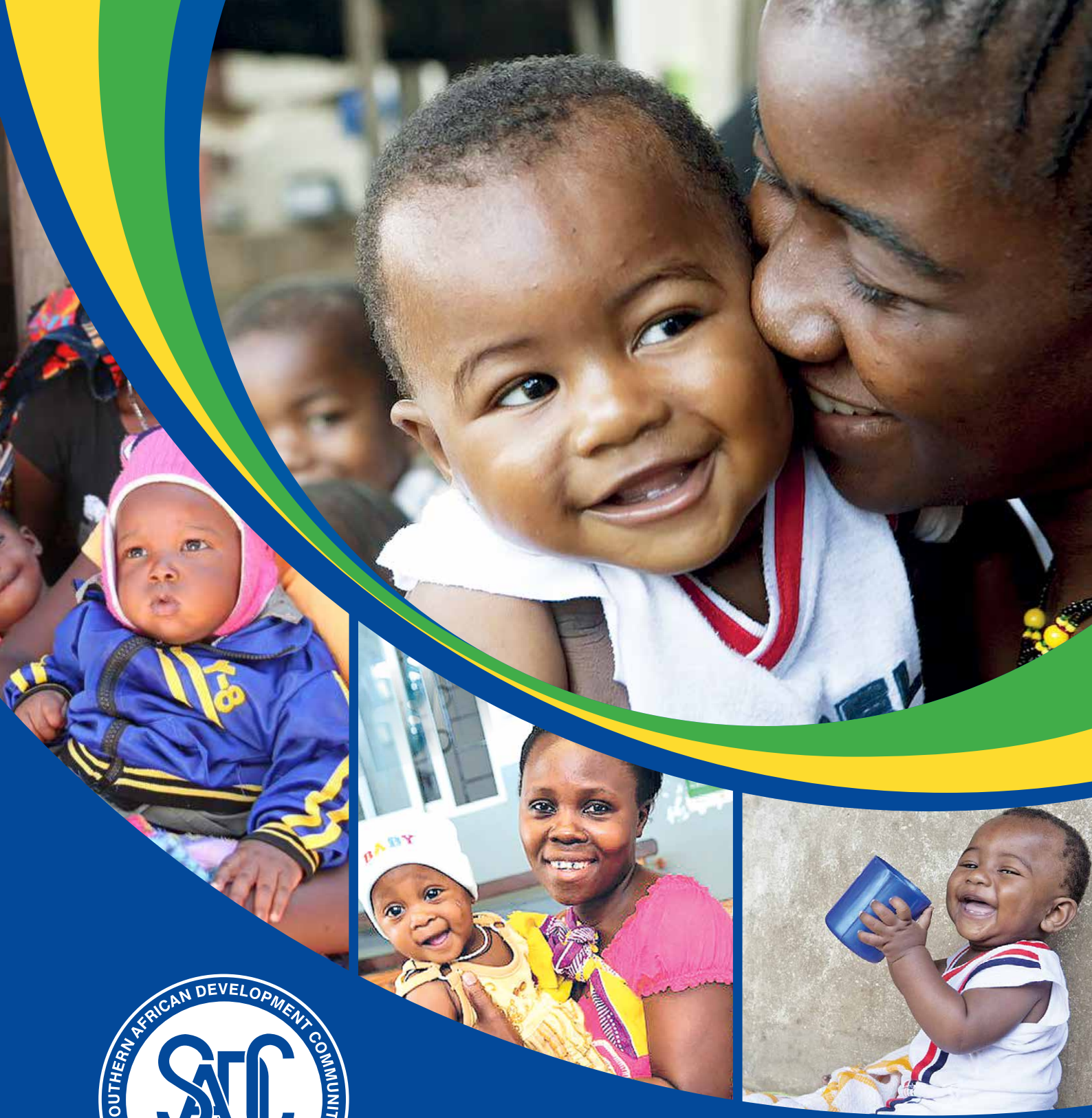

REGIONAL GUIDELINES FOR THE REGULATIONS ON MARKETING OF BREASTMILK SUBSTITUTES AND DESIGNATED PRODUCTS IN THE SADC MEMBER STATES

August 2019

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FOR THE REGULATIONS ON MARKETING OF BREASTMILK SUBSTITUTES AND DESIGNATED PRODUCTS IN THE SADC MEMBER STATES

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ISBN: 978-99968-913-1-1

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Background

One of the most critical times for good nutrition is in the first 1,000-day period from the start of a woman's pregnancy until a child's second birthday. Breastmilk is the best food for children's health and development during this critical window. It provides all the vitamins, minerals, enzymes and antibodies that children need to grow and thrive. In 2016, *The Lancet* confirmed the critical importance of breastfeeding. Better breastfeeding practices could save 823,000 children (mainly by preventing approximately half of all diarrhea episodes and one-third of infections). Approximately, 228,000-311,000 children's deaths and 2.6% of Gross National Income are lost in Africa, US$42 billion in Sub-Saharan Africa. Optimal breast-feeding can also prevent 20,000 breast cancer deaths in mothers worldwide each year and generate economic savings of US $300 billion.[1]

Oxford University and the nongovernmental organization Alive and Thrive found that sub-optimal breastfeeding was responsible for the deaths of 600,000 children due to diarrhea and pneumonia and 100,000 mothers due to breast and ovarian cancers annually can be attributed to sub-optimal breastfeeding.[2]

In May 1981, the World Health Assembly (WHA) adopted the *International Code of Marketing of Breast-milk Substitutes* (hereafter referred to as 'the *Code*') to limit these inappropriate marketing practices. The *Code*, plus subsequent relevant resolutions of the World Health Assembly related to supporting, promoting and protecting breastfeeding, express the collective will of the highest global authority on health and carry substantial political and moral weight. Nevertheless, 38 years after the adoption of the *Code*, global sales of breast-milk substitutes total nearly $70 billion. Although the rate of exclusive breastfeeding did rise slightly between 1995 and 2014 from 33% to 41%,[3] milk-based formula manufacturers took advantage of population growth during the period and anxiety about rising rates of HIV infection in mothers of infants. Between 2008 and 2013 the total world milk-based formula sales volume grew by 40.8 % from 5.5 to 7.8 kg per infant/child per year, a rate greatly exceeding GDP growth over the same period. Between 2014 and 2018 this figure was estimated to rise by 30·4 % to 10·8 kg per infant/child per year, with growth led by the infant and follow-up categories.[4]

In October of 2018, a meeting was convened where Member States in SADC agreed to jointly work together in the development of Regional standards on the Code of Marketing Breastmilk Substitutes and Maternity Protection. Subsequently, the approval to develop the regional standards was granted by the Health Ministers at their November 2018 meeting in Windhoek, Namibia.

It was agreed that a coordinated approach to *Code* implementation will help prevent the problem of the cross-border promotion that occurs when a country with strong *Code* legislation is subjected to advertisements from a neighbouring country with weak regulation. Additionally, it was noted that *Code* protections, generally, do not govern exports. Accordingly, strong regional policies and regulations to protect, promote and support breastfeeding and complementary feeding will help the region and countries in it to have healthier populations, less demands on health care systems, and be better prepared in case of emergencies.

It is with this background that a legal consultant was engaged by UNICEF ESARO to support SADC to strengthen the content of regulations and legislation and compliance with such laws in alignment with the *International Code of Marketing of Breast-milk Substitutes*, subsequent relevant resolutions of the World Health Assembly, and the aims of the International Labour Organization's *Maternity Protection Convention*.

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[1] Cesar G Victora, Rajiv Bahl, Aluísio J D Barros, Giovanny V A França, Susan Horton, Julia Krasevec, Simon Murch, Mari Jeeva Sankar, Neff Walker, Nigel C Rollins for The Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effects. *The Lancet*. Vol 387 January 30, 2016 Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)01024-7/fulltext estimated that 823,000 children die from suboptimal breastfeeding. This total was not disaggregated regionally, the World Health Organization did estimate regional and global totals in WHO. Global Health Risks: Mortality and burden of disease attributable to selected major risks. Geneva: WHO, 2009. P. 50, table A3 "Table A3: Attributable mortality by risk factor and income group in WHO regions, estimates for 2004." Available at: https://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf

[2] Walters DD, Phan LTH, Mathisen R. The cost of not breastfeeding: global results from a new tool. *Health Policy and Planning*, 2019, 1–11.

[3] UNICEF IYCF Global Databases, May 2019; 2019 Global Breastfeeding Scorecard; http://www.fao.org/3/ca5162en/ca5162en.pdf

[4] P Baker,, J Smith, L Salmon, S Friel, G Kent, A Iellamo, JP Dadhich, and M Renfrew. Global trends and patterns of commercial milk-based formula sales: is an unprecedented infant and young child feeding transition underway? *Public Health Nutrition*: page 1 of 11.

SADC context

Despite the remarkable scientific evidence on the health benefits of breastfeeding, there has been limited progress in the last forty years to significantly raise breastfeeding rates. Globally, only 43% of children under six months are exclusively breastfed (fed only breastmilk, with no additional foods or liquid, including water).

In the SADC region, exclusive breastfeeding rates range from 11 percent in Comoros to 72 percent in Zambia. Exclusive breastfeeding rates in the first 6 months in the SADC Region has been increasing in several Member States, however, only 7 out of the 16 Member States (Lesotho, Eswatini, DRC, Malawi, Tanzania Zambia and Zimbabwe) have exclusive breastfeeding rates of 50 percent and above which is the target set by the World Health Organisation (WHO)[5]. **See table 1**

Table 1: Exclusive Breastfeeding Rates in SADC Member States

SADC Member States	Most recent Data Collection Period	% Babies Exclusively Breastfed to 6 Months
Angola	2015-16	38.7
Botswana	2007-08	20
Comoros	2012	21
DR of the Congo	2013-14	54
Eswatini	2014	64
Lesotho	2014	67
Madagascar	2012-13	42
Malawi	2015-16	61
Mauritius	no data	25
Mozambique	2013	41
Namibia	2013	48
Seychelles	no data	no data
South Africa	2016	32
United Rep. of Tanzania	2015-16	57.8
Zambia	2018	70
Zimbabwe	2018	61

[5] Member state reports

While manufactured breast-milk substitutes are not the only products that undermine breastfeeding, they are promoted by aggressive, sophisticated and well-funded means that are likely to contribute to an overall reduction in exclusive breastfeeding. In some cases, mothers that are influenced by such marketing switch to using inexpensive substitutes, such as plain water, evaporated milk, or various filler ingredients popularised in local cultures either immediately, or when their financial resources to continue purchasing manufactured infant formula declines during the recommended period of exclusive breastfeeding. The clearest indication of the far-reaching benefits of curbing commercial promotion of manufactured breast-milk substitutes, is the rise in national exclusive breast-feeding rates after national regulations are proposed and finalised. Implementing regulations to curb the marketing correlate closely with a modest and sometimes dramatic rise in breast-feeding rates, often rising when the draft regulations are proposed and again when they are finalized.

Situations in which breast-feeding are medically discouraged are rare. The current guidance advocates permanently refraining from breastfeeding *only* when infants suffer from three rare conditions: classic galactosemia (in which case a special galactose-free formula is needed), infants with maple syrup urine disease (in which case, a special formula free of leucine, isoleucine and valine is needed), and phenylketonuria. Other situations require temporary discontinuation of breastfeeding (including when mothers are suffering from certain temporary illnesses such as sepsis or when they are ingesting certain pharmaceutical drugs including opioids, iodine, radioactive drugs, and chemotherapy).

However, UNICEF found that despite the moderate and growing uptake of national regulations implementing the *International Code* worldwide, only six countries had implemented adequately resourced monitoring and enforcement programs, none of which were African countries[6]. Plainly, there is much to do to ensure that regulatory controls are enforced.

The AU Commission support expresses the highest level of political support and the most specifically relevant issue of breastfeeding in the region. In February 2019, the AU Commission launched the continental nutrition accountability scorecard and which adapted to SADC context to depict performance of SADC Member States. It should be noted that, according to the Continental accountability nutrition scorecard, only Six (6) Member States (Botswana, Madagascar, Mozambique, South Africa, United Republic of Tanzania and Zimbabwe) have Full Provisions of the Law on code of marketing of Breastmilk Substitutes. There are other Member States that have many provisions of the law namely, Comoros, Democratic Republic of Congo, Malawi and Zambia.

Globally, children under six months are exclusively breastfed

Member States have exclusive breastfeeding rates

Breastfeeding rates target set by (WHO)

[6] UNICEF/World Health Organization, and the International Baby Food Action Network. *Marketing of Breast-Milk Substitutes: National Implementation of the International Code Status Report 2018,* (New York: UNICEF, 2018) Online at: http://apps.who.int/iris/bitstream/handle/10665/272649/9789241565592-eng.pdf?ua=1 Though Rwanda has, by far, the highest rates of exclusive breastfeeding worldwide: 87%."

Breastfeeding during emergency situations

There are contexts such as emergencies and HIV where breastfeeding has been undermined through the marketing and distribution of breast-milk substitutes and designated products.

According to the Global Breastfeeding Collective, a network of NGOs and UN institutions led by UNICEF and the World Health Organization, there is much countries can and must do to protect and support[7] Conflicts, natural disasters and epidemics often force families from their homes and result in devastating food insecurity, limited access to clean water and disruptions to basic services—with women and children bearing the greatest consequences. In these settings, where access to clean water and the hygienic conditions needed to prepare and use powdered infant formula safely are frequently compromised, the risk of diarrhoea and other diseases increases. Breastfeeding guarantees a safe, nutritious and accessible food source for infants and young children and a protective shield against disease and death. According to global guidance, breastmilk substitutes required for an emergency response should ONLY be purchased.

Despite this directive, infant formula and powdered milk are commonly donated in emergency contexts based on commercial interests or a lack of awareness. In the short term, unregulated donations can undermine breastfeeding. Over the long term, mothers and their children become reliant on breastmilk substitutes and may not be able to afford to purchase them once the donations cease, giving them no choice but to turn to inadequate and often dangerous alternatives. *Code* implementation is thus important in such situations to prohibit the dangerous unregulated distribution of breastmilk substitutes and ensure that they are only procured and made available to those infants who really need them, without undermining those babies who can be breastfeed and whose health and survival depends upon it.

The *Code* does:

- not restrict the availability of breastmilk substitutes, feeding bottles or teats, only how they are marketed;
- does not prohibit the use of BMS during emergencies, only the way in which they are procured and distributed: and
- is intended to protect artificially fed babies by ensuring breast-milk substitutes will be used as safely as possible on the basis of impartial, accurate information and adequate labelling.

[7] Global Breastfeeding Collective. Breastfeeding in Emergencies Situations. (New York: UNICEF, 2018) at https://www.unicef.org/nutrition/files/8_Advocacy_Brief_on_BF_in_Emergencies.pdf

Breastfeeding and HIV/ADS

Breastfeeding is best for babies, even for mothers with HIV/AIDS.

WHO's 2016 *Guideline: Updates on HIV and Infant Feeding* was prepared with research-quality-graded evidence collected from a systematic review of the scientific literature.

Mothers living with HIV can breastfeed without negative consequences for their own health and the health of their children. When these mothers take antiretroviral medicine consistently throughout the breastfeeding period, the risk of transmitting HIV to their children is extremely low.

Achieving 'HIV-free survival' for children means balancing the prevention of HIV with the prevention of other causes of child mortality—and the approach depends largely on context. In settings where undernutrition is widespread, access to clean water and adequate sanitation are limited and infections such as pneumonia and diarrhoea threaten children's lives, breastfeeding combined with good adherence to HIV treatment gives HIV-exposed infants the best chance to survive and thrive.

International guidance calls on national or subnational health authorities to decide whether health services will mainly counsel, and support mothers known to be living with HIV to either:

- breastfeed and receive ARV drug interventions or
- avoid all breastfeeding as the strategy that will most likely give infants the greatest chance of HIV-free survival.

In either case, implementation of the Code is important in protecting parents from commercial pressures to give up breastfeeding and switch to substitutes and ensuring that these products are used as safely as possible where they are needed, on the basis of impartial, accurate information and adequate labelling.

Rationale for restricting the advertising and promotion of breastmilk substitutes and designated products

A key challenge in protecting, supporting, and promoting breastfeeding is the lack of adequate policies and legislation to protect, promote, and support breastfeeding mothers from the aggressive and unethical promotion of breastmilk substitutes, and designated products such as feeding bottles and teats. Promotional tactics are often designed to undermine women's confidence in their ability to breastfeed and persuade them to forego it or give it up in favour of inferior and expensive breast-milk substitutes that can put their baby's health and survival at risk.

While regulations specifically tailored to curb inappropriate commercial advertising and promotional practices by breast-milk substitute manufacturers and retailers are important, fully enforcing them requires coordination and collaboration among a variety of law enforcement officials involved in consumer protection, administration of corporate taxation, international trade and border controls, trademarks, billboard advertising, regulation of health care facilities, health professionals, and health research ethics. Other statute-empowered officials have analogous law enforcement experience (such as tobacco control officials) or relevant issue-dedication (such as women's or youth advisory councils) that may help improve the effectiveness of regulatory control of breast-milk substitutes.

[8] WHO/UNICEF. Guideline: UPDATES ON HIV AND INFANT FEEDING. (Geneva: WHO, 2016). Available at: https://apps.who.int/iris/bitstream/handle/10665/246260/9789241549707-eng.pdf;jsessionid=C0449E1EB5ABA1192D6186A5C8E457B1?sequence=1

Some laws of general application may provide protection against commercial marketing practices if enforced by motivated and informed consumer protection enforcement officials (or citizen activists), such as general laws prohibiting misleading or deceptive advertising. Where possible, such laws could be enforced with requests that judges issue restraining orders against future, similarly misleading or harmful advertising. Similarly, law enforcement agencies could be asked to issue enforcement-policy statements clarifying that it considers certain common commercial promotional practices to be inherently misleading, deceptive, and/or harmful. If efforts to obtain legal recourse against breast-milk substitute companies are always delayed until after the campaign is launched, they may provide too little protection to infants and young children. Enforcement officials, public health advocates, and child protection advocates need speedy cost-effective tools to prevent prohibited marketing practices and immediately restrain them. Delays in regulatory action until after advertising campaigns, discount campaigns, and promotional events have run their course are ineffectual paper victories.

Monitoring is a key element of implementing the *International Code* because simply enacting legislation or regulations does not automatically ensure that it will be adhered to. Inspection and enforcement authorities may not be aware of violations, may not alone be equipped or adequately resourced to take enforcement action. Likewise, BMS companies have a track record of exploiting loopholes in regulatory restrictions. For instance, companies have a demonstrated practice of promoting breast-milk substitutes even in Zambia where many provisions of the *International Code* have been implemented in domestic regulations for more than a decade. A 2016 study in the country showed that: "non-compliance with the *Code* and/or [*Statutory Instrument*] no 48[9] of 2006 of the Laws of Zambia by manufacturers and distributors was prevalent. This is despite the efforts to control unethical marketing strategies through the implementation of the Infant and Young Child Feeding (IYCF) programme and enforcement of the Law. Of note, manufacturers' labels may employ visuals that violate the *Code* and/or SI no. 48 Researchers found many examples of product labels idealizing the food as well as price reductions and in-store promotional displays.

Effective systematic monitoring by government officials requires inter-departmental collaboration because regulatory controls at marketplace access points (e.g., national border controls, grocery and pharmacy retailers) and advertising and promotional activities (multi-media advertising channels promotion by health care professionals) are traditionally regulated in diverse departments. While there is only modest internal African cross-border trade in this (and other) goods and services, all SADC countries import these products, approximately 85% of which originates from Europe and, even there, companies based in only four of 27 EU Member States dominate: France, The Netherlands, Ireland, and Switzerland. Unless comprehensive regulatory controls are implemented and strictly enforced, the 2.7 billion-tonne global infant formula market-which rose by 7% between 2011 and 2016 - is expected to grow by 4% per year from 2017 to 2021.[10]

Conducting surveys of new mothers is one way of monitoring the success of breastfeeding promotion policies. UNICEF houses a database of the results of such surveys.[11] According to a global UNICEF survey of U.N. Member States, while approximately 40% of nations have fully implemented the *International Code of Marketing of Breastmilk Substitutes*, only six countries have implemented comprehensive monitoring programs to ensure that regulations are being followed. Furthermore, according to a collection of national surveys of six-month exclusive breastfeeding rates compiled by UNICEF, only two African countries come within 20 percentage points of the what *The Lancet* considers to be optimal rates of six-month exclusive breastfeeding (90%[12]): Rwanda (87%) and Zambia (72%).

[9] P. Funduluka1,2, S. Bosomprah3,4, R. Chilengi3, R.H. Mugode5, P.A. Bwembya1,B. Mudenda1,6 Marketing of breast-milk substitutes in Zambia: Evaluation of compliance to the international regulatory code. *Journal of Public Health* at pp. 1–7. Available at: : https://www.researchgate.net/publication/315669425

[10] Global infant formula products market: estimations and forecasts for production and consumption Author Yi Chen of Gira; Published in *China Dairy* July 2018 Available at: https://www.girafood.com/wp-content/uploads/2018/09/GIRA_ChinaDairy_GlobalInfantFormulaProductsMarketEN_June 2018.pdf

[11] See: UNICEF. Infant and Young Child Feeding. Updated July 2018. On-line Database: https://data.unicef.org/topic/nutrition/infant-and-young-child-feeding/

[12] Cesar G Victora, Rajiv Bahl, Aluísio J D Barros, Giovanny V A França, Susan Horton, Julia Krasevec, Simon Murch, Mari Jeeva Sankar, Neff Walker, Nigel C Rollins for The Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effects. The Lancet . Vol 387 January 30, 2016 at 476. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)01024-7/fulltext

Purpose

The SADC guidelines for the regulations on Marketing of Breastmilk Substitutes and designated products are developed to provide guidance to the Member States on key prescripts that should be put in place in national legislations to regulate the marketing of Breastmilk Substitutes and designated products.

The guidelines are adopted from the technical regulations developed by the International Code Documentation Center (ICDC) to assist national government to implement the *International Code of Marketing of Breast-milk Substitutes at* the national level as a statute, regulation, or decree. The guidelines can serve as a benchmark against which SADC national governments can measure the scope of protections already in place in their national legislation. It can also serve as a legislative drafting aide to governments that plan to implement a law for the first time.

While the *International Code* is widely supported, globally, it is unevenly implemented at the national level. For instance, 12 of 16 SADC Member States have implemented some of the provisions of the international *Code*, however not all have enacted national regulations which affects enforcements. The SADC Member States have demonstrated some leadership in standard-setting, even if compliance monitoring needs to be strengthened.

Importantly, however, enacting legislation does not guarantee the end of marketing practices or the provision of breast-feeding-friendly employment standards. Rates of exclusive breastfeeding to six months are far short of optimal in most countries worldwide, with the single exception of Rwanda. Monitoring is a vital tool for tracking violations of national laws and the *International Code* to help identify where a failure to enforce existing laws is contributing to low breastfeeding rates. Monitoring can also help identify areas where formula marketers have identified regulatory loopholes that need to be closed by governments to more effectively achieve the purposes of the legislation: healthier children. See Annex 1 (Monitoring Report Form).

Scope of the technical regulation of marketing of breastmilk

The adoption and use of the guidelines will enable the Member States of the Southern African Development Community to implement and amend national regulations and, where necessary, national enabling legislation to start adoption process with effect from July 1, 2021.

Member States will also convene a technical working group to monitor the impact of and create a regional council to monitor compliance with such regulations by national inspection authorities, and the impact on national rates of exclusive breastfeeding and other health-related indicators, and report progress with recommendations for improving enforcement, closing regulatory gaps, and strengthening conflict of interest safeguards, and protecting the best interests of infants and their mothers.

The scope of the guidelines outlined below provides a **model regulation** or guide with sections and recommended legislative prescripts for inclusion in the national regulations on the ***Marketing of Breast-milk Substitutes.***

Preamble

These regulations propose way of protecting mothers from marketing pressure from breast-milk substitutes, to support breastfeeding consistent with international best-practices and the best interests of the child and mother. While preventing up to approximately 310,000 deaths of infants in the continent is the primary achievable benefit of adopting and enforcing these laws, doing so would also help ensure that the consumption of breast-milk substitutes does not undermine the market for agri-food products that breastfeeding mothers ordinarily consume and reduce the health care costs and workforce productivity losses caused by premature death and cognitive impairment.

The regulations to ensure safe and adequate nutrition for infants and young children by protecting breastfeeding and by regulating the marketing of food products manufactured for infants and young children and of feeding bottles, teats and pacifiers.

UNDERSTANDING that the restrictions on commercial advertising and promotional activities are to be interpreted in such a manner that protects the best interests of children by promoting breast feeding.

RECOGNIZING THAT In all cases, the safeguards described in this regulations should be interpreted to best protect children and, to that end, should be construed as providing the most protection of mothers and children from the manipulation inherent in commercial marketing of designated products and to the fullest extent possible regulatory officers and judicial officials should be able to restrain future activities of companies that violate the regulations.

FURTHER APPRECIATING THAT typeface and other specifications to ensure prominence in instructions for use and warnings relevant to sections 4-10 can be achieved by ensuring that any material promoting a breastmilk substitutes or complementary food product must include a statement in characters no smaller than the size of characters used to display the product name in printing at least as clearly visible as black text on a white background and positioned on the front of the package label.

Chapter I
Introductory

Section 1. Short Title and Commencement

- This Regulations may be called the [Regulations of Marketing of Foods and Related Products for Infants and Young Children or Protection of Breastfeeding].
- The Regulations shall come into effect 60 days after the date of enactment.
- These regulations extend to the whole of [Any land].

Section 2. Definitions

For purposes of this Regulations

- "**Advertise**" means to make any communication or representation by any means whatsoever for the purpose of promoting the sale or use of a designated product, including but not limited to:
  - written publication, television, radio, film, electronic transmission including the Internet, social media, video, telephone or mobile application;
  - display of signs, billboards, or notices; or
  - exhibition of pictures or models.

- "**Advisory Board**" means a Board set up under Section 18.
- "**Artificial feeding**" means feeding with any manufactured food product which replaces breastmilk either partially or totally.
- "**Brand name**" means a name given by the manufacturer to a product or range of products.
- "**Bottle feeding**" means feeding liquid or semi-solid food from a bottle with a nipple.
- "**Complementary food**" means any food suitable or represented as suitable as an addition to breastmilk, infant formula or follow-up formula for infants from the age of six months (180 days) up to the age of 36 months.[5]
- "**Complementary food product**" means a complementary food that is commercially processed.
- "**Container**" means any form of packaging of a designated product for sale as a retail unit, including wrappers.
- "**Cross-promotion**" means the use of similar brand names, packaging designs, labels, text, images, colour schemes, symbols or slogans or other means for the purpose of promoting another product.
- "**Designated product**" means
  - infant formula;
  - any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;
  - follow-up formula;
  - young child formula;
  - ready-to-use therapeutic food;
  - complementary food product;
  - feeding bottles, teats, pacifiers; and
  - such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a "designated product" for the purposes of this Regulations.

- "**Distributor**" means a person, corporation or other entity engaged in the business of marketing any designated product, whether wholesale or retail.
- "**Follow-up formula**" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [citation to the country's standard for follow-up formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Follow-up Formula] and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age. It is also referred to as "follow-on formula" or "follow-on milk". For the purposes of this Regulations, the term 'follow-up formula' includes any follow up formula for special medical purposes or dietary requirements and any follow-up therapeutic milk product for acutely malnourished infants and young children.
- "**Health care facility**" means a public or private institution or organisation or private practice engaged directly or indirectly in the provision of health care or in health care education. It also includes a day-care centre, a nursery or other infant and young child-care facility.
- "**Health claim**" means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. A health claim includes but is not limited to the following:
  - a nutrient function claim that describes the physiological role of the nutrient in growth,

[5] P. Funduluka

development and normal functions of the body;
- any other function claim concerning specific beneficial effects of the consumption of foodsor their constituents that relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health; and
- a reduction of disease risk claim relating to the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

In this context, health means a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.

- "**Health professional**" means a health worker with a professional degree, diploma or license, such as a medical practitioner, a registered nurse or midwife or such other person as may be specified by the Minister of Health by a Notice in the Official Gazette.
- "**Health worker**" means a person providing or in training to provide health care services in a health care facility, whether professional or non-professional, including voluntary unpaid workers.
- "**Infant**" means a child from birth up to the age of 12 months.
- "**Infant formula**" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [citation to the country's standard for infant formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Infant Formula] and intended to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months and includes products that continue to meet part of an infant's nutritional requirements after the first six months. For the purposes of this Regulations, the term 'infant formula' includes any formula for special medical purposes or dietary requirements and any therapeutic milk product for acutely malnourished children.
- "**Inspector**" means an inspector appointed under Section 22.
- "**Label**" means a tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on a container of a designated product. For the purposes of Sections 5(1), 5(3), 10 and 11, the term "label" includes packaging and inserts.
- "**Labelling**" includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.
- "**Logo**" means an emblem, picture or symbol by means of which a company or a product is identified.
- "**Manufacturer**" means a person, corporation or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through a person controlled by or under an agreement with it.
- "**Market**" means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.
- "**Minister**" means Minister of Health of [Any land].
- "**Nutrition claim**" means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute a nutrition claim:
  - the mention of substances in the list of ingredients;
  - the mention of nutrients as a mandatory part of nutrition labelling;
  - quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.

- "**Pacifier**" means an artificial teat for babies to suck, also referred to as a "dummy".
- "**Prescribed**" or "as prescribed" means prescribed or as prescribed by rules or written decision made pursuant to this Regulations.
- "**Promote**" means to employ any method of directly or indirectly encouraging a person, a health facility or any other entity to purchase or use a designated product whether or not there is reference to a brand name.
- "**Ready-to-use therapeutic food**" means an energy-dense, vitamin- and mineral-enriched food specifically designed to treat severe acute malnutrition in children above 6 months.
- "**Sample**" means a single or small quantity of a designated product provided without cost.
- "**Sponsorship**" means any financial or in-kind assistance to a person or a group of persons or an entity, whether public or private, and sponsor has a corresponding meaning.
- "**Young child**" means a child from the age of 12 months up to the age of three years (36 months
- "**Young child formula**" means an industrially formulated milk or milk-like product of animal or vegetable origin that is marketed or otherwise represented as suitable for feeding young children from 12 months of age. It is it is also referred to as "growing up milk", "formulated milk" or "toddler milk" (note: There is yet no international quality standard for young child formula).

Chapter II
Prohibitions

Section 3. Sale of a designated product

A person shall not distribute for sale, sell, stock or exhibit for sale any designated product that

- is not registered according to Section 21 of this Regulations or is not in accordance with the conditions of its registration; or
- has exceeded its date of minimum durability.

Section 4. Promotion

- [Except as provided in Subsections 4(4) and 4(5)], a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to:
  - advertising;
  - sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;
  - giving of one or more samples of a designated product to any person;
  - donation or distribution of information or education material referring to infant or young child feeding, or performance of educational functions related to infant or young child feeding, except as provided in Section 15;
  - the use of health or nutrition claims on labels of designated products or in any information and education materials referring to infant and young child feeding, except as provided in Section 15; and
  - cross-promotion of a designated product.

- A manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf
  - donate, waive payment through any means or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 per cent of the retail price, any quantity of a designated product to a health worker or a health care facility;
  - donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, note pads, growth charts and toys or any other materials which refer to or may promote the use of a designated product;
  - offer or give any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value to a health worker or to an association of health workers engaged in maternal and child health, including but not limited to fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences;
  - sponsor events, telephone counselling lines, campaigns or programmes related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics;
  - directly or indirectly establish relationships with parents and other caregivers through baby clubs, social media groups, child care classes, contests and any other means; or
  - include the volume of sales of designated products in the calculation of its employee remuneration or bonuses, nor set quotas for sales of designated products.

- A health worker or an association of health workers engaged in maternal and child health shall not:
  - accept any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value, from a manufacturer or distributor or any person on his or her behalf;
  - accept or give samples of designated products to any person; or
  - demonstrate the use of infant formula, except to individual mothers or members of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of infant formula as well as the other information required by Chapter IV.
- A manufacturer or distributor may promote a complementary food product provided that:
  - such promotional practice does not take place in a health care facility;
  - any material promoting a complementary food product must include a statement in characters [insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”] on:

- the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
- the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.

- Notwithstanding Subsection 4(4), a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote a complementary food product through the use of messages in any form or media that are prohibited by Subsection 7 (1) (a) – (f).

Section 5. Prohibitions related to labelling of designated products

- Except as provided in Subsection 7(1), a manufacturer r distributor shall not offer for sale or sell a designated product if the labelling thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.

- A manufacturer or distributor shall not offer for sale or sell a designated product, other than a feeding bottle, teat or pacifier, unless the labelling thereto indicates in a clear, conspicuous and easily readable manner, in [insert appropriate language(s)], the following particulars:
  - instructions for appropriate preparation and use in words and in easily understood graphics;
  - the age in numeric figures after which the product is recommended;
  - a warning about the health risks of improper use, preparation or storage and of introducing the product prior to the recommended age;
  - the list of ingredients and the declaration of nutritional value in accordance with relevant national standards or, in the absence of such standard, with the relevant Codex Alimentarius Standard;
  - the required storage conditions both before and after opening, taking into account climatic conditions;
  - the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;
  - the name and national address of the manufacturer or distributor; and
  - such other particulars as may be prescribed.

- A manufacturer or distributor shall not offer for sale or sell a designated product if the labelling thereto contains any health or nutrition claim or any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development and normal functions of the body.

Section 6. Prohibitions related to labelling of infant formula, follow-up formula and young child formula.

- A manufacturer or distributor shall not offer for sale or sell infant formula or follow-up formula unless the container or label affixed thereto, in addition to the requirements of Section 5, conforms to the following:
  - contains the words, “IMPORTANT NOTICE” in capital letters and indicated thereunder, the statement “Breastfeeding is the normal and optimal way to feed infants and young children. Breastmilk is important for the healthy growth and development of infants and young children. It protects against diarrhea and other illnesses” in characters [insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”];
  - contains the word, “WARNING” and indicated thereunder, the statement, “Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby’s health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup” in characters [insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height”];
  - has preparation instructions for infant or follow-up formula in powdered form that state that:
    - powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
    - it is necessary for formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and

- any unused milk must be discarded immediately after every feed.
- includes a feeding chart in the preparation instructions;
- does not use the terms “maternalised”, “humanised” or terms similar thereto or any comparison with breastmilk;
- does not use text that may tend to discourage breastfeeding;
- specifies the source of the protein; and
- in the case of follow-up formula, states that the product shall not be used for infants less than six months old or used as the sole source of nutrition of infants in characters [insert particulars relating to character size, placement, appearance, etc.]

- A manufacturer or distributor shall not offer for sale or sell young child formula unless the container or label affixed thereto, in addition to the requirements of Subsections 5 and 6(1)(c) – (g), states that the product shall not be used to feed infants below 12 months or used as the sole source of nutrition for young children” in characters [insert particulars relating to character size, placement, appearance, etc.]

Section 7. Prohibitions related to labelling of ready-to-feed therapeutic food and complementary food product.

- In addition to the requirements of Subsections 5(2) and 5(3), a manufacturer or distributor shall not offer for sale or sell a ready-to-feed therapeutic food or a complementary food product if the container or label affixed thereto contains:
  - any text, image or other representation that suggests the suitability of the product for infants under six months including but not limited to references to development milestones clearly reached before six months, the use of pictures of infants appearing to be younger than six months;
  - any text, image or other representation that idealises the product or is likely to undermine or discourage breastfeeding or create a belief that the product is equivalent or superior to breastmilk;
  - any text, image or representation that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared complementary foods;
  - any recommendation to feed the product in a bottle or otherwise promote the use of bottle feeding;
  - any endorsement, or anything that may be conveyed or construed as an endorsement by a health professional, an association of health professional or other body; and
  - any element that allows for cross-promotion of any other designated product.

- In addition to the requirements of Subsection (1), the label of a ready-to-feed therapeutic food or a complementary food product shall include:
  - A statement in characters [insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”] on:
    - the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
    - the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
  - instructions for preparation, storage, handling and use; and
  - a feeding chart showing the appropriate ration/serving size consistent with guiding principles issued by the World Health Organization.

Section 8. Prohibitions related to labelling of skimmed or condensed milk.

A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used to feed infants” in characters [insert particulars relating to character size, placement, appearance, etc.]

Section 9. Prohibitions related to labelling of low-fat and standard milk

A manufacturer or distributor shall not offer for sale or sell low-fat or standard milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used as an infant’s sole source of nourishment” in characters [insert particulars relating to character size, placement, appearance, etc.]

[Note: The milks in Sections 8 and 9 do not fall within the scope of this Regulations unless they are marketed or otherwise represented as suitable for infants. It is recommended that these labelling provisions be incorporated into the country's food labelling laws. In addition, Sections 8 and 9 will require revision according to the types of milk products available in individual countries.]

Section 10. Prohibitions related to labelling of feeding bottles and teats

A manufacturer or distributor shall not offer for sale or sell a feeding bottle or teat unless the package or label affixed thereto, in addition to the requirements of Section 5(1), indicates in a clear, conspicuous and easily readable manner, in [insert appropriate language(s)], the following particulars:

- the words, "IMPORTANT NOTICE" in capital letters and indicated thereunder, the statement, "Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhea and other illnesses" in characters [insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"];
- the statement, "Warning: It is important for your baby's health that you follow the cleaning and sterilisation instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast" in characters [insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"];
- instructions for cleaning and sterilisation in words and graphics;
- a statement explaining that feeding with a cup is more hygienic than bottle feeding;
- a warning that children should not be left to self-feed for long periods of time because extended contact with sweetened liquids, including infant formula, may cause severe tooth decay; and
- the name and national address of the manufacturer or the distributor.

Section 11. Prohibitions related to labelling of pacifiers (dummies)

A manufacturer or distributor shall not offer for sale or sell a pacifier unless, in addition to the requirements of Section 5(1), it is labelled with the words, "Warning: Use of a pacifier can interfere with breastfeeding" in characters [insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height"].

Chapter III
Health worker responsibilities

Section 12. Health worker responsibilities

- Heads of health care facilities and national and local health authorities shall take measures to encourage and protect breastfeeding and to implement these regulations and shall give information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all of the information specified in Chapter IV.
- Health workers shall encourage, support and protect breastfeeding. They are expected to know the provisions of this Regulations, particularly the information specified in Chapter IV.
- Health workers shall work to eliminate practices that directly or indirectly impede the initiation and continuation of breastfeeding, such as prelacteal feeds.
- Health workers shall make in writing a report to the head of their work place, who shall in turn report to the Advisory Board, on any offer a health worker receives for a sample or gift or other benefit from a manufacturer or distributor or on any other contravention of the provisions of these regulations.

Chapter IV
Information and education

Section 13. Information and education materials about infant and young child feeding

Information and education materials, whether written, audio or visual, which refer to infant and young child feeding shall:

- contain only correct and current information and shall not use any pictures or text that encourage artificial feeding, or the use of feeding bottles or that discourage breastfeeding;
- be written in [insert appropriate language(s)];
- not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or to breastfeeding;
- not contain the brand name or logo of any designated product nor of any manufacturer or distributor of a designated product; provided that this clause shall not be applicable to information about designated products intended for health professionals as authorised by Section 15 of these regulations; and
- clearly and conspicuously explain each of the following points:
  - the benefits and superiority of breastfeeding;
  - the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;
  - how to initiate and maintain exclusive and sustained breastfeeding;
  - why it is difficult to reverse a decision not to breastfeed;
  - the importance of introducing complementary foods from the age of six months;
  - how and why any introduction of artificial feeding, the use of a feeding bottle or the early introduction of complementary foods negatively affects breastfeeding; and
  - that complementary foods can easily be prepared at home using local ingredients.

Section 14. Information and education materials about artificial feeding or feeding bottles.

- If the material referred to in Section 13 includes the topic of artificial feeding or the use of a feeding bottle, it must also include the following points:

- instructions for the proper preparation, storage and use of the product including cleaning and sterilisation of feeding utensils;
- how to feed infants with a cup;
- the health risks of artificial feeding, the use of a feeding bottle and improper preparation of the product;
- explain that
  - powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
  - it is necessary for powdered formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and
  - any unused milk must be discarded immediately after every feed.
- the approximate financial cost of feeding an infant or a young child with such a product in the recommended quantities and
- that the practice of providing follow-up formula and young child formula is not necessary.

- Except as provided in Section 15 concerning product information for health professionals, materials that include the topic of artificial feeding shall not contain any health or nutrition claims or other representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the body.

Section 15. Product information for health professionals

Manufacturers and distributors may give materials about designated products to health professionals if such materials

1. are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;
2. provide references to published and peer-reviewed studies to support any representation or claim that states or suggests that a relationship exists between the product or a constituent thereof and health, growth or development; and
3. are otherwise in accordance with Sections 13 and 14 of these regulations.

Section 16. Submission of materials to Advisory Board (OPTIONAL)

Any person who produces or distributes any materials referred to in this Chapter shall submit copies to the Advisory Board according to procedures as shall be prescribed.

Chapter V
Administration

Section 17. Implementation

- The Ministry of Health is principally responsible for the implementation of these regulations.
- The Minister of Health shall, when necessary, call upon other ministries to ensure the implementation of these regulations.
- For the purpose of implementing these regulations, the Minister of Health shall have the following powers and functions:
  - to promulgate such rules as are necessary or proper for the implementation of these regulations and the accomplishment of its purposes and objectives;
  - to call for consultations with government agencies and other interested parties to ensure implementation and strict compliance with the provisions of these regulations and the rules promulgated hereunder;
  - to cause the enforcement of these regulations and to appoint an official within the Ministry of Health to carry out this function on his or her behalf; and
  - to exercise such other powers and functions that may be necessary for or incidental to the attainment of the purposes and objectives of these regulations.

Section 18. National Advisory Board for the Promotion and Protection of Breastfeeding

- (1) There shall be a National Advisory Board for the Promotion and Protection of Breastfeeding to be composed of the following members:
  [In this section, list the members to be included in this inter-disciplinary committee. Countries usually include representatives of relevant ministries such as Health, Education, Communications and Trade, and representatives of organisations of health professionals, consumers, breastfeeding support groups as well as experts in relevant fields. The proviso excludes manufacturers and distributors of designated products from the committee because their involvement would create conflicts of interest. Such conflicts would compromise independence, integrity and credibility of a committee that advices the government on enforcement of the law.]
  - The Minister of Health or his representative who shall be its ex officio Chairman;
- The Minister shall appoint the members of the Advisory Board within 90 days of the date of enactment.
- The members of the Advisory Board shall hold office for a term of 3 years and shall be eligible for re-nomination.
- Any member of the Advisory Board may, at any time, resign his or her office by writing to the Minister or shall vacate his or her office if the Minister so directs. A vacancy shall be filled in the same manner as the original appointment for the balance of the unexpired term.
- The Advisory Board may invite national or foreign experts to take part in the meetings as observers and may constitute committees or appoint experts for the purpose of detailed study of any matter set before it.
- The Minister may, by Notice published in the Official Gazette, change the size and composition of the Advisory Board.

Section 19. Administration of the Advisory Board

- The Minister shall appoint the Secretary of the Advisory Board and such other officers as he or she deems necessary to carry out the purposes of these regulations.
- The Advisory Board shall hire permanent staff necessary to carry out its functions, subject to the budgetary approval of the Minister.
- The Advisory Board shall meet as often as it deems necessary, but not less than once every month at such time and place as the Secretary shall indicate.
- The Secretary shall call meetings at the direction of the Chairman; shall maintain minutes of the meetings and shall perform such other duties as may be directed by the Advisory Board.
- Two-thirds of the members of the Advisory Board shall constitute a quorum for a meeting.
- A majority vote of the members present shall be sufficient to approve any business presented in a meeting of the Advisory Board.
- Decisions of the Advisory Board shall be certified by the Secretary.
- The Advisory Board may make such other administrative rules as may be required for its proper functioning.

Section 20. Powers and functions of the Advisory Board

- The Advisory Board shall have the following powers and functions:
  - to advise the [insert Head of State] and the Minister on national policy for the promotion and protection of breastfeeding;
  - to create regional committees to carry out the functions of the Advisory Board at the regional level, as may be prescribed;
  - to advise the Minister on designing a national strategy for developing communication and public education programmes for the promotion of breastfeeding; information and educational materials on the topics of infant and young child feeding; continuing education for health workers on lactation management and the requirements of these regulations; curricula for students in the health professions that include lactation management and to ensure widespread distribution of and publicity concerning these regulations, in a method as may be prescribed;
  - to review reports of violations or other matters concerning these regulations;
  - to issue instructions to inspectors as to actions to be taken, or take such other actions, against any person found to be violating the provisions of these regulations or the Rules promulgated pursuant thereto;
  - to scrutinize materials submitted in accordance with Section 16 and recommend appropriate actions to be taken in the case of a violation of Chapter IV; and
  - such other powers and functions, including the powers of an Inspector, as are conferred by the provisions of these regulations and as may be prescribed.

Section 21. Registration of designated products

- The Minister of Health shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.
- The Minister of Health shall, by notification in the Official Gazette, fix the date after which no designated product that is not registered may be imported, manufactured or sold.
- A person applying for registration of a designated product shall furnish such information and samples as may be prescribed.
- Once the registration of a designated product has been approved, a Certificate of Registration shall be issued.
- No Certificate of Registration shall be granted unless the designated product is in accordance with the [insert applicable Food Quality Standards] and has a label which is in accordance with the requirements contained in Chapter II of these regulations.

Section 22. Inspectors

The Minister shall appoint such persons as he or she sees fit having the prescribed qualifications to be Inspectors for purposes of these regulations within such local limits as he or she may assign to them respectively, provided that no person who has any direct or indirect financial interest in any designated product shall be so appointed.

Section 23. Powers of inspectors

- An inspector may, within the local limits for which he or she is appointed:
  - inspect any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted and all relevant records;
  - institute prosecution with respect to violations of these regulations and the Rules made pursuant thereto; and
  - exercise such other powers as may be prescribed.

Section 24. Procedure for inspectors

- Inspectors shall inspect, not less than the number of times as may be prescribed, the premises as may be prescribed.
- After each inspection, the inspector shall submit a report including any finding of a violation of these regulations and the Rules made pursuant thereto, to the Advisory Board and seek instructions as to the action to be taken in respect of such contravention.
- Institute enforcement, where applicable.

Chapter VI
Sanctions, procedure

Section 25. Penalties

- Any person who him or herself or on behalf of any other person contravenes Sections 3 and 4 shall be punishable with imprisonment for a term which shall not be less than [time] or a fine which shall not be less than [amount] or both.
- Any person having been convicted of an offence under Subsection (1) and who is again convicted of an offence under that Subsection, shall be punishable with imprisonment for a term which shall not be less than [time] or with a fine that shall not be less than [amount].
- Any person who contravenes any other provision of these regulations or the Rules made pursuant thereto may be subject to a fine of up to [amount] or a period of imprisonment of up to [time].

Section 26. Improvement Notices, Cease and desist orders, etc.

- If the Minister or any official appointed by the Minister has reasonable grounds for believing that any person is failing to comply with the provisions of these regulations or the Rules promulgated thereto, he or she may, by a notice served on that person (in these regulations referred to as an "improvement notice"):
  - state the grounds for believing that the person is failing to comply with these regulations or the rules promulgated thereto;
  - specify the matters which constitute the person's failure so to comply;
  - specify the measures which the person must take to secure compliance; and
  - require the person to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.

- In addition to the powers conferred under Subsection (1), the Minister or any official appointed by the Minister shall have the power to make cease and desist orders upon receiving a report from an inspector or the Advisory Board of a violation of the provisions of these regulations or the Rules promulgated pursuant thereto.
- Any person who fails to comply with an improvement notice or cease and desist order under Subsection (1) or (2) shall, after notice and an opportunity to be heard have been given, be guilty of an offence.

Section 27. Suspension or revocation of certificate of registration

Where any person has been found to have contravened any of the provisions of these regulations, or the Rules pursuant thereto, the Minister, upon written recommendation of the Advisory Board, and after notice and an opportunity to be heard have been given, may suspend or revoke any Certificate of Registration that has been issued to that person pursuant to these regulations.

Section 28. Suspension or revocation of professional license

Where any health professional has been found to have contravened any provision of these regulations, or the Rules pursuant thereto, the Minister may recommend to the relevant authority the suspension or revocation of any license for the practice of that person's profession.

Section 29. Suspension or revocation of license, permit or authority

[Note: If a license to manufacture, import or sell is required, give the Minister the power to suspend or revoke that license.]

Section 30. Appeal

There shall be a right of appeal to the [insert higher court] within 35 days of the judgment.

Section 31. Strict liability for officers, directors, etc.

When the person guilty of an offence under these regulations is a corporation, company, partnership, firm or other association, every director, officer, partner, and employee of the corporation, company, partnership, firm or other association, shall also be liable for that offence unless he or she proves that the offence was committed without his or her knowledge or consent.

Section 32. Institution of prosecution

- Prosecution under these regulations may be instituted only by:
  - an Inspector appointed pursuant to Section 22;
  - a member of the Advisory Board; or
  - a representative of such voluntary organisation engaged in the field of child welfare and development or child nutrition as the Minister, by notification in the Official Gazette, may authorise in this behalf

Section 33. Public enforcement

- Any person has the right to lodge a formal complaint to the Advisory Board, which may recommend that proceedings be instituted against any person relating to a violation of any provision that constitutes an offence under these regulations or Rules made pursuant thereto.
- Any person has the right to commence an action for damages in [a court of law] against any manufacturer or distributor or other person for any harm suffered as a result of a violation of any provision that constitutes an offence under these regulations or Rules made pursuant thereto.

Section 34. Power to make Rules

- The Ministry of Health may, by notification in the Official Gazette, make Rules for carrying out the purposes of these regulations.
- In particular but notwithstanding the generality of the foregoing provision, such Rules may prescribe:
  - the functions of the Advisory Board;
  - conditions and procedures for the registration of designated products;
  - qualifications and powers of and procedures for Inspectors appointed pursuant to these regulations; and
  - procedures for submitting educational or informational materials to the Advisory Board.

Conclusion

Restricting the advertising and promotion of breast milk substitutes is a demonstrably effective—though imperfect—technique for improving population level breast-feeding rates. This can be achieved by enacting and fine-tuning natioanal legislation based on the guidelines of regulations on the marketing of breastmilk substitutes and designated products.

Supporting breast-feeding with improved employment standards for mothers in the workforce can also help. In both policy areas, it is critical to monitor compliance and develop a regiment of domestic and regional cooperation among multi-departmental law enforcement agencies.

ANNEX 1

Monitoring and Reporting Record

Excerpt from
UNICEF/WHO, *Netcode Toolkit: Monitoring the Marketing of Breast-Milk Substitutes: Protocol for Ongoing Monitoring Systems,* (New York: UNICEF, 2017).

Available at in English, French, Spanish and Russian at: https://www.who.int/nutrition/publications/infantfeeding/netcode-toolkit-monitoring-systems/en/

UNIVERSAL MONITORINIG AND REPORTING FORM

Use this form to report any practice that violates national Code laws. Please complete the form below, send it together with a copy of the materials, pictures of the same (if any) to the following address: (xxx,xxx), email address: xxx@xxx.com; web site: www.xxx.com, sms to:09xx- xxxxxx.

Description of Violation

1. When was the violation observed: (dd/mm/yyyy and time): _____

2. Where (place, town, others)

(For newspapers and periodicals, indicate the name and date of publication; for TV/radio indicate channel, or frequency; webpage; Facebook account or other social media accounts; name of health facility; shop)

3. Company name: _____

4. Brand name (if no brand can be identified please describe logo or any promotional device): _____

_____

5. Type of product being promoted: Please indicate the relevant item by ticking (✓) the box.

- ☐ Infant formula (0+ months)
- ☐ Follow up/on formula (6+ months)
- ☐ Growing-up milk (12+ months)
- ☐ Any other milk for children 0-36 months
- ☐ Any other food or liquid marketed for infants (0-6 months)
- ☐ Commercial complementary food or liquid (6+ months) describe _____
- ☐ Feeding bottles or teats
- ☐ Other product (describe) _____
- ☐ No specific product(s) promoted, but practice undermines breastfeeding (describe)

6. Type of violations: Please indicate the relevant item by ticking (✓) the box.

- ☐ Advertisement (TV, radio, printed materials)
- ☐ Online or social media promotion
- ☐ Promotion in retail outlets
- ☐ Free samples
- ☐ Promotional material for health professionals
- ☐ Promotion in health facilities
- ☐ Gifts or scholarships to health workers
- ☐ Sponsorship of health professional associations
- ☐ Inadequate labelling
- ☐ Health and nutrition claims on labels
- ☐ Non-compliant informational/educational materials
- ☐ Events/gifts targeting pregnant women or mothers
- ☐ Industry contact with pregnant women and mothers
- ☐ Sales incentives/sales quota for company personnel
- ☐ Donations of relevant products
- ☐ Other(s) _____

7. Additional details and observations (you may want to add details related to the violation you have detected):

_____

_____

8. Attached picture/sample materials/sample label/product: Yes/No (circle the answer)

Name of monitor	
Address/Agency	
Contact number	
Email address	

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