



MINISTRY OF HEALTH

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

APRIL, 2021

Contents

FOREWORD.....	iv
ACKNOWLEDGEMENTS.....	v
LIST OF ACRONYMS.....	vii
EXECUTIVE SUMMARY	viii
1.1 Introduction.....	1
1.2 The Regulation - Making Authority.....	2
1.3 Requirements of the Statutory Instruments Act	3
1.4 Methodology	4
1.4.1 Document analysis	5
1.4.2 Consultation with relevant stakeholders.....	5
1.5 Purposes and Objectives of the Proposed Regulations.....	5
1.6 Salient Features of the of the Proposed Regulations	6
2.0 BACKGROUND AND CONTEXT	7
2.1 Global Context	7
2.2 Domestic Context.....	9
2.3 Policy and Legal Context	10
2.4 Legal and Policy Framework for Breast Milk Substitutes and Designated Products in Kenya	11
2.5 Overview of the Proposed Regulatory Instrument.....	18
3.0 CONSULTATIVE PROCESS.....	20
3.1 Legal Requirements Relating to Public Participation and Consultation.....	20
3.2 Initial Development and Consultation Process.....	21
4.0 Statement On Regulatory and Non-Regulatory Options	30
4.1 Options and Impact Analysis	34
5.0 Statement Explaining the Effects of the Proposed Regulation: Benefits and Costs Analysis	35
5.1: Benefits.....	35
5.2 Financial Costs	37
5.3 Effects on the Public Sector	37
5.4 Effects on the Private Sector	39
5.5 Effects on Business	39

5.6 Fundamental Rights and Freedoms	40
5.7 Taxes /Fees and Revenue	40
5.8 Effects on Existing Legal Frameworks	40
6.0 Conclusion.....	41
6.1 Recommendations.....	41
6.2 References.....	42

DRAFT

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 UNICEF, 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

DRAFT

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	<p>The Constitution of Kenya, 2010 guarantees every person the right to:</p> <ul style="list-style-type: none"> • 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	<p>An Act of Parliament to provide for the:</p> <ul style="list-style-type: none"> 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	<p>An Act of Parliament that seeks to:</p> <ul style="list-style-type: none"> 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
	<ul style="list-style-type: none"> 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	<p>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.</p> <p>It identified suboptimal breastfeeding as one on the</p>

Policies and laws	Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations
	<p>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.</p>
<p>National Food and Nutrition Security Policy (FNSP), 2012</p>	<p>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.</p> <p>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.</p> <p>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.</p>
<p>Kenya Nutrition Action Plan (2018-2022)</p>	<p>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</p>

Policies and laws	Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations
	<p>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.</p>
Maternal Infant and Young Child Policy	<p>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</p>

Policies and laws	Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations
	<p>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.</p>
<p>National Programs Supporting Infant and Young Child Feeding</p>	<p>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</p>

Policies and laws	Measures supporting the Breast Milk substitutes (Regulation and Control) (General) Regulations
	<p>and Dietetics is responsible for coordination of nutrition interventions in line with global and country strategies. Some of the key interventions include:</p> <ul style="list-style-type: none"> a) Baby Friendly Hospital Initiative (BFHI); b) Baby Friendly Community Initiative (BFCl); 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 with the draft

Regulations. The AG through a letter date 20th November 2020, 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. 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	<p>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.</p> <p>Expiry date is for purposes of harmonization with internal laws; Cap 254 emphasizes expiry date for purposes of Food Safety and Hygiene.</p>
11.(1) Certificate of analysis:	<p>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.</p> <p>KAM recommends deletion of the provision since</p>	<p>Retain the clause</p> <p>The certificate of analysis referred to in this section is issued after sampling and analysis by</p>	<p>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.</p>

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
<p>18 Prohibition on Labeling:</p>	<p>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.</p> <p>KAM recommends deletion of the section to avoid conflict with the existing harmonized EAS</p>	<p>Retain the clause</p> <p>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.</p>	<p>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.</p> <p>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.</p>
<p>19.(1) Labeling of infant formula and follow-up formula:</p>	<p>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".</p>	<p>Same as 18 above</p>	<p>Same as justification under 18 above in that the Codex language would not be effective or appropriate to achieve Kenya's objective.</p>
<p>21.(a) & (b): Labelling of formula in powdered form</p>	<p>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.</p>	<p>Retain the clause</p>	<p>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</p>

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)	<p>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).</p> <p>Proposal: Remove restrictions on interactions with</p>	Retain the clause	<p>Article 27 is aligned to the WHO Code and prescribes interactions that are allowed under the proposed regulations.</p> <p>Through the Regulations, the MOH seeks to control 'conflict of interest' to protect the best interests of infants and young children.</p>

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 of 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

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
<p>This option will mean that the BMS Act is implemented without regulations.</p> <p>Merits</p> <p>The BMS Act is aligned to global commitments such as International Code for marketing of BMS and subsequent WHA resolutions; and</p> <p>The Act already establishes the National Committee on Infant and Young Child feeding to advise the Cabinet Secretary Health.</p> <p>Demerits</p> <p>The Act lacks a legal instrument/guidance to fully implement, monitor and enforce the Act; and</p> <p>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.</p> <p>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</p>	<p>This entails putting in place administrative measures to ensure implementation of the Act.</p> <p>Merits</p> <p>None</p> <p>Demerits</p> <p>This means that the regulatory concerns will remain un-addressed.</p>	<p>Provision for legal instrument/guidance to implement, monitor and enforce the Act.</p> <p>Merits</p> <p>Provides for how the clauses on donations, labeling, ethical interactions between health workers and manufacturers, IEC materials among others should be implemented;</p> <p>It will deter continued noncompliance with the Act as it envisions regulations to support its implementation;</p> <p>It prescribes a mechanism for monitoring and determining compliance with the law;</p> <p>It will provide basis and guidance for co-regulation by the industry;</p> <p>The regulations will provide for mechanism and basis for enforcement and sanctions;</p> <p>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</p>

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 respectively⁵ 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.

6.2 References

- Azeze, Gedion Asnake et al. 2019. "Exclusive Breastfeeding Practice and Associated Factors among Mothers in Boditi Town, Wolaita Zone, Southern Ethiopia, 2018: A Community-Based Cross-Sectional Study." *International Journal of Pediatrics* 2019: 1–11. <https://doi.org/10.1155/2019/1483024> (March 22, 2021).
- Central Bureau of Statistics (CBS) [Kenya], Ministry of Health (MOH) [Kenya], and partners. 2019. *Social and Economic Impact of Child Undernutrition in Kenya*.
- Ching, Constance et al. 2021. "Old Tricks, New Opportunities: How Companies Violate the International Code of Marketing of Breast-Milk Substitutes and Undermine Maternal and Child Health during the Covid-19 Pandemic." *International Journal of Environmental Research and Public Health* 18(5): 1–29.
- Chowdhury, Ranadip et al. 2015. "Breastfeeding and Maternal Health Outcomes: A Systematic Review and Meta-Analysis." *Acta Paediatrica, International Journal of Paediatrics* 104: 96–113.
- Eberwein, Julia Dayton et al. 2016. "AN INVESTMENT FRAMEWORK FOR NUTRITION IN KENYA : REDUCING STUNTING AND OTHER FORMS OF CHILD MALNUTRITION Sicily Matu , and Meera Shekar December 2016 Health , Nutrition and Population (HNP) Discussion Paper." (December).
- GNR. 2020. The Global Nutrition Report's Independent Expert Group 2020 *Global Nutrition Report: Action on Equity to End Malnutrition*. Bristol, UK: Development Initiatives.
- Hoddinott, Pat, David Tappin, and Charlotte Wright. 2008. "Breast Feeding." *Bmj* 336(7649): 881–87.
- Horta, Bernardo L., Christian Loret De Mola, and Cesar G. Victora. 2015. "Long-Term Consequences of Breastfeeding on Cholesterol, Obesity, Systolic Blood Pressure and Type 2 Diabetes: A Systematic Review and Meta-Analysis." *Acta Paediatrica, International Journal of Paediatrics* 104: 30–37.
- Humphrey, Jean H. 2010. "The Risks of Not Breastfeeding." *Journal of Acquired Immune Deficiency Syndromes* 53(1): 1–4.
- Jones, Gareth et al. 2003. "The Lancet CHILD SURVIVAL II How Many Child Deaths Can We Prevent This Year? Child Survival II." *The Lancet* 362(July 5): 65–71.
- Kenya National Bureau of Statistics, and ICF Macro. 2015. "Kenya Demographic and Health Survey." : 603.
- Lodge, Cj et al. 2015. "Breastfeeding and Asthma and Allergies: A Systematic Review and Meta-Analysis." *Acta Paediatrica, International Journal of Paediatrics* 104: 38–53.
- Ministry of Health. 2018. "Kenya Nutrition Action Plan (KNAP) 2018 -2022." (December): 2018–22.
- Neves, Paulo A.R. et al. 2020. "Infant Formula Consumption Is Positively Correlated with Wealth, Within and between Countries: A Multi-Country Study." *Journal of Nutrition* 150(4): 910–17.
- Peres, Karen Glazer, Andreia Morales Cascaes, Gustavo Giacomelli Nascimento, and Cesar Gomes Victora. 2015. "Effect of Breastfeeding on Malocclusions: A Systematic Review and Meta-Analysis." *Acta Paediatrica, International Journal of Paediatrics* 104: 54–61.
- Sankar, Mari Jeeva et al. 2015. "Optimal Breastfeeding Practices and Infant and Child Mortality :

A Systematic Review and Meta-Analysis." : 3–13.

van Tulleken, Christoffer et al. 2020. "Marketing of Breastmilk Substitutes during the COVID-19 Pandemic." *The Lancet* 396(10259): e58. [http://dx.doi.org/10.1016/S0140-6736\(20\)32119-X](http://dx.doi.org/10.1016/S0140-6736(20)32119-X).

UNICEF & WHO. 2019. "Increasing Commitment To Breastfeeding Through Funding and Improved Policies and Programmes." *Global Breastfeeding Collective* (3): 4. <https://www.who.int/nutrition/publications/infantfeeding/global-bf-scorecard-2019/en/>.

Victora, Cesar G. et al. 2015. "Association between Breastfeeding and Intelligence, Educational Attainment, and Income at 30 Years of Age: A Prospective Birth Cohort Study from Brazil." *The Lancet Global Health*.

———. 2016. "Breastfeeding in the 21st Century: Epidemiology, Mechanisms, and Lifelong Effect." *The Lancet* 387(10017): 475–90. [http://dx.doi.org/10.1016/S0140-6736\(15\)01024-7](http://dx.doi.org/10.1016/S0140-6736(15)01024-7).

Walters, Dylan D., Linh T.H. Phan, and Roger Mathisen. 2019. "The Cost of Not Breastfeeding: Global Results from a New Tool." *Health Policy and Planning* 34(6): 407–17.

WHO. 1981. "International Code of Marketing of Breast-Milk Substitutes." *WHO chronicle* 35(4): 112–17.

———. 2009. "Global Health Risks." http://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf.

———. 2017. World Health Organization WHO *Protecting, Promoting and Supporting Breastfeeding in Facilities Providing Maternity and Newborn Services*. <https://apps.who.int/iris/bitstream/handle/10665/259386/9789241550086-eng.pdf>.

WHO (World Health Organization), and UNICEF (United Nations Children's Fund). 2003. "Global Strategy for Infant and Young Child Feeding." *World Health Organization*: 1–30. http://www.paho.org/english/ad/fch/ca/GSIYCF_infantfeeding_eng.pdf.

World Bank. 2006. *Repositioning Nutrition as Central to Development: A Strategy for Large-Scale Action*. Washington, DC: World Bank.

World Health Organization et al. 2016. "POLICY BRIEF: World Health Assembly Resolution on The Inappropriate Promotion of Foods for Infants and Young Children." (2003): 15–18. http://onlinelibrary.wiley.com/doi/10.1111/mcn.2016.12.issue-S2/issuetoc%0Ahttp://www.who.int/nutrition/topics/CF_babyfood_trends_brazilandnorway_euromonitor.pdf%0Ahttp://onlinelibrary.wiley.com/doi/10.1111/mcn.2016.12.issue-S2/issuetoc%0Ahttp://onlinelib.