

**MARKETING OF INFANT AND YOUNG CHILDREN FOOD AND
OTHER DESIGNATED PRODUCTS (REGISTRATION, SALES, ETC),
REGULATIONS 2019**

Realising the need to protect and promote optimal Infant and Young Child Feeding (IYCF) and eliminate practices that undermine it and need to ensure the proper use of Breastmilk Substitutes when necessary on the basis of adequate information and through appropriate marketing and distribution;

Realising the implication of the uncontrolled marketing of the infant and young child foods on the breastfeeding of children and the health, social and economic implications of this act on infants and young children;

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act Cap. N1 LFN 2004 and of all the power enabling it in that behalf, the Governing Council of National Agency For Food and Drug Administration and Control (NAFDAC), with the approval of the Honourable Minister for Health, hereby makes the following Regulations:-

1. SCOPE

These Regulations seek to control and regulate the marketing and practices related to Breastmilk Substitutes and complementary food when marketed or otherwise represented to be suitable with or without modification for use as a partial or total replacement of Breastmilk and *related* products; and

These Regulations shall also apply to the control of quality of Breastmilk Substitutes and Complementary food and information concerning the use of *the Breastmilk Substitutes, Complementary food and Related Products.*

2. PRODUCT REGISTRATION:

- 1) Every product shall be registered.
- 2) Application for registration of the Products shall be made in such form as may be stipulated from time to time by the Agency.
- 3) Every application shall be accompanied by:-
 - (a) a non-refundable fee as may be stipulated by the Agency;
 - (b) samples of the Product as the Agency may demand;
 - (c) the original certificate of analysis of the Product;

- (d) evidence of any special labeling of the character, quality and safety of the Product;
 - (e) original copy of combined certificate of Manufacture and Free Sale for the imported product from the statutory body in the country of origin responsible for the safety of the product duly authenticated by the Nigeria Mission in that country;
 - (f) original copy of radiation-free test certificate;
 - (g) evidence of Trademark ownership;
 - (h) a notarized declaration that the information contained in the Registration form are correct and that all the documents submitted are genuine;
 - (i) a Power of Attorney or a contract manufacturing agreement from the manufacturer signed by a General Manager or Director of the manufacturing company and notarized in the country of manufacture authorizing a Nigeria representative to register the product in Nigeria;
 - (j) an undertaking that the Breastmilk Substitutes and Related products shall NOT be promoted or advertised.
- 4) Complementary foods (home-made or commercially produced) may be promoted subject to these Regulations and relevant Guidelines made from time to time by the Agency.

3. INVALIDATION OF CERTIFICATE OF REGISTRATION:

The Agency may suspend, withdraw or cancel the certificate of registration of a product if:-

- (a) the ground on which the product was registered was found to be false or incomplete;
- (b) the circumstances under which the product was registered no longer exist;
- (c) any of the conditions or undertaking under which the product was registered has been contravened;
- (d) the standard of quality, safety or efficacy as stipulated in the documentation for registration is not being complied with;
- (e) the premises where the product is being manufactured, processed, or stored by the holder of the certificate of registration or his agent or nominee is not suitable for the manufacturing, processing, or storage of the product; or
- (f) the undertaking not to promote or advertise Breastmilk Substitutes and Related products has been breached.

4. INFORMATION & EDUCATION

- 1) The Agency shall control the planning, design, production, provision and dissemination of Information and Educational (IEC) materials on Infant and Young Child's Foods designed to be used by families and those involved in the field of infant and young child's health and nutrition.
- 2) Information and Educational materials dealing with the feeding of infants intended to reach pregnant women, mothers of infants and young children or members of their families shall be written in **English and three other major Nigerian languages** and include clear and appropriate information on all the following points:
 - (a) the benefits and superiority of breastfeeding;
 - (b) process of breastfeeding and how to maintain breastfeeding including maternal nutrition;
 - (c) the negative effects of introduction of artificial feeding on lactation;
 - (d) the danger of inappropriate use of the Products and artificial feeding;
 - (e) the difficulty of returning to breastfeeding after a period of artificial feeding; and
 - (f) importance of exclusive breastfeeding for six months and continued breastfeeding with appropriate complementary feeding until the child is 24 months of age or beyond.

5. PROHIBITION OF PROMOTION TO MOTHERS AND THE PUBLIC

- 1) Advertisement or promotion to the public of the breastmilk substitutes and related products are hereby prohibited;
- 2) Manufacturers and distributors are hereby prohibited from providing, directly or indirectly, samples of Breastmilk Substitutes and Related products to pregnant women, mothers or members of their families;
- 3) In conformity with subsections (1) and (2) of this section, there shall not be point-of-sale advertising, giving of samples, discounted sales, coupon, tie-in sales or any other promotional method devised to induce sales of Breastmilk Substitutes and Related products directly to the consumer at the retail level;
- 4) Manufacturers and distributors shall not seek direct or indirect contact of any kind with pregnant women or mothers of infants or young children or distribute to them or members of their families any gift of articles, utensils or any material whatsoever which may promote artificial feeding or use of the breastmilk substitutes;

- 5) Persons employed in marketing of Breastmilk Substitutes and Related products shall not, as part of their job responsibilities, perform educational functions to pregnant women or mothers of infants and young children;
- 6) The marketers of breastmilk substitutes shall not seek direct or indirect contact of any kind with pregnant women or mothers of infants and young children;
- 7) Marketing personnel in their personal capacity shall not take advantage of their personal relationship to promote the breastmilk substitutes to pregnant women, mothers of infants and young children or members of the families when they visit or come in contact with them;
- 8) No manufacturer, distributor or retailer of the breastmilk substitutes shall:-
 - (a) use a system of sales of incentive for the marketing personnel which includes the volume of sales of any of Breastmilk Substitutes and Related products for the purpose of the calculation of bonuses;
 - (b) set quotas specifically for the sale of any Breastmilk Substitute;
 - (c) do cross-promotion of Breastmilk Substitutes and Related products;
 - or
 - (d) have special display of any Breastmilk Substitute.
- 9) The government, non-governmental organisations and the private enterprises may promote the use of Complementary foods for complementary feeding as being appropriate for the child of age 6 months to 24 months of age or beyond.

6. HEALTH CARE SYSTEM

- 1) It is an offence for the manufacturers or distributors of Breastmilk Substitutes and Related products to compromise or seek to compromise the healthcare system including a health care facility, health worker, the regulator or their staff with inducements contrary to the provisions of these Regulations;
- 2) No facility of healthcare system shall be used for the purpose of promoting or displaying placards, posters or materials concerning Breastmilk Substitutes and Related products;
- 3) No individual or body corporate shall offer Breastmilk Substitutes at a low price to health care institutions;
- 4) No healthcare facility shall allow manufacturers or distributors of the Breastmilk Substitutes to use their facilities for commercial events, contests or campaigns;

- 5) Manufacturers or distributors of the products shall not directly or indirectly be allowed to provide education to parents or other caregivers in health facilities;
- 6) Donation of Breastmilk Substitutes and related products, equipment, information and educational materials to a health care facility by manufacturers or distributors of the Products is hereby prohibited;
- 7) Nothing in sub-regulation (6) shall prevent donation of the product for humanitarian purposes during emergency or prevent the government from procuring the products for health or humanitarian programmes;
- 8) The manufacturer shall ensure that Breastmilk Substitutes and related products donated for emergency or procured by government for humanitarian programmes do not display company's brand name and logo;

7. HEALTH CARE WORKERS TO PROMOTE BREASTFEEDING

- 1) Health workers responsible for maternal and infant nutrition shall make themselves familiar with their responsibilities under these Regulations;
- 2) Health workers shall encourage and protect breastfeeding and shall eliminate practices that directly or indirectly undermine the initiation and continuation of breastfeeding;
- 3) Feeding with the Breastmilk Substitutes, where necessary, shall be demonstrated only by health workers to mothers or family members who are medically in need of any of the substitutes;
- 4) Information or education provided by manufacturers and distributors to health professionals relating to the Breastmilk Substitutes or complementary food shall not imply or create a belief that artificial feeding is equivalent or superior to breastfeeding or that Breastmilk Substitute is equivalent or superior to breastmilk;
- 5) No financial or material inducements to promote Breastmilk Substitutes shall be offered by manufacturers or distributors to health workers or members of their families or accepted by health workers or members of their families;
- 6) The head of any health facility shall prohibit acceptance into the health care facility of gifts of Breastmilk Substitutes or gift of any article which may idealize or promote use of the Breastmilk Substitutes;
- 7) Samples of Breastmilk Substitutes or equipment for their preparation or use shall not be provided to health workers;

- 8) Manufacturers and distributors of Breastmilk Substitutes and related products shall not sponsor meetings of health professionals and scientific meetings
- 9) Health workers shall not give samples of the Breastmilk Substitutes to pregnant mothers, mothers of infants and young children or members of their families except to satisfy medical needs;
- 10) The head of a health facility shall fully disclose to the Agency in writing of any offer made by a manufacturer or distributor of the products to the health care facility or health workers working in the facility;
- 11) Health workers shall have power to ban Breastmilk Substitutes from their health facility and seize and confiscate such Breastmilk Substitute brought to their healthcare facility without medical prescription;
- 12) Any Breastmilk Substitutes seized by any health worker shall be documented and forwarded to the Agency by the head of the health care facility.

8. LABELLING FORMAT AND CONTENT

- 1) The following regulations, in addition to the Extant NAFDAC Pre-Packaged Food (Labelling) Regulations, shall apply to the labelling of the Product
 - (a) Labels shall be clear, easily readable, printed on or firmly attached to the container and shall include:
 - (i) trade name of Breastmilk Substitutes and Related products;
 - (ii) name and address of the manufacturer;
 - (iii) net content by 'mass/volume';
 - (iv) country of manufacture;
 - (v) batch number;
 - (vi) instruction for use;
 - (vii) storage condition;
 - (viii) date of manufacture;
 - (ix) expiry date;
 - (x) ingredients used in descending order of magnitude;
 - (xi) nutritional information;
 - (xii) the age after which the product is recommended in numeric figures;
 - (xiii) the words 'important notice' or their equivalent which shall be conspicuous;

- (xiv) a statement of the superiority of breastfeeding;
 - (xv) instructions for appropriate preparation and warning against the health hazards of inappropriate preparation,
 - (xvi) the text in English and three (3) national languages (Hausa, Igbo and Yoruba) and
 - (xvi) a statement that Breast milk is the best food for the child.
- (b) Labels shall not show any baby, photograph, drawing or other graphic representation to idealize or promote the use of the Products
 - (c) The use of graphics shall be permitted only for the purpose of illustrating the method of preparation of the Products;
 - (d) Labels and its contents shall not contain nutritional or health claims;
 - (e) Warning on possible presence of intrinsic microbial contaminant such as Cronobacter (Enterobacter) sakazakii and other pathogenic microorganisms in the Breastmilk Substitutes and complementary food shall be on the label;
 - (f) No label shall contain telephone, website or other electronic communication contacts.

9. QUALITY OF FOODS FOR INFANTS AND YOUNG CHILDREN

1. All imported or locally manufactured Products being sold or otherwise distributed shall meet existing prescribed National Industrial Standard or any international standard for the time being in force;
2. Products imported to Nigeria shall be of equal standard with the same or similar products being used in the manufacturing country;
3. An importer shall obtain from relevant accredited Government Agencies combined certificate of manufacture and free sale relating to the quality of Breastmilk Substitutes and Related products intended for importation;
4. An importer shall obtain certificate of analysis relating to the quality of Breastmilk Substitutes and Related products intended for importation;
5. Agency shall monitor compliance of the products with these Regulations and assess through the Good Manufacturing Practices and other appropriate regulatory measures the risk of intrinsic contamination of powdered infant formula by pathogenic microorganisms during the manufacturing, storage, preparation and handling of Breastmilk Substitutes and Related products.

10. **IMPLEMENTATION AND MONITORING**

- 1) It shall be the duty of the manufacturers and distributors of the breastmilk substitutes and complementary food, appropriate nongovernmental organisations, professional groups and consumer organisations to collaborate with the Agency in the implementation of these Regulations;
- 2) Non-Governmental organisations, professional groups, institutions, and individuals shall have the responsibility of notifying the Agency of any observed activities of manufacturers or distributors incompatible with these Regulations;
- 3) Agency shall report to the Minister the annual compilation of the implementation status of the Regulations in each of the States of the Federation and this may form the basis of **annual national report** to the Director-General of WHO;
- 4) The Minister shall annually communicate the status of implementation of these Regulations to the Director-General of World Health Organizations (WHO);
- 5) The Agency shall implement these Regulations together with any subsequent explanations, clarifications and additions made to the International Code of Marketing of Breastmilk Substitutes 1981 in the Resolutions of WHA's Annual General Meeting that have been adopted, adapted and approved by the Minister for implementation in Nigeria;
- 6) The Agency shall within 4 weeks after WHA meeting, obtain from the Minister adopted, adapted and approved explanations, clarifications and additions made to the Code referred to in the sub-regulation (5) above and implement them as if they were part of these Regulations;
- 7) Notwithstanding the provisions of sub-regulation (6) above, the Minister may direct Director Family Health to convene a meeting of the relevant stakeholders to consider any WHA resolution and make necessary recommendation for the approval of the Minister.

11. **SELF-MONITORING BY MANUFACTURERS AND DISTRIBUTORS**

- 1) Notwithstanding any other measures that may be taken by the Agency for the implementation of these Regulations, manufacturers and distributors of the Products shall be responsible for the monitoring of their marketing and practices for compliance with the provisions of these Regulations.
- 2) Every manufacturer and distributor of the Products shall regularly apprise each member of their marketing personnel of these Regulations and their responsibilities under it.

12. **RESPONSIBILITY OF THE AGENCY**

The Agency shall:-

- (1) Ensure full implementation of the provisions of these Regulations and relevant National guidelines;
- (2) Monitor compliance with these Regulations by the manufacturers, distributors, health care workers, supermarkets, pharmacies, day care centers etc;
- (3) Ensure that health workers and health professionals discharge their responsibilities to disseminate information as specified in these Regulations; and
- (4) Periodically appraise record of self-monitoring.

13. **OFFENCES AND PENALTY**

- (1) A person who contravenes any provision of these Regulations is guilty of an offence and liable on conviction with the following Penalties;
 - Warning letters for first offenders.
 - Seizure of offending articles for destruction.
 - Hold or detention of product to allow possible corrective action.
 - Administrative fines.
 - Closure of business premises.
 - Invalidation of Marketing License.
 - Confiscation of assets.
 - Prosecution of recalcitrant offenders, leading to fines running between no less than **₦150,000 – ₦2,000,000** and jail term not exceeding 6 months, as appropriate.
- (2) Where an offence under these Regulations is committed by a body corporate or firm or other association of individuals, every:
 - (a) director, manager, head, secretary or other similar officer of the company;
 - (b) partner or officer of the company;
 - (c) trustee of an Incorporated Trustee Organization concerned; or
 - (d) person concerned in the management of the affairs of the association shall be guilty of that offence and liable to be proceeded against and punished for the offence in the same manner as if he had himself committed the offence unless it is proved that the act or omission constituting the offence took place without his knowledge, consent or connivance.

- (3) Where a director, a staff, a partner or a trustee of a body corporate **in the course of duty** commits an offence under these Regulations, the body corporate shall be guilty of that offence and liable to be proceeded against and punished for the offence as if the offence had been committed by the body corporate.

14. **FORFEITURE AFTER CONVICTION**

- 1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government: -
 - (a) any Product, asset or property constituting the offence, or such asset and property derived from any proceeds directly or indirectly obtained as a result of the offence; and
 - (b) any property, equipment or facilities used to commit or to facilitate the commission of the offence.
- 2) Any violating Product seized by the Agency shall be forfeited to the Federal Government and shall be dealt with in such manner as the Agency may from time to time determine.

15. **REVIEW AND AMENDMENT**

- 1) These Regulations repealed and replaced the Marketing of Infant and Young Children Food and other Related products (Registration, Sale, etc.) 2005.
- 2) These Regulations may be reviewed within 5 years of its commencement;
- 3) Notwithstanding the provision of sub-regulation (2) above, these regulations shall continue to be in force until when they are reviewed.

16. **INTERPRETATIONS:**

- (a) Interpretation of these Regulations shall take into cognizance the International Code of Marketing Breastmilk Substitutes 1981 as adopted by the WHA in its Resolution WHA34.22 of 1981 and subsequent relevant WHA Resolutions on the subject of Marketing Breastmilk Substitutes that have been adopted, adapted and approved by the Minister.
- (b) For purposes of these Regulations:
 - (1) "**Advertisement**" means any communication or representation by any means whatsoever for the purpose of promoting the sale or use of a Product, and it includes:

- (a) written publication, television, radio, film, electronic transmission including the Internet, social media, video, telephone or mobile application;
 - (b) display of signs, billboards, or notices; and
 - (c) exhibition of pictures or models.
- (2) "**Agency**" means National Agency for Food and Drug Administration and Control (NAFDAC)
 - (3) "**Artificial feeding**" means feeding with any manufactured food product which replaces breastmilk either partially or totally;
 - (4) "**Bottle feeding**" means feeding liquid or semi-solid food from a bottle with a teat;
 - (5) "**Brand name**" means a name given by the manufacturer to a product or range of products.
 - (6) "**Breastmilk Substitute**" means any food being marketed or otherwise represented as a partial or total replacement of breastmilk whether or not suitable for that purpose.
 - (7) "**Code**" shall mean the International Code of Marketing Breastmilk Substitutes 1981 as adopted by WHA in 1981 and subsequent relevant WHA Resolutions on the subject of Marketing Breastmilk Substitutes.
 - (8) "**Complementary food**" means any food manufactured or locally prepared whether suitable or represented to be suitable as an addition to breastmilk or infant formula or other acceptable milk sources for infants after the age of six months (180 days) up to the age of 24 months or beyond when breastmilk or infant formula is no longer sufficient **PROVIDED** that those complementary foods that are milk or milk like products shall be regarded as breastmilk substitutes;
 - (9) "**Container**" includes anything in which or with which food is served, stored, displayed, packed, wrapped, kept or transported and with which food is in direct contact;
 - (10) "**Cross-promotion**" is a marketing programme or promotion that targets customers of a product or service with an offer to purchase a related product;
 - (11) "**Distributor**" means a person, corporation or other entity in the public or private sector directly or indirectly engaged in the business of marketing and or distribution of any of the Products at a wholesale or retail level;

- (12) "**Educational information**" means any written or audio-visual material or Information disseminated by an individual that seeks to impart knowledge in relation to products covered by these regulations;
- (13) "**Educational material**" means any written or audio-visual material intended for the public such as flyers, brochures, books, newspaper articles, video tapes, information from the Internet or other forms, that purports to give guidance on the appropriate use of products for infants and young children;
- (14) "**Feeding bottle**" means a device with an artificial teat, which is used to feed infants or young children;
- (15) "**Feeding cup**" means a cup with an artificial teat, spout or straws which is used to feed infants or young children;
- (16) "**Feeding Utensils**" means manufactured products with which an infant or young children can be fed in partial or total replacement of breastfeeding, which shall include feeding bottle and any of the Related Product as defined in this section.
- (17) "**Follow-up formula**" includes:
- (a) a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with Nigerian Industrial Standard (NIS) for follow-up formula or, in the absence of such standard, 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;
 - (b) products referred to as "follow-on formula" or "follow-on milk" or "Growing up milk"; and
 - (c) any products referred to as "Young child formula" which are formulated milk or milk-like product of animal or vegetable origin and usually called "growing up milk", "formulated milk" or "toddlers' milk" being marketed or otherwise represented as suitable for feeding young children from 12 months of age;
- (18) "**Health care facility**" includes:
- (a) 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; and
 - (b) nurseries or other infant and young child-care facility.
- (19) "**Health claim**" is any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health, and it includes:

- (a) a nutrient function claim that describes the physiological role of the nutrient in growth, development and normal functions of the body;
 - (b) any other function claim concerning specific beneficial effects of the consumption of foods or their constituents that relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health; and
 - (c) 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.
- (20) "**Health professional**" means any technical personnel involved in matters of human health or nutrition.
- (21) "**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.
- (22) "**Infant**" means a child from birth up to the age of 12 months.
- (23) "**Infant formula**" means industrially prepared milk or milk-like product of animal or vegetable origin and home-prepared formula 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.
- (24) "**International Standard**" shall mean the standard laid down under the directive of Codex Alimentarius Commission (CAC), the Codex Code of Hygienic Practice for Foods for Infants and Young Children or any other future standard that may be developed by CAC to improve the quality standards of the products;
- (25) "**Label**" means a tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, attached or otherwise appearing on a container of a food for infants and young children and related products. For the purposes of Sections 10(1), 10(3), 11-16, the term "label" includes packaging and inserts;
- (26) "**Logo**" means an emblem, picture or symbol by means of which a company or a Product is identified;
- (27) "**Low price**" means price below 80% of current market price as at the time of purchase.

- (28) "**Manufacturer**" means any person, corporation or entity engaged in the business of manufacturing a product whether directly, through an agent, or through a person controlled by or under an agreement with it;
- (29) "**Marketing**" means an act of promotion, distribution, sale or advertisement of a product and includes product public relations and information services;
- (30) "**Minister**" means the Federal Minister charged with the responsibilities for Health in Nigeria;
- (31) "**Ministry**" means the ministry charged with responsibilities for health in Nigeria;
- (32) "**Nutritional claim**" is 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; PROVIDED THAT the following "**claims**" shall not be regarded as nutritional claim:
- (a) the mention of substances in the list of ingredients;
 - (b) the mention of nutrients as a mandatory part of nutrition labelling;
 - (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label as required by these Regulations or the Agency;
- (33) "**Pacifier**", also referred to as a "dummy", means an artificial teat for babies to suck;
- (34) "**Partial replacement**" exists where there is a token breastfeeding;
- (35) "**Practices that directly or indirectly undermine the initiation and maintenance of breastfeeding**" include use of prelacteals and lactagogues;
- (36) "**Products**" means *breastmilk substitutes* and complementary food;
- (37) "**Promote**" means to employ any method directly or indirectly to encourage a person, a health facility or any other entity to purchase or use a product whether or not there is reference to a brand name;
- (38) "**Related Product**" includes feeding bottle, pacifier, teats and feeding cups (with spouts, straws or teats) or any children feeding utensils.
- (39) "**Sample**" means a single or small quantity of the product provided without cost;
- (40) "**Relevant Stakeholders**" means members of the National Technical Committee of the BMS and any other person or professional body the Minister may deem to be a relevant stakeholder"

- (41) **"These Regulations"** also means **'the Regulation'** and shall refer to each and every section of this body of Subsidiary Legislation titled *Marketing of Infant and Children Food and Other Designated Products (Registration, Sales, Etc), Regulations 2019* either read alone or together with other provisions;
- (42) **"Total replacement"** means not to give a child breastmilk at all and complete reliance on the complementary food as only source of nutrition of a child;
- (43) **"Young child"** means a child from the age of 12 months up to the age of 36 months;
- (44) **"WHA"** means World Health Assembly.

Short Title:

This Subsidiary Legislation can be cited as "MARKETING OF INFANT AND YOUNG CHILDREN FOOD AND OTHER DESIGNATED PRODUCTS (REGISTRATION, SALES, ETC), REGULATIONS 2019"

COMMENCEMENT: 1st June, 2019