MODEL LAW

An Act to ensure safe and adequate nutrition for infants and young children by promoting and protecting breastfeeding and by regulating the marketing of certain foods for infants and young children and of feeding bottles, teats and pacifiers.

It is hereby enacted as follows:

CHAPTER I
INTRODUCTORY

Section 1. Short Title and Commencement

(1) This Act may be called the [*Insert short title*].

(2) This Act shall come into effect 60 days after the date of enactment.

(3) It extends to the whole of *[Anyland].*

Section 2. Definitions

For purposes of this Act—

(1) "Advertise" means to make any representation by any means whatsoever for the purpose of promoting the sale or use of a designated product including but not limited to—

(a) written publication, television, radio, film, electronic transmission including the Internet, video or telephone;

(b) display of signs, billboards, or notices; or

(c) exhibition of pictures or models.

(2) "Advisory Board" means a Board set up under Section 17.

(3) "Brand name" means a name given by the manufacturer to a product or range of products.

(4) "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 6 months up to the age of 24 months.

(5) "Container" means any form of packaging of a designated product for sale as a retail unit, including wrappers.

(6) "Designated product" means

(a) infant formula;

(b) any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;[1]

(c) follow-up formula;

(d) complementary food;

(e) feeding bottles, teats, pacifiers; and

(f) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a "designated product" for purposes of this Act.

(7) "Distributor" means a person, corporation or other entity engaged in the business, whether wholesale or retail, of marketing any designated product.

(8) "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.

(9) "Health care facility" means a public or private institution or organisation or private practitioner engaged directly or indirectly in the provision of health care or in health care education. It also includes day-care centres, nurseries or other infant-care facilities.

(10) "Health professional" means a health worker with a professional degree, diploma or licence, such as a medical practitioner, certain registered nurses and midwives or such other person as may be specified by the Minister of Health by a Notice in the Official Gazette.

(11) "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.

(12) "Infant" means a child from birth up to the age of 12 months.

(13) "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. [*Explanatory Note*: *Some brands of infant formula are marketed for infants up to 12 months.]*

(14) "Inspector" means an inspector appointed under Section 21.

(15) "Label" means a tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, attached or otherwise appearing on a container of a designated product.

(16) "Logo" means an emblem, picture or symbol by means of which a company or a product is identified.

(17) "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.

(18) "Market" means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.

(19) "Minister" means Minister of Health of *[Anyland].*

(20) "Pacifier" means an artificial teat for babies to suck, also referred to as a "dummy".

(21) "Prescribed" or "as prescribed" means prescribed or as prescribed by rules or written decision made pursuant to this Act.

(22) "Promote" means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.

(23) "Sample" means a single or small quantity of a designated product provided without cost.

(24) "Young child" means a child from the age of 12 months up to the age of three years (36 months).

CHAPTER II
PROHIBITIONS

Section 3. Sale of a designated product

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

(a) is not registered according to Section 20 of this Act or is not in accordance with the conditions of its registration; or

(b) has reached its expiration date.

Section 4. Promotion

(1) Except as provided in Subsection 4(2),[2] a manufacturer or distributor shall not him or herself, or by any other person on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to—

(a) advertising;

(b) sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;

(c) giving of one or more samples of a designated product to any person; and

(d) donation or distribution of information or educational 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 14.

(2) A manufacturer or distributor may promote a complementary food provided that—

(a) such promotional practice does not take place in a health care facility; and

(b) any material promoting complementary food encourages exclusive breast-feeding for six months and sustained breastfeeding for up to two years and beyond.

(3) A manufacturer or distributor shall not him or herself, or by any other person on his or her behalf—

(a) donate or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 percent of the retail price, any quantity of a designated product to a health worker or a health care facility;

(b) donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, notepads, growth charts and toys, which refer to or may promote the use of a designated product;

(c) offer or give any gift, contribution or benefit to a health worker or to associations 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;

(d) sponsor events, contests, telephone counselling lines or campaigns related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics; or

(e) include the volume of sales of designated products when calculating employee remuneration or bonuses, nor set quotas for sales of designated products.

(4) A health worker engaged in maternal and child health shall not—

(a) accept any gift, contribution or benefit, financial or otherwise, of whatever value from a manufacturer or distributor or any person on his or her behalf;

(b) accept or give samples of designated products to any person; or

(c) 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.

Section 5. Prohibitions related to labels of designated products

(1) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation. [*Optional:* This section shall not apply to complementary foods.]

(2) A manufacturer or distributor shall not offer for sale or sell a designated product, other than a feeding bottle, teat or pacifier unless the container or label affixed thereto indicates in a clear, conspicuous and easily readable manner, in [*insert appropriate language(s)*], the following particulars:

(a) instructions for appropriate preparation and use in words and in easily understood graphics;

(b) the age after which the product is recommended in numeric figures and in the case of a complementary food, the recommended age shall not be less than six months;

(c) a warning about the health risks of improper preparation and of introducing the product prior to the recommended age;

(d) the ingredients used;

(e) the composition and nutritional analysis;

(f) the required storage conditions both before and after opening, taking into account climatic conditions;

(g) the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;

(h) the name and national address of the manufacturer or distributor; and

(i) such other particulars as may be prescribed.

(3) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed thereto contains 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 or normal functions of the body.

Section 6. Prohibitions related to labels of infant formula and follow-up formula

(1) 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:

(a) contains 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 diarrhoea 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"*];

(b) 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"*];

(c) states in preparation instructions for infant or follow-up formula in powdered form that powdered formula may be contaminated with micro-organisms during the manufacturing process or may become contaminated during preparation and that it is therefore necessary to discard any unused formula immediately after every feed;

(d) includes a feeding chart in the preparation instructions;

(e) does not use the terms "maternalised", "humanised" or terms similar thereto or any comparison with breastmilk;

(f) does not use text that may tend to discourage breastfeeding;

(g) specifies the source of the protein; and

(h) in the case of follow-up formula, states that the product shall not be used for infants less than six months old.

Section 7. Prohibitions related to labels 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 8. Prohibitions related to labels of low-fat and standard milk

A manufacturer or distributor shall not offer for sale 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 7 and 8 do not fall within the scope of this Act unless they are marketed or otherwise represented as suitable for infants. We recommend that these labelling provisions be incorporated into the countries' food labelling laws. In addition, Sections 7 and 8 will require revision according to the types of milk products available in individual countries*.]

Section 9. Prohibitions related to labels of feeding bottles and teats

(1) 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:

(a) 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 diarrhoea 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"*];

(b) 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"*];

(c) instructions for cleaning and sterilisation in words and graphics;

(d) a statement explaining that feeding with a cup is more hygienic than bottle feeding;

(e) 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

(f) the name and national address of the manufacturer or the distributor.

Section 10. Prohibitions related to labels 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 11. Health worker responsibilities

(1) Heads of health care facilities and national and local health authorities shall take measures to encourage and protect breastfeeding and to promote this Act, 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.

(2) Health workers shall encourage, support and protect breastfeeding. They are expected to know the provisions of this Act, particularly the information specified in Chapter IV.

(3) Health workers shall work to eliminate practices that directly or indirectly retard the initiation and continuation of breastfeeding, such as prelacteal feeds.

(4) Health workers shall make in writing a report to the head of his or her work place, who shall in turn report to the Advisory Board, of any offer he or she receives for a sample or gift or other benefit from a manufacturer or distributor or any other contravention of the provisions of this Act.

CHAPTER IV
INFORMATION AND EDUCATION

Section 12. Information and educational materials about infant feeding

Information or educational materials, whether written, audio or visual, which refer to infant feeding shall—

(1) contain only correct and current information and shall not use any pictures or text that encourage bottle feeding or discourage breastfeeding;

(2) be written in [*insert appropriate language(s)*];

(3) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or to breastfeeding;

(4) 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 provided to health professionals as authorised by Section 14 of this Act; and

(5) clearly and conspicuously explain each of the following points:

(a) the benefits and superiority of breastfeeding;

(b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;

(c) how to initiate and maintain exclusive and sustained breastfeeding;

(d) why it is difficult to reverse a decision not to breastfeed;

(e) the importance of introducing complementary foods from the age of six months;

(f) how and why any introduction of bottle feeding or early introduction of complementary foods negatively affects breastfeeding; and

(g) that complementary foods can easily be prepared at home using local ingredients.

Section 13. Information and educational materials about infant formula, follow-up formula or feeding bottles

If the material referred to in Section 12 includes the topic of bottle feeding, it must also include the following points:

(1) instructions for the proper preparation and use of the product including cleaning and sterilisation of feeding utensils;

(2) how to feed infants with a cup;

(3) the health risks of bottle feeding and improper preparation of the product; and

(4) the approximate financial cost of feeding an infant with such a product in the recommended quantities.

Section 14. 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 studies to support any representation that states or suggests that a relationship exists between the product or constituent thereof and health, growth or development; and

(3) are otherwise in accordance with Sections 12 and 13 of this Act.

Section 15. Submission of materials to Advisory Board

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 16. Implementation

(1) The Ministry of Health is principally responsible for the implementation of this Act.

(2) The Minister of Health shall, when necessary, call upon other ministries to ensure the implementation of this Act.

(3) For the purpose of implementing this Act, the Minister of Health has the following powers and functions:

(a) to promulgate such rules as are necessary or proper for the implementation of this Act and the accomplishment of its purposes and objectives;

(b) to call for consultations with government agencies and other interested parties to ensure implementation and strict compliance with the provisions of this Act and the rules promulgated hereunder;

(c) to cause the enforcement of this Act; and

(d) to exercise such other powers and functions that may be necessary for or incidental to the attainment of the purposes and objectives of this Act.

Section 17. 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 it would constitute a conflict of interest for companies who are regulated by the law to take part in a committee that advises the government on enforcement of the law.]*

(a) The Minister of Health or his representative who shall be its ex officio Chairman;

(b)

(c)

. . .

(x) Such other persons as the Minister may, by Notice in the Official Gazette, appoint as members of the Advisory Board.

provided that no person shall be appointed who has any direct or indirect financial interest in any designated product.

(2) The Minister shall appoint the members of the Advisory Board within 90 days of the date of enactment.

(3) The members of the Advisory Board shall hold office for a term of 3 years and shall be eligible for renomination.

(4) 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.

(5) 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.

(6) The Minister may, by Notice published in the Official Gazette, change the size and composition of the Advisory Board.

Section 18. Administration of the Advisory Board

(1) 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 this Act.

(2) The Advisory Board shall hire permanent staff necessary to carry out its functions, subject to the budgetary approval of the Minister.

(3) 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.

(4) 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.

(5) Two-thirds of the members of the Advisory Board shall constitute a quorum for a meeting.

(6) A majority vote of the members present shall be sufficient to approve any business presented in a meeting of the Advisory Board.

(7) Decisions of the Advisory Board shall be certified by the Secretary.

(8) The Advisory Board may make such other administrative rules as may be required for its proper functioning.

Section 19. Powers and functions of the Advisory Board

(1) The Advisory Board has the following powers and functions:

(a) to advise the [*insert Head of State*] and the Minister on national policy for the promotion and protection of breastfeeding;

(b) to create regional committees to carry out the functions of the Advisory Board at the regional level, as may be prescribed;

(c) 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 this Act; curricula for students in the health professions that include lactation management and to ensure widespread distribution of and publicity concerning this Act, in a method as may be prescribed;

(d) to review reports of violations or other matters concerning this Act;

(e) to issue instructions to inspectors as to actions to be taken, or take such other actions as the case may be, against any person found to be violating the provisions of this Act or the Rules promulgated pursuant thereto;

(f) to scrutinize materials submitted in accordance with Section 14 and recommend appropriate actions to be taken in the case of a violation of Chapter IV; and

(g) such other powers and functions, including the powers of an Inspector, as are conferred on him or her by the provisions of this Act and as may be prescribed.

Section 20. Registration of designated products

(1) The Minister of Health shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.

(2) 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.

(3) A person applying for registration of a designated product shall furnish such information and samples as may be prescribed.

(4) Once the registration of a designated product has been approved, a Certificate of Registration shall be issued.

(5) No Certificate of Registration will 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 this Act.

Section 21. Inspectors

The Minister shall appoint such persons as he or she sees fit having the prescribed qualifications to be Inspectors for purposes of this Act 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 22. Powers of inspectors

(1) An inspector may, within the local limits for which he or she is appointed—

(a) inspect any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted and all relevant records;

(b) institute prosecution with respect to violations of this Act and the Rules made pursuant thereto; and

(c) exercise such other powers as may be prescribed.

Section 23. Procedure for inspectors

(1) Inspectors shall inspect, not less than the number of times as may be prescribed, the premises as may be prescribed.

(2) After each inspection, the inspector shall submit a report including any finding of a violation of this Act 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.

(3) Institute enforcement, where applicable.

CHAPTER VI
PENALTIES, PROCEDURE

Section 24. Penalties

(1) Any person who him or herself or on behalf of any other person contravenes Sections 3, 4(1), 4(2) or 4(3) 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.

(2) 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*].

(3) Any person who contravenes any other provision of this Act 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 25. Cease and desist orders, etc.

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 this Act or the Rules promulgated pursuant thereto.

Section 26. Certificate of registration may be suspended or revoked

Where any person has been found to have contravened any of the provisions of this Act, 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 this Act.

Section 27. Professional licence may be suspended or revoked

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

Section 28. Licence, permit or authority may be suspended or revoked

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

Section 29. Appeal

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

Section 30. Strict liability for officers, directors, etc.

When the person guilty of an offence under this Act 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 31. Institution of prosecution

(1) Prosecution under this Act may be instituted only by—

(a) an Inspector appointed pursuant to Section 21;

(b) a member of the Advisory Board; or

(c) 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 32. Public enforcement

(1) 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 this Act or Rules made pursuant thereto.

(2) Any person has the right to commence an action for damages in [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 this Act or Rules made pursuant thereto.

Section 33. Power to make Rules

(1) The Ministry of Health may, by notification in the Official Gazette, make Rules for carrying out the purposes of this Act.

(2) In particular but notwithstanding the generality of the foregoing provision, such Rules may prescribe—

(a) the functions of the Advisory Board;

(b) conditions and procedures for the registration of designated products;

(c) qualifications and powers of and procedures for Inspectors appointed pursuant to the Act; and

(d) procedures for submitting educational or informational materials to the Advisory Board.

[1] Note that some countries will choose to prohibit promotion of all infant foods including complementary foods for infants up to one year or even for infants and young children up to three years of age. Countries choosing that option must delete "up to the age of six months" in Subsection (6)(b) and specify the upper age limit. They should also delete Subsection (6)(d) "complementary foods", as they would already be included under Subsection (6)(b). *See also* note 2 in Section 4.

[2] The exception provided in Subsection 4(2) for complementary foods is only applicable to countries that choose to allow some types of promotion for complementary foods. Countries that choose to prohibit all promotion for complementary foods should delete this exception. *See supra* note 1.