

## Model Law

An Act<sup>1</sup> to ensure safe and adequate nutrition for infants and young children by protecting breastfeeding and by regulating the marketing of food products manufactured for infants and young children and of feeding bottles, teats and pacifiers.

It is hereby enacted as follows:

### Chapter I Introductory

#### Section 1. Short Title and Commencement

- (1) This Act may be called the *[Marketing of Foods and Related Products for Infants and Young Children Act or Protection of Breastfeeding Act]*.<sup>2</sup>
- (2) This Act shall come into effect 60 days after the date of enactment.
- (3) This act extends to the whole of *[Anyland]*.

#### Section 2. Definitions

For purposes of this Act

- (1) “**Advertise**” means to make any communication or representation by any means whatsoever for the purpose of promoting the sale or use of a designated product, including but not limited to:
  - (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; or
  - (c) exhibition of pictures or models.
- (2) “**Advisory Board**” means a Board set up under Section 18.
- (3) “**Artificial feeding**” means feeding with any manufactured food product which replaces breastmilk either partially or totally.
- (4) “**Brand name**” means a name given by the manufacturer to a product or range of products.
- (5) “**Bottle feeding**” means feeding liquid or semi-solid food from a bottle with a nipple.
- (6) “**Complementary food**” means any food suitable or represented as suitable as an addition to breastmilk, infant formula or follow-up formula for infants from the age of six months (180 days) up to the age of 36 months.<sup>3</sup>
- (7) “**Complementary food product**” means a complementary food that is commercially processed.
- (8) “**Container**” means any form of packaging of a designated product for sale as a retail unit, including wrappers.
- (9) “**Cross-promotion**” means the use of similar brand names, packaging designs, labels, text, images, colour schemes, symbols or slogans or other means for the purpose of promoting another product.

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1. In common law jurisdictions, a law adopted in parliament is known as an ‘Act’ and this is the approach taken in CE2. Each distinct article in an Act is called a ‘section’. If the Code is implemented as subsidiary legislation under an existing Act, it is usually referred to as a set of ‘Regulations’. In civil law jurisdictions, the terminology used and the drafting convention may differ but the substance of legal provisions should be the same.

2. Text in [ ] brackets can be replaced with different wording that is more appropriate to national circumstances.

3. The definition of “complementary food”, in particular its age range, will determine which complementary food product falls within the definition of “designated product”. The upper age limit for “complementary food” can be adjusted if a country chooses to limit the ban on promotion of complementary food products to say, infants or young children up to 12 or 24 months. Such discretion on age range cannot be exercised for formula products. See also Subsections 4(4) and 4(5) and footnote 6.

- (10) “**Designated product**”<sup>4</sup> means
- (a) infant formula;
  - (b) any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;
  - (c) follow-up formula;
  - (d) young child formula;
  - (e) ready-to-use therapeutic food;
  - (f) complementary food product;
  - (g) feeding bottles, teats, pacifiers; and
  - (h) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a “designated product” for the purposes of this Act.
- (11) “**Distributor**” means a person, corporation or other entity engaged in the business of marketing any designated product, whether wholesale or retail.
- (12) “**Follow-up formula**” means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country’s standard for follow-up formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Follow-up Formula*] and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age. It is also referred to as “follow-on formula” or “follow-on milk”. For the purposes of this Act, the term ‘follow-up formula’ includes any follow up formula for special medical purposes or dietary requirements and any follow-up therapeutic milk product for acutely malnourished infants and young children.
- (13) “**Health care facility**” means a public or private institution or organisation or private practice engaged directly or indirectly in the provision of health care or in health care education. It also includes a day-care centre, a nursery or other infant and young child-care facility.
- (14) “**Health claim**” means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. A health claim includes but is not limited to the following:
- (a) 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

- (15) “**Health professional**” means a health worker with a professional degree, diploma or licence, such as a medical practitioner, a registered nurse or midwife or such other person as may be specified by the Minister of Health by a Notice in the Official Gazette.
- (16) “**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.
- (17) “**Infant**” means a child from birth up to the age of 12 months.
- (18) “**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*

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4. By introducing this collective term, one can avoid the use of the term “breastmilk substitute”, the meaning of which is a subject of long drawn controversy. If a full range of products is listed as being covered by the term “designated product” like in this Model Law, there will be no room for dispute about the scope of the law. Text in the substantive parts of the law will be neater and easier to read as well.

*absence of such standard, citation to the Codex Alimentarius Standard for Infant Formula]* and intended to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months and includes products that continue to meet part of an infant's nutritional requirements after the first six months. For the purposes of this Act, the term 'infant formula' includes any formula for special medical purposes or dietary requirements and any therapeutic milk product for acutely malnourished children.

- (19) "**Inspector**" means an inspector appointed under Section 22.
- (20) "**Label**" means a tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on a container of a designated product. For the purposes of Sections 5(1), 5(3), 10 and 11, the term "label" includes packaging and inserts.
- (21) "**Labelling**" includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.
- (22) "**Logo**" means an emblem, picture or symbol by means of which a company or a product is identified.
- (23) "**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.
- (24) "**Market**" means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.
- (25) "**Minister**" means Minister of Health of [Anyland].
- (26) "**Nutrition claim**" means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute a nutrition claim:
- (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 if required by national legislation.
- (27) "**Pacifier**" means an artificial teat for babies to suck, also referred to as a "dummy".
- (28) "**Prescribed**" or "as prescribed" means prescribed or as prescribed by rules or written decision made pursuant to this Act.
- (29) "**Promote**" means to employ any method of directly or indirectly encouraging a person, a health facility or any other entity to purchase or use a designated product whether or not there is reference to a brand name.
- (30) "**Ready-to-use therapeutic food**" means an energy-dense, vitamin- and mineral-enriched food specifically designed to treat severe acute malnutrition in children above 6 months.
- (31) "**Sample**" means a single or small quantity of a designated product provided without cost.
- (32) "**Sponsorship**" means any financial or in-kind assistance to a person or a group of persons or an entity, whether public or private, and sponsor has a corresponding meaning.
- (33) "**Young child**" means a child from the age of 12 months up to the age of three years (36 months).
- (34) "**Young child formula**" means an industrially formulated milk or milk-like product of animal or vegetable origin that is marketed or otherwise represented as suitable for feeding young children from 12 months of age. It is also referred to as "growing up milk", "formulated milk" or "toddler milk"(note: There is as yet no international quality standard for young child formula).

## **Chapter II Prohibitions**

### **Section 3. Sale of a designated product**

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

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

### **Section 4. Promotion**

- (1) [Except as provided in Subsections 4(4) and 4(5)]<sup>5</sup>, a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to:
- (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;
  - (d) donation or distribution of information or education material referring to infant or young child feeding or performance of educational functions related to infant or young child feeding, except as provided in Section 15;
  - (e) the use of health or nutrition claims on labels of designated products or in any information and education materials referring to infant and young child feeding, except as provided in Section 15; and
  - (f) cross-promotion of a designated product.
- (2) A manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf
- (a) donate, waive payment through any means or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 per cent of the retail price, any quantity of a designated product to a health worker or a health care facility;
  - (b) donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, note pads, growth charts and toys or any other materials which refer to or may promote the use of a designated product;
  - (c) offer or give any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value to a health worker or to an association of health workers engaged in maternal and child health, including but not limited to fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences;
  - (d) sponsor events, telephone counselling lines, campaigns or programmes related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics;
  - (e) directly or indirectly establish relationships with parents and other caregivers through baby clubs, social media groups, child care classes, contests and any other means; or
  - (f) include the volume of sales of designated products in the calculation of its employee remuneration or bonuses, nor set quotas for sales of designated products.
- (3) A health worker or an association of health workers engaged in maternal and child health shall not:
- (a) accept any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value, from a manufacturer or distributor or any person on his or her behalf;

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5. Delete as appropriate. See footnote 6 below.

- (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.
- (4)<sup>6</sup> A manufacturer or distributor may promote a complementary food product provided that:
- (a) such promotional practice does not take place in a health care facility;
  - (b) any material promoting a complementary food product must include a statement in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]* on:
    - i. the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
    - ii. the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
- (5)<sup>7</sup> Notwithstanding Subsection 4(4), a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote a complementary food product through the use of messages in any form or media that are prohibited by Subsection 7 (1) (a) – (f).

## **Section 5. Prohibitions related to labelling of designated products**

- (1) Except as provided in Subsection 7(1), a manufacturer or distributor shall not offer for sale or sell a designated product if the labelling thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.
- (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 labelling 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 in numeric figures after which the product is recommended;
  - (c) a warning about the health risks of improper use, preparation or storage and of introducing the product prior to the recommended age;
  - (d) the list of ingredients and the declaration of nutritional value in accordance with relevant national standards or, in the absence of such standard, with the relevant Codex Alimentarius Standard;
  - (e) the required storage conditions both before and after opening, taking into account climatic conditions;
  - (f) the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;
  - (g) the name and national address of the manufacturer or distributor; and
  - (h) such other particulars as may be prescribed.
- (3) A manufacturer or distributor shall not offer for sale or sell a designated product if the labelling thereto contains any health or nutrition claim or any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development and normal functions of the body.

6. Subsections 4(4) and 4(5), based on the Guidance on ending the inappropriate promotion of foods for infants and young children (69/7 Add.1) and WHA resolutions, are only applicable to countries that choose to permit certain types of promotion for complementary food products f.eg, in retail outlets. Countries that choose to prohibit ALL promotion of complementary food products should delete these Subsections. Otherwise; there will be a contradiction with preceding Subsections 4(1), 4(2) and 4(3) which ban the promotion of ALL designated products. See also footnote 3.

7. Delete as appropriate; see footnote 6 above

## **Section 6. Prohibitions related to labelling of infant formula, follow-up formula and young child 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 the normal and optimal way to feed infants and young children. Breastmilk is important for the healthy growth and development of infants and young children. It protects against 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) has preparation instructions for infant or follow-up formula in powdered form that state that:
    - i. powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
    - iii. it is necessary for formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and
    - iii. any unused milk must be discarded 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 or used as the sole source of nutrition of infants in characters *[insert particulars relating to character size, placement, appearance, etc.]*
- (2) A manufacturer or distributor shall not offer for sale or sell young child formula unless the container or label affixed thereto, in addition to the requirements of Subsections 5 and 6(1)(c) – (g), states that the product shall not be used to feed infants below 12 months or used as the sole source of nutrition for young children” in characters *[insert particulars relating to character size, placement, appearance, etc.]*

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

- (1) In addition to the requirements of Subsections 5(2) and 5(3), a manufacturer or distributor shall not offer for sale or sell a ready-to-feed therapeutic food or a complementary food product if the container or label affixed thereto contains:
  - (a) any text, image or other representation that suggests the suitability of the product for infants under six months including but not limited to references to development milestones clearly reached before six months, the use of pictures of infants appearing to be younger than six months;
  - (b) any text, image or other representation that idealises the product or is likely to undermine or discourage breastfeeding or create a belief that the product is equivalent or superior to breastmilk;
  - (c) any text, image or representation that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared complementary foods;
  - (d) any recommendation to feed the product in a bottle or otherwise promote the use of bottle feeding;
  - (e) any endorsement, or anything that may be conveyed or construed as an endorsement by a health professional, an association of health professional or other body; and
  - (f) any element that allows for cross-promotion of any other designated product.
- (2) In addition to the requirements of Subsection (1), the label of a ready-to-feed therapeutic food or a complementary food product shall include:
  - (a) A statement in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]* on:
    - i. the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
    - ii. the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
  - (b) instructions for preparation, storage, handling and use; and
  - (c) a feeding chart showing the appropriate ration/serving size consistent with guiding principles issued by the World Health Organization.

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

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

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

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

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

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

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

- (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 11. Prohibitions related to labelling of pacifiers (dummies)**

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

## **Chapter III**

### **Health Worker Responsibilities**

#### **Section 12. Health worker responsibilities**

1. Heads of health care facilities and national and local health authorities shall take measures to encourage and protect breastfeeding and to implement 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 impede the initiation and continuation of breastfeeding, such as prelacteal feeds.
4. Health workers shall make in writing a report to the head of their work place, who shall in turn report to the Advisory Board, on any offer a health worker receives for a sample or gift or other benefit from a manufacturer or distributor or on any other contravention of the provisions of this Act.

## **Chapter IV**

### **Information and Education**

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

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

- (1) contain only correct and current information and shall not use any pictures or text that encourage artificial feeding, or the use of feeding bottles or that discourage breastfeeding;
- (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 intended for health professionals as authorised by Section 15 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 artificial feeding, the use of a feeding bottle or the early introduction of complementary foods negatively affects breastfeeding; and
  - (g) that complementary foods can easily be prepared at home using local ingredients.

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

- (1) If the material referred to in Section 13 includes the topic of artificial feeding or the use of a feeding bottle, it must also include the following points:
  - (a) instructions for the proper preparation, storage and use of the product including cleaning and sterilisation of feeding utensils;
  - (b) how to feed infants with a cup;
  - (c) the health risks of artificial feeding, the use of a feeding bottle and improper preparation of the product;
  - (d) explain that
    - i. powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
    - ii. it is necessary for powdered formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and
    - iii. any unused milk must be discarded immediately after every feed.
  - (e) the approximate financial cost of feeding an infant or a young child with such a product in the recommended quantities and
  - (f) that the practice of providing follow-up formula and young child formula is not necessary.
- (2) Except as provided in Section 15 concerning product information for health professionals, materials that include the topic of artificial feeding shall not contain any health or nutrition claims or other representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the body.

## **Section 15. Product information for health professionals**

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

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

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

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

## **Chapter V Administration**

### **Section 17. Implementation**

- (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 shall have 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 to appoint an official within the Ministry of Health to carry out this function on his or her behalf; 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 18. National Advisory Board for the Promotion and Protection of Breastfeeding**

- (1) There shall be a National Advisory Board for the Promotion and Protection of Breastfeeding to be composed of the following members:

[In this section, list the members to be included in this inter-disciplinary committee. Countries usually include representatives of relevant ministries such as Health, Education, Communications and Trade, and representatives of organisations of health professionals, consumers, breastfeeding support groups as well as experts in relevant fields. The proviso excludes manufacturers and distributors of designated products from the committee because their involvement would create conflicts of interest. Such conflicts would compromise independence, integrity and credibility of a committee that 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 19. 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 20. Powers and functions of the Advisory Board**

- (1) The Advisory Board shall have 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 16 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 by the provisions of this Act and as may be prescribed.

## **Section 21. 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 shall be granted unless the designated product is in accordance with the [insert applicable Food Quality Standards] and has a label which is in accordance with the requirements contained in Chapter II of this Act.

## **Section 22. Inspectors**

The Minister shall appoint such persons as he or she sees fit having the prescribed qualifications to be Inspectors for purposes of 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 23. 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 24. 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**

### **Sanctions, Procedure**

#### **Section 25. Penalties**

- (1) Any person who him or herself or on behalf of any other person contravenes Sections 3 and 4 shall be punishable with imprisonment for a term which shall not be less than *[time]* or a fine which shall not be less than *[amount]* or both.
- (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 26. Improvement Notices, Cease and desist orders, etc.**

- (1) If the Minister or any official appointed by the Minister has reasonable grounds for believing that any person is failing to comply with the provisions of this Act or the Rules promulgated thereto, he or she may, by a notice served on that person (in this Act referred to as an “improvement notice”):
  - (a) state the grounds for believing that the person is failing to comply with this Act or the Rules promulgated thereto;
  - (b) specify the matters which constitute the person’s failure so to comply;
  - (c) specify the measures which the person must take in order to secure compliance; and
  - (d) require the person to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.
- (2) In addition to the powers conferred under Subsection (1), the Minister or any official appointed by the Minister shall have the power to make cease and desist orders upon receiving a report from an inspector or the Advisory Board of a violation of the provisions of this Act or the Rules promulgated pursuant thereto.
- (3) Any person who fails to comply with an improvement notice or cease and desist order under Subsection (1) or (2) shall, after notice and an opportunity to be heard have been given, be guilty of an offence.

#### **Section 27. Suspension or revocation of certificate of registration**

Where any person has been found to have contravened any of the provisions of 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 28. Suspension or revocation of professional licence**

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 29. Suspension or revocation of licence, permit or authority**

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

### **Section 30. Appeal**

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

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

When the person guilty of an offence under 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 32. Institution of prosecution**

- (1) Prosecution under this Act may be instituted only by:
- (a) an Inspector appointed pursuant to Section 22;
  - (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 33. 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 [*a court of law*] against any manufacturer or distributor or other person for any harm suffered as a result of a violation of any provision that constitutes an offence under this Act or Rules made pursuant thereto.

### **Section 34. 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 this Act; and
  - (d) procedures for submitting educational or informational materials to the Advisory Board.