.P.
9. The Hon. (Dr.) Wilberforce Oundo, M.P.
10. The Hon. Nicholas Tindi Mwale, M.P.
11. The Hon. Patrick Mariru, M.P.

IN-ATTENDANCE

National Assembly Secretariat

1. Ms. Susan Maritim - Senior Clerk Assistant
2. Mr. Mohamed Jimale - Clerk Assistant II
3. Mr. Wilson Dima Dima - Principal Legal Counsel
4. Mr. Faith Makena - Serjeant-at-Arms
5. Mr. Charles Ayari - Superintendent of Electronics (Audio)
6. Mr. Marc Chirchir - Pupil

Kenya Association of Manufacturers

1. Mr. Rajan Malde	-	Director
2. Mr. James Odhiambo	-	Member KAM *(Virtual Attendance)*
3. Mr. Kevin Saola	-	Member KAM *(Virtual Attendance)*
4. Ms. Brenda Warema	-	Member KAM *(Virtual Attendance)*
5. Ms. Tracy Waithaka	-	Member KAM *(Virtual Attendance)*
6. Ms. Susan Maendia	-	Member KAM *(Virtual Attendance)*
7. Ms. Elizabeth Gichangi	-	Member KAM
8. Ms. Akinyi Gikonyo	-	KAM Consultant
9. Mr. George Kiongo	-	KAM Member *(Virtual Attendance)*
10. Mr. Brian Kaloche Arusha *(Virtual Attendance)*	-	East Africa Business Counsel of Manufacturers,
11. Mr. Goodluck Wesonga *(Virtual Attendance)*	-	East Africa Business Counsel of Manufacturers

MIN.NO. /NA/CDL/2021/071 PRAYERS AND PRELIMINARIES

The meeting commenced at 10.25 a.m. with the Prayers.

MIN.NO. /NA/CDL/2021/072 ADOPTION OF THE AGENDA

The Committee unanimously adopted the Agenda as presented having being proposed by Hon. Jennifer Shamalla, MP and seconded by Hon. George Murugara, MP.

MIN.NO. /NA/CDL/2021/073 CONFIRMATION OF MINUTES OF THE PREVIOUS SITTINGS

Minutes of the previous sittings were read and confirmed as follows –

Minutes of the 12th Sitting held on 17th February, 2021 were confirmed as a true record of the proceedings having been proposed by Hon. Jennifer Shamalla, M.P. and seconded by Hon. George Murugara, M.P.

Minutes of the 13th Sitting held on 5th March, 2021 (Morning Sitting) were confirmed as a true record of the proceedings having been proposed by Hon. Jennifer Shamalla, M.P. and seconded by Hon. George Murugara, M.P.

Minutes of the 14th Sitting held on 5th March, 2021 (Afternoon Sitting) were confirmed as a true record of the proceedings having been proposed by Hon. George Murugara, M.P. and seconded by Hon. Jennifer Shamalla, M.P.

Minutes of the 15th Sitting held on 6th March, 2021, 2021 (Morning Sitting) were confirmed as a true record of the proceedings having been proposed by Hon. Sammy Seroney, M.P. and seconded by Hon. Munene Wambugu, M.P.

Minutes of the 16th Sitting held on 6th March, 2021, 2021 (Afternoon Sitting) were confirmed as a true record of the proceedings having been proposed by Hon. Robert Gichimu, M.P. and seconded by Hon. Sammy Seroney, M.P.

MIN.NO. /NA/CDL/2021/074 MATTERS ARISING

No matter arose.

MIN.NO. /NA/CDL/2021/075 CONSIDERATION OF THE DRAFT BREASTMILK SUBSTITUTE (GENERAL) REGULATIONS, 2021

The delegation from the Kenya Association of Manufacturers led by the Mr. Rajan Malole introduced themselves and presented the Association's concerns regarding the draft Breastmilk Substitute Regulations, 2021 to the Committee.

Background

In 2019, the Ministry of Health published the draft Regulations and subjected them to public participation. The Industry under KAM participated and presented its Memorandum.

In February 2021, the Industry was made aware of the Ministry of Health's request to the World Trade Organization (WTO) for approval of the draft Regulations in order to gazette the Regulations.

The WTO notified Kenya that it has received concerns on the Regulations from Member States - the United States of America and Switzerland as well as the Industry in Kenya (Bottled Water Industry and Nutrition and Infant Sub Sector) on the impact of the Regulations.

Kenya is currently preparing its position to submit to the WTO led by the Ministry of Health.

Key Concerns

1. **Lack of public consultation on new provisions under Regulation 26**: Inclusion of provisions to regulate bottled water, cereals and porridge under the law. Newly introduced provisions under Regulation 26 were not previously included in the draft Breastmilk Substitutes Control Regulations 2020.

   The Act does not provide for regulation of such items – focus is on milk products.

2. **Non-compliance with the Statutory Instruments Act, 2013:** The Act mandates the conducting of an impact analysis of the Regulations due to its economic impact to businesses. To date the impact assessment has not been carried out despite escalation to the World Trade Organization for approval.
3. **Economic impact:** The Regulations will greatly affect investments, economic contribution and employment contribution to the country.
4. Product labelling provisions are extremely restrictive and will negatively affect the Industry despite being an approved and lawful product in the Country.
5. Inclusion of cross-promotion terminology in product scope.

Recommendations to the Committee

1. Require the Ministry of Health to withdraw the Regulations from the World Trade Organization (WTO) process in order to firstly comply with the provisions of the Statutory Instruments Act, 2013.
2. **Reg. 2 and 32 on cross-promotion**: Reg. 32 bars manufacturers or distributors of a designated product or a pre-packaged complementary food from engaging in cross-promotion. KAM proposed alignment with CODEX decision not to adapt.
3. **Reg. 6** requires all products to be registered with the Nutrition and Dietetic Division, in the Ministry of Health. KAM proposed that MOH maintains registration as provided for under the Standards Act by KEBS since additional regulation without adequate justification will only put more pressure in an already over-regulated and strained industry. Creation of multiple registration procedures will enhance barriers to trade.
4. **Reg 17, 18, 19 and 21 on product labelling**: KAM proposes maintenance of provisions as per the harmonized EAC Standards e.g replace the word "**warning**" in Reg. 19 with "**important notice.**"
5. **Reg. 21(b)** on preparation methods of formula milk using (70) degrees Celsius boiling point, KAM proposes deletion of this provision as it is not practical and not be implementable. WHO/FAO recommended use of other viable hygienic preparation methods where there's high level of confidence in the safety of the product.
6. **Reg 27, 28 and 29 on interactions between manufacturers, distributors and health workers**: KAM proposed that the Regulations should state that interactions with healthcare professionals to follow the existing ethical codes of conduct.

   Reg. 27(2) infringes on consumer rights e.g. business practices and offends the right of association. KAM proposed deletion of this provision.
7. **Under Reg. 29 on professional evaluation**, KAM proposed deletion of the regulation for reasons that once an annual plan has been approved no need for health professionals to seek further approval for interaction, KAM justifies that it will be a second layer of complexity.

Way Forward

The Committee requested the Kenya Associations of Manufacturers to submit their correspondences exchanged with World Trade Organisation (WTO).

MIN.NO. /NA/CDL/2021/076 ANY OTHER BUSINESS

1. **Retreat with the Public Service Commission**: the Committee was informed that Public Service Commission invited the Committee for a pre-publication consultative meeting to consider the draft Public Service Commission (Performance Management) Regulations.

The Committee resolved to undertake the activity from Thursday, 15 to Monday 19 April, 2021 in Mombasa County.

2. The Committee also resolved to invite the National Treasury & Planning to the retreat to consider the draft Public Finance Management (Public Investment Management) Regulations, 2021 and Public Finance Management (Equalization Fund) Regulations, 2021.

MIN.NO. /NA/CDL/2021/077 ADJOURNMENT

The meeting was adjourned at 11.45 a.m. The next meeting will be called on notice.

Signed:..... **Date.**25/03/2021.....

HON. KASSAIT KAMKET, M.P.
(CHAIRPERSON)

MINUTES OF THE 9TH SITTING OF THE COMMITTEE ON DELEGATED LEGISLATION HELD ON FRIDAY, 5TH FEBRUARY, 2020 AT 10.30 A.M. IN BARAZA 2 CONFERENCE ROOM AT THE WHITESANDS RESORT, MOMBASA

PRESENT

1. **The Hon. Kassait Kamket, M.P.** - **Chairperson**
2. **The Hon. Muriuki Njagagua, M.P.** - **Vice Chairperson**
3. The Hon. Waihenya Ndirangu, M.P.
4. The Hon. Alice Wahome, M.P.
5. The Hon. Cecily Mbarire, MGH, M.P.
6. The Hon. Daniel Maanzo, M.P.
7. The Hon. Kamoti Mwamkale, M.P.
8. The Hon. Martha Wangari, M.P
9. The Hon. Robert Mbui, M.P.
10. The Hon. Ronald Tonui, M.P.
11. The Hon. Timothy Wanyonyi, M.P.
12. The Hon. (Dr.) Wilberforce Oundo, M.P.
13. The Hon. Abdi Tepo, MP
14. The Hon. Edith Nyenze, M.P
15. The Hon. George Murugara, M.P.
16. The Hon. Jennifer Shamalla, M.P.
17. The Hon. Munene Wambugu, M.P.
18. The Hon. Patrick Mariru, M.P.
19. The Hon. Robert Gichimu, M.P.
20. The Hon. Sammy Seroney, M.P.
21. The Hon. Tindi Mwale, M.P.

ABSENT WITH APOLOGY

The Hon. William Cheptumo, M.P
The Hon. Gideon Mulyungi, M.P.

IN-ATTENDANCE

National Assembly Secretariat

1. Mrs. Florence Abonyo-Atenyo - Director, Audit, Appropriations & Other Select Committees
2. Ms. Susan Maritim - Senior Clerk Assistant
3. Mr. Mohamed Jimale - Clerk Assistant II
4. Mr. Dima Dima - Principal Legal Counsel
5. Mr. Charles Ayari - Superintendent of Electronics (Audio)
6. Mr. Anthony Wamae - Serjeant-at-Arms
7. Ms. Beatrice Auma - Personal Secretary
8. Ms. Mary Otieno - Office Superintendent
9. Ms. Yvonne Kiprop - Pupil

Ministry of Health

1. Dr. Mercy Mwangangi	-	Chief Administrative Secretary
2. Dr. Pacificah Onyancha	-	Ag. Director of Medical Services
3. Ms. Veronica Kirogo	-	Head, Division of Nutrition
4. Prof. Ruth Nduati	-	Lecturer/Nutrition Expert, University of Nairobi
5. Dr. Boniface Kimuyu	-	Public Health Specialist
6. Dr. Hezron Omollo	-	Technical Advisor, MOH
7. Mr. Peter Mutua	-	Quality Assurance Manager, KEBS
8. Mr. Bernard Kuria	-	Senior State Counsel
9. Mr. Terry Rotich	-	Senior State Counsel
10. Ms. Annette Omwoyo	-	Principal Legal Officer, Kenya Law Reform Commission
11. Dr. Bashir M. Issak	-	Nutrition Department
12. Ms. Sahara S. Ali	-	Senior Assistant Public Health Officer
13. Ms. Rose Wambu		

MIN.NO. /NA/CDL/2021/033 PRAYER AND PRELIMINARIES

The meeting commenced at 11.00 a.m. with the Prayers after which a round of introductions was conducted. The Chairperson thereafter welcomed the CAS to present the draft Regulations.

MIN.NO. /NA/CDL/2021/034 CONSIDERATION OF THE PROPOSED BREAST MILK SUBSTITUTE (GENERAL) REGULATIONS, 2020

Remarks by Dr. Mercy Mwangagi, Chief Administrative Secretary, Ministry of Health

The Chief Administrative Secretary thanked the Committee for the invitation to the meeting for prepublication scrutiny on the proposed Breast Milk Substitute (General) Regulations, 2020. She affirmed the importance of the Regulations to the sector and the wellbeing of the children in Kenya. She emphasized that breastfeeding is the single most important health, social & economic investment towards achieving 9 out of the 17 Sustainable Development Goals (SDGs).

The government is working hard to protect breastfeeding from inappropriate, aggressive and unethical marketing of breastmilk substitutes which undermine efforts to improve breastfeeding rates and negatively affect choice and ability of a mother to breastfeed her infant optimally. Continued breastfeeding with complementary feeding to 6-23 months can achieve another 50% reduction in deaths & hospital admissions. Breastfed children and adolescents have higher performance on intelligence tests. Breastfeeding can protect women against breast and ovarian cancer.

The CAS further reiterated Art 43 of the Constitution of Kenya (2010) which provides that every person has the right to be free from hunger and to have adequate food of acceptable quality and Art 53 which guarantees every child the right to basic nutrition.

She further noted that good nutrition is essential for health development, survival, dignity and economic productivity. Better nutrition is related to improved infant, child and maternal health,

stronger immune systems, safer pregnancy and childbirth, lower risk of non-communicable diseases and longevity.

The CAS outlined that the draft Breast Milk Substitutes (BMS) Regulations seek to ensure that all persons that use, manufacture, sell and market BMS understand that BMS undermines breastfeeding and that sub-optimal feeding is a leading but preventable cause of serious child illnesses and deaths.

The Regulations prescribe the manner of conduct in the following areas as required by the BMS Act, 2012: donations, labelling, interaction between health workers and manufacturers/distributors, cross-promotion, advertisement, demonstrations on the use of designated products, publication of information, education and communication materials and the penalties for failure to adhere to the BMS Act and its Regulations.

Plenary discussions

1. **Public Participation**

It was observed that public participation was done in accordance with the Constitution through various stakeholders' meetings including consultations with Kenya Association of Manufacturers, Kenya Health Federation, Kenya Nutritionist and Dieticians Institute was received.

CAS further pointed out that public participation was done in accordance with the Constitution through various stakeholders' forums. The proposed draft Regulations were also circulated to internal stakeholders via email in May 2019, internal consultative meeting held on 28th June 2019, a public notice published in MyGov on 13th August, 2019 and stakeholders' consultative forum held on 27th August, 2019. The Ministry of Health also conducted a workshop for finalization of the Regulations and submitted to the AG's office for review.

2. **Support of mothers in the process**

The Ministry informed the Committee that it had introduced certain programmes to ensure that breastfeeding mothers are taken care of, for instance, through counselling programmes offered at the hospital where mothers at the wards are given sufficient information on breast milk nutrition.

Further, the Ministry also introduced breastfeeding community initiatives which targets mothers who have been discharged from hospital so as to train them on how to properly breastfeed their children and to sensitize them on breastfeeding nutrition.

3. **Quality assurance & standards**

MoH assured the Committee that through interaction with various bodies including World Health Organization (WHO), the Ministry has been able to come up with the required standards which are considered safe for use in the Kenyan market.

4. **Delay in preparation of the Regulations**

The Committee noted that the Breast Milk Substitutes (Regulation and Control) Act was enacted in 2012 yet the draft regulations are still in draft form. The Ministry responded that development of the Regulations has been an ongoing process since the enactment of the Act and involved engaging with the private sector, some of whom, were opposed to regulation.

5. **Ethics revolving around the regulations**

Members raised concerns on the ethics behind the selling of the breast milk substitutes by the various players in the industry. In response, the Ministry responded that Part V of the Regulations spells out the manner of interaction between manufacturers, distributors and health workers. Reg. 31 specifically limits this interaction by outlining what is prohibited during the interactions.

6. **Regulatory Impact Statement (RIS)**

Pursuant to section 6 of the Statutory Instruments Act, 2013, the Ministry is required to attach a Regulatory Impact Statement whether the Regulations are likely to impose significant costs on the community or a part of the community.

7. **Labelling of BMS products**

On the labelling of the breast milk substitutes products citing examples of the warning labels that are compulsory for substances such as tobacco and alcohol. It was noted Reg. 26 specifically lays out the exact words in English and Kiswahili language in bold and in a prominent position on the container.

Professor Nduati who is a member of the BMS Taskforce informed the Committee that some of the already existing samples are from foreign countries and are written in foreign languages e.g., Saudi Arabian products being written in Arabic. Regulation 19 of the draft regulations specifically mandates manufacturers to label the instructions either in English or Kiswahili.

8. **Consultations with Committee on Delegated Legislation**

The Committee brought to the attention of the CAS that section 28 of the BMS Act which empowers the National Assembly to make amendments to the regulations and other provisions for processing the Regulations once laid before the House.

Section 28 (1) - The Cabinet Secretary is required to consult the Committee in making the Regulations.

Section 28 (4) - Regulations shall not come into operation upon publication but shall be laid before the National Assembly.

Section 28 (5) - If a resolution is passed by the National Assembly within twenty-one days on which it next sits after the regulations are laid before it that the regulation be annulled or amended in a specific manner, the regulation shall thenceforth be void or amended as resolved by the Assembly.

Section 28 (6) - If no resolution is made by the National Assembly within the expiry of twenty-one days from the date on which the Assembly next sits from the date on which the regulations are laid under subsection (4), the Regulations shall come into operation in the form laid before the Assembly under that subsection.

Remarks by the Chief Administrative Secretary

The Chief Administrative Secretary appreciated the Committee for the engagement and assured the Committee of her commitment to work closely with the Committee including consultations prior to publication of instruments. She also assured the Committee that the Regulatory Impact Statement will be availed to the Committee as soon as possible.

Remarks by the Vice Chairperson

The Vice Chairperson appreciated the officials from the Ministry of Health for the fruitful engagements on the draft Regulations. He concluded by advising the Ministry to engage the Committee prior to publication of Regulations for scrutiny as a best practice.

MIN.NO. /NA/CDL/2021/035 ADJOURNMENT

The meeting was adjourned at 1.15 p.m. to be reconvened on Wednesday, 10th February, 2021 at 2.30 p.m.

Signed..... **Date**...10/2/2021.....

HON. KASSAIT KAMKET, M.P.

(CHAIRPERSON)

Head, Take this receipt
To register, acknowledge and process.
4/10/21.

3) Moses Lemuna
Please register, acknowledge the receipt
04/10/2021

MINISTRY OF HEALTH
OFFICE OF THE CABINET SECRETARY

Telephone: +254-2-2717077
E-mail: cshealth2015@gmail.com
When replying please quote:

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

Ref: MOH/LEGAL/111 (15)

Date: 28th September, 2021

Mr. Michael Sialai, EBS
Clerk of the National Assembly
Parliament Buildings
NAIROBI

(1) DL&P 30/9/21

RE: BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

Breastfeeding is the natural way of providing infants with the nutrients they need for healthy growth and development. The World Health Organization (WHO) and the United Nation Children's Fund (UNICEF) recommends initiation of breastfeeding within one hour after birth, exclusive breastfeeding in the first 6 months of life and continued breastfeeding with introduction of nutritionally adequate complementary food up to 2 years or beyond.

Recognizing that breastfeeding is an important aspect of primary health care in addressing infant malnutrition, morbidity and mortality, and that improper practices in the marketing of breast-milk substitutes (BMS) and related products can contribute to these major public health problems, the World Health Assembly adopted the International Code of Marketing of Breastmilk Substitutes in 1981. Subsequently, the Kenyan Parliament enacted the Breast Milk Substitutes (Regulation and Control) Act in 2012 to give effect to the Code by providing for the appropriate marketing and distribution of breast milk substitutes; safe and adequate nutrition for infants through the promotion of breastfeeding and proper use of breast-milk substitutes.

Section 28 (1) of the Breast Milk Substitutes (Regulation and Control) Act, 2012 provides that the Cabinet Secretary may, in consultation with the Committee, make Regulations generally for the better carrying out of the objects of the Act, and in particular, for prescribing:

a) the wording, size and manner of notices, warnings and information required under section 9;
b) the procedures and requirements under which informational or educational material may be approved under section 10 (3); and
c) any other thing that is required by this Act to be prescribed.

In exercise of the above powers, the Ministry of Health through a widely consultative process prepared and published the Breast Milk Substitutes (Regulation and Control) (General) Regulations, 2021 to give full effect to the Act. The Instrument has been signed into law and requires to be laid before the National Assembly in order to become operational.

Therefore, in line with the Statutory Instruments Act, 2013, we submit the Regulations for operationalization. Additionally, enclosed please find the supporting documents for your further necessary action.

SEN. MUTAHI KAGWE, EGH
CABINET SECRETARY

Encl.

LEGAL NOTICE NO. 184

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) ACT

(No. 34 of 2012)

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) ACT

(No. 34 of 2012)

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

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

Citation.

1. These Regulations may be cited as the Breast Milk Substitutes (General) Regulations, 2021.

Interpretation.

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

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

"cross-promotion" means a form of marketing promotion where customers of one product or service are targeted with the promotion of a related product using symbols, colouring, naming, shelf placement or any other means that implies benefit or suitability;

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

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

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

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

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

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

"public analyst" means a health officer who examines, reviews, evaluates, or conducts research of designated products and pre-packaged complementary food.

Guiding principles.

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

(a) applies or interprets any provision of these Regulations;

(b) are involved in the manufacture, distribution, study, or advising about the use of designated products or complementary foods or about breastfeeding; and

(c) makes or implements public policy decisions.

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

(a) in the provision of nutrition services, the best interest of an infant and young child is protected;

(b) initiation of breastfeeding of the infant is done within an hour of delivery and exclusive breastfeeding for the first six (6) months of life;

(c) timely introduction of appropriate, adequate and safe complementary food with continued breastfeeding for a period of twenty-four (24) months 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 designated products shall be done in the manner prescribed under the Act and these Regulations.

Objects.

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

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

Production and packaging of designated and complementary food products.

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

(a) the provisions of the Act, the Food, Drugs and Chemical Substances Act, the Public Health Act, the Standards Act and the Kenya Standards KSEAS 39 and any other written law; and

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

(b) the Kenya standards for infant formula (KS EAS4), follow up formula (KS CODEX STAN 156), formulated pre-packaged complementary food for older infants and young children (KS-2515) and processed cereal based foods for infants and young children (KS EAS 72).

Registration.

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

Sampling and testing.

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

Complying with Regulations.

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

Manufacturing, sell and expiry date.

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

Use of alternative containers from the original.

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

Certificate of analysis.

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

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

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

Application to donate.

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

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

Restrictions to donations.

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

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

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

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

(5) Without prejudice to the generality of sub-regulation (3),

donations made to a charitable children institution or social welfare institution shall be used within the institution to which they are donated and shall not be distributed outside that institution unless further donated to another charitable children or social welfare institution with prior written consent of the Committee.

Filing of returns.

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

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

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

Application by charitable and social institutions.

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

Use of donations.

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

(2) No person shall, for the purpose of donating any designated product or a pre-packaged complementary food product, without the written approval of the Committee, directly donate or give to any person, institution or health facility any designated product or a pre-packaged complementary food product thereof.

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

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

17. (1) The label of a designated product or complementary food product, shall in addition to the provisions of the relevant written legislation or Kenya standard, contain the name, physical address, website address, email address and telephone number of the manufacturer, seller and, if imported to Kenya, contact information of 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 or Kiswahili language in bold and conspicuous characters in a prominent position and in not less than fifty percent (50%) of the size of the largest words on the label in red lettering on white background and not less than 3 mm in height based on the lower case "o" preceded by the word "WARNING" in capital letters:

"'Breast milk is best. Breast milk is ideal for the healthy growth and development of infants and young children. It protects against potentially fatal diarrhea, lung infections and other illness. It is often difficult to resume breastfeeding after beginning to feed your baby breast milk substitutes."

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

(a) not include words such as "maternalised" or "humanised" or images, symbols or words 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 or Kiswahili language and easily understood graphics indicating—

(a) instructions for appropriate preparation and use;

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

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

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

Labelling of formula in powdered form.

21. Despite any other requirement in these Regulations with respect to containers or labels of infant formula or follow up formula, labelling for infant or follow up formula in powdered form shall, in addition to including a feeding chart, indicate 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 that has been boiled and cooled within 30 minutes;

(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 or 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 idealizing 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 or 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 or Kiswahili language the following words in not less than 50% of the size of the largest words on the label not less than 3 mm based in height based on the lower case "o" in red lettering on white background preceded by the word "WARNING" in capital letter:

"Use of pacifier can interfere with breastfeeding".

Particulars to be inscribed on container.

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

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

(i) ingredients;

(ii) required storage condition;

(iii) date of manufacture;

(iv) batch number; and

(v) 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 or 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 labeler 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.

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

Interactions.

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

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

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

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

(2) The interactions between a manufacturer or distributor with any health worker referred to under sub-regulation (1), shall take place

in a public venue approved by the Committee pursuant to a decision-making process consistent with the Fair Administrative Action Act, 2015. No. 4 of 2015.

Creating awareness.

27. (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 complementary 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.

28. (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 approval by the Committee.

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

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

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

relationship, collaboration or partnership with the manufacturer or distributor.

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

(a) an approved research protocol;

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

(c) a certificate of analysis; No. 28 of 2013.

(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.

29. Any health worker who wishes to participate in any interaction with a manufacturer or distributor, for the purposes of professional evaluation, or research on a designated product or pre-packaged complementary food, shall prepare a formal record of the interaction and submit it to the Committee, within 30 days following the interaction.

Restrictions to interactions.

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

(a) distribute any promotional material or items;

(b) give misleading information prohibited under the Act;

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

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

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

(f) brand the venue in any way to promote a designated or packaged complementary food.

Cross-promotion.

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

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.

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

33. 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 up to 2 years or beyond;

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

(d) that use of cup or spoon feeding is safer than 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.

34. (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 month of life and continued breastfeeding with introduction of nutritionally adequate and safe complementary foods for up to 2 years or beyond;

(e) the importance of optimal maternal nutrition;

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

(g) the approximate financial cost of adequate feeding of an infant with breastmilk substitutes during the first six months of life;

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

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

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

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

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

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

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

Procedure for demonstrating proper complementary feeding.

35. (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 of life and continued breastfeeding with introduction of nutritionally adequate and safe complementary foods for up to two years or beyond;

(b) the importance of optimal maternal nutrition;

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

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

PART VI—INFORMATION, EDUCATION AND COMMUNICATION MATERIALS

Publication of information, education and communication materials.

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

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

(3) The Committee shall respond, in writing, to the application made under sub-regulation (1) within twenty-one days of the receipt of the application, and may approve upon satisfaction that the information, education and communication materials comply with the provisions of regulation 37 of these Regulations.

Contents of information, education and communication materials.

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

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

(b) not make reference to any brand name or logo of any breast milk substitutes;

(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 a brand name, logo or name of the manufacturer or distributor of designated products or pre-packaged complementary food;

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

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

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

(i) not include words or images that create the impression that the use of designated products are manufactured in accordance with the recommendation of a health professional registered under any of the health professional regulatory bodies in Kenya.

PART VII—ENFORCEMENT

Authorised persons.

38. 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.

Access to breast milk substitutes.

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

Seizures.

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

(a) prohibited goods; or

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

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

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

Conflict of Interest.

41. (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.

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

Spot fines.

43. 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.

44. 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.

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

SCHEDULE

(r. 12(2))

Form BMS 1

APPLICATION FOR DONATION

Donation 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/Donee

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

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

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

FORM BMS 2

(r. 14(1))

RETURNS FOR DONATION

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

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

DESCRIPTION OF THE DONOR

Name: .....

Address:.....

Telephone:.....

Email: .....

Type of institution: .....

Date of incorporation: .....

Reason for donation: .....

.....

DESCRIPTION OF THE DONEE

Name: .....

Address.....

Telephone:.....

Email: .....

Types of institution: .....

Date of incorporation: .....

DESCRIPTION OF THE DONATION

Name: .....

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

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

Expiry date:.....

Quantity donated:.....

Donee/Donor

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

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

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

FORM BMS 3

(r. 14(2))

RETURNS FOR USE OF DONATION

Donation 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
r.14(3)

RETURNS FORM

DESCRIPTION OF THE DONEE

Name: .....

Address.....

Telephone: .....

Email: .....

Types of institution: .....

Date of incorporation: .....

DESCRIPTION OF THE DONATION

Name: .....

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

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

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:.....

SEIZURE FORM A

(r. 42(2))

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

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

.....

.....

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

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

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

DETAILS OF THE GOODS

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

Postal Address..... ....

Physical location ....

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

Physical seal ....

Description of goods ....

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

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.

SEIZURE FORM B

(r.42(2))

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

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

.....

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

.....

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

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

DETAILS OF THE GOODS.

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

Postal address .....

Physical location .....

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

Physical seal .....

Description of goods .....

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

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.

Made on the 5th August, 2021.

MUTAHI KAGWE,
Cabinet Secretary for Health.

PRINTED AND PUBLISHED BY THE GOVERNMENT PRINTER, NAIROBI

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

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

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

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

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

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

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

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

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

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

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

The regulation making process also involved active participation of the United Nations Agencies working on maternal, infant and young child feeding in Kenya, i.e., United Nations Children's Fund (UNICEF) and World Health Organization (WHO). Additionally, further consultations were made with global experts on matters related to the WHO International Code of Marketing of Breastmilk Substitutes.

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

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

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

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

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

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

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

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

c) Brief Explanation of the way consultation was carried out

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

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

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

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

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

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

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

On 10th June 2020, the Principal Secretary, Ministry of Health wrote to the Attorney General seeking legal guidance and concurrence with the draft Regulations. The AG advised the PS to publish the Regulations and transmit the same to the National Assembly.

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

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

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

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

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

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

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
1. Regulation 2 (Cross promotion) ***"Cross-promotion" means a form of marketing where customers of a product of service are targeted with promotion of a related product***	Discussions on definition of cross-promotion are still on-going at the CODEX There is no global position as at now that countries can adopt Proposal to put this regulation on hold until the process is concluded	Maintain the clause	The clause is maintained with the following justifications. • Kenya law and regulation takes precedence over any regional standards and regulations. • The term was discussed under a particular standard and the issue of concern was whether or not the resulting standard be out of the 'Mandate of Codex' as relates to IP & trade marks within WTO, TBT and TRIP. • The term cross promotion is used as defined by WHO technical guidance documents. It is important in controlling unethical promotions & advertising. • According to Para 49 and 50 of 2019 CCNFSDU[1] report, the discussion was not on the **definition of cross promotion**

[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

KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
		rather on whether or not the term applies to a 'label or labelling'. Clause 9.6.4 of appendix III of the report put both 'Label & Labelling' in square brackets and not the term, 'cross promotion'. • According to Para 24 to 28, of 2019 CCFL[2] report, the committee noted that the standard for follow-up formula did not have a definition for what 'cross promotion' though the request by CCNFSDU was related to the use of the words, 'label or labelling' in the phrase. WHO sought to clarify this as indicated in Para 27 of the report. The report concludes (Para 28) the committee decided to return the sentence "*Cross promotion between product categories is not permitted on the [label/ labelling] of the product*" to CCNFSDU for further discussion based on the reservation the committee had.

/ho-codexalimentarius/sh-

KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
		• 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.
This has potential to different interpretation Already, industry in self-regulation recalls expired products from stores to safeguard babies There is transferred liability from stockists to the manufacturer Let the stockists take liability Proposed R16[1] "*The label of a designated product shall be in accordance to East African standards and codex standards adopted by Kenya*"	The committee will consider the comment	• Is to ensure consistency with other regulatory practices
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.	Maintain the section	KAM was given an opportunity to present to the committee an artwork sample to demonstrate that the font size as proposed would be a challenge to implement. The presentation did not come up with designed label to justify their concern but rather they

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
	KAM recognizes that the warning should still be legible but font size cannot be increased for all things. A presentation with current labels, one with prescribed font size and one with what industry proposes which was expected did not happen. There was only one which was poorly done as KAM did not interpret the proposed Regulation well KAM requested restraint from sharing/publicising the sample label presented as it contains a company name which needs to be protected as this was for demonstration by KAM.		presented a superimposed artwork of an existing label
4. Regulation 17 (Prohibition on labelling)	KAM proposes revision of this regulations subsection 17 [1], [2] and [3] *(see appended KAM proposals)*	Maintain the text in the draft regulations.	Kenya Standard for infant formula (KS EAS 4, clause 10.11.4) has similar wording to that of original draft regulation. According to BMS Act all products for the ages up to 24 months are considered BMS. This statement therefore applies to all that category. The law and regulation does not seek to regulate products beyond its scope.
5 Regulation 18[1] **Labelling of Infant Formula and Follow-up Formula**	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	Maintain the text in the draft regulations.	• Research has revealed that breastfeeding protects infants against diarrhea and other illness

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
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".**	affixed thereto, contains the following words expressed in English and / or Kiswahili language in bold and conspicuous legible characters. In a prominent position in a manner that maximizes noticeability and legibility of the word: 'IMPORTANT NOTICE" in capital letters. **"Breast milk is best. Breast milk is ideal for the healthy growth and development of infants and young children or a similar statement as to the superiority of breastfeeding or breast milk.** *Remove the health claim – "It protects against diarrhoea and other illness". Retain only the first part of proposed 'IMPORTANT NOTICE"*		
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.	The comment was adopted to allow for use of either Kiswahili and/or English	This was considered for consistency with Cap 254 and the EAC protocol The Kenya Standards allows for both the use of either English or Kiswahili. In Tanzania, Kiswahili is a mandatory requirement.

KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
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'**		• Same as issue 5
KAM recommends reference and harmonization to WHO/FAO recommendations giving options that allow for use of other viable hygienic preparation KAM proposed inclusion of recommendation to boil water to 100°C then cool it to ambient temperatures as reconstituting with hot water (70°C) interferes with the formulation and introduces risk of scalding.	The requirement was maintained at 70° C	The committee reviewed UNICEF, WHO and CDC guidance on the same. It was noted that maintaining water temperatures above 70° C protects babies from E. Sakazakii and Salmonella. It was noted that some formulas would contain some nutrients that would be denatured at this temperature. However, the risk of denaturing nutrient is less compared to the risk of exposing the infants and young children to E. Sakazakii or Salmonella. In its effort to ensure infants are protected from E. Sakazakii, KS CAC/RCP 66:2008[4] section IX Para 5 requires appropriate information be provided to caregivers to avoid this contamination.

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
			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 This temperature controls for possible contamination of the product or contamination due to handling during preparation

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

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
8. Regulation 21 (Languages in bottles) 9. Regulation 22 (2) (Labelling for teats) 10. Regulation 23[1] (Labelling for teats and pacifiers)	KAM advices that most traders of these products are importers and emphasized the need to engage this group.	Maintain as in the draft regulations.	Engagement and notification of the regulations will be made.
11. Regulation 23 (minimum information on containers)	Specialised products operate in a highly regulated industry because the consumer is highly vulnerable. This is achieved through; a. Legibility and information. (Presentation) b. Statutory instruments Act as a standard that all regulators must refer to in its development. c. Rights and liability for violations	Maintain as in the draft regulations.	There is no applicable Kenya Standard and hence the regulation The regulation are coming in to address the existing regulatory gaps
12. Regulation 24 (Ethical interaction with health workers)	The general feeling of industry is that the issue of interactions in the Regulations has been over-belaboured KAM noted that regulating venue does not give rise to ethical interactions The industry already employing self-regulation and so sees no need for creating hurdles through regulations	Maintained the section	The notification of venue will guide the inspectors/monitors if they need to investigate or confirm activities are in compliance to the Act. Documented evidence of continued violation of the Act and the code is indication of nonexistence or inadequate of self-regulation

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
	The proposed regulations do not include traders/importers who are major players KAM proposes that they are required t report annually for ease of trade noting that reports are more collaborative and empowering KAM noted that health care providers (HCP) are already regulated and therefore there is no need to have regulation targeting HCPs. KAM proposed adoption of the Pharma Industry where marketers' names are submitted upfront for approval In the event that Government upholds this Regulations which prescribe clearance by the committee, there is concerned about timelines for approvals/ rejection		The section includes all players i.e manufacturer and distributors which include traders' importers etc. There will be binding procedures governing timelines related to receipt, acknowledgement and decision by the committee on request for venue
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	Maintain the section	The section does not prohibit rather it provides guidance on how awareness by the industry should be approved and conducted

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
	In such an instance, KAM would support industries with guidelines for self-regulation Also supports access to information by consumers (constitutional right) who value information		
14. Regulation 26 Professional evaluation	KAM underscored the need to allow for self-regulation which supports the heavy liability that falls on industry in the case of legal matters rising. KAM indicated that regulation on professional evaluation is covered for in R 27 which is on research Following discussions, KAM requested that this be changed to read 'clinical validation' which MoH was going discuss further	Maintain Professional evaluation is different from research and so needs to be regulated differently MoH proposes that companies present an annual schedule of planned professional evaluation activities to the committee for approval	Regulation provided for minimum requirements which any stakeholder may use for self-regulation if they deem fit
15. Regulation 28 (Formal record)	According to KAM. the prohibitive aspect is the indication that the committee will approve which counters administrative law which dictates that the standards the committee uses to make the decision will be stipulated in regulation.	Maintain	The section does not provide any prohibitive act. The clause is only requiring information and no approval is envisaged in the section
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	Maintain	Documented evidence of continued violation of the Act and the code is indication of nonexistence or inadequate of self-regulation

Clause/Regulations Proposal	KAM submission	Position from standards/MOH & (NCIYCF)	Explanation of the Action Taken
	health workers on products while enforcing the ethics.		
17. Regulation on 'cross promotion'	Discussed in issue 1 above.	Discussed under issue 1.	Discussed under issue 1.
18. Regulation 32 (Advertisement)	KAM proposes deletion of the word 'indirectly' as it proposes liability on uncertain actions Also proposed replacing specific examples (displays, signs, bill-boards, notices) with 'outdoor displays'	Maintain	The objective to regulate all persons and media involved in advertisement given that advertisement is prohibited in the Act itself.
19. Regulation 38 (Access to BMS)	KAM proposes that there is inclusion of the word 'in writing'	Maintain	MoH in response noted that the proposed regulation is consistent with other existing laws (CAP 254, 242)
20. Adherence to statutory instruments Act	KAM requested that there is consistency with the statutory instruments Act, 2013	The drafting are done in compliance of the Statutory Instruments Act and other obligations such as WTO/TBT agreements	

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

Responses to concerns raised by the United States of America

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
PART II – PROCEDURES RELATING TO THE USE OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD			
5. (a) & (b): International Standards:	The document "The Breast Milk substitutes (Regulation and Control) (General) Regulations, 2020" references the "Kenya standards for infant formula (KS EAS4), follow up formula (KS CODEX STAN 156), formulated pre-packaged complementary food for older infants and young children (KS-2515) and processed cereal based foods for infants and young children (KS EAS 72)." We request confirmation that these standards were developed considering, and are in harmony with, the following Codex Standards: Codex Guidelines on Nutrition, Labeling (CAC/GL-1985), Codex General Guidelines on Claims (CAC/GL 1979), Codex Standard for Vitamin and Mineral Food Supplements (CAC/GL 55-2005), Codex Guidelines on Formulated Complementary Foods for Older, Infant formula and formulas for special medical purposes intended for infants (CODEX STAN 72-1981, Standard for Labelling of Claims for Foods for Special Medical Purposes (CODEX STAN 181-1991), Formula Foods for Use in Very Low Energy Diets for Weight Reduction (CODEX STAN203-1995),General Standard for Bottled/Packaged Drinking Waters (CODEX STAN 227-2001), Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981).	The codex standards were used as the reference documents during the development of the corresponding Kenyan standards, which are adopted from the harmonized East African standards.	The objective of the regulations is to contribute to prevention of deceptive practices and protection of human health and safety by regulating the marketing/advertising or promotion of BMS products as well as donation and interaction of health workers with distributors/manufacturers among others. The standards do not address these aspects as recommended under the WHO International Code for marketing of breastmilk substitute to which Kenya has committed to implement in its entirety.
9. Manufacturing, sell, and expiry date:	To provide the justification for requiring products to have three dates on the label: a "manufacturing date, sell by date and an expiry date." The Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985	Kenya accepts to revise section 9 and requirement for two dates i.e. Manufacture date and Expiry date	Manufacturing date is used at the point of importation and this is very important for the country- the law requires that products have less than 75% expiry date during importation.

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
			Expiry date is for purposes of harmonization with internal laws; Cap 254 emphasizes expiry date for purposes of Food Safety and Hygiene.
10.Use of alternative containers from the original	Please clarify how Kenya will promote food safety and hygiene, prevent product contamination and adulteration, and prevent consumer misinformation by allowing re-packaging of these products in alternative containers? How will Kenya ensure that any re-packaging will remain consistent with international standards?	These provision allows for bulk importation and packaging in retail unit, a practice which is already happening	This provision will ensure continuity in business. Food quality and safety is assured through the implementation of existing national regulations and standards.
11.(1) Certificate of analysis:	Please confirm that this provision indicates routine monitoring and verification of product characteristics and does not indicate that each product must be accompanied by a certificate of analysis. Please clarify the frequency and method of inspection for products under the scope of this provision.	The certificate of analysis referred to in this section is issued after sampling and analysis by authorized officers. Note: It is not carried out by the manufacturers or distributors.	This is for purposes of routine monitoring. The government inspectors collect samples and send to government recognized analysts for analysis and issuance of certificate of analysis for decision making. The frequency is as need arises as guided by the existing routine monitoring and verification framework s for the country.
PART III – DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOODS			
13.2 Labelling of Donations	The United States recommends that Kenya eliminate the provisions of this proposed regulation pertaining to the "shelf life" of donated products. Has Kenya considered that these products are not packed just-in-time when donations are needed and how these proposed measures could impact response to an emergency necessitating the mass feeding of infants or young children?	This is important to ensure the products going to charitable homes do not have short expiry because they may keep them for long. This will also protect against dumping.	The expiry date requirement of 50% has been brought down from the normal 75% that applies for the other imported food products for general household use. This is also consistent with government policies on donated food products.
17.(1) Labeling of designated products and pre-packaged	Please provide the justification for requiring website, email address, and telephone number of the manufacturer, seller, and importer on the label. We note that Article 4.4 of the Codex General Standard for the Labelling of Pre-packaged	Kenya has accepted to amend this requirement to have: **name, physical address** and	Most of the BMS designated products are imported hence this information is required for traceability.

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
complementary food product:	Foods (CODEX STAN 1-1985 (Rev. 1-1991)) only requires the name and address of the manufacturer, seller, and importer.	**contacts** where contacts could be either be **website, email address or telephone)**	The requirements are also provided for in the existing national legislations.
18 Prohibition on Labeling:	The United States suggests using the language found in the Codex Standard for Infant Formula (Codex Stan 72-1981) which states that labels should not discourage breastfeeding nor contain pictures of infants and women, or any other picture which idealizes infant formula	Kenya considered the statement in the standards and found them not sufficient enough to underscore the importance of breast feeding and therefore not effective or appropriate to achieve Kenya's objective.	Based on Article 9.2 of the International Code of marketing of BMS, the government has developed this statement to emphasize on the superiority of breast feeding. This message is consistently communicated during promotion of breast feeding and has contributed to improvement in the rated of exclusive breast feeding from 31% in 2008/9 to 62 % in 2014.
19.(1) Labeling of infant formula and follow-up formula: The	United States supports using the specific language for infant formula found in Article 9.6.1(b) of the Codex Standard for Infant Formula and Formula for Special Medical Purposes for Infants: "Breast milk is the best food for your baby". The United States also suggests that Kenya include language that identifies which products should be given to infants in situations where human milk is not available.	**Same as 18 above**	Same as justification under 18 above in that the Codex language would not be effective or appropriate to achieve Kenya's objective.
21.(a) & (b): Labelling of formula in powdered form	The manufacturing and safe handling characteristics of specific products within the scope of this regulation can vary considerably. The United States suggests that Kenya include information about the health hazards of inappropriate preparation, storage and use, rather than requiring general statements on containers that indicate a product may be contaminated during the manufacturing process or during preparation. Such recommendations may conflict with product-specific instructions and thus inadvertently undermine safe use.	**Maintain clause**	Evidence shows that contamination of food including powder formula can happen at any level from manufacturing to transportation to handling and consumption. This aims to educate the consumers as provided for in article 46 (1) (b) of the Constitution of Kenya.

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
25.(1) (a) & (b) Particulars to be inscribed on container:	The United States notes its previous comments on Part II 9. on the use of expiration dates. Additionally, has Kenya considered whether the proposed warning statement on complementary foods may prevent them from being used appropriately? The United States notes that at about age 6 months, infants should be introduced to nutrient-dense, developmentally appropriate foods to complement human milk or infant formula feedings.	**Maintain clause**	The consideration of appropriate complementary feeding was considered and there are other guidelines and policies in the country addressing this to complement the regulations.
26.Warnings on nutrients:	The United States appreciates Kenya's desire to ensure that infants and young children receive nutrition appropriate to their stage of development. However, the proposed inclusion of warning statements on a broad range of fluid milk, cereal, and bottled water products could create significant barriers to trade in these products. The public consumes many of these products. Has Kenya considered whether the proposed statement may lead to consumer confusion and prevent their use even in appropriate contexts? Has Kenya considered whether the proposed warning statement would deter the use of bottled water products in the preparation of powdered breast milk substitutes in situations where they are needed as the sole source of potable water? If Kenya implements this requirement, we ask for clarification on: the exact scope of products subject to the requirement, if the requirement will apply to both domestically produced and imported products, and if any required statements were developed with consideration to the Codex General Standards for Bottled/Packaged Drinking Waters (CODEX STAN 227-2001) and Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981).	Kenya has considered this comments and taking into consideration '22' and '25' has decided to DELETE the entire clause 26 from the regulations	The intent is covered in other clauses of the regulations.
32. Cross-promotion:	Can Kenya explain the need for this provision? We note that in section Part IV 17.2 Kenya specifies, "the label of a designated product or prepackaged complementary food shall not refer to, promote or advertise any other	**Maintain clause**	Section Part IV 17.2 refers to the label of a designated product or complementary food promoting another designated product while 32 covers general cross promotion in the

Article in the BMS with comment	US submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification
	designated product". This appears to adequately cover the concept of cross-promotion.		context of designated products and complementary foods. The two types of cross promotion are of interest to Kenya based on the marketing methods in the country.
33.Advertisement:	Please clarify whether the restriction on promotion of sale or use would extend to the manufacturing companies' ability to use logos and trademarks on their websites.	**Maintain clause**	This is not a restriction on the use of the companies' logos and trademarks as stipulated in the Kenya Trade Marks Act.
PART VII – ENFORCEMENT			
40. Inspections:	Please clarify the frequency and method of inspection for products under the scope of this proposal that are imported into Kenya	Routine inspection for both imported and locally produced products is carried out in accordance with national legislations or based on complaints as the case may be.	This is a routine inspection for all designated products whether imported or locally manufactured. The inspection is done routinely for purposes of compliance to the BMS Act,2012

Responses to comments raised by the Governments of Switzerland

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
PART I – PRELIMINARY			
Interpretation **Cross promotion (2)**	Switzerland considers this definition should be removed as the term is currently not defined internationally and it is not aligned with the Codex discussions in the frame of the revision of the Codex Standard for follow-on formula. Indeed "Cross-promotion" was discussed at CODEX Committee for Nutrition and Foods for Special Dietary Uses	The term cross promotion is used as defined by WHO technical guidance documents. It is important in controlling unethical	Codex standards often follow national practice, not lead them. The consensus on the definition at the World Health Assembly is a prudent basis for Kenya's regulatory definition. Kenya will consider constructive suggestions to revise the proposed

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
	(CCNFSDU 41) in December 2019 and it has been concluded not to use the term "Cross-promotion" to avoid confusion.	promotions & advertising	definition provided they do not propose to abandon the regulatory objective.
Objects (4)	Switzerland notes the information provided in this paragraph undermines the legitimacy of breast milk substitutes and is not scientifically founded nor in line with international standards, including the WHO International Code of Marketing of Breast-Milk Substitutes. When mothers are unable to breastfeed or choose not to, a safe and nutritious alternative is required. In this context, scientifically developed breast-milk substitutes are the only recognized and proven alternative to breastmilk for infants as acknowledged by the WHO International Code of Marketing of Breast-Milk Substitutes. In its introduction, the WHO Code acknowledges that "there is legitimate market for infant formula [...] these products should accordingly, be made accessible to those who need them [...]". Switzerland recommends a revision of this paragraph according to the objective to protect and promote breastfeeding and not undermining breast milk substitutes.	**Maintain the paragraph**	Section 4 does not prohibit the sale of breast-milk substitutes, it only prohibits the promotion of these products and prohibits their sale if they fail to meet labelling, compositional, and other related requirements. This provision is consistent with WHO guidance, generally, and, in particular, World Health Assembly (WHA) resolution of 2016 that calls on countries to implement the WHO *Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children* to further protect breastfeeding, prevent obesity and chronic disease, and promote a healthy diet. In addition, the guidance aims to ensure that caregivers receive clear and accurate information on feeding. WHO developed the guidance as a response to a growing body of evidence that shows that the promotion of BMS and some commercial foods for infants and young children undermines progress on optimal infant and young child feeding.
Manufacturing, sell, and expiry date (9)	Having these three dates on the same products will increase the misunderstanding and misuse of date marking. A clear and unique date marking would be better understood by the consumer and could reduce food waste.	Kenya accepts to revise section 9 and requirement for two dates i.e.	Manufacturing date is used at the point of importation and this is very important for the country; the law requires that products have at least

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
		Manufacture date and Expiry date	75% of time remaining before the expiry date at the time of importation. Expiry date is for purposes of harmonization with internal laws; *Food, Drugs and Chemical Substances Act, Cap 254* requires the reporting the expiry date for purposes of food safety and hygiene by the consumer.
Use of alternative containers from the original (10)	Switzerland considers this practice should not be allowed from a safety perspective, due to the risk of re-contamination, risk of adulteration, losing product integrity and proper information. In case the Codex General Principles of Food Hygiene (CXC 1-1969) is not followed, such a practice could affect the health of the infant and young children. Moreover, the use of alternative containers raises questions over responsibility aspect as well as accountability if the person who put the product in the alternative container does not represent the Food Business Operator of the original product.	This provision allows for bulk importation and packaging in retail unit, a practice which is already happening	This provision will ensure continuity in business. Food quality and safety is assured through the implementation of existing national regulations and standards.
PART III – DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOODS			
Restrictions on Donations (13.2)	Switzerland believes that there should not be a prescribed period of shelf life before expiration for donation as this would be restrictive and not viable to be implemented. It needs to be noted that the products within the scope of the regulation should generally provide for a "Best- Before Date" or "Best Quality-Before Date" in accordance with (ii) the respective Codex Standard above (Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)). Such products should do not have any 'expiry date' and it would be difficult to define what 50% of the expiry date are. This requirement may result in addition in an increase in food waste which is not in line with Sustainable Development Goal Target 12.3 which seeks to halve global food waste at retail and consumer levels by 2030.	This is important to ensure the products going to charitable homes do not have short expiry because they may keep them for long. This will also protect against dumping.	The expiry date requirement of 50% has been brought down from the normal 75% that applies for the other imported food products for general household use. This is also consistent with government policies on donated food products.

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
	Switzerland also notes that considering that the current draft Regulation proposed by Kenya is not aligned with international standards, products will not be able to meet "both Kenyan and applicable International Standards".		
Labeling of designated products and pre-packaged complementary food product (17.1)	This requirement goes beyond what is indicated in the Codex General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), which requires in its point 4.4 only 'The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food' to be declared. Switzerland considers that this text should be aligned with Codex requirements.	Kenya has considered this comment and decided to amend this requirement to have: **name, physical address** and **contacts** where contacts could be either be **website, email address or telephone)**	Most of the BMS designated products are imported hence this information is required for traceability.
Prohibition on Labeling (18)	Switzerland notes that this requirement goes beyond what is indicated in the Codex Standard for Infant Formula (CXS 72-1981), which already states that labels should not discourage breastfeeding and does not allow pictures of infants and woman nor any other picture or text which idealizes the use of infant formula. Therefore, the proposed provision should be redrafted accordingly in order to be aligned with the Codex Standard for Infant Formula (CXS 72-1981). Graphic representation for easy identification of the products and for illustrating methods of preparation should be permitted. For mothers who cannot or choose not to breastfeed, infant formula is the only suitable breast milk substitute recognized as appropriate by the WHO.	Kenya considered the statement in the standards and found them not sufficient enough to underscore the importance of breast feeding and therefore not effective or appropriate to achieve Kenya's objective.	Based on Article 9.2 of the *International Code of Marketing of Breast-milk Substitute*, the government has developed this statement to emphasize on the superiority of breast feeding. This message is consistently communicated during promotion of breast feeding and has contributed to improvement in the rated of exclusive breast feeding from 31% in 2008/9 to 62 % in 2014. Switzerland did not identify any use of images that are not used for promotional purposes and the use of which would not interfere with providing mandatory information on labels. The use of company logos,

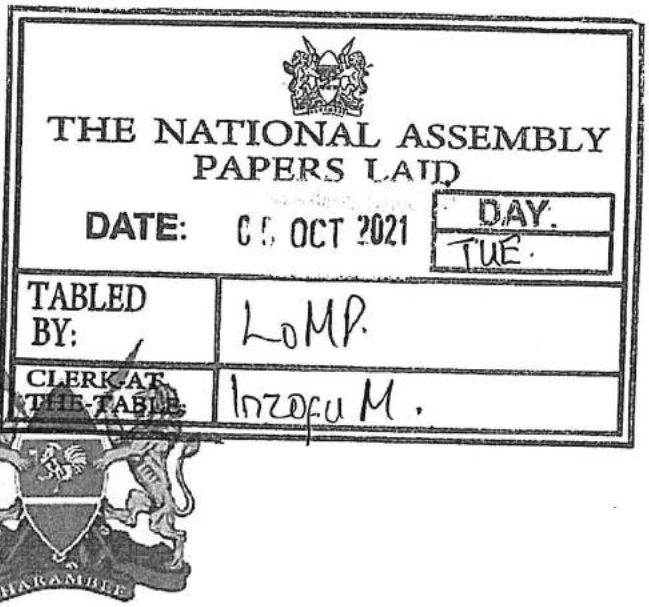
Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
			provided they do not idealize artificial breast-milk substitutes may be used.
Labeling of infant formula and follow-up formula (19.1)	Switzerland notes that the draft provisions established by this article are not aligned with the labelling requirements established by Codex Standard for Infant Formula (CXS 72-1981) and the Codex Standard for Follow-up formula (CXS 156-1987), including the draft version currently under discussion/revision by CCNFSDU.	**Kenya proposed to retain section 19.(1)**	Same as justification under 18 above and the overview above the table in that Codex language would not be effective or appropriate to achieve Kenya's objective.
Labelling of formula in powdered form (21(a) (b))	This labelling requirement could arouse fears in consumers and will go against the general principles of labelling standards in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) that says: "3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect." Switzerland suggest that this part should be replaced by a piece of information calling to follow carefully instructions of use, as otherwise improper preparation can make the baby ill. With regard to point b) on formula preparation, bottle preparation and instructions for use should refer to the Code of Hygienic practice developed and adopted by Codex (Code of Hygienic Practice for powdered formulae for infants and young children (CXG 66-2008)) which provides for a range of risk management options in preparation and handling of bottles including alternatives to the 70°C recommended by WHO in 2008, and to CXS 72-1981 and CXS 156-1987. In addition, such details, in principle, should fall under national standards rather than a national code.	**Maintain clause**	Evidence shows that contamination of food including powder formula can happen at any level from manufacturing to transportation to handling and consumption. This aims to educate the consumers as provided for in article 46 (1) (b) of the Constitution of Kenya. This risk is widely recognized in the scientific literature, but it has not been brought to the attention of Kenyan consumers. The labelling instructions are for the benefit of consumers who do not have laboratory equipment or expertise to judge the microbiological equivalence of alternative risk management approaches not the equipment to sustain them.
PART V: INTERACTIONS BETWEEN MANUFACTURERS, DISTRIBUTORS AND HEALTH WORKERS			
Cross-promotion (32)	Industry should enable parents and caregivers to easily rely on the same family of products as the child grows. Expert use of text, images and colors should support the goal of providing	**Maintain clause**	The intend of this section is to restrict promotion of designated products through products outside the scope of

Article in the BMS	Switzerland comments/proposals	Kenya's Response	Justification
	distinctly labelled products, specifically to avoid the risk of consumer confusion between infant formula, Follow Up Formula, and Food for Special Medical Purposes ("FSMP"). Adding to strict restrictions may lead to consumer confusion in identifying safe, legitimate, nutritious products for young children. It could have the unintended consequence of depriving mothers and caregivers of the necessary information to make appropriate nutrition decisions for their young children. Switzerland considers that the adoption of such restrictions are incompatible with the established rules for international trade and could result in trade impediments. Such restrictions would be considered more trade restrictive than necessary to meet the legitimate objective of protecting human health and increase breastfeeding rates (contrary to Article 2.2 of the TBT Agreement).		designated products such as complementary foods. The suitable age of for consumption of the product meets the objective of reducing consumer confusion. Linking one product to another using, symbols, colour-coding or other means serves a prohibited promotional objective.

Responses to comments raised by KAM/WBAK/CMA

Article in the BMS with comment	KAM/WBAK/CMA submitted comment on WTO Notified Draft regulations	Kenya's Response	Justification	Article in the BMS with comment
26.Warnings on nutrients:	A person shall not offer for sale or sell fluid milk, cereal and its products or bottled water, unless the container and the label affixed thereto, contains the following words expressed in English and Kiswahili language in bold and conspicuous characters in a prominent position and in not less than fifty percent (50%) of the size of the largest words on the label and not less than 3mm in height based on the lower case "o" in red lettering on white background preceded by the word "WARNING" in capital letters:	Delete proposed provisions of regulation 26 on warning nutrients requiring warnings on bottled water, grain-based porridge, and other fluid and solid foods should not be used as breast milk substitutes	Kenya has considered this comments and taking into consideration and accepted to Delete the entire clause 26 from the regulations	The intent is covered in other clauses of the regulations.

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



MINISTRY OF HEALTH

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

AUGUST, 2021

Contents

FOREWORD

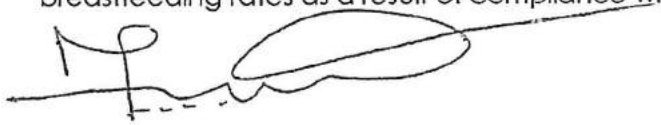
Kenya was the first government to vote in favor of World Health Assembly Resolution (WHA34.22) adopting the International Code of Marketing of Breast Milk Substitutes (the "WHO Code") at the May 2-22, 1981 Assembly meeting in Geneva. The adoption of the WHO Code was informed by the significant contribution of breastfeeding to combating infant malnutrition, morbidity, mortality, and the realization that advertising and promotion of breast-milk substitutes undermine breastfeeding.

Subsequently, governments are called upon to undertake reform to their respective social and legislative frameworks and their overall development objectives to give effect to the principles and purpose of the Code, including the enactment of legislation, regulations and other suitable measures.

The Kenyan Parliament enacted the Breast Milk Substitutes (Regulation and Control) Act in 2012 to give effect to the Code by providing for the appropriate marketing and distribution of breast milk substitutes; safe and adequate nutrition for infants through the promotion of breastfeeding and proper use of breast-milk substitutes. Section 28 (1) of the Act provides that the Cabinet Secretary may, in consultation with the National Committee on Infant and Young Child Feeding make Regulations generally for the better carrying out of the objects of the Act.

The Ministry therefore conducted this Regulatory Impact Assessment on the proposed Breast Milk Substitutes (Regulations and Control) (General) Regulations, 2021 to examine and measure the economic, social and environmental costs and benefits of the Regulations.

The Regulatory Impact Assessment concludes that the proposed Regulations are necessary due to the significant public health benefits of reducing childhood illnesses and deaths in addition to potential net economic benefits resulting from reductions in lifelong chronic diseases expected from increased breastfeeding rates as a result of compliance with the Regulations.



HON MUTAHI KAGWE, EGH
CABINET SECRETARY

ACKNOWLEDGEMENTS

The development of the Regulatory Impact Assessment (RIA) statement on the proposed Breast Milk Substitutes (Regulation and Control) (General) Regulations was a widely consultative process that was coordinated by the Department of Family Health through the Division of Nutrition and Dietetics in the Ministry of Health (MOH).

Special acknowledgement is given to the following members of legal team for providing the legal expertise as well as guiding the impact assessment process and the drafting of the Regulatory impact assessment report: Bernard Kuria and Terry Rotich of Ministry of Health, Annette Omwoyo and Irene Kabua of the Kenya Law Reform Commission, Maurice Nzuki of the Competition Authority of Kenya and Bill Jeffrey, UNICEF legal consultant.

We acknowledge with gratitude the following technical experts for their invaluable contribution in the drafting and refinement of the technical sections on infant and young child nutrition of this assessment report: Dr. Bashir Issak, Veronica Kirogo Rose Wambu and Sahara Ali from MOH; Dr. Martin C. Joseph from World Health Organization, Kenya; Patrick Codjia and Laura Kiige of UNCEF, Kenya; Prof. Ruth Nduati from the Department of Pediatrics at the University of Nairobi; Peter Mutua from the Kenya Bureau of Standards; and Mary Kimani from Action against Hunger, Kenya.

Finally, we would like also to express our deep appreciation to UNICEF and WHO for the financial and technical support accorded throughout the process in the development of this assessment report.

Susan Mochache, CBS
PRINCIPAL SECRETARY

LIST OF ACRONYMS

AU	Africa Union
BMS	Breast Milk Substitutes
CBS	Central Bureau of Statistics
EBF	Exclusive Breastfeeding
FBO	Food Business Operators
FSN	Food Security and Nutrition
GDP	Gross Domestic Product
GNR	Global Nutrition Report
IYCF	Infant and Young Child Feeding
IYCN	Infant and Young Child Nutrition
KDHS	Kenya Demographic and Health Survey
KNDP	Kenya National Develop Plan
MOH	Ministry of Health
MOH	Ministry of Health
NCIYCF	National Committee on Infant Young Child Feeding
RIA	Regulatory Impact Assessment
SDG	Sustainable Development Goals
TBT	Technical Barriers Trade
UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

Kenya acknowledges the importance of and commits to the principles of the International Code of Marketing of Breast-Milk Substitutes adopted on 21st May 1981 (the "WHO Code") and the subsequent relevant resolutions of the World Health Assembly ("WHA").

Kenya has always advocated the importance of safe and adequate nutrition for infants by supporting and encouraging breast-feeding as the best start in life. Kenya aims to provide support for each stage of an infant's development. This includes nutritional guidance through education and counseling services as well as high quality and nutritious age appropriate foods.

The Ministry of Health has a key role to play in both promoting and initiating change, including the area of responsible and ethical marketing practices towards mothers, caregivers, and health workers with regards to the use of Breast Milk Substitutes and designated products. This Regulatory Impact Assessment (RIA) has been prepared by the Ministry of Health for the proposed Breast Milk Substitutes (Regulation and Control) (General) Regulations, 2021 pursuant to Section 6 and 7 of the Statutory Instruments Act (No. 23 of 2013).

This Regulatory Impact Assessment (RIA) is a policy tool whose purpose is to examine and measure the likely benefits, costs, and effects of the proposed Breast Milk Substitutes (Regulation and Control) (General) Regulations.

The RIA takes note of the COVID-19 pandemic, which has prompted promulgation of numerous health protocols prohibiting holding of public meetings and keeping social distance. These measures have influenced the methodology adopted for undertaking public consultations.

Finally, the RIA concludes that Breast Milk Substitutes (Regulations and Control) (General) Regulations, 2021 is necessary for Kenya.

1.1 Introduction

The first two years of life provide a critical window of opportunity for ensuring children's appropriate growth and development through optimal feeding especially since this is the period of greatest brain development and deficits at this stage have a life-time adverse effect (World Bank 2006). Optimal Infant and Young Child Feeding (IYCF) refers to early initiation to breastfeeding within one hour of birth, exclusive breastfeeding for the first six months of life and introduction to nutritionally adequate and safe complementary foods at six months with continued breastfeeding up to two years of age or beyond (WHO and UNICEF 2003).

Optimal IYCF improves the survival, health and development of all children and contributes to human capital development. Global evidence shows that universal coverage of optimal breastfeeding and appropriate complementary feeding practices, would prevent 13% and an additional 6% of deaths among children less than five years of age respectively(Jones et al. 2003). An exclusively breastfed child is 14 times less likely to die in the first six months than a non-breastfed child (Azeze et al. 2019). Nearly half of diarrhea episodes and a third of respiratory infections would be avoided through optimal breastfeeding.

Nearly all mothers are physically able to breastfeed and will do so if they have accurate information and support. Inappropriate and aggressive marketing of breast milk substitutes (BMS) and other designated products is known to undermine optimal IYCF practices(Ching et al. 2021), hence the need for regulation and financial investments to protect, promote, and support optimal IYCF to realize its full benefits.

Recognizing that optimal IYCF is an important aspect of primary health care to address infant and young child malnutrition, morbidity and mortality, and that improper practices in the marketing of breast milk substitutes (BMS) and designated products can contribute to major public health problems, the World

Health Assembly adopted the International Code of Marketing of Breast milk Substitutes in 1981(WHO 1981). Kenya subsequently enacted the Breast Milk Substitutes (Regulation and Control) Act in 2012. The Act provides for appropriate marketing and distribution of breast milk substitutes. The Act also requires the Cabinet Secretary to make Regulations to give effect to certain sections of the Act.

The Ministry of Health pursuant to the Constitution, Public Health Act, Cap 242, and the Health Act No. 21 of 2017 is mandated to protect, respect and promote the health rights of all persons in Kenya. The Constitution of Kenya guarantees every person the right to be free from hunger and to have adequate food of acceptable quality as stipulated under Articles 43 (1c) and 53 (1c). Kenya's long-term development blueprint, Kenya Vision 2030, focuses on creating a globally competitive and prosperous nation with a high quality of life by 2030. In particular, the social pillar focuses on shifting from curative to preventive and promotive healthcare in lowering the disease burden. This is in recognition that good health and nutrition boosts the human capacity to be productive. The government commitment to providing a high quality of life to all its citizens as affirmed by the declaration of H.E President Uhuru Kenyatta's Big Four Agenda in 2017 in which universal health coverage (UHC), food and nutrition security by the year 2022 is prioritized. In this case, the only recommended way of meeting food and nutrition security for infants under 6 months is through promotion, protection, and support of breastfeeding.

The Kenya Health Policy 2014-2030 identified child malnutrition, sub-optimal breastfeeding and poor infant and young child feeding practices as major risk factors and contributors to disease and death. Therefore, protection, promotion and support of optimal infant and young child feeding is a priority high impact nutrition intervention in preventive and promotive health care.

1.2 The Regulation - Making Authority

The regulation- making authority in the Ministry of Health is conferred upon the Cabinet Secretary. The Cabinet Secretary has the responsibility of implementing the Breast Milk Substitutes Act, 2012, in collaboration with the National Committee on Infant and Young Child Feeding.

Section 28 (1) of the Breast Milk Substitutes (Regulation and Control) Act, 2012 provides that the Cabinet Secretary may, in consultation with the Committee, make Regulations generally for the better carrying out of the objects of the Act, and in particular, for prescribing-

a) the wording, size and manner of notices, warnings and information required under section 9;

b) the procedures and requirements under which informational or educational material may be approved under section 10(3); and

c) any other thing that is required by this Act to be prescribed.

In exercise of the above powers, the Ministry of Health has drafted the Breast Milk Substitutes Regulations, 2021. This is a statutory instrument which seeks to give full effect to the Breast Milk Substitutes (Regulation and Control) Act, 2012.

The Ministry now therefore prepares this RIA and undertakes public consultations in partial fulfillment of the requirements of the Statutory Instruments Act.

1.3 Requirements of the Statutory Instruments Act

The Statutory Instruments Act, No. 23 of 2013 is the legal framework governing the conduct of RIA in Kenya. Sections 6 and 7 require that 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 Act further sets out key elements that must be contained in the RIA namely:

(a) a statement of the objectives of the proposed legislation and the reasons;

(b) a statement explaining the effect of the proposed legislation;

(c) a statement of other practicable means of achieving those objectives, including other regulatory as well as non-regulatory options;

(d) an assessment of the costs and benefits of the proposed statutory rule and of any other practicable means of achieving the same objectives; and

(e) the reasons why the other means are not appropriate.

Section 5 of the Act requires a regulation-making authority to conduct public consultations drawing on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument and ensuring that persons likely to be affected by the proposed statutory instrument are given an adequate opportunity to comment on its proposed content.

1.4 Methodology

This regulatory impact assessment involved an analysis of Kenya's laws, regulations, policies, and plans related to BMS measures. The results and findings of this assessment can be used as a basis for identifying potential gaps, ambiguities, or opportunities for improving the regulatory framework for BMS in Kenya.

This assessment was performed between January and March 2021. In terms of methodology, the following steps were undertaken:

1.4.1 Document analysis

A collection and analysis of relevant documentation was performed, among other tasks, to obtain preliminary information on the regulation of BMS and other designated products in Kenya.

The main data sources were official country reports such as progress reports, national government assessments, national human development reports and databases (FAOSTAT, UNDP, World Bank), as well as national statistics services and other relevant national documentation in particular, policy documents and official public information provided by national authorities and other relevant stakeholders.

1.4.2 Consultation with relevant stakeholders

Using preliminary results from data and information collected, specific issues were identified. Then relevant stakeholders were surveyed on those issues, using round table discussions. In addition, this process included consultations with civil society organizations, in the context of the Regional Network for IYCF in Kenya.

1.5 Purposes and Objectives of the Proposed Regulations

The purposes and objects of the proposed Regulations are to give full effect to the Breast Milk Substitutes (Regulation and Control) Act, 2012. Particularly, the Regulations seek to:

1. reduce preventable infant and young child illnesses and deaths through protection, promotion and support of optimal breastfeeding and complementary feeding and proper use of breast milk substitutes where necessary;
2. promote and protect the best interests of an infant and young child in the following ways:

a) initiation of breastfeeding of the infant done within an hour of birth and promotion, protection and support of exclusive breastfeeding for the first six months of life;
b) timely introduction of appropriate, nutritionally adequate and safe complementary food with continued breastfeeding for a period of twenty-four (24) months or beyond;
c) where necessary, breast milk substitutes and prepackaged complementary food shall be safe for the consumption by an infant or young child; and
d) adequate and accurate information on breastfeeding and infant and young child feeding shall be available to the general public.

3. Guide the ethical interaction of manufacturers with health workers, the manner in which donations are used or received, demonstration on use, development of informational and educational communication materials and labeling of BMS and other designated products.

1.6 Salient Features of the of the Proposed Regulations

The Regulations guides all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons are informed that breast milk substitutes undermine breastfeeding and that suboptimal breastfeeding is a leading but preventable cause of death and serious illnesses in infants and young children.

The Regulations prescribe the manner of conduct in the following areas as required by the Breast Milk Substitutes (Regulation and Control) Act, 2012:

i. donations;
ii. labelling;
iii. interaction between health workers and manufacturers/distributors;

iv. cross-promotion;
v. advertising;
vi. demonstrations on the use of designated products;
vii. publication of Information, education and communication materials; and
viii. penalties for failure to adhere to the Breast Milk Substitutes (Regulation and Control) Act and its Regulations.

2.0 BACKGROUND AND CONTEXT

2.1 Global Context

The International Code of Marketing of Breast Milk Substitutes (The WHO Code) is an international health policy framework for promoting, protecting, and supporting breastfeeding adopted by the World Health Assembly (WHA) of the World Health Organization (WHO) in 1981. The WHO Code was developed as a global public health strategy to mitigate an exponential increase in mortality, malnutrition and other diseases in very young infants in the developing world associated with aggressive marketing of BMS and designated products. It recommends restrictions on the marketing of breast milk substitutes, such as infant formula, to ensure that mothers are not discouraged from breastfeeding.

The WHO Code also recommends regulating ethical interactions between manufacturers and distributors with the health systems, the marketing of designated products such as feeding bottles, teats and pacifiers and to prohibit any advertising of BMS including the giving of any gifts given to mothers or inducement of health workers. The WHO Code represents the "*bare minimum*" in international legislative terms concerned with matters of IYCF worldwide. Other recognized international commitments supporting optimal IYCF include:

i. 1995 United Nations Convention on the Rights of the Child (Article 24) which emphasizes the need to diminish infant and child mortality and

ensure that parents are supported in the use of basic knowledge of child health, nutrition and the advantages of breastfeeding;

ii. UNICEF/WHO Global Strategy for Infant and Young Child Feeding adopted by the World Health Assembly in 2002;

iii. 19 subsequent relevant resolutions of the World Health Assembly;

iv. Innocenti Declaration of 1990 on the Protection, Promotion and Support of Breastfeeding; and

v. Innocenti Declaration of 2005 on Infant and Young Child Feeding.

Unsurprisingly, health systems in many countries continue to be used as major conduits for promoting products falling under the scope of the WHO Code (WHO 2017). Key target audiences, such as pregnant women and mothers of infants as well as their family members, can easily be reached. Numerous medical publications highlight that BMS-related feeding is responsible for 13% of child mortality and 10% of child disease(Jones et al. 2003) while failure to breastfeed increases the risk of gastrointestinal disease, acute otitis media and acute lower respiratory tract infection in infancy·

To reduce child mortality, WHO and UNICEF recommend, among other actions, exclusive breastfeeding (EBF) during the first six months of life. EBF reduces the risk of infant morbidity, hospitalization, and mortality (Sankar et al. 2015). The benefits of breastfeeding to the child extend well beyond the breastfeeding period and include a lower risk of obesity (Horta, Loret De Mola, and Victora 2015), asthma (Lodge et al. 2015), malocclusion (Peres et al. 2015) and an increased intelligence quotient (IQ)(Horta, Loret De Mola, and Victora 2015). Moreover, breastfeeding mothers have a lower risk of breast cancer, ovarian cancer, type II diabetes, and postpartum depression (Chowdhury et al. 2015) The total global economic losses attributed to not breastfeeding are estimated

to be USD341.3 billion, or 0.70% of global gross national income (Walters, Phan, and Mathisen 2019).

Despite these proven benefits of breastfeeding, globally, only 41% of infants younger than 6 months are exclusively breastfed (UNICEF &WHO 2019)· In Kenya, the prevalence of EBF among children aged 0-6 months was slightly higher at 61% in 2014(Kenya National Bureau of Statistics and ICF Macro 2015) although the proportion of babies who are exclusively breastfed until the sixth months may be as low as 30%. A cost–benefit analysis conducted in Kenya by UNICEF, the World Bank and Ministry of Health in 2016 reported that every USD1 invested in scaling up breastfeeding has a potential return of USD 13. Overall high impact nutrition interventions would return USD 22 for every USD 1 invested, higher than the global estimates of USD16–18 (Eberwein et al. 2016).

2.2 Domestic Context

The Parliament of Kenya enacted the Breast Milk Substitutes (Regulation and Control) Act in 2012 and in doing so committed to adopting recommendations put forward in the WHO Code. Despite Kenya enacting the BMS Act, there are activities that have continued to undermine the efforts to improve breastfeeding rates. Inappropriate BMS marketing tactics have taken the form of direct promotion to consumers through to health professionals and systems, and to policymakers among others.

Sub-optimal breastfeeding and poor IYCF practices continue to contribute to the high rates of child under nutrition. According to the Kenya Cost of Hunger Study, 2019 spearheaded by the National Treasury and Planning, the country is estimated to have lost KES 373.9B in 2014 (6.9 % of GDP) through health, education and productivity related costs due to child under nutrition (Central Bureau of Statistics (CBS) [Kenya], Ministry of Health (MOH) [Kenya] 2019).

In order to fully realize the objects of the BMS Act in addressing the challenges of child malnutrition, certain sections in the Act require regulations to become enforceable. Section 28 of the Act mandates the Cabinet Secretary-Health to make regulations on among other things, ethical interactions with health workers, donations, demonstrations on the use of BMS and designated products, development of informational and educational materials and labelling of BMS and other designated products.

2.3 Policy and Legal Context

The Twenty-seventh World Health Assembly, in 1974, noted the general decline in breast-feeding in many parts of the world was due to socio-cultural and other factors including the promotion of manufactured breast-milk substitutes, and urged "Member countries to review sales promotion activities on baby foods to introduce appropriate remedial measures, including advertisement codes and legislation where necessary." The issue was taken up again by the Thirty-first World Health Assembly in May 1978. Among its recommendations were that Member States should give priority to preventing malnutrition in infants and young children by, among other things supporting and promoting breast-feeding, taking legislative and social action to facilitate breast-feeding by working mothers, and regulating inappropriate sales promotion of infant foods that can be used to replace breast milk. Interest in the problems connected with infant and young child feeding and emphasis on the importance of breast-feeding in helping to overcome them have, of course, extended well beyond WHO and UNICEF. Governments, non-governmental organizations, professional associations, scientists, and manufacturers of infant foods have also called for action to be taken on a world scale as one step towards improving the health of infants and young children.

2.4 Legal and Policy Framework for Breast Milk Substitutes and Designated Products in Kenya

The following analysis illustrates the legal and policy framework within which the Breast Milk substitutes (Regulation and Control) (General) Regulations, 2021 are being developed.

Policies and laws	**Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations**
The Constitution of Kenya, 2010	The Constitution of Kenya, 2010 guarantees every person the right to: • the highest attainable standard of health (Article 43(1)(a)); • protection of their health, safety and economic interests (Article 46 (1) (c)); • to be free from hunger, and to have adequate food of acceptable quality (Article 43(1)(c)); • basic nutrition, shelter and health care (Article 53 (1) (c)) and to parental care and protection for every child (Article 53 (1) (e)); • the information necessary for consumers to gain full benefit from goods and services (Article 46 (1) (b)).

Policies and laws	**Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations**
The Breast Milk Substitutes (Regulation and Control) Act No. 34 of 2012	An Act of Parliament to provide for the: i. appropriate marketing and distribution of breast milk substitutes; ii. manner of advertising and promotion of breast milk substitutes to ensure safe and adequate nutrition for infants through the promotion of breastfeeding and proper use of breast milk substitutes; iii. prohibits displays to the public, material which refers directly or indirectly to a designated or complementary food product; and iv. prohibits promoting designated or complementary food product by use of sale devices such as special discounts, special displays to promote sales, competitions with prizes, tie-in sales, provision of premiums and rebates, discount coupons, loss leaders, giving of gifts and free samples to mothers.
The Public Health Act, Cap 242	An Act of Parliament that seeks to: i. prevent and guard against the introduction of infectious disease into Kenya from outside; ii. promote the public health and the prevention, limitation or suppression of infectious, communicable or preventable diseases within Kenya;

Policies and laws	**Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations**
	iii. advise and direct local authorities in regard to matters affecting public health; iv. promote or carry out researches and investigations in connection with the prevention or treatment of human diseases; and v. prepare and publish reports and statistical or other information relative to the public health.
The Health Act No. 21 of 2017	The Act provides under section 71 (3) that all employers shall take strict measures to prevent any direct or indirect form of promotion, marketing and or selling of infant formula and or breast substitutes within the lactation stations and seeks to protect, respect, promote and fulfill the rights of children to basic nutrition and health care services contemplated in Articles 43(1) (c) and 53(1) (c) of the Constitution.
The Kenya Health Policy (KHP), 2014-2030	KHP envisages as its goal the attainment of the highest possible level of health and well-being for Kenyans at all ages, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face financial hardship as a consequence. This would be achieved through increasing access, improving quality and lowering the cost of healthcare delivery. It identified suboptimal breastfeeding as one on the

Policies and laws	**Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations**
	leading risk factors to morbidity and mortality. Increasing breastfeeding worldwide to optimal levels (at least 90% exclusive breastfeeding to six months) would prevent more than 823,000 child deaths globally each year, particularly those associated with diarrhea and pneumonia.
National Food and Nutrition Security Policy (FNSP), 2012	It is the policy of the Government that all Kenyans throughout their life cycle enjoy at all times safe food and water in sufficient quantity and quality to satisfy their nutritional needs for optimal health. The broad objectives of the FNSP are to: achieve adequate nutrition for optimum health of all Kenyans; increase the quantity and quality of food available, accessible, safe and affordable to all Kenyans at all times; and protect vulnerable populations using innovative and cost-effective safety nets linked to long-term development. The FNSP proposes a life cycle approach to improve not only infant feeding but also maternal and newborn, early childhood and survival, late childhood, adolescent, adult and older person's nutrition.
Kenya Nutrition Action Plan (2018-2022)	KNAP is an evidence-based multi-sectoral five-year strategic action plan that seeks to address malnutrition in Kenya in all its forms and for all ages. It is aligned to

Policies and laws	**Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations**
	FNSP and KHP taking into account commitments of the Kenya Vision 2030, implemented in five-year midterm plans and the Big Four Agenda, together with the overall global health and nutrition agenda and within the framework of the Constitution and legislation. The plan applies a life cycle approach and promotes cross-sectoral collaboration to address the social determinants of malnutrition sustainably. The overall expected result of the KNAP is Kenyans achieving optimal nutrition for a healthier and better-quality life and improved productivity for the country's accelerated social and economic growth. The theory of change was used to develop a set of key result areas to ensure certain inputs, activities are in place and implemented through different sectors which have committed contribute to improved nutritional status of all Kenyans. The KNAP has nineteen key result areas (KRAs), nine of the KRAs are very specific to health issues and address the immediate causes of malnutrition with emphasis on maternal infant and young child nutrition, five of the KRAs address nutrition sensitive issues i.e., the underlying causes of malnutrition while the other five pertains to fostering an enabling environment.
Maternal Infant and Young Child Policy	The Policy provides for the nutrition of the mother during pregnancy and lactation, newborn and early childhood (up to five years). It also includes a focus on

Policies and laws	**Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations**
	nutrition during difficult circumstances; including in the context of HIV and AIDS, low birth weight, children with special medical conditions, malnourished children, children in institutional care and infants and young children in emergency situations, and emerging focus on adolescence and childhood obesity. The policy integrates issues covered in the WHO Code and subsequent relevant WHA Resolutions, key child survival strategies and responsibilities of decision makers and health care personnel implementing maternal, child health and nutrition programmes at national, county, district, facility and community levels. The policy also identifies actions that should be taken to strengthen the capacity of health care services, communities and stakeholders to ensure that the nutritional needs of pregnant and lactating mothers, infants and young children are met.
National Programs Supporting Infant and Young Child Feeding	The Ministry of Health through the department of Family Health ensures maternal infant and young child feeding interventions are actualized through an integrated approach and existing coordination structures in the undermentioned; Division of Nutrition and Dietetics, Division of Neonatal and Child Health, Division of Reproductive and Maternal Health, and Division of Adolescent and School Health. The Division of Nutrition

Policies and laws	Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations
	and Dietetics is responsible for coordination of nutrition interventions in line with global and country strategies. Some of the key interventions include: a) Baby Friendly Hospital Initiative (BFHI); b) Baby Friendly Community Initiative (BFCI); c) Antenatal Care; d) Growth Monitoring and Promotion; e) Integrated Management of Acute Malnutrition; f) Vitamin A Supplementation; g) Iron and folic acid supplementation; h) Micronutrient deficiency prevention and control; i) Food fortification; j) Integrated Management of Childhood Illnesses; k) Prevention of Mother-to-Child Transmission of HIV; l) Kenya Expanded Programme on Immunization; m) Community Health Strategy; n) World Breastfeeding Week; o) Malezi Bora weeks; p) Deworming; q) School Health and School Feeding Programme; and r) Water, sanitation and hygiene.

2.5 Overview of the Proposed Regulatory Instrument.

The proposed statutory instrument which is the subject of this analysis is the proposed the Breast Milk Substitutes (Regulation and Control) (General) Regulations, 2021.

i. Purpose of the Regulations

The Regulations aim to:

(a) guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons are informed 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;

(b) prohibit marketing activities such as cross-promotions and informational inserts; and

(c) establish rules to restrict promotional marketing of BMS and designated products, donations, labelling and establish requirements for Informational and educational materials and activities.

The Regulations prescribe the manner of conduct in the following areas as required by the BMS Act, 2012:

i. Donations;

During emergencies there are often donations of breast milk substitutes. Frequently these come from organizations and individuals who are reacting to the perceived rather than actual need and misguidedly believe that they are helping infants and young children. They may also come from the infant feeding industry who may view the emergency as an 'opportunity' to enter into or strengthen markets or as a public relations exercise.

Unfortunately there are many problems with these donations as follows:

I. they often violate the International Code of Marketing of Breast-milk Substitutes (the Code);
II. sometimes they may be past or near their expiry date;
III. the donations may be inappropriate for the needs or be unrecognizable because they are labelled in a foreign language; or
IV. they may have been sent in unwanted quantities.

Donations of BMS can lead to breastfeeding being undermined and an increase in morbidity and mortality. It should be noted that the effect of the donations lasts much longer than the emergency thereby undermining breastfeeding which leads to increased infant morbidity and mortality for years to come. The regulations prescribe the manner in which donations of BMS will be undertaken and how the committee will receive donations.

ii. Labelling

To ensure that BMS and designated products provide actual and truthful information, labelling requirements are provided for under the regulations. This is to ensure informed consumer choice. The users of BMS and designated products should be informed of the nutritional content of food at the time of purchase through easy-to-understand nutrition labels.

A food label should include key facts, such as the content and values of key ingredients in line with country standards, as well as the manufacturing and expiry date. Food labels should make reasonable claims about the characteristics of the food, or its intended effect on the body. The regulations prescribe font size to enable legibility and effective communication.

iii. Interactions between health workers and manufacturers/distributors;

The Regulations seek to clarify the minimum standards of behavior that are expected from the BMS and designated products industry players and their interactions with health workers (such as, without limitation, event support, contracting donations etc.)

Other areas covered by the Regulations include:

iv. Cross-promotion and advertising;
v. Demonstrations on the use of designated products; and
vi. Publication of information, education and communication materials;

3.0 CONSULTATIVE PROCESS

3.1 Legal Requirements Relating to Public Participation and Consultation

Constitutional Provisions

Article 10 provides that participation of the people, inclusivity, transparency and accountability are constitutional requirements whenever a State or public officer applies the Constitution, enacts any law or makes or implements a public policy. This requirement is premised on the sovereignty principle espoused under Article 1 which vests all sovereign power to the people of Kenya. This power entitles the people to unfettered access to the process of making public decisions through their involvement. This ensures transparency in the formulation of policy. Article 174 (c) give powers of self-governance to the people and enhances their participation in the exercise of the powers of the State and in making decisions affecting them and recognize the rights of communities to manage their own affairs and to further their development.

Finally, the values and principles of public service envisaged under Article 232 (1) require the involvement of the people in the process of policymaking and transparency and provision to the public of timely and accurate information.

With regard to the subsidiary legislation making process, the Statutory Instruments Act requires that the regulation making authorities shall undertake consultations before making statutory instruments in particular where the proposed regulations are likely to have a direct, or a substantial indirect effect on business or restrict competition. The Act provides that in determining whether any consultation undertaken is appropriate, the regulation making authority shall have regard to all relevant matters, 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.

The Statutory Instruments Act further requires that the persons to be consulted should either directly or by advertisement through representative organizations be invited to make submissions by a specified date, which should not be less than 14 days or be invited to participate in public hearings concerning the proposed instrument.

3.2 Initial Development and Consultation Process

The Regulations were made in consultation with the National Committee of Infant and Young Child Feeding (NCIYCF) established under the Breast Milk Substitutes (Regulation and Control) Act (No 34 of 2012). The NCIYCF members enriched the Regulation making process given their varied and extensive knowledge and expertise.

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

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

The regulation making process also involved participation of the United Nations agencies working on maternal, infant and young child feeding in Kenya, i.e., UNICEF and WHO. Additionally, further consultations were made with global experts on matters related to WHO Code of Marketing of Breast milk Substitutes.

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

Efforts were made to reach out to key stakeholders through public notice, email and hard copy invitation letters and through Departments of health in the counties, particularly with regard to invitation to the external consultative forum that was held on 27th August, 2019 to provide stakeholders with an opportunity to present their views and submissions. Access to information was ensured by availing the draft Regulations at the Ministry of Health website www.health.go.ke and the Division of Nutrition and Dietetics website www.nutritionhealth.or.ke

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

On 10th June 2020, the Principal Secretary, Ministry of Health wrote to the Attorney General (AG) seeking legal guidance and concurrence on the draft

Regulations. The AG through a letter date 20th November 2020, advised the Ministry to publish the Regulations and transmit the same to the National Assembly.

The Ministry notified the World Trade Organization (WTO) on the proposed BMS regulations on 22nd December 2020. Comments from two member states namely the United States and Switzerland were received in February 2021. A consultative meeting on the proposed Regulations was held on 5th February 2021 with the Committee on Delegated Legislation of the National Assembly. The draft responses to the comments from the United States and Switzerland were presented to the National Technical Barriers to Trade (TBT) committee on 10th March 2021.

Input from stakeholders were taken into account and assessed by the team that was involved in the drafting of the regulations and issues that were agreed upon to be included in the Regulations were incorporated. Below is a summary of issues raised by stakeholders and MOH responses—

Article in the BMS with comment	Stakeholders' Recommendations	MOH Response	Justification
PART I – PRELIMINARY			
Interpretation **Cross promotion (2)**	The definition should be removed as the term is currently not defined internationally and it is not aligned with the Codex discussions in the frame of the revision of the Codex Standard for follow-on formula.	Retain the definition term The term cross promotion is used as defined by WHO technical guidance documents.	Codex standards often follow national practice, not lead them. The consensus on the definition at the World Health Assembly is a prudent basis for Kenya's regulatory definition. Regulation of cross promotion is important in controlling unethical promotions & advertising.
Objects (4)	The statement in the regulation that Breast Milk Substitutes undermine breastfeeding is misleading, regarding the role of scientifically formulated infant formula.	Retain the clause	Clause 4 does not prohibit the sale of breast-milk substitutes, it only prohibits the promotion of these products and their sale if they fail to meet labelling, compositional, and other related requirements. This provision is consistent with WHO guidance, generally, and, in particular, World Health Assembly (WHA) resolution of 2016.
Registration (6)	Delete this provision and maintain the product approval process as per KEBS Standards Act. The regulators should collaborate in terms of exchange of information to confirm the approval status of the products.	Retain the clause	While KEBS is the competent authority in matters of standards MOH on the other hand is the competent authority on matters of infant and young child feeding. The registration with

Article in the BMS with comment	Stakeholders' Recommendations	MOH Response	Justification
			MOH is necessary to facilitate its regulatory mandate as provided for in the BMS Act. This is also in line with the Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013).
PART II – PROCEDURES RELATING TO THE USE OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD			
9. Manufacturing, sell by, and expiry date:	Is there justification for requiring products to have three dates on the label: a "manufacturing date, sell by date and an expiry date?" Having the three dates will increase misunderstanding and misuse of date marking.	Revise section 9 and provide for two dates i.e. Manufacture date and Expiry date	Manufacturing date is used at the point of importation and this is very important for the country- the law requires that products have at least 75% expiry date during importation. Expiry date is for purposes of harmonization with internal laws; Cap 254 emphasizes expiry date for purposes of Food Safety and Hygiene.
11.(1) Certificate of analysis:	Please confirm that this provision indicates routine monitoring and verification of product characteristics and does not indicate that each product must be accompanied by a certificate of analysis. KAM recommends deletion of the provision since	Retain the clause The certificate of analysis referred to in this section is issued after sampling and analysis by	This is for purposes of routine monitoring. The government inspectors collect samples and send to government recognized analysts for analysis and issuance of certificate of analysis for decision making.

Article in the BMS with comment	Stakeholders' Recommendations	MOH Response	Justification
	it is provided for under Standards Act.	authorized officers.	
PART III – DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOODS			
13.2 Labelling of Donations	The United States recommends that Kenya eliminate the provisions of this proposed regulation pertaining to the "shelf life" of donated products. Has Kenya considered that these products are not packed just-in-time when donations are needed and how these proposed measures could impact response to an emergency necessitating the mass feeding of infants or young children?	Retain the provision This is important to ensure the products going to charitable homes do not have short expiry because they may keep them for long. This will also protect against dumping.	The expiry date requirement of 50% has been brought down from the normal 75% that applies for the other imported food products for general household use. This is also consistent with government policies on donated food products.
17.(1) Labeling of designated products and pre-packaged complementary food product:	US and Switzerland requests justification for requiring website, email address, and telephone number of the manufacturer, seller, and importer on the label. We note that Article 4.4 of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985 (Rev. 1-1991)) only requires the name and address of the manufacturer, seller, and importer. KAM recommends deletion of the section claiming that this is already covered under the Standards Act.	Revise the clause Kenya has accepted to amend this requirement to have: **name, physical address** and **contacts** where contacts could be either be **website, email address or telephone)**	Most of the BMS designated products are imported hence this information is required for traceability. The requirements are also provided for in the existing national legislations.

Article in the BMS with comment	Stakeholders' Recommendations	MOH Response	Justification
18 Prohibition on Labeling:	The United States and Switzerland suggest using the language found in the Codex Standard for Infant Formula (Codex Stan 72-1981) which states that labels should not discourage breastfeeding nor contain pictures of infants and women, or any other picture which idealizes infant formula. KAM recommends deletion of the section to avoid conflict with the existing harmonized EAS	Retain the clause Kenya considered the statement in the standards and found them not sufficient enough to underscore the importance of breast feeding and therefore not effective or appropriate to achieve Kenya's objective.	Based on Article 9.2 of the International Code of marketing of BMS, the government has developed this statement to emphasize on the superiority of breast feeding. This message is consistently communicated during promotion of breast feeding and has contributed to improvement in the rates of exclusive breast feeding from 31% in 2008/9 to 62 % in 2014.
19.(1) Labeling of infant formula and follow-up formula:	The United States and Switzerland supports using the specific language for infant formula found in Article 9.6.1(b) of the Codex Standard for Infant Formula and Formula for Special Medical Purposes for Infants: "Breast milk is the best food for your baby".	Same as 18 above	Same as justification under 18 above in that the Codex language would not be effective or appropriate to achieve Kenya's objective.
21.(a) & (b): Labelling of formula in powdered form	The United States and Switzerland suggest that Kenya include information about the health hazards of inappropriate preparation, storage and use, rather than requiring general statements on containers that indicate a product may be contaminated during the manufacturing process or during preparation.	Retain the clause	Evidence shows that contamination of food including powder formula can happen at any level from manufacturing to transportation to handling and consumption. The aim of the clause is to educate the consumers as provided for in

Article in the BMS with comment	Stakeholders' Recommendations	MOH Response	Justification
	KAM recommends the section to be deleted and be replaced with provisions in the Standards Act.		Article 46 (1) (b) of the Constitution of Kenya.
26.Warnings on nutrients:	KAM/US/Switzerland - The proposed inclusion of warning statements on a broad range of fluid milk, cereal, and bottled water products could create significant barriers to trade in these products.	Delete the clause MOH has considered the comments and taking into consideration '22' and '25' has decided to delete the entire clause 26 from the regulations	The intent is covered in other clauses of the regulations.
PART V: INTERACTIONS BETWEEN MANUFACTURERS, DISTRIBUTORS AND HEALTH WORKERS			
Interactions (27)	The Regulations impose restrictions on interactions between healthcare professionals and manufacturers/distributors and prescribes lengthy bureaucratic procedures with no time limits. This deviates from international norms in marketing of such ethical products, where manufacturers interact with health professions for purposes of sharing factual and scientific information about their products and to create awareness and prescription whenever required. This is the recommendation in the WHO Code of marketing Breast Milk Substitutes (Article 7). **Proposal:** Remove restrictions on interactions with	Retain the clause	Article 27 is aligned to the WHO Code and prescribes interactions that are allowed under the proposed regulations. Through the Regulations, the MOH seeks to control 'conflict of interest' to protect the best interests of infants and young children.

Article in the BMS with comment	Stakeholders' Recommendations	MOH Response	Justification
	health professionals and state that engagements should comply with health professionals' codes of ethics.		
33.Advertisement:	Please clarify whether the restriction on promotion of sale or use would extend to the manufacturing companies' ability to use logos and trademarks on their websites.	Retain the clause	This is not a restriction on the use of the companies' logos and trademarks as stipulated in the Kenya Trade Marks Act.
PART VII – ENFORCEMENT			
40. Inspections:	Please clarify the frequency and method of inspection for products under the scope of this proposal that are imported into Kenya	Retain the clause Routine inspection for both imported and locally produced products is carried out in accordance with national laws or based on complaints as the case may be.	This is a routine inspection for all designated products whether imported or locally manufactured. The inspection is done routinely for purposes of compliance to the BMS Act, 2012

4.0 Statement on Regulatory and Non-Regulatory Options

Option 1: Maintaining the Status Quo/Doing Nothing /Defining the problem

Breastfeeding gives all children the healthiest start in life. Breast milk promotes cognitive development, and acts as a baby's first vaccine, giving babies everywhere a critical boost. Breastfeeding reduces the burden of childhood and maternal illness, lowering health care and economic costs and creating healthier families. The *Kenya Health Policy 2014-2030* has identified suboptimal breastfeeding as one on the leading risk factors to morbidity and mortality. Increasing breastfeeding worldwide to optimal levels (at least 90% exclusive breastfeeding to six months) would prevent 823,000 child deaths each year, particularly those associated with diarrhea and pneumonia (Victora et al. 2016).

While *The Lancet* report does not include an estimate for the African region, it is likely that more than 300,000 deaths of African infants and young children are attributable to sub-optimal breastfeeding, if the new estimate corresponds to the same proportionate regional breakdown as the 2009 WHO estimate(WHO 2009). This is more than double the 137,000 African deaths attributable to all food-borne pathogens in adults and children.[1]

[1] See: JOINT FAO/WHO FOOD STANDARDS PROGRAMME FAO/WHO COORDINATING COMMITTEE FOR AFRICA, AFRICA CONTINENTAL FREE TRADE AREA (AfCFTA) – A QUEST FOR TRADE IN SAFE FOOD EXECUTIVE SUMMARY (Prepared by Dr Jean Kamanzi). Twenty-third Session Nairobi, Kenya, 2 - 6 September 2019 Agenda Item 2 CX/AFRICA 19/23/2. Available at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-707-23%252FWorking%2BDocuments%252Fca23_2e.pdf

Despite the known benefits of breastfeeding, less than half (44%) of infants aged 0-5 months on the African continent are exclusively breastfed.[2] The United Nations Special Rapporteur on the Right to Food observed that "*One of the major obstacles to breastfeeding is the misleading marketing by baby food companies of breast milk substitutes and the lack of corporate accountability for the adverse consequences of such abuses.*"[3]

According to the 2020 Global Nutrition Report, only 20 countries in Africa are on track to meet the 2025 World Health Assembly (WHA) target of increasing the rate of exclusive breastfeeding in the first 6 months up to at least 50% (GNR 2020). Similarly, the *2020 Status Report on the National Implementation of the Code of Marketing of Breast-milk Substitutes* indicated that only 9 African countries have adopted legal measures substantially aligned with the WHO Code, and only 14 including Kenya have measures that are even moderately aligned with the WHO Code. The *Status Report* did not assess the sufficiency of the enforcement of these laws, but an implementation monitoring report on the WHO Code indicates that violations are widespread, monitoring systems are weak and anecdotal evidence suggests that prosecutions for violations and penalties are rare continent-wide (Ching et al. 2021).

Efforts by African Union member States to strengthen national legislation that allows for full protection of breastfeeding will contribute positively to progress on the WHO target and, even more importantly, to the survival and welfare of

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[2] See UNICEF Statistics (2019): http://data.unicef.org/topic/ nutrition/infant-and-young-child-feeding/

[3] United Nations Special Rapporteur on the Right to Food. Interim report, 3 August 2016. Seventy-first session Item 69 (b) of the provisional agenda. Promotion and protection of human rights: human rights questions, including alternative approaches for improving the effective enjoyment of human rights and fundamental freedoms Right to food.

A/71/282.: https://documents-dds-ny.un.org/doc/UNDOC/GEN/N16/247/21/PDF/N1624721.pdf?OpenElement

mothers and their children. This aligns with Article 5 of the African Charter on the Rights and Welfare of the Child which affirms:

(a) every child has an inherent right to life. This right shall be protected by law; and

(b) State Parties to the present Charter shall ensure, to the maximum extent possible, the survival, protection and development of the child.[4]

At the moment, since the enabling legislation was enacted by Parliament in 2012, many limitations on the advertising and promotion of breast milk substitutes have been in effect, However, manufacturers and distributors of breast milk substitutes and designated products have continued their marketing practices unabated. While there has been a rise in exclusive breastfeeding since 2012, the proportion of Kenyan babies who are exclusively breastfed until the end of the fifth month of life continues to fall short of the desired goals.

There is a global consensus, embodied in the WHO Code in 1981, that the advertising and promotion of breast milk substitutes and designated products undermines breastfeeding. This consensus has been reinforced, particularized, or extended by subsequent relevant resolutions of the World Health Assembly, the governing body of the World Health Organization(World Health Organization et al. 2016).

Option 2: Administrative Measures

This is a non-regulatory measure which if applied, will depend on the good will of public officers to implement the provisions of the new Act. Administrative measures involve issuance of directives and circulars to the various entities and hoping that

[4] Available at: https://www.globalhealthrights.org/instrument/african-charter-on-the-rights-and-welfare-of-the-child/

they will be implemented. Administrative measures do not have the force of law and may be challenged in court of law.

Option 3: Publication of the BMS (Regulation and Control) (General) Regulations

This option supports the Kenyan policy which underpins the need "to bring health through food to as many people as possible (citation)." It does this by ensuring that the Ministry of Health contributes to the provision of safe and adequate nutrition for infants, by protecting and promoting breast-feeding, and by ensuring the proper use of breast milk substitutes and designated products, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution practices. It further contributes to achievement of the presidential agenda on food and nutrition security as breast milk is the most effective way we can ensure food security for infants less than six months.

In Kenya, there has been improvement in reduction of neonatal, infant and under five mortality rates from 24, 54 and 74 per 1,000 live births in 2008-9 to 22, 39 and 52 per 1,000 live births in 2014 respectively. In spite of this improvement and renewed focus on child survival, achieving sustainable development goals (SDGs) targets for under five mortality (25 out of 1000 live births) and neonatal mortality (12 out of 1000 live births) by 2030 will require acceleration of evidence-based approaches of which breastfeeding is proven to be incomparable with none.

As a country, it is important that we are consistent, clear and transparent as to the standards of behavior expected from manufacturers, importers and retailers in the performance of their duties. The proposed Regulations have been designed for this purpose. The Regulations detail areas where the BMS and designated product industry players need to make responsible and ethical decisions relating to the marketing of foods for infants.

4.1 Options and Impact Analysis

Option 1: **Maintaining the status quo/doing nothing**	**Option 2:** ***Administrative Measures***	**Option 3:** **Publication of the BMS (Regulation and Control) (General) Regulations**
This option will mean that the BMS Act is implemented without regulations. **Merits** The BMS Act is aligned to global commitments such as International Code for marketing of BMS and subsequent WHA resolutions; and The Act already establishes the National Committee on Infant and Young Child feeding to advice the Cabinet Secretary Health. **Demerits** The Act lacks a legal instrument/guidance to fully implement, monitor and enforce the Act; and A lack of regulations results in the inoperability of some sections of the Act, frustrating Parliament's intent and gives insufficient guidance to both public and private stakeholders in implementing the Act. The lack of instruments, guidance and continued non-compliance with the Act will lead to sustained promotion and inappropriate use of BMS and other designated products. This will contribute to high rates of under nutrition among IYC resulting in under-developed immune system, exposure to acute	This entails putting in place administrative measures to ensure implementation of the Act. **Merits** None **Demerits** This means that the regulatory concerns will remain un-addressed.	Provision for legal instrument/guidance to implement, monitor and enforce the Act. **Merits** Provides for how the clauses on donations, labeling, ethical interactions between health workers and manufacturers, IEC materials among others should be implemented; It will deter continued noncompliance with the Act as it envisions regulations to support its implementation; It prescribes a mechanism for monitoring and determining compliance with the law; It will provide basis and guidance for co-regulation by the industry; The regulations will provide for mechanism and basis for enforcement and sanctions; The regulations will deter promotion and inappropriate use of BMS and other designated products hence a reduction in under nutrition among IYC, improved intellectual development and subsequently enhanced school performance, improved income later in life thus improved economic growth and development, increased incidence of preventable diseases and death; and

Option 1: **Maintaining the status quo/doing nothing**	**Option 2:** ***Administrative Measures***	**Option 3:** **Publication of the BMS (Regulation and Control) (General) Regulations**
infection risks, illnesses and death and increased incidence of preventable chronic diseases and death later in life. Sub-optimal breastfeeding also causes impaired intellectual development which leads to poor schooling and reduced income in later life, thus economic loss to the country,		More effectively ensures that parents and care givers are not misled, better informed of risks of formula feeding instead of breast feeding. **Demerits** None

Preferred Option
Based on the above analysis, **Option 3** is the preferred option.

Reasons why the other Options are not appropriate
Based on the above analysis, Option 1 and Option 2 are not appropriate for Kenya.

5.0 Statement Explaining the Effects of the Proposed Regulations: Benefits and Costs Analysis

5.1: Benefits

Suboptimal breastfeeding and poor infant and young child feeding have been an impediment to Kenya's development for decades. The proposed Regulations form an essential part of Kenya's strategy to achieve optimal rates of breastfeeding, namely 90-95% EBF from birth to six months of age and continued breastfeeding to 24 months or beyond which is expected to significantly reduce the thousands of deaths and many more cases of severe diarrhea and pneumonia attributed to suboptimal breastfeeding.

Breastfeeding will reduce illnesses, hospitalization and deaths among Kenyan children and especially in the first year of life, an area that has continued to lag

behind and currently accounts for up to 39 and 52 deaths per 1000 live births for infant and under five mortalities respectively[5] despite significant investment by government and communities. The benefits of breast feeding extend beyond to adulthood in preventing and modifying the severity of chronic conditions such as asthma, diabetes and prevention of breast cancer.

Globally optimal breastfeeding would avert:

(a) 823,000 under five deaths annually;
(b) 20,000 cases of cancer among mothers annually in low middle income countries;
(c) 72% of hospital admissions due to diarrhea and 57% due to lower respiratory infection;
(d) 54% and 32% of all diarrhea and respiratory infection episodes respectively;
(e) 13% overweight obesity; and
(f) 35% in the incidence of type 2 diabetes(Ministry of Health 2018).

Breastfeeding is a fundamental investment towards Kenya's intellectual human capital by conserving or promoting the brain development of the young infant. Exclusively breastfed babies have a higher IQ which translates to better school performance and ultimately higher income in their entire lifetime. It should be of great concern that one in four Kenyan children is stunted and failure to correct that malnutrition by age two is associated with long-term impaired cognitive deficit(Victora et al. 2015).

The protection of optimum breastfeeding and consumption of age appropriate nutritionally adequate complementary feeding are prudent public health child protective measures for Kenya that would contribute to reduction of economic losses due to child under nutrition estimated at Kshs. 373.9B based on 2014 Gross Domestic Products (GDP) estimates, approximately 7% of the annual

[5] Kenya Demographic and Health Survey, 2014

GDP(Central Bureau of Statistics (CBS) [Kenya], Ministry of Health (MOH) [Kenya] 2019).

Breastfeeding protects women's physical and mental health by reducing the risk of hemorrhage, post-partum depression and spacing their pregnancies. In the long-term, breast feeding helps reduce the mother's risk of diabetes, breast and ovarian cancers, cardiovascular disease and osteoporosis later in life (Chowdhury et al. 2015).

Breastfeeding is explicitly recognized by the United Nations Convention on the Rights of the Child as a key component of every child's human right to the highest attainable standard of health. Breastfeeding provides a natural, renewable food that needs no packaging, transportation, storage, or cooking, making it environmentally friendly and a climate smart investment. When a population with limited access to health systems and infrastructure relies on breastfeeding, it mitigates inequities in access to health services. The protection of breastfeeding and ensuring safe and appropriate complementary feeding is an investment for Kenya's today and tomorrow.

5.2 Financial Costs

There is currently no financial cost for the Ministry of Health in the promulgation of these Regulations. Over the years, the Ministry may need to budget on strengthening enforcement mechanisms proposed in the Regulations.

5.3 Effects on the Public Sector

The potential beneficial impact of the proposed Regulations on the public sector is high. It provides for child protection by ensuring safe and adequate nutrition for infants and young children through protection, promotion and support of breastfeeding and optimal complementary feeding. It ensures that

infants and young children have the best start in life, which leads to improved health of the children into adulthood, reduce hospitalization and health costs, and improved school performance. Nourishing IYC well safeguards public health, resulting in a more productive society (Victora et al. 2016)

The Regulations provide an opportunity to improve public sector accountability and transparency in the regulation of the marketing of BMS products and designated products, and improves consumer protection. Members of the public shall receive accurate information, in a standardized legible format, without any language barriers on the labels of BMS and designated products. Currently, labels of breast milk substitutes are not required to be written in Kiswahili. Though convenient for foreign suppliers seeking to serve multiple African markets without accommodation, English only labels deprive the vast majority of Kenyan parents of information in their native tongue and puts too many children at risk that parents' decisions about their daily feeding will not be adequately informed. This is dangerous and unfair, especially for vulnerable consumers who, when they consume BMS, often do so exclusively every day.

The Regulations give an opportunity for the government to protect the public from health risks arising from misuse and unsafe use of the BMS and designated products. The proposed Regulations provide for anti-dumping measures for BMS, complementary and other designated products in the form of donations. The Regulations help operationalize Kenya's commitment to the law and WHO Code, as well as supporting universal health coverage by reinforcing prevention efforts that obviate the need for care and intensive care. The Regulations give clearer directions to Kenyan inspection officers about what is expected in monitoring and enforcement.

5.4 Effects on the Private Sector

The benefits of the Regulations on the private sector are improved clarity about the application of controls mandated by Parliament and further assurance of a level playing field. In addition, the Regulations shall improve compliance with the BMS Act and the quality and safety requirements. The private sector shall support the promotion of breastfeeding and proper use of BMS.

The Regulations will ensure that interactions between regulated companies and workers in the health systems are ethical and not thinly veiled efforts to promote their products.

5.5 Effects on Business

The Regulations have minimal effect on businesses that currently comply with the Act and WHO Code. The Regulations level the playing field by mandating the form and content of certain information to be presented. Moreover, the Regulations shall improve accountability for national and multinational companies that are involved in the business of BMS and complementary products and other designated products, and ensure compliance in the marketing, donations and labelling of BMS and designated products.

In order to promote ethical interactions between health care providers and the BMS industry players, these Regulations preclude BMS and complementary products manufacturers, importers, distributors and retailers from promoting their products directly to and through health systems and providers by offering stipends to attend sponsored meetings, free gifts, among others and providing BMS or other designated products in maternity discharge packs.

The Regulations allow for appropriate use, manufacturing, distribution, labeling and importation of BMS and designated products for purposes of sale and distribution.

Companies will incur compliance costs such as revising labels to reflect language requirements. Printing costs can be minimized by allowing companies to exhaust 6-12 months of preprinted label stock. Prohibitions on advertising or contact with health workers or caregivers requires only that companies refrain from doing something that Parliament has signaled since 2012 is inappropriate. Refraining from doing something is not a financial cost.

In analyzing the effects on businesses, the Ministry of Health was guided by the Competition Authority Guideline on Assessment of Regulatory Impact on Competition in Kenya.

5.6 Fundamental Rights and Freedoms

These Regulations do not limit the fundamental rights and freedoms set out under the Constitution.

The proposed regulatory instrument will facilitate the full enjoyment of the rights as stipulated under Articles 43(1) (a) (c) (d), 53(1) (c) (e) and 46 of the Constitution.

5.7 Taxes /Fees and Revenue

These Regulations do not impose, waive nor vary any tax or fees imposed under any law in Kenya.

5.8 Effects on Existing Legal Frameworks

Statutory instruments proposed to be amended

There are no statutory instruments proposed for amendment.

Statutes proposed for consequential amendments

There are no proposed consequential amendments.

6.0 Conclusion

1. There are significant public health benefits from promulgating the Regulations.
2. There is minimal cost to industry; revising labels is infrequent and likely non-inflationary.
3. There are significant potential net economic benefits to Kenya resulting from increased breastfeeding rates expected from compliance with the Regulations and concomitant reductions in acute and chronic illnesses in breastfed infants.
4. The environmental benefits of breastfeeding are established.
5. No loss of business is expected in companies that already voluntarily follow ethical marketing practices consistent with the objectives of the WHO Code and the Breast Milk Substitutes Act, 2012. Advertising and promotion of breast milk substitutes and designated products are a continuing threat to breastfeeding rates in Kenya.
6. The breast milk substitute market is growing and interfering with breastfeeding, despite Parliament's nine-years-old direction to industry and various national and international programmatic efforts to promote breastfeeding in Kenya.

6.1 Recommendation

We recommend that this proposed Breast Milk Substitutes (Regulations and Control) (General) Regulations, 2021 be promulgated.

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Approved
12/7/21

MINISTRY OF HEALTH
DIVISION OF FAMILY HEALTH
12 JUL 2021
SIGN: .....
NUTRITION & DIETETICS UNIT

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PUBLIC PARTICIPATION

REQUEST FOR COMMENTS ON THE DRAFT REGULATORY IMPACT STATEMENT OF THE PROPOSED BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

Kenya enacted the Breast Milk Substitutes (Regulation and Control) Act No. 34 in 2012 to give effect to the International Code of Marketing Breast Milk Substitutes and the relevant World Health Assembly resolutions.

The Cabinet Secretary for Health has drafted the Breast Milk Substitutes (Regulation and Control) (General) Regulations, 2021. The objects of the Regulations is to guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons understand that breast milk substitutes undermine breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children.

The draft Regulations have been subjected to stakeholders and public participation including the World Trade Organization and are due for publication in the Kenya Gazette.

In compliance with Section 6 of the Statutory Instruments Act No. 23 of 2013, the Ministry has prepared a regulatory impact statement for the proposed Regulations. The Regulatory Impact Assessment and the draft Regulations are available at https://www.health.go.ke/.

All interested persons should submit written comments on the draft Regulatory Impact Statement in the prescribed format; ***Regulation/clause, Issues of Concern, Justification and Recommendation***, to reach the undersigned via email not later than fourteen (14) days from the date of publication of this notice.

The Principal Secretary
Ministry of Health
Afya House
Cathedral Road
P.O. Box 30016-00100 NAIROBI.

Email to: infant.nutrition@health.go.ke

MINISTRY OF HEALTH

RESPONSES TO THE KENYA ASSOCIATION OF MANUFACTURERS MEMORANDUM ON THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021

SUBMITTED TO THE COMMITTEE ON DELEGATED LEGISLATION

8TH NOVEMBER 2021

Preamble

Breastfeeding is the natural way of providing infants with the nutrients they need for healthy growth and development. Human milk contains all of the nutrients critical to infant growth-a unique balance of proteins, carbohydrates, water, antibodies, hormones, micronutrients, and macronutrients-with the balance of these components adjusting during each feeding and over the course of lactation to provide the most appropriate nutritional content to the infant.

- Optimal breastfeeding of infants under two years of age *(also known as the first 1000 days' window of opportunity)* has the greatest potential impact on child survival of all preventive interventions, with the potential to **prevent over 823,000 deaths (13 per cent of all deaths) per year in children under five** in the developing world (Lancet 2016)[1].
- According to Lancet 2008, **breastfed children have at least six times greater chance of survival** in the early months of life than non-breastfed children.
- An **exclusively breastfed child is 14 times less likely to die in the first six months** of life than a non-breastfed child[1,2].
- Among older children (from six months to two years of life), the non-breastfed child is about **two times more likely to die than breastfed babies**[2].
- Breastfeeding prevents **72 percent of all admissions for diarrhea and 57 percent for respiratory infections**[2].
- A total of **54 percent of diarrhea episodes and 32 percent of respiratory infections** would be avoided through optimal breastfeeding[2].
- **Long-term maternal health benefits of breastfeeding** include reduced risk of type 2 **diabetes, breast and ovarian cancers.**

[1] Victora CG, Bahl R, Barros AJD, França GVA, Horton S, Krasevec J, et al. Breastfeeding in the 21st century: Epidemiology, mechanisms, and lifelong effect. Lancet. 2016;387(10017):475–90.

[2] Rollins NC, Bhandari N, Hajeebhoy N, Horton S, Lutter CK, Martines JC, et al. Why invest, and what it will take to improve breastfeeding practices? Lancet. 2016;387(10017):491–504.

- Exclusively breastfed babies have a higher IQ which translates to better school performance and ultimately higher income in their entire lifetime.
- Numerous research evidence indicate that prolonged and exclusive breastfeeding plays an important role in early neurodevelopment and childhood cognitive outcomes.

Despite this unrivalled lifesaving potential achievable at a comparatively minimal costs, inappropriate, aggressive and unethical marketing of breast-milk substitutes undermine efforts to improve breastfeeding rates, negatively affecting the choice and ability of a mother to breastfeed her infant optimally. Many families use commercial infant formula, imperilling these health benefits to maternal, infant and child health. Through aggressive marketing in an increasingly deregulated market, formula manufacturers have created a multi-billion-dollar industry worldwide, pushing their product far beyond their original markets and causing irreversible health harms, especially in the developing world.

Given the incomparable and unique benefits of breastfeeding, the support of early, exclusive, and continued breastfeeding-with age appropriate, adequate and safe complementary feeding-is therefore considered the "gold standard" for public health, reflecting both the important nutrients and protections of breast milk and the unmitigated dangers of breast milk substitutes. While scientific evidence shows that formula is inherently inferior to breast milk-unable to replicate the immunological or living cells necessary to protect infants from an infectious environment-far greater consequential harm is inflicted when formula is used under sub-optimal environmental conditions. Commercial formulas generally meet minimal safety standards under international law[3]. However, due to the dangers of mixing formula with unclean water, high bacterial contamination of bottles and teats, and improper dilution from inadequate educational and financial resources, the process of bottle-feeding has unnecessarily harmful consequences in parts of the developing world.

Recognizing that breastfeeding is an important aspect of primary health care in addressing infant malnutrition, morbidity and mortality, and that improper practices in the marketing of breast-milk substitutes (BMS) and related products can contribute to these major public health problems, the World Health Assembly adopted the **International Code of Marketing of Breastmilk Substitutes in 1981**[4]. The aim of the Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of BMS, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution. The Code aims to shield breastfeeding from commercial promotion that affects mothers, health workers and health care systems. One of the main principles of the Code is that health care facilities should not be used for the purpose of promoting BMS, feeding bottles or teats.

Subsequent to the adoption of the Code, governments were called upon to take action appropriate to their respective social and legislative framework and their overall development objectives to give effect to the principles and aim of this Code, including the enactment of legislation, regulations or other suitable measures.

Breast Milk Substitutes (Regulation and Control) Act, 2012

In aligning to the Code, Kenya enacted the Breast Milk Substitutes (Regulation and Control) Act in 2012 to provide for appropriate marketing and distribution of breast milk substitutes;

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[3] Cf Codex Alimentarius, Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, Codex Stan 72 - 1981 (rev. 2007), available at http://www.codexalimentarius.net/download/standards/288/CXS-072e.pdf.

[4] https://www.who.int/nutrition/publications/code_english.pdf

safe and adequate nutrition for infants through the promotion of breastfeeding and proper use of breast milk substitutes, where necessary and for connected purposes[5].

The Act provides for the establishment of the National committee on infant and young child feeding; Restriction on advertisement, labelling of packages, education and information materials; and Enforcement. Additionally, article 28 (1) of the Act gives the Cabinet Secretary for Health powers in consultation with the committee to make Regulations prescribing how implementation of certain sections of the Act should be accomplished.

In spite of the Act, continued violations have been reported in the recent past, for example, Nestle Kenya sponsored the construction of lactation room at the Kenyatta National Hospital, a total violation of section 6 (2) of the Act. The event was extensively reported in the social media. Subsequently, the Director General for Health wrote to the 2 organizations bringing to their attention the contravention and advising removal of the event photos from the social media and official websites.

Process undertaken in the development of the Breast Milk (Regulation and Control) (General) Regulations, 2021

- The development of the BMS Regulations commenced in 2012, spearheaded by the NCIYCF and with technical and financial support from UNICEF and WHO.
- However, during a workshop to review the draft Regulations that was held in October 2018, significant gaps in the content and legal consistency were identified and it was recommended that regulations be redrafted, with technical support from legal drafters.
- A re-drafting workshop was held on 21st to 25th January 2019 and a revised draft BMS regulations developed with legal expertise provided by the Kenya Law Reform Commission.
- The revised draft BMS was circulated to internal stakeholders within the ministry via email to obtain their input in May 2019, and thereafter a consultative meeting was held on 28th June 2019.
- In the spirit of public participation envisaged in the Constitution, a public notice was published in MyGov on 13th August 2019 requesting stakeholders to submit written submission by 20th August 2019 and inviting them to a stakeholder consultative forum on 27th August 2019.
- Written submissions were received from the Kenya Association of Manufacturers (KAM) and the Kenya Healthcare Federation (KFH)- the health sector board of the Kenya Private Sector Alliance (KEPSA).
- A consultative meeting was held on 27th August 2019, where stakeholders presented their memorandum.
- At the end of the meeting, KAM requested two things: i) to revise their memorandum in line with corrected version of the draft BMS regulations; ii) a one-on-one meeting with the drafting committee to present their memorandum in details.

[5] http://kenyalaw.org/kl/fileadmin/pdfdownloads/bills/2012/BreastMilkSubstitutes_Regulation_and_Control_Bill__2012.doc

- The two requests were granted: KAM to submit their revised memorandum by close of business on 2nd September 2019; and the meeting to be held on 13th September 2019.
- On 13th September 2019, KAM legal team and representatives of the food and beverage sector presented their comprehensive memorandum, and some of the issues were discussed and position of the drafting committee provided, while other issues were considered during the finalization of the draft regulations.
- The drafting committee reviewed and incorporated some of the submissions from stakeholder's validation including KAM on 25th to 27th November 2019
- Validation of the final draft by the National Infant and young child feeding conducted on 4th February 2020.
- The draft BMS Regulations were submitted to the Solicitor General vide a letter Ref: /ADM/1/1/2 of 10th June 2020 for concurrence and clearance for tabling in the National Assembly.
- Submission of the draft regulations to the National Assembly on 21st Dec 2020 and notification to the World Trade Organization (WTO).
- Following WTO notification, comments were received from the European Union, US and Switzerland Governments. KAM also submitted comments.
- Consultative meeting with the committee on delegated legislation was held on 5th February 2021. The committee recommended that a regulatory impact assessment (RIA) be conducted.
- Preparatory for conducting regulatory impact assessment (RIA) commenced on 10th February 2021
- Responses to WTO-USA and Switzerland's submissions were drafted and presented to the Technical Barrier to Trade (TBT) committee on10th March 2021. The responses were adopted.
- A drafting workshop for RIA was held on 15th -19th March 2021. Participants were drawn from MOH, National committee on infant and young child feeding, Nairobi Metropolitan Services, UNICEF, WHO, Kenya Law Reforms Commission, and Competition Authority of Kenya.
- Public participation on the draft RIA carried out in July 2021 and the Final RIA signed in August 2021
- Breast Milk Substitutes regulations, 2021 were launched during the World Breastfeeding week on 5th August 2021.
- The Regulations were published in the Kenya Gazette on 27th August 2021.
- In compliance to section 28 (4) of the Breast Milk Substitutes Act, 2012, the published Regulations were submitted to the National Assembly on 28th September 2021.

Responses to Issues Raised in KAM Memorandum

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
1	"Cross-promotion" means a form of marketing promotion where customers of one product or service are targeted with the promotion of a related product using symbols, colouring, naming, shelf placement or any other means that implies benefit or suitability	**Delete** this definition and in place address the issue product distinction through Labeling in the Labeling section that products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow up formula and formula for special medical purposes and align with text in existing standards.	**Maintain** the term 'cross promotion'.	– The term has been defined and used in the International Code of Marketing of breastmilk substitutes (WHA 63.14; and WHA 69.7 Add 1). – The objection of use of the term in Codex Standard was based on consideration of mandate of Codex and concern that it is not defined in Codex text hence may be misinterpreted (REP20/NFSDU[6], Para. 23 & 24). – The Codex Committee on Nutrition resolved that the intend of 'cross promotion' was to avoid consumer confusion through the clear differentiation in labelling between the different products, whereas the intent of not permitting cross-promotion was to prevent reference to related products (REP20/NFSDU[1], Para. 25). – Cross promotion will be included in the Codex Standard for follow-up by alternative texts, "*The labelling of follow-up formula for older infants shall not refer to infant formula, [name of product] for young children, or formula for special medical purposes intended for infants, including numbers, text, statements, or*

[6] Report of the forty-first Session of the Codex Committee on Nutrition and Foods for special Dietary Uses: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-41%252FReport%252FAdoption%252FREP20_NFSDUe_Rev.pdf

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
				images of these products" (REP 20/NFSDU[1], Para 26). – The alternative text, which basically is the definition of Cross Promotion has been finalised and endorsed by Codex and is now awaiting adoption by the Codex Alimentarius Commission (REP21/CCFL[7], Para 23). **Based on the above, the proposed regulation does not in any way introduced unnecessary terminology, rather it is aligned to International standards and WHO documentation.**
2.	**Regulation 4** The objects of these Regulations is to guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons understand that breast milk substitutes undermine breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children.	**Introduce the following new paragraph:** 4. The objects of these Regulations is to guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons understand that **inappropriate and unethical promotion of breast milk substitutes undermine** breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children	**Maintain the Objects as it is in the published regulations**	Article 6 (1) of the Breastmilk Substitutes Act No. 34 of 2012 prohibits promotion and advertisement. Hence, introducing the new paragraph can be interrupted to mean that promotion of BMS will be allowed by the regulations, which is a violation of the Act.

[7] Report of the forty-sixth Session of Codex Committee on food labelling, https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-46%252Freport%252FREP21_FLe.pdf

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
3	18. A label or a container of a designated product or a prepackaged complementary food shall not contain a photograph, drawing or other graphic representation other than for illustrating how the product is to be used	Rephrase the draft regulation 18 provisions as follows: The label shall have no pictures photographs, drawings, or any other graphics which represent infants and/or women other than illustrating methods of preparations. The label shall not idealize the use of the designated product	**Maintain** the statement as proposed in the regulation.	– The reference made by KAM for their justification is only based KS EAS 4 that is based on Codex Standard, CXS 72[8], which is one of the breast milk substitute developed by Codex Committee on Nutrition in 2016, with standard amended for food additives in 2020. – Since then, a number of violation had been observed and the same committee (Nutrition) while revising the standard for follow-up formula (REP20/NFSDU[1], Appendix II) (another breastmilk substitute) recognising the need to further protect the infant adopted under clause 9.6.2 that reads, '*The label shall have no pictures of infants, young children and women nor any other picture, text or representation that might:* o *idealize the use of Follow-up Formula for Older Infants;* o *suggest use for infants under the age of 6 months (including references to milestones and stages);* o *recommend or promote bottle feeding;* o *undermine or discourage breastfeeding; or that makes a comparison to breast-milk, or* o *suggests that the product is similar, equivalent to or superior to breast-milk;*

[8] Standard for infant formula and formula for special medical purposes intended for infants: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
				○ *convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities.* – **Based on the above development within the Codex itself, it is a demonstration that the spirit and intent is to prevent the idealization of any form on the labels and thus the proposed regulation is within that spirit and intent.** – Other jurisdiction like Tanzania has been implementing such a statement over a long period of time
4.	6. Every manufacturer or importer of designated products shall register with the office in charge of nutrition and dietetics in the Ministry responsible for matters relating to public health, by providing its physical address, telephone, website, and email contact information and declaring that the products it imports and distributes are subject to this Act and shall provide information within 30 days of these declared information changing.	**We propose reformulation of this Regulations.** The 30-day period is too short for updating changes There exist multiple importers and the products	**Maintain article 6 as it is in the published Regulations.** In the previous consultation, KAM never objected the 30 days period	– 30 days period is adequate
5	11. (1) An authorized officer may at any time, collect and submit to a public analyst a sample of a	We propose that the clause be deleted	**The clause should not be deleted**	– The appointment is provided in the BMS Act and thus not introducing a new requirement

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
	designated product pre-packaged or a complementary food product for analysis			but providing clarity (Section 11 of BMS Act).
7.	13. (1) A person donating under the Act or these Regulations shall not advertise or publicize the making of such donation 13. (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	We propose the following changes: *(1) A person donating under the Act or these Regulations shall not use the donation to advertise the designated products* *(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 ensure fresh stock is used*	**It is important to maintain minimum shelf-life of product**	– This is aimed at preventing dumping of products to facilities. – It will also allow the facilities to have ample time for storing the products and avoid the risk of donated products expiring in storage.
9	19. (1) 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".	We propose the following changes: i (i). Replace the word "Warning" with "**Important Notice**" and include 'or an equivalent statement' at the end to provide flexibility where a similar statement has been provided with sufficient meaning.	**Retain the word "Warning"**	– This is to warn and caution users of the breast milk substitutes that always "breastfeeding is the best" – The "Warning" is meant to draw the attention of the users to the fact that breastfeeding is the best
11	26.(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	Where the MOH seeks more stringent regulations on such interactions, they may adopt guidelines as those applied in	**Maintain article 26 (2) as it is in the published Regulations.**	– Article 6 (4) of the BMS Act provides for development of regulations to prescribe the conduct for ethical interactions between the manufacturers or distributor and health workers

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
	approved by the Committee pursuant to a decision-making process consistent with the Fair Administrative Action Act, 2015.	the pharmaceutical industry and practice. We also recommend a definition of what constitutes a public venue. We recommend the MOH comes up with guidelines or adopts the Health Professionals Guide to the International Code of Marketing of Breast-milk Substitutes		– The term 'Public place' is already defined under Public Order Act, Cap 56 of LoK
12	27. (1) (2) and (3) 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 complementary 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	27 (2) (1d) A definition of a public place is required to avoid misinterpretation 27 (2) (1f) A certificate of analysis from an accredited lab Add to 27 (3) (3) The decision of the Committee shall be communicated to the applicants within 21 days of receipt of the application or final correspondence	**Maintain the text in article 27(1,2 & 3) as it is in the published Regulations.**	– The term 'Public place' is already defined under Public Order Act, Cap 56 of LoK. – Public analyst is already used and defined under Public Health Act (Cap 242) and Food, Drugs and Chemicals Substances Act (Cap 254). – The government has designated laboratories which may not necessarily be accredited given that accreditation is optional and has a cost implication.

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
	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.			

	KAM Issue	KAM Proposal & Justification	MoH Response	MoH Rationale
13	28 (2). Any health worker participating in the interaction under sub-regulation (1), shall- (a) Before any interaction seek written approval from the committee	**We propose the clause be deleted.** This is double approval since health workers governed by the Code of Ethics and industry will have sought approval	**Maintain article 28 (2) as it is in the published Regulations.**	– Through the Regulations, the MOH seeks to control 'conflict of interest' in order to protect the best interests of infants and young children.
14	29. 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 prepackaged complementary food, shall prepare a formal record of the interaction and submit it to the Committee, within 30 days following the interaction.	**We propose that this Regulation be amended to shorten the time in emergency situations.**	**Maintain article 29 as it is in the published Regulations.**	– This regulation prescribes interaction between a manufacturer or distributor and health case for purposes of professional evaluation or research and NOT emergency situations
15	31. A manufacturer or distributor of a designated product or a pre-packaged complementary food shall not engage in cross-promotion.	Replace this clause with provision in the labelling section that states: Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow up formula and formula for special medical purposes.	**This is similar to 1 above**	– Same rationale as 1 above.

MINISTRY OF HEALTH

Kenya enacted the Breast Milk Substitutes (Regulation and Control) Act in 2012 to give effect to the International Code of Marketing Breast Milk Substitutes and the relevant World Health Assembly (WHA) resolutions. The Act provides for the appropriate marketing and distribution of breast milk substitute (BMS); safe and adequate nutrition for infants through the promotion of breastfeeding and proper use of BMS.

The *Act* gives the Cabinet secretary for Health powers to make regulations prescribing how implementation of certain sections of the *Act* should be accomplished. Therefore, the Ministry of Health in collaboration with the National Committee on Infant and Young Child Feeding, the Competition Authority of Kenya, the Kenya Law Reforms Commission, the Kenya Bureau of Standards, UNICEF, and the World Health Organization conducted a regulatory impact assessment (RIA).

In line with the requirement for public participation and stakeholder engagement as prescribed under Article 10 of the Constitution and sections 6 and 7 of the Statutory Instruments Act (No. 23 of 2013), the Ministry of Health invited members of the public and all stakeholders to submit comments on the Regulatory Impact Statement. The Public Notice was published in the local Daily newspapers on 19th July 2021 and the Regulatory Impact Statement and the proposed Regulations made available at the Ministry of Health website www.health.go.ke. Stakeholders were advised to send written submissions to the Principal Secretary vide info.headnutrition-bmsact@health.go.ke

Written submissions (attached) were received from the Kenya Association of Manufacturers (KAM), the Kenya Nutritionists and Dieticians Institute (KNDI) and Africa Improved Foods Ltd within the 14 days that had been prescribed. A meeting to review the written submissions was held on 4th August 2021 and the general observation was that most of the comments were on the Regulations which had previously been considered and only a few were based on the Regulatory Impact Statement as per the instructions in the public Notice.

This report presents the responses and justification to issues relevant to the Regulatory Impact Statement. Noting that some of the comments submitted were touching on the proposed Regulations and had been comprehensively addressed during the consultative process in the development of the Regulations, the summary of these responses can be found in the Regulatory Impact Statement section 3.2 on Initial Development and Consultation Process.

MINISTRY OF HEALTH (MOH) RESPONSES TO COMMENTS SUBMITTED BY STAKEHOLDERS ON THE DRAFT REGULATORY IMPACT STATEMENT OF THE PROPOSED BREASTMILK SUBSTITUTES REGULATIONS, 2021

The matrix below presents the responses to the issues raised on the draft Regulatory Impact Statement and received within the 14 days' notice since the publication of the public notice inviting comments on 19th July 2021. Written submission from three (3) organizations namely Kenya Association of Manufacturers (KAM), the Kenya Nutritionists and Dieticians Institute (KNDI) and Africa Improved Foods Ltd were received with the deadline.

(1) Kenya Association of Manufacturers (KAM)

Section in the RIA	Issue of Concern	MOH Response	Justification of the Response
Executive Summary Section 28 (1) of the BMS Act 2012 provides that the Cabinet Secretary may, in consultation with the committee, make regulations for the better carrying out of the objects of the Act...	Section 28 (1) of the Act notwithstanding, RIA does not present the specific industry malpractices, non-compliance to the Act, evidence of increased rates of infant formula consumption (KDHS shows less than 0.6%), reduced rates of breastfeeding and gaps in the implementation of the BMS Act in the Kenya Market.	Kenya scored 69% and was categorized as moderately aligned to the International Code of marketing of BMS in the 2020 monitoring report, (WHO, 2020). Specifically, Kenya scored 0 out of 15 in labelling category. Therefore, the Regulations are necessary to prescribe how labelling and other aspect of the Act should be carried out.	A regulatory Impact statement provides a high-level summary of the problem being addressed, the options and their associated costs and benefits.
1.4.2 Consultation with relevant stakeholders. "Then relevant stakeholders were surveyed on those issues, using round table discussions".	For the regulatory impact assessment process, industry members were not consulted/surveyed	Industry members were consulted as they were invited to make written submissions	The regulatory impact assessment was conducted by competent bodies which include: MOH (Legal unit, Public Health dept, Family Health Dept, Nutrition Division), the Kenya Law Reforms Commission, Competition Authority of Kenya, Kenya Bureau of Standards,

			University of Nairobi-Pediatric dept, WHO and UNICEF. Additionally, the Ministry invited comments from the public and stakeholders vide public notice published in the Daily Nation and Standard Newspapers on 19th July 2021.
1.6 Salient Features of the of the Proposed Regulations The Regulations guides all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons are informed that breast milk substitutes undermine breastfeeding and that suboptimal breastfeeding is a leading but preventable cause of death and serious illnesses in infants and young children.	Whereas 61% of infants in Kenya are exclusively breastfed only less than 1% are on infant formula hence Breastmilk substitutes do not undermine breastfeeding in Kenya (KDHS 2014). This statement is no substantiated by any specific data, report/research in Kenya on how BMS undermine breastfeeding in terms of consumption rates.	The statement " BMS undermines breastfeeding" is well documented by competent authorities in breastfeeding such as WHO, UNICEF and IBFAN.	MOH develop all its policies, regulations and technical guidelines based on scientific evidence. Evidence for this particular statement can be found in "The aggressive marketing of BMS that violates the Code continues to undermine breastfeeding and contribute to infant and young child morbidity and mortality" (WHO, 2013).
2.2 Domestic Context Despite Kenya enacting the BMS Act, there are activities that have continued to undermine the efforts to improve breastfeeding rates. Inappropriate BMS marketing tactics have taken the form of direct promotion to consumers	These are unsubstantiated allegations. The WHO Code Article 6 and 7 provides for interaction between healthcare professionals and industry as the only platform to interact ethically on scientific matters pertaining to	What is being deemed 'unsubstantiated allegations' is factual information that is verifiable by sources quoted.	This factual information that is verifiable by sources quoted.

through to health professionals and systems, and to policymakers among others.	breastmilk substitutes (BMS) products.		
The Twenty-seventh World Health Assembly, in 1974, noted the general decline in breast-feeding in many parts of the world was due to socio-cultural and other factors including the promotion of manufactured breast-milk substitutes, and urged "Member countries to review sales promotion activities on baby foods to introduce appropriate remedial measures, including advertisement codes and legislation where necessary."	Whereas the Twenty-seventh World Health Assembly, in 1974 recommends that member countries to review sales promotion activities on baby foods to introduce appropriate remedial measures, such a review was not included as part of this RIA.	The development of the Regulations is provided for in the BMS Act.	The Regulations prescribe how certain provisions of the BMS Act will be carried out.
2.4 Legal and Policy Framework for Breast Milk Substitutes and	The measures albeit grounded in law seek to promote breastfeeding at the expense of BMS. Breast milk and BMS are both important for the growth of a child because in absence or insufficiency of breast milk, BMS becomes the viable option	The BMS Act provides for appropriate marketing and distribution of BMS; safe and adequate nutrition for infants through promotion of breastfeeding and proper use of BMS, where necessary.	The Regulations prescribe the manner of conduct in the following areas as required by the Breast Milk Substitutes (Regulation and Control) Act, 2012: donations; labelling; interaction between health workers and manufacturers/distributors; cross-promotion; advertising; demonstrations on the use of designated products; publication of Information, education and communication materials; and penalties

2.5 Overview of the Proposed Regulatory Instrument The Regulations aim to: a) guide all persons that use, manufacture, sell and market BMS and to ensure that all persons are informed that BMS undermines breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children.	This statement is not substantiated by any specific data, report/research in Kenya on how BMS undermine breastfeeding in terms of consumption rates. Whereas 61% of infants in Kenya are exclusively breastfed only less than 1% are on infant formula hence BMS does not undermine breastfeeding in Kenya (KDHS 2014). The statement also assumes that all consumers of BMS have a choice of breastfeeding.	The statement " BMS undermines breastfeeding" is factual not just for Kenya but worldwide	"The aggressive marketing of BMS that violates the Code continues to undermine breastfeeding and contribute to infant and young child morbidity and mortality" (WHO, 2013).
(b) prohibit marketing activities such as cross-promotions and informational inserts;	There is no clarity on the definition on "cross promotion" in the regulations. Reference is made to the Codex Alimentarius Commission 41st Session held between 24-29th November 2019 in Germany in which no consensus was reached on the definition of cross-	The term *cross promotion* is used as defined in the WHO technical guidance documents. *"Cross-promotion* carries particular risk as it can be an effective strategy for companies to continue indirect promotion of infant formula where national legislation or regulations prohibit direct marketing of such products".	Codex standards often follow national practice, not lead them. The consensus on the definition at the World Health Assembly is a prudent basis for Kenya's regulatory definition. This is important in controlling unethical promotions and advertising.

	promotion and what it covers.		
i Donations; "During emergencies there are often donations of breast milk substitutes. Frequently these come from organizations and individuals who are reacting to the perceived rather than actual need and misguidedly believe that they are helping infants and young children. They may also come from the infant feeding industry who may view the emergency as an 'opportunity' to enter or strengthen markets or as a public relations exercise.	These are unsubstantiated allegations/statements. Country specific data is fundamental in developing regulations that meet the specific needs of Kenya. MOH to provide specific information/ examples of violations on donations, which company was involved and actions they undertook as the regulator.	This is a factual statement. Source: UNICEF IYCF-E TOOLKIT Rapid start-up for emergency nutrition personnel	This is a factual statement. Source: UNICEF IYCF-E TOOLKIT Rapid start-up for emergency nutrition personnel
ii. Labelling The regulations prescribe font size to enable legibility and effective communication.	Labelling provisions is one the key priorities/standards that have been developed or harmonized globally to facilitate consumer information plus enable	According to the Status report on the implementation of the Code (2020), Kenya is **moderately aligned** to the Code with a score of 69%, (WHO,	Article 9 of the BMS Act, 2012 gives the CS for Health powers to prescribe the font size for designated products.

	product supply. At EAC level, partner states have agreed to apply harmonized standards for labeling. For BMS products there is harmonized standards EAS 38, EAS 4, EAS 72. The regulations prescribe requirements that are not practical. It is recommended that technical regulations at country level should harmonize or refer to agreed EAC standards. Deviations will create trade barriers and cut off market supply.	2020). Specifically, Kenya scored **0 out of 15 in labelling category.** The Kenya Standards are silent of font sizes. However, the BMS Act gives the CS for Health powers to prescribe the font size. Therefore, article 19 (1) of the BMS Regulations is maintained as it is: *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 or 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"*	The current standards will be revised to align to the font size prescribed by the Regulations. Note: The Regulations are designed to contribute to the legitimate objectives of protecting human health. Additionally, the Regulations are intended to contribute to Kenya's commitment to implement the recommendations made in, and comply with the intent of the WHO International Code on marketing of breast milk substitutes.
iii. Interactions between health workers, manufacturers or distributors Other areas covered by the Regulations include:	There is no clarity on the definition on "cross promotion" in the regulations. Without a definition for "cross-promotion" and	The term *cross promotion* is used as defined in the WHO technical guidance documents. *"Cross-promotion* carries particular risk as it can be an	Codex standards often follow national practice, not lead them. The consensus on the definition at the World Health Assembly is a

iv. Cross-promotion and advertising;	understanding of the intent of the provision, it would be difficult to consider endorsement of the provision. Such lack of definition could lead to different interpretations of the provision and to trade barriers.	effective strategy for companies to continue indirect promotion of infant formula where national legislation or regulations prohibit direct marketing of such products".	prudent basis for Kenya's regulatory definition. This is important in controlling unethical promotions and advertising.
3.1 Legal Requirements Relating to Public Participation and Consultation Participation and Consultation Constitutional Provisions: The Statutory Instruments Act further requires that the persons to be consulted should either directly or by advertisement through representative organizations be invited to make submissions by a specified date, which should not be less than 14 days or be invited to participate in public hearings concerning the proposed instrument.	KAM took part in the public participation process vide their Memorandum of September 2019 and February 2021 Leading to the publishing of the 2020 Regulations for preparation of a Regulatory Impact Assessment Statement. However, KAM's views were not adequately addressed. The essence of public participation is to ensure democratic governance in decision making as provided under Article 10 of the Constitution. As a tenet of public participation, those most affected by a policy, legislation or action must	The process of writing of the Regulations was widely consultative in line with the requirements of the Statutory Instruments Act. The following issues raised by KAM were considered and their recommendation adopted: **PART IV—Labelling of Designated Products and Pre-Packaged Complementary Food** – Use of "English or Kiswahili" instead of "English and Kiswahili" – Deletion of clause 26 "Warning on nutrient" in its entirety which was had included fluid milk, cereals and its products and bottled water.	The Ministry called for submission of written submission on the draft regulations vide a public notice published in the Daily newspapers on 13th August 2019. A stakeholder consultative meeting was held on 27th August 2019 where KAM presented their written submission. Additionally, following KAM request for a follow-up engagement, MOH granted KAM the request and a meeting was held on 13th September 2019. On 10th June 2020, the Principal Secretary, Ministry of Health wrote to the Attorney General (AG) seeking legal guidance and concurrence with the draft Regulations. The AG vide a letter date 20th November 2020, advised the Ministry to publish the

	have a bigger say: and their views more deliberately sought and put into account. Therefore, we ask that industry views be taken into account before the Regulations are promulgated.	– Clause 21 on labelling of formula in powdered form revised from water at 70^{0}C to ...using clean and safe water that has been boiled and cooled within 30 minutes. – Delete the provision requiring sell by date in clause 9	Regulations and transmit the same to the National Assembly. Further, Kenya notified the World Trade Organization on the proposed instruments in December 2020. KAM resubmitted their concerns in February 2021 and these were considered even if only submissions from member states were expected. The draft responses to the comments from the United states and Switzerland were presented to the National Technical Barriers to Trade (TBT) committee on 10th March 2021. During the meeting KAM issues were also discussed and MOH present its position. A consultative meeting with the Committee on delegated legislation of the National Assembly was held on 5th February 2021. The Ministry also responded to issues raised by KAM through the CS for Industrialization, Trade and Enterprise Developed.

3.2 Initial Development and Consultation Process Input from stakeholders were taken into account and assessed by the team that was involved in the drafting of the regulations and issues that were agreed upon to be included in the Regulations were incorporated.	Industry submitted a total of 14 areas of concern but only clause 26 was removed from the draft regulations.	The following issues that were raised by the Industry were considered and proposed recommendations accepted: – Use of "English or Kiswahili" instead of "English and Kiswahili" – Deletion of clause 26 "Warning on nutrient" in its entirety which was had included fluid milk, cereals and its products and bottled water. – Clause 21 on labelling of formula in powdered form revised from water at 70^0C to ...using clean and safe water that has been boiled and cooled within 30 minutes. – Delete the provision requiring sell by date in clause 9 – Clause 17 was amended to have: name, physical address and contacts where contacts could be either be website, email address or telephone.	All concerns submitted by the Industry, WTO member states and other stakeholders were considered and those that had merit were accepted.
Note: We note that in the submission of comments in the draft RIA, KAM has also included issues on the Proposed Regulations which had been previously addressed and communicated to the Chief Executive Officer. The summary of these responses can be found in the Regulatory Impact Statement section 3.2 Initial Development and Consultation Process.			

(2) Africa Improved Foods Limited

The submission made by the Africa Improved Foods Limited focused on the Proposed Regulations and NOT on the draft Regulatory Impact Statement as per the Public Notice that was published in the Daily Nation and The Standard on 19th July 2021.

General Comment: Regulations should distinguish complementary foods that are not given as replacement of breastfeeding.

Response: The definition of "Complementary food product" is as defined in the Breast Milk Substitutes (Regulation and Control) Act No. 34 of 2012 i.e., any food suitable or presented as a suitable complement to breastmilk, for infants from age of six months up to the age of twenty-four months.

Detailed Comments

Section in the RIA	Issue of Concern	MOH Response	Justification of the Response
18 Prohibition on Labelling: Part IV-18: 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.	The provisions on labelling are already covered under the standards Act through Kenya or adopted harmonized EAC standards or Codex standards; hence manufacturers should follow these standards - Image and illustration are key for product branding. The image, graphic, drawing on complementary food should be allowed if done within the restrictions of the regulations and if messaging on superiority Allow label or container for complementary food products to contain photograph, drawing or other graphic if they are appropriate and stick to the restrictions indicated in the "WHO Guidance on	The clause is in line with the Breast Milk Substitute Act, 2012 and the Code and therefore it is maintained	We maintain the position of the BMS Act, 2012. The Standard Act is insufficient in realization of the public health goal as envisaged in the BMS Act 2012. Further section 9 of the Act gives the CS for Health power to prescribe how labelling of packages should be carried out

	Ending the inappropriate Promotion of Foods for Infants and Young Children, 2017".		
Part V–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.	Clarification is needed on the following: Does this point concern "complementary food products"? Is this point specific to advertisement within a health facility or towards health workers only? As it is indicated "a person who makes a representation either directly or indirectly" Our understanding and recommendations are: - Advertisement for complementary food products is allowed however not within health facilities or among health workers. - No advertisement is allowed within any health system networks - Appropriate advertisement is allowed outside health systems networks This is also in line with recommendations of the "WHO Guidance on Ending the inappropriate Promotion of Foods for Infants and Young Children, 2017".	The section is maintained.	Complementary food products is a designated product under the BMS Act 2012 and therefore Section 32 of the Regulations applies.

(3) Kenya Nutritionists and Dieticians Institute

Overall comments (Conclusion and recommendations): "Having looked at the procedure for the formulation of these regulations, the content and the impact they have as a bottleneck to trade, service delivery from health workers' perspectives and deterrent to employment of nutritionists and dieticians in diverse sectors including food industry; it is our humble prayer that these regulations are dropped in entirety and a comprehensive amendment to the Act done through parliament".

Response: The recommendation to drop the regulations due to the impact they have on issues highlighted is not justifiable. There were no arguments levelled in the submission with regard to the Regulations deterring trade, service delivery and employment of nutritionists and dieticians. Further, Article 28 of the BMS Act gives the Cabinet Secretary for Health the powers to develop regulations to prescribe how certain sections of the Act should be implemented.

Detailed Comments

Section in the RIA	Issue of Concern	MOH Response	Justification of the Response
PART A Explanatory Memorandum on Compliance to provisions of section 5 of the Statutory Instruments Act, NO.23, 2013	Legitimacy of the National committee on infant and young child feeding given lack of representation of the KNDI chairperson in the committee and development of the Regulations	Article 4 (2)(h) of the BMS Act refers to the chairperson of an institution representation nutritionists and NOT explicitly KNDI which is a regulatory body. This notwithstanding KNDI was represented in the drafting of the Regulations by a member of the secretariat. Further, KNDI participated in the Stakeholder consultative meeting held in July 2019 in addition to submitting written comments.	Any organization representing nutritionists is eligible for consideration of membership to National committee on infant and young child feeding. There are several institutions representing nutritionists that qualify for the membership and not necessarily KNDI.

Part II—Procedures Relating to the Use of Designated Products and Pre-Packaged Complementary Food – clause 5(a) and (b) and clause 6	When drafting regulations, we use the mother Act to create regulations which then operationalizes the Act. An attempt to use other existing laws to operationalize objects within an existing Act is unconstitutional as it undermines the objects of such Act making it inferior to the other Acts. It is not of any value to pull existing approved standards from other statutes to be part of new regulations for a different statute. Such relevant Acts only assist in implementation process of regulations of statutes through Standard Operating Procedures (SOPs) and such procedures can only be approved by the Cabinet Secretary in consultation with the National Committee on infant and young child feeding for that purpose. Clause 6: The BMS Act does not give any mandate to the Nutrition and Dietetics Division under MOH to register any product. Delegation of registration of products as an operation activity under the Act can only be approved by Parliament through Amendment of the BMS Act.	In drafting of statutory instruments, cross referencing is encouraged and employed to ensure statutory harmony. The drafting of the regulations was spearheaded by competent legal drafters from the Kenya Law reforms commission in consultation with MOH Legal unit and the office of the Attorney	Article 28 of the BMS Act gives the Cabinet Secretary for Health the powers to develop regulations to prescribe how certain sections of the Act should be implemented. Further, section 28 (4) requires that the regulations be laid before the National Assembly in order to become operational. SOPs are formulated for internal use.

	It is our considered opinion that the proposers of these regulations are attempting to amend an Act of Parliament through subsidiary regulations which is unconstitutional and a deliberate attempt to confuse the public		

Note: Some of the submission by KNDI touched on the Proposed Regulations and NOT on the draft Regulatory Impact Statement as per the Public Notice that was published in the Daily Nation and The Standard on 19th July 2021.

--------END--------

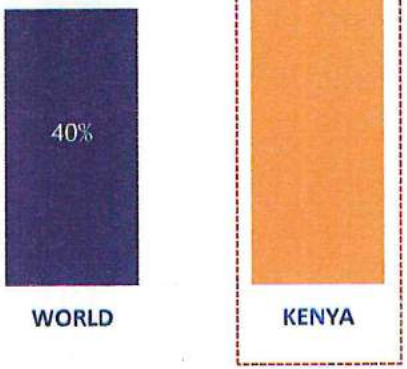
KAM PRESENTATION
to
THE COMMITTEE ON DELEGATED LEGISLATION
on
THE DRAFT BREASTMILK SUBSTITUTES (REGULATION & CONTROL) REGULATIONS 2020

TOPLINE AGENDA | DISCUSSION POINTS

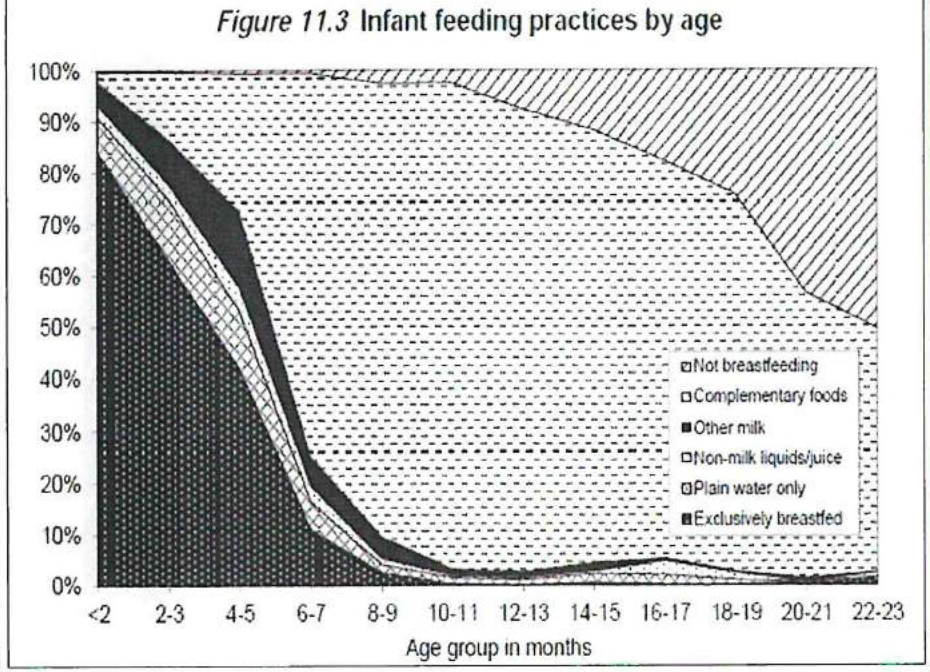
1. **INTRODUCTIONS**
2. **STATISTICS OF INFANT FEEDING PRACTICE** in Kenya vs world average.
3. **ROLE OF INFANT** formula
4. **INFANT FORMULA CONTEXT** | pricing |affordability |parallel | todays regulations
5. **INDUSTRY CONCERNS ON 2020 DRAFT REGULATION** (Breastmilk) regulation + IMPACT & RECOMMENDATION

HIGH RATES OF BREASTFEEDING IN KENYA AND GROWTH OF USE OF UNSUITABLE BREASTMILK SUBSTITUTES

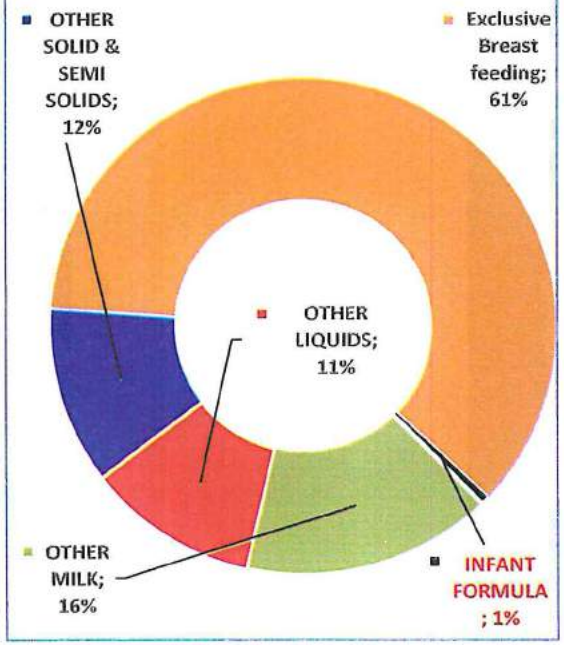
MOH has made great efforts to deliver 61% exclusive breastfeeding rate at 0-6 months



NEGLIGIBLE USE OF INFANT FORMULA IN KENYA, AS COMPARED TO THE WORLD



Breastfeeding at 61%, other liquids (cow milk + porridge & semi foods at 39%.



There is still usage of Unsuitable Breast milk substitutes between 4-5 months in KDHS, 2014

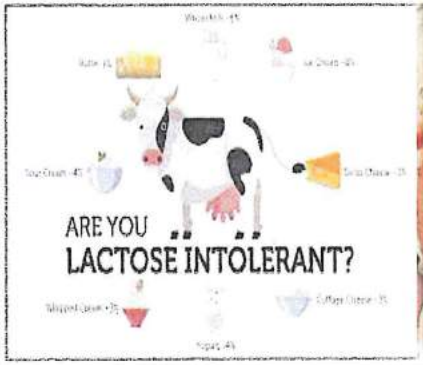
SOURCE OF DATA: KDHS 2014; PAGE 165-9

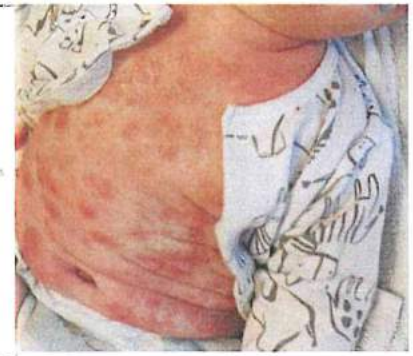
ROLE OF INFANT FORMULA WHERE BREASTMILK IS NOT AVAILABLE OR ENOUGH

MOTHERS WITH ILL HEALTH OR CASES WHEN BREASTMILK IS NOT ENOUGH- i.e. multiple babies or mothers with inadequate breastmilk

ABANDONED BABIES OR & ORPHANS who lose their mother at birth

NOT ENOUGH
BREAST MILK





FOOD FOR SPECIAL MEDICAL PURPOSES | Low birth weight |Lactose intolerant |allergies |malabsorption | short gut from intestinal surgeries

INFANT FOOD INDUSTRY PROFILE KENYA

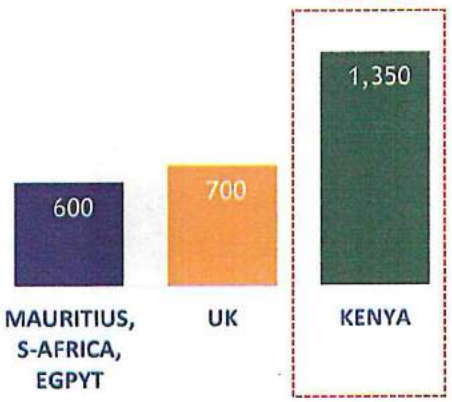
1. Baby food industry is composed of **manufacturers & distributors of infant formula and cereal** (Complementary foods), for infants' young children (from birth to 36 months).
2. The industry **EMPLOYS 1,720 DIRECTLY & over 12,500** indirectly.

INFANT FORMULA AFFORDABLY & IMPACT/RISK- IN KENYA

KENYA IS 125% MORE EXPENSIVE THAN MOST COUNTRIES, IMPACTING AFFORDABILITY & INCREASE OF SMUGGLING.

RETAIL SELLING PRICE OF 400G TIN

EQUIVALENT PRICE IN KES



DID YOU KNOW INFANT FORMULA IS THE SECOND MOST STOLEN PRODUCT IN KENYAN SUPERMARKETS?

INFANT FORMULA RETAIL SELLING PRICE IN KENYA IS VERY PROHIBITIVE, esp to mothers who are unable to breastfeed/ or abandoned babies.

In Kenya **average selling price is Kes 1350 per a tin of 400g**. This has seen influx of parallel import + duty not paid (smuggling) infant formula.

PS-Parents use up to 4-5 tins a month, spending Kes 5400 to 6750.

ANTI-PILFERAGE ON INFANT FORMULA, AT MOST SUPERMARKETS IN KENYA

EXISTING REGULATIONS ON MARKETING & INTERACTIONS ON BREASTMILK SUBSTITUTE PRODUCTS

INFANT FORMULA IS HEAVILY RESTRICTED IN KENYA as compared to other countries

THE ONLY PERMITTED MARKETING ACTIVITY in KENYA is **interactions between industry & healthcare professionals**, to create awareness on designated products.

The industry **RESPECTS & COMPLIES** with WHO international code on marketing of breastmilk substitute & KENYA BMS ACT 2012

Legal requirements regarding ethical interactions within various countries in Africa, US & EU

KENYA	ET	TZ	UG	ZIM	S.AFRICA	NIGERIA	EGYPT	US/EU	RWA	DRC	IVORY COAST	GHANA	ZAMBIA
LIMITED	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

INDUSTRY CONCERNS & PROPOSALS ON THE DRAFT BREASTMILK CONTROL REGULATIONS 2021

DISCUSSION POINTS

1. RESTRICTED INTERACTIONS WITH MEDICAL PRACTIONERS
2. CROSS PROMOTION (AMBIGUITY)
3. UNIQUE LABELLING OF PRODUCTS AS COMPARED OTHER COUNTRIES.

Issue 1: Interactions between Manufacturers, Distributors and health workers

Clause	Issue/Impact	Proposal
26(2). The interactions between a manufacturer or distributor with any health worker referred to sub-Regulation (1), shall take place in a public venue approved by the Committee pursuant; to a decision-making process consistent with the Fair Administrative Action Act,2015. 27. (1),(2 a-j). Creating Awareness (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 complementary food product, shall before commencing interactions with any health worker apply in writing to the Committee for approval.	The BMS Act,2012 (Part 3: Art 6,3a) and Art 7.2 of the WHO code provides for interactions between healthcare professionals and manufacturers for the purposes of sharing factual and scientific information about the products. The provisions this regulation are so restrictive that they **prohibit** this interaction hence inflicting with the BMS Act and WHO Code. The complexity of seeking daily approvals for every individual healthcare professional to be met in a different public places where procedures and timelines for such approvals have not been provided, infringes on consumer right to information provided in Art. 46 of the Kenyan Constitution.	The regulations to state that interactions with healthcare professionals to follow the existing ethical codes of conduct.

Issue 1: Interactions between Manufacturers, Distributors and health workers cont.....

Clause	Issue/Impact	Proposal
26(2). The interactions between a manufacturer or distributor with any health worker referred to sub-Regulation (1), **shall take place in a public venue approved by the Committee pursuant; to a decision-making process** consistent with the Fair Administrative Action Act,2015. 27. (1),(2 a-j). Creating Awareness (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 complementary food product, **shall before commencing interactions with any health worker apply in writing to the Committee for approval.**	Ethical interactions with health professionals is the only option available to our industry to create awareness about the products, since marketing to the public is restricted. These prohibitions prevent manufacturers from **creating awareness** hence **Infringe on consumer rights to information** and inappropriate use of substitutes. **Not sustainable.** This would lead to a **collapse of the Industry.**	The regulations to state that interactions with healthcare professionals to follow the existing ethical codes of conduct and **Aligned to article 7.2 of the WHO Code.** **Clarity is required on:** ✓ **Public Venue** ✓ **Sworn statements on endorsement and relations** ✓ **Particulars of the Healthcare professionals** ✓ **the timelines for the approval process.**

Issue 2: Inclusion of Cross-promotion terminology in product scope

Clause	Issue/Impact	Proposal
2. Cross-promotion is a form of marketing where customers of a product or service are targeted with promotion of a related product using symbols, coloring, naming, **shelf placement** or any other means that implies benefit or suitability.  	• Term cross promotion has not been clearly defined or adopted globally. • **Ambuguity** and **infringement on intellectual property rights and trademark rights** on its application scope in the Kenyan market. • Terminology discussed at international forums CODEX meetings of 2018-19 and not endorsed (term vague/lead to legal misinterpretation). Ref. CODEX CCNFSDU 2019 Report para 21-24 PDF Microsoft Edge PDF Document	Align with Codex position not to define cross promotion

Issue 2: Inclusion of Cross-promotion terminology in product scope cont'd

Clause	Issue/Impact	Proposal
32. A manufacturer or distributor of a designated product or a pre-packaged complementary food shall not engage in cross-promotion.	• Term cross promotion has not been clearly defined or adopted globally. • May lead to confusion and infringement on intellectual property rights and trademark rights on its application scope in the Kenyan market.  Microsoft Edge PDF Document	Delete this clause as cross promotion is prone to misinterpretation. Instead **address the issue product distinction through labeling in the labeling section** that products shall be labelled in such a way as to avoid any risk of confusion between infant formula and complementary foods or other foods.

Issue 3: UNIQUE LABELLING OF PRODUCTS

1. IMAGES

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.

ISSUE/IMPACT

CONFLICTS with the existing harmonized EAC Standards.

INFRINGEMENT on INTELLECTUAL PROPERTY rights and trademark rights to use company registered identification marks and logos

PROPOSAL

RECOMMEND TO MAINTAIN THE EAS STANDARD DEAS 4.2019

10.11.4 The label shall have no pictures photographs, drawings, or any other graphics which represents infants and or women other than illustrating methods of preparations. The label shall not idealize the use of the designated product.

2. EXTRA ADDRESSES ON TIN

The label of a designated product shall in addition to the provisions of the relevant written legislation or Kenya standard,

- *name, physical address,* ***website address, email address***
  Telephone number of the manufacturer, seller
- *contact information for the responsible importer*

ISSUE/IMPACT

SPECIFIC KENYAN LABEL due *to increased factory complexity &cost*

INCREASED COST OF PRODUCT & MOQ LIMITATIONS *to meet these complexities*

PROPOSAL

MAINTAIN PROVISIONS AS PER THE HARMONIZED **EAC STANDARDS**

DEAS 4.2019 10.6 The name and address of the manufacturer packer, distributor, importer, exporter, or vendor of the food shall be declared

Issue 3: UNIQUE **LABELLING OF PRODUCTS cont'd**

3. WARINING AS OPPOSED TO IMPORTANT NOTICE

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 English or 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 3mm in height preceded by the word "**WARNING**" in capital letters.

ISSUE/IMPACT

SPECIFIC KENYAN LABEL due *to increased factory complexity &cost*

INCREASED COST OF PRODUCT & MOQ LIMITATIONS *to meet these complexities*

Font sizes *prescribed will limit compliance to all mandatory labelling requirements in the EAC Standards.*

PROPOSAL

1. **MAINTAIN PROVISIONS** as per the harmonized **EAC Standards 10.11.3**

"Each container label shall have a clear, conspicuous and easily readable message which includes the words "important notice" or their equivalent ....."

1. **Replace the word "Warning" with "Important Notice" and include 'or an equivalent statement' at the end to provide flexibility where a similar statement has been provided with sufficient meaning.**

DONATION CLAUSE

	CLAUSE	ISSUE/PROPOSAL
CLAUSE NUMBER 	**PART III—DONATIONS OF DESIGNATED PRODUCTS AND PRE-PACKAGED COMPLEMENTARY FOOD** 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** **14. (1)** A person or institution making a donation under the Act and these Regulations **shall within two weeks of making such donations, file returns with the Committee and the Director of Children Services,** in Form BMS 2 in the Schedule to these Regulations. (2) A donee upon receipt of the donations under the Act and these Regulations, **shall within two weeks, file returns for use to the Committee in Form BMS 3** in the Schedule to these Regulations. **(3)** A donee shall upon utilization of the donations under sub-Regulation (1), file returns with the Committee in Form BMS 4 in Schedule to these Regulations indicating details **of the number of children benefiting from the donations and the health outcomes of those recipients** 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.**	**Kenyan BMS Act** –Donations or distributions of breastmilk substitutes or complementary food products to charitable children institutions shall be in such manner as may be prescribed by the cabinet secretary Our concern is the prolonged approval period and increased paper work

IMPACT OF 2020 DRAFT REGULATION GOES THROUGH

TOPLINE AGENDA | DISCUSSION POINTS

1. **HIGH IMPORT OF PARALLEL GOODS,** ascribed to fear on Kenya labelling, + TAX & KEBS evasion & no traceability.
2. **PRICE INCREASE** ascribed to complexity in factories & likelihood of delisting key products/ est special nutrition which are sold direct to hospitals.
3. **HIGH PRODUCT WRITE-OFF / NO TRANSITION,** as MOH didn't accord or & collaborate with industry to review end to end inventories + decent impact analysis.
4. **IMMEDIATE JOB LOSES & MID-LONG TERM** factories closure or opportunity lost.
5. **AMBIGUITY + DELAY ON PRODUCT USAGE,** especially during emergencies or & approval window by 'the said committee', which could be a risk to infants.
6. **KENYANS OR INSTITUTIONS WILL AVOID DONATING** to homes or and needy infants, if any, as it's been 'almost interdicted'

MEMORANDUM ON THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) (GENERAL) REGULATIONS, 2021 UNDER LEGAL NOTICE 184 IN THE KENYA GAZETTE SUPPLEMENT NO. 167.

Submitted to

MR. MICHAEL SIALAI, EBS
THE CLERK OF NATIONAL ASSEMBLY
THE NATIONAL ASSEMBLY, PARLIAMENT OF REPUBLIC OF KENYA

By

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

OCTOBER 2021

1.0 INTRODUCTION

This is Memorandum is developed by the Kenya Association of Manufacturers on behalf of its **Nutrition and Food Infant Industry** to share feedback on **The Breastmilk Substitutes (Regulation and Control) Regulations, 2021 under Legal Notice No. 184 dated 27th August 2021.**

2.0 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 represents 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.

3.0 PROPOSED AMENDMENTS TO THE FINANCE BILL 2021

In response to the development of the Breastmilk Regulations, we propose the following amendments to be considered before the Regulations are approved:

MEMORANDUM ON THE BREASTMILK SUBSTITUTES (REGULATION AND CONTROL) REGULATIONS, 2021 BY THE NUTRITION AND FOOD INFANT INDUSTRY			
Part I			
	Provision/ Reference in the LN e.g., Clause 1	**Proposal**	**Justification**
1.	**"Cross-promotion"** means a form of marketing promotion where customers of one product or service are targeted with the promotion of a related product using symbols, coloring, naming, shelf placement or any other means that implies benefit or suitability	**Delete this definition and in place address the issue product distinction through labeling** in the labeling section that products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow up formula and formula for special medical purposes **and align with text in existing standards.**	National and international standards, particularly the International Code of Marketing of Breastmilk Substitutes, exist to regulate marketing activities and set out obligations that manufacturers and distributors of formula milk products are required to meet. The Code prohibited any advertising of baby formula, bottles or teats and gifts to mothers or 'bribery' of health workers. malnutrition and diarrhoea in very young infants in the developing world was associated with aggressive marketing of formula. The Code prohibited any advertising of baby formula, bottles or teats and gifts to mothers or 'bribery' of health workers. Despite successes, it has been weakened over the years by the seemingly inexhaustible resources of the global pharmaceutical industry. This article reviews the long and tortuous history of the Code through the Convention on the Rights of the Child,

			This definition is subject to misinterpretation as it may impact, product logos, branding, colour schemes which are IP rights and proper placements of products on shelfs for hygiene and safety We propose to address product distinction through labeling and align with text in existing standards This is in line with Kenya standard KS EAS 4 the Infant formula specification Section 10.11.5
2.	**Regulation 4** The objects of these Regulations is to guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons understand that breast milk substitutes undermine breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children.	**Introduce the following new paragraph:** 4. The objects of these Regulations is to guide all persons that use, manufacture, sell and market breast milk substitutes and to ensure that all persons understand that **inappropriate and unethical promotion of breast milk substitutes undermine** breastfeeding and suboptimal breastfeeding is a leading but preventable cause of death and serious illness in infants and young children	The statement in the regulation that Breast Milk Substitutes undermine breastfeeding is misleading, regarding the role of scientifically formulated infant formula. Proposal to incorporate the phrase "inappropriate and unethical promotion of breast milk substitutes" undermines breastfeeding. The information provided in this paragraph that totally undermines the legitimacy of breast milk substitutes and is not scientifically founded nor in line with international standards, including the WHO International Code of Marketing of Breast-Milk Substitutes. When mothers are unable to breastfeed or choose not to,

			a safe and nutritious alternative is required. In this context, scientifically developed breast-milk substitutes are the only recognized and proven alternative to breastmilk for infants as acknowledged by the WHO International Code of Marketing of Breast-Milk Substitutes. In its introduction, the WHO Code acknowledges that "there is legitimate market for infant formula [...] these products should, accordingly, be made accessible to those who need them [...]".
3.	18. A label or a container of a designated product or a prepackaged complementary food shall not contain a photograph, drawing or other graphic representation other than for illustrating how the product is to be used.	**Rephrase the draft regulation 18 provisions as follows:** The label shall have no pictures photographs, drawings, or any other graphics which represent infants and/or women other than illustrating methods of preparations. The label shall not idealize the use of the designated product	The statement as is implies that even manufacturers logos are prohibited on the label. • To align with existing KS EAS 4 standard. • Manufacturers' corporate logo illustration should be part of the label for identification of the product.
4.	6. Every manufacturer or importer of designated products shall register with the office in charge of nutrition and dietetics in the Ministry responsible for matters relating to public health, by providing its physical address, telephone, website, and email contact information and declaring that the products it imports and distributes are subject this Act and shall provide information within 30 days of these declared information changing	**We propose reformulation of this Regulations.**	• The 30-day period is too short for updating changes • There exist multiple importers and the products are meant for other markets as well

5.	11. (1) An authorized 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	**We propose that the clause be deleted.**	• There is no justification for adding a public analyst as KEBS and KDB conduct product reviews and analysis
		6.	
7.	13. (1) A person donating under the Act or these Regulations shall not advertise or publicize the making of such donation 13. (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	We propose the following changes: (1) A person donating under the Act or these Regulations shall not use the donation to advertise the designated products (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 ensure fresh stock is used	Clause 13 (1) will lead to a reduction in donations from well wishers
		8.	
9.	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 or 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:	We propose the following changes: (i). Replace the word "Warning" with "**Important Notice**" and include 'or an equivalent statement' at the end to provide flexibility where a similar statement has been provided with sufficient meaning.	We maintain the statement but use the heading 'Important Notice' which sufficiently communicates the importance of breastfeeding and provides flexibility to accommodate similar wordings of equivalent meaning.

	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".	We propose clause 19 (1) to read as follows. 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 or 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 "IMPORTANT NOTICE" in capital letters: "IMPORTANT NOTICE": 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" **or an equivalent statement.**	
	10.		

11.	26.(2) The interactions between a manufacturer or distributor with any health worker referred to under sub-regulation (1), shall take place in a public venue approved by the Committee pursuant to a decision-making process consistent with the Fair Administrative Action Act, 2015.	Where the MOH seeks more stringent regulations on such interactions, they may adopt guidelines as those applied in the pharmaceutical industry and practice. We also recommend a definition of what constitutes a public venue. We recommend the MOH comes up with guidelines or adopts the Health Professionals Guide to the International Code of Marketing of Breast-milk Substitutes	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 must 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
12.	27. (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 complementary 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	27 (2) (1d) A definition of a public place is required to avoid misinterpretation 27 (2) (1f) A certificate of analysis from an accredited lab Add to 27 (3)	Health workers may not be willing to give up their information citing privacy issues thus compromising their willingness to work with the industry. Regarding 27 (2) (f) importers provide COA and COC before importation to show credibility of the product.

	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.	(3) The decision of the Committee shall be communicated to the applicants within 21 days of receipt of the application or final correspondence	
13.	28 (2). Any health worker participating in the interaction under sub-regulation (1), shall- (a) Before any interaction seek written approval from the committee	**We propose the clause be deleted.**	This is double approval since health workers governed by the Code of Ethics and industry will have sought approval

14.	29. 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 prepackaged complementary food, shall prepare a formal record of the interaction and submit it to the Committee, within 30 days following the interaction.	**We propose that this Regulation be amended to shorten the time in emergency situations.**	There is need to address emergency issues.
15.	31. A manufacturer or distributor of a designated product or a pre-packaged complementary food shall not engage in cross-promotion.	Replace this clause with provision in the labeling section that states: **Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow up formula and formula for special medical purposes.**	The definition for cross promotion is subject to misinterpretation as it may impact, product logos, branding, colour schemes which are IP rights and proper placements of products on shelfs for hygiene and safety We propose to address product distinction through labeling and align with text in existing standards This is in line with Kenya standard KS EAS 4 the Infant formula specification Section 10.11.5

16.	37. The contents of the information, education and communication materials under these Regulations shall-- (a) be written in easily readable and understandable English or Kiswahili; (b) not refer to any brand name or logo of any breast milk substitutes; (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 a brand name, logo or name of the manufacturer or distributor of designated products or pre-packaged complementary food; (f) include only factual, scientific, and current information and is not presented in any picture that encourages bottle feeding or discourages breastfeeding; (g) comply with the provisions of the Act and these Regulations; (h) not include a photograph of an infant; and (i) not include words or images that create the impression that the use of designated products are manufactured in accordance with the recommendation of a health professional registered under any of the health professional regulatory bodies in Kenya.	37 (b) Delete 37 (c) Not clear, needs clarity 37 (e) Delete	37(b) Purpose of engaging the health professional is to create awareness about the product, which should include the brand name 37(e) Purpose of engaging the health professional is to create awareness about the product, which should include the brand name and producer.

6.7 Where donated supplies of infant formula or other products within the scope of this Code are distributed outside an institution, the institution or organization should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.

6.8 Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.

Article 7. Health workers

7.1 Health workers should encourage and protect breast-feeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.

7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. It should also include the information specified in Article 4.2.

7.3. No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.

7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.

7.5 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.

Article 8. Persons employed by manufacturers and distributors

8.1 In systems of sales incentives for marketing personnel, the volume of sales of products within the scope of this Code should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should