SIXTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES First Regular Session



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SENATE S.B. No. 671

RECEIVED BY:

### Introduced by Senator Loren Legarda -

### **EXPLANATORY NOTE**

Breastmilk is the ideal food for newborns and infants because it not only provides them all the nutrients they need for healthy development, but also contains antibodies that protect them from common childhood illnesses including diarrhea and pneumonia. The WHO recommends that infants be restricted to breastfeeding for the first six months of their life, after which, other foods should be given along with continuous breastfeeding for up to two years and beyond.

Breastfeeding has also been proven to bring mothers several health benefits, such as reduced risks of acquiring breast and ovarian cancer, faster restoration of prepregnancy weight, and less probability of being obese.

Studies have also revealed that breastfeeding provides health benefits later in life. Most adults who were breastfed as babies have lower blood pressure and lower cholesterol, are less likely to become overweight and obese, and are less prone to type-2 diabetes.

In contrast, the use of infant formula can lead to some health hazards, primarily because it lacks the antibodies found in breastmilk. Also, many families do not have access to safe water, therefore, children are at greater risk of acquiring water-borne diseases when powdered milk is mixed with unsafe water.

With the worldwide rate of less than 40% of infants under six months of age being exclusively breastfed, a lot of parents are obviously still unaware of the necessity of practicing breastfeeding. This is due to the lack of information on the multitude of benefits that come with breastfeeding and on the consequences of using substitute formula.

This bill aims to inform families, health workers, and those involved in the field of infant and young child nutrition, on the advantages and superiority of breastfeeding, maternal nutrition, and the proper use of infant formula, among others.

In view of the foregoing, the passage of this bill is earnestly sought.

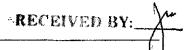
LOREN LEGARDA Senator



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### AN ACT PROTECTING, PROMOTING AND PRIORITIZING BREASTFEEDING AS A MEANS OF ENSURING THE HEALTH AND WELL-BEING OF INFANTS

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

### **CHAPTER I** GENERAL PROVISIONS.

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SECTION 1. Short Title. This Act shall be known as the "Breastfeeding Promotion Act of 2013."

- SEC. 2. Objectives. This Act aims to contribute to the provision of safe and adequate nutrition for infants by the protection, promotion and support of breast feeding and by ensuring the proper use of breastmilk substitutes when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.
- SEC. 3. Scope. This Act applies to the marketing and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; and feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.
- Definition of Terms: For the purposes of this Act, the following SEC. 4. definition of terms shall govern:
- "Advertising" means the business of conceptualizing, presenting or making available to the public, through any form of mass media, fact, data or information about the attributes, features, quality or availability of products within the scope of this Act.
- "Breastmilk Substitute" means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.
- "Complementary Food or Breastmilk Supplement" means any food whether manufactured or locally prepared, suitable as a complement to breastmilk or to

infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. This can include products also commonly called as "weaning food".

- (d) "Container" means any form of packaging of products for sale as a normal retail unit, including wrappers.
- (e) "Distributor" means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Act. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.
  - (g) "DoH" refers to the Department of Health

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- (h) "Infant" means a person falling within the age bracket of 0-12 months.
- (i) "FDA" refers to the Food and Drug Administration (FDA) created pursuant to Republic Act No. 9711, formerly known as the Bureau of Food and Drugs (BFAD).
- (j) "Health care system" means governmental, non-governmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child care institutions. It also includes health workers in private practice. For the purpose of this Act, the health care system does not include pharmacies or other established sales outlets.
- (k) "Health Worker" means a person working in the health care system, whether professional or non-professional, including volunteer workers. It also includes health workers in private practice. Traditional and other birth attendants, their assistants and other community volunteers involved in health and nutrition promotion and education shall likewise be included.
- (l) "Infant Formula" means a breastmilk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four to six months of age, and adapted to their physiological characteristics. Infant formula may also be prepared at home in which case it is described as "home-prepared."
- (m) "Label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a container of any product within the scope of this Act.
- (n) "Manufacturer" means a corporation or other entity in the public or private sector engaged in the business or function (whether directly or through an agent or an entity controlled by or under contract with it) of manufacturing a product within the scope of this Act.
- (o) "Marketing" means product promotion, distribution, selling, advertising, product public relations, and information services.
- (p) "Marketing firm" refers to any entity that does marketing or provides marketing services.

- (q) "Marketing personnel" means any person whose functions involve the marketing of a product or products coming within the scope of this Act.
- (r) "Milk company" shall refer to the owner, manufacturer, distributor, of breastmilk substitute or supplements, including their representatives who promote or otherwise advance their commercial interests in marketing those products.
- (s) "Other milk products, foods and beverages" refers to any provision or drink marketed as a partial or total replacement of breastmilk.
- (t) "Other related products" refers to all materials used to administer breastmilk substitutes, such as, but not limited to, feeding bottles, teats and other artificial feeding paraphernalia.
- (u) "Products within the scope of this Act" shall pertain to breastmilk substitutes, including infant formula, other milk products, food and beverages, including bottle-fed complementary foods, as well as teats and other commodities which intend to replace or substitute, in whole or in part, breastmilk and breastfeeding.
- (v) "Promotions" means the practice of giving temporary additional value to a product or service to achieve specific marketing objectives.
- (w) "Sample" means single or small quantities of a product provided without cost.
  - (x) "Secretary" shall mean the Secretary of Health.
- (y) "Supplies" means quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.
- (z) "Young child" means a person from the age of more than twelve (12) months up to the age of three (3) years (36 months)

# CHAPTER II INFORMATION AND EDUCATION

**SEC. 5.** The Department of Health shall ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility shall cover the planning, provision, design and dissemination of information, and the control thereof, on infant and young child nutrition.

The Department of Health should take appropriate measures to encourage and protect breastfeeding and promote the principles of this code. It should give appropriate information, training and advice to health workers in regard to their responsibilities, including the information specified in Section 6.

**SEC. 6.** Standards. Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants, shall include clear information on all the following points:

 (a) the benefits and superiority of breastfeeding

- (b) maternal nutrition, and the preparation for and maintenance of breastfeeding
  - (c) the negative effect on breast feeding of introducing partial bottle-feeding
  - (d) the difficulty of reversing the decision not to breastfeed
- (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes. Such materials shall not use any picture or text which may idealize the use of breastmilk substitutes.
- **SEC. 7.** Donations of informational or educational equipment or materials by manufacturers or distributors should be made only upon written approval of the appropriate government authority. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Act, and should be distributed only through the health care system.
- SEC. 8. Manufacturers, distributors or representatives of products covered by the Code may be allowed to conduct or be involved in the promotion, education and production of Information, Education and Communication (IEC) materials on breastfeeding, infant and young child care and nutrition, as long as the programs and materials used are reviewed and approved by the Secretary. Promotion of products intended for infants 0-12 months as covered by this code will not be allowed in such venues.
- **SEC. 9.** Personnel employed in marketing products within the scope of this Code shall not, as part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children. This should not be understood as preventing such personnel from being used for other functions by the health care systems at the request and with the written approval of the appropriate authority of the government concerned.

### CHAPTER III RESEARCH

**SEC. 10.** Research, Ethics Committee, Purpose - The DOH shall ensure that research conducted for public policy purposes, related to infant and young child feeding, should, at all times, be free from any commercial influence/bias; accordingly, the health worker or researcher involved in such must disclose any actual or potential conflict of interest with the company/person funding the research. In any event, such research and its funding shall be subjected to independent peer review. Towards accomplishing these ends;

Assistance for research and clinical trials given by manufacturers and 1 distributors are allowed only upon approval by an Ethics Committee and the DOH. 2 The same committee shall monitor said researches. 3 4 The researches shall be conducted in accordance with an approved protocol. Any changes in the protocol after it has been approved will be subject to a 6 new review and approval by the Ethics Committee 7 8 Assistance for research may be allowed subject to the following 9 conditions: 10 11 1. Researches involving well or ill infants and children as subjects shall be 12 limited to physiological factors and therapeutic studies 13 14 2. These studies should in no case be harmful to the subject 15 16 3. Should be limited to those with potential benefits for the particular 17 subject. 18 19 Recipients of research awards shall not allow themselves, their 20 organizations or their subjects, to be used directly or indirectly for any promotional 21 activity related to products within the scope of this Code. These may be by way of 22 display of posters and streamers patronizing the company, their products and/or as 23 lecturers/speakers or testimonials in the promotion of the products that undermine 24 breastfeeding. 25 26 27 28 29

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- Assistance for support of laboratory costs, reagents and other materials shall be allowed only upon approval and review by the Ethics Committee regarding the used based on submitted protocol.
- SEC. 11. Public Disclosure For transparency purposes, a disclosure and/or disclaimer of the sponsoring company should be done by the company itself, health worker, researcher involved through verbal declaration during public presentation of the research and in print upon publication.

### **CHAPTER IV** ADVERTISING, PROMOTION AND SPONSORSHIPS

SEC. 12. Responsibilities of the Secretary - The Secretary shall review all advertising, promotion or other marketing materials, whether written, audio, visual, audio-visual and electronics, including but not limited to mail, email, text messages, telephone calls and web site advertising for products as defined under section 9 and 10 of this code.

The Secretary shall develop, update substantive and procedural guidelines for reviewing advertising, promotional and marketing materials, including its screening when deemed appropriate. All such materials must have been approved and consented to in writing by the Secretary before the company's first public or commercial' exhibition.

SEC. 13. Prior Written Consent and Approval of the Secretary - No advertising, promotion or other marketing materials as defined in sections 14 and 15, whether

written, audio, visual, audio-visual, and electronic shall be printed, published, distributed, exhibited and broadcasted or in any manner released to the public without the prior review and approval by the Secretary. No blanket or general approval shall be allowed. Such written approval must be specific in product and time bound.

### SEC. 14, Advertising.

- (a) Advertising for infant formula and other products within the scope of this code intended for infants 0-6 months shall not be allowed.
- (b) Advertising for infant formula and other products within the scope of this code intended for infants 6-12 months shall be allowed upon review and approval of the Secretary.
- (c) Advertising of breastmilk supplement for a young child 12 months and older shall be allowed.

### SEC. 15. Promotions.

- (a) The General Public and Mothers
  - 1. Promotion for products within the scope of this code intended for infants 0-12 months shall not be allowed.
  - 2. Promotions of breastmilk supplement for a young child 12 months and older shall be allowed as long as it does not undermine superiority of breastfeeding.
- (b) , Healthcare System and Health Workers
  - 1. Promotion of products within the scope of this code intended for infants 0-12 months shall be allowed upon the review and approval of the Secretary.
  - 2. Promotion of products for a young child 12 months and older shall be allowed as long as it does not undermine superiority of breastfeeding.
- **SEC 16.** *Contents of Materials.* The following shall not be included in advertising, promotional and marketing materials:
- (a) Texts, pictures, illustrations or information which discourage or tend to undermine the benefits or superiority of breastfeeding or which idealize the use of breastmilk substitutes and milk supplements. In this connection, no pictures of babies and children together with their mothers, fathers, siblings, grandparents, other relatives or caregivers (or yayas) shall be used in any advertisements for infant formula and breastmilk supplements.
- (b) The term "humanized", "Maternalized", "close to mother's milk" or similar words describing breastmilk substitutes or milk supplements
  - (c) Pictures or texts that idealize the use of infant and milk formula.

### SEC. 17. Health and Nutritional Claims.

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- (a) Health and nutritional claims for products within the scope of the Act are allowed as long as it is based on scientific and factual information upon review and approval by the Secretary.
- (b) False or misleading information or claims of products within the scope of the Code are prohibited.
- (c) Promotion of products within the scope of this Code must be objective and should not equate or make the product appear to be as good or equal to breastmilk or breastfeeding in the advertising concept. It must not in any case undermine breastmilk or breastfeeding.
- **SEC. 18.** Information to Healthcare Workers. Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code shall be restricted to scientific and factual information, and such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It shall also include the information specified in Section 6 (c).

### SEC. 19. Promotions in Healthcare System. -

- (a) No facility of the health care system shall be used for the purpose of promoting products intended for infant 0-12 months within the scope of this Act. This Act does not however preclude the dissemination of scientific and factual information to health professionals as provided in Section 18.
- (b) Facilities of the health care system shall not be used for the display of products, posters and materials intended *for infants 0-12 months* within the scope of this Code as provided by a manufacturer or distributor.
- (c) Manufacturers, distributors and marketing firms or the representatives are prohibited from using the health workers in the dissemination, distribution and promotion of *products intended for infants 0-12 months* within the scope of this Act.
- (d) The use by the health care system of "professional service" representatives, "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, shall not be permitted.
- **SEC. 20.** Classes, Seminars for Women. Manufacturers, distributors and representatives of milk companies shall not be allowed to hold activities, classes and seminars for pregnant women and mother of infants related to the promotion of products intended for infants 0-12 months as covered by this Act.
- **SEC. 21.** *Inducements.* Financial or material inducements to promote products within the scope of this Act shall not be given by milk companies to nor shall this be accepted by the general public, mothers, pregnant women, health workers, hospital and other health institution, as well as to personnel within the health care system including members of their families except as provided for in section 6 and 20.
- **SEC. 22.** Samples and Supplies. Samples and supplies of products within the scope of this code intended for infants 0-12 months or equipment/utensils for the preparation or use of these products from manufacturers, distributors and representatives shall not be allowed to be given to any member of the general public,

mothers, pregnant women, health workers, hospitals and other health institutions, as well as personnel within the healthcare system, including members of their families except as provided for in sections 6 and 26.

Samples and supplies of products within the scope of this code intended for infants 0-12 months cannot be given by health workers to the general public, mothers and pregnant women including members of their families.

SEC. 23. Gifts of Any Sort. - Gift of any sort with or without company product name/logo, or brand name to promoțe products equipment/utensils/articles for the preparation or use of these products within the scope of this Act intended for infants 0-12 months from manufacturers, distributors and representatives shall not be allowed to be given to any member of the general public, mothers, pregnant women, health workers, hospitals and other health institutions, as well as personnel within the healthcare system, including members of their families.

**SEC. 24.** *Point of Sale.* - There shall be no point of sale advertising, giving of samples or any promotion devices to induce sales directly to the consumers at the retail level, such as special displays, discount coupons, premiums, rebates, special sales, bonus and tie-in sales, loss-leaders, prizes or gifts for the products intended for infants 0-12 months within the scope of this Act. This provision shall not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.

# CHAPTER V CONTINUING EDUCATION

**SEC. 25.** Continuing Education and Training. - Manufacturers and distributors of products within the scope of this Act may assist in the research, scholarships and continuing education of health professionals, in accordance with the rules and regulations promulgated by the Department of Health.

### CHAPTER VI DONATION

**SEC. 26. Donations.** – Nothing herein contained shall prevent donations from manufacturers and distributors of products within the scope of this Act upon the approval of the Secretary.

(a) Government and non-profit organizations accredited by the Department of Social Work and Development that care for infants and children, and lack access to wet nurses and lactating mothers may receive donations from manufacturers/distributors of products.

(b) In cases of disasters/emergencies, donations from manufacturers/distributors/ organizations and other of products within the scope of the code may be received/distributed to the affected population under the supervision of government agencies or non-profit organizations. The organizations concerned shall submit a written report within thirty (30) days from receipt of donations including name of organization, donations received, distribution list and other permanent details.

Donations should only be the last resort when other means such as human milk banking and wet nursing have failed after reasonable effort. Equipment and materials, in addition to those referred to in Section 7, donated to health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Act. **CHAPTER VII** CONTAINERS AND LABELS SEC. 27. Containers/Labels. (a) Containers and/or labels shall be designed to provide the necessary information about the appropriate use of the products, and in such a way as not to discourage breastfeeding. Each container shall have a clear, conspicuous and easily readable and understandable message in Pilipino or English printed on it, or on a label, which message can not readily become separated from it, and which shall include the following points: 1. The words "Important Notice" or their equivalent A statement of the superiority of breastfeeding 2. 3. A statement that the product shall be used only on the advice of a health worker as to the need for its use and the proper methods of use; and Instructions for appropriate preparation, and a warning against the health 4.hazards of inappropriate preparation. Neither the container nor the label shall have pictures or texts which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product and for illustrating methods of preparation. The term "humanized," "maternalized" or similar terms shall not be used. (d) Neither the container nor the label of milk products intended for infants 0-12 months within the scope of this Act shall have pictures of babies and children together with their mothers, fathers, siblings, grandparents, other relatives or caregivers (or yayas) or such other pictures and graphics of similar import. SEC. 28. Infant Feeding Warning. - Food products within the scope of this Act marketed for infant feeding, which do not meet all the requirements of an infant formula but which can be modified to do so, shall carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. SEC. 29. Authority of the FDA. - The labels of food products within the scope of this Act shall, in addition to the requirements in the preceding paragraphs, conform with the rules and regulations of the Food and Drugs Administration.

Receiving institutions shall not participate in any promotional activities of

manufacturer/distributors of products within the scope of the Code.

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# CHAPTER VIII QUALITY

### SEC. 30. Quality. -

- (a) The quality of products is an essential element for the protection of the health of infants, and therefore shall be of high recognized standard.
- (b) Food products within the scope of this Act shall when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.
- (c) To prevent quality deterioration, adulteration or contamination of food products within the scope of this Act, distribution outlets, including the smallest sarisari store, shall not be allowed to open cans and boxes for the purpose of retailing them by the cup, bag or in any other form.

# CHAPTER IX IMPLEMENTATION AND MONITORING

### SEC. 31. Powers and Functions of the Secretary.-

- (a) For purposes of Section 8 of this Act, the Secretary shall have the following powers and functions:
  - 1. To review and examine all advertising, promotion or other marketing materials, whether written, audio or visual, on products within the scope of this Act;
  - 2. To approve or disapprove, delete objectionable portions from and prohibit the printing, publication. distribution, exhibition and broadcast of, all advertising promotion or other marketing materials, whether written, audio or visual, on products within the scope of this Act;
  - 3. To prescribe the internal and operational procedure for the exercise of its powers and functions as well as the performance of its duties and responsibilities; and
  - 4. To promulgate such rules and regulations as are necessary or proper for the implementation of Section 8 of this Act.
- (b) The Department of Health (DOH) shall be principally responsible for the implementation and enforcement of the provisions of this Act. For this purpose, the Department of Health shall have the following powers and function:
  - 1. To promulgate such rules and regulations as are necessary or proper for the implementation of this Act and the accomplishment of its purposes and objectives.

- 2. To call the assistance of government agencies and the private sector to ensure the implementation and enforcement of, and strict compliance with, the provisions of this Act and the rules and regulations promulgated in accordance herewith.
- 3. To cause the prosecution of the violators of this Act and other pertinent laws on products covered by this Act.
- 4. To exercise such other powers and functions as may be necessary for or incidental to the attainment of the purposes and objectives of this Act.

# CHAPTER XI SANCTIONS

#### SEC. 31. Sanctions. -

- (a) Any person who violates the provisions of this Act or the rules and regulations issued pursuant to this Act shall, upon conviction, be punished by a penalty of Two Hundred Fifty Thousand Pesos (P250,000.00). Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/ or the persons directly responsible therefore, shall be penalized.
- (b) Any license, permit or authority issued by any government agency to any health worker, distributor, manufacturer, or marketing firm or personnel for the practice of their professional or occupation, or for the pursuit of their business, may, upon recommendation of the Department of Health, be suspended or revoked in the event of repeated violations of this Act, or of the rules and regulations issued pursuant to this Act.

### CHAPTER XIII FINAL PROVISIONS

- **SEC. 32.** *Implementing Rules and Regulations.* The DOH shall issue the implementing rules and regulations for this Act within one hundred twenty days (120) days from its effectivity.
- **SEC. 33.** Separability Clause. If for any reason, any part or provision this Act be declared invalid or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions which shall remain in full force and effect.
- **SEC. 34.** Repealing Clause. Executive Order No. 51, promulgated on October 20, 1986 is hereby repealed. All orders, issuances, and rules and regulations or parts thereof inconsistent with this Act are hereby repealed and modified accordingly.
- SEC. 35. Effectivity. This Act shall take effect fifteen (15) days after its publication in any newspaper of general circulation.

Approved,