



MFDA-FS/R1:2008

# REGULATION ON IMPORT, PRODUCE AND SALE OF BREAST MILK SUBSTITUTES IN THE MALDIVES

**Maldives Food and Drug Authority**

Male', Republic of Maldives

# **Regulation on Import, Produce and Sale of Breast Milk Substitutes in the Maldives.**

## **CHAPTER I INTRODUCTORY**

### **Section 1. Short Title and Commencement**

- (1) This regulation shall be called the “Regulation on Import, Produce and Sale of Breast Milk Substitutes in the Maldives”.
- (2) This regulation shall enter into force on the date of its publication by the Maldives Food and Drug Authority. (MFDA)
- (3) Manufacturers, distributors and importers have up to 180 (one hundred and eighty) days from the date of publication of this regulation to adapt their behaviour and products to its provisions.
- (4) It extends to the whole of the Republic of Maldives.

### **Section 2. Aim of this regulations**

The aims of this regulation is to contribute to the good health, safe and optimal nutrition of infants and young children and of pregnant and lactating women, by

- (1) Regulating the production quality, marketing and distribution, and the information and instructions for the correct use, of infant formula, follow up formula, infant foods/complementary foods for infants and young children as well as feeding bottles and teats;
- (2) Regulating the marketing of nutritional supplements for pregnant and lactating women;
- (3) Promoting exclusive breastfeeding for the first six months of life;
- (4) Protecting and promoting continued breastfeeding for up two years or beyond, with introduction of new foods into the infants’ diet after the period of exclusive breastfeeding.

### **Section 3. Scope of the regulations**

This regulation shall apply to the following designated products:

#### **DESIGNATED PRODUCTS**

- (1) Infant formula, including special formula;
- (2) Follow-up or follow-on formula;
- (3) Any other product marketed or otherwise represented as suitable for feeding children below 6 months;

- (4) Liquid milk, powdered milk, modified milk and milk of plant origin marketed or represented as suitable for infants and young children;
- (5) Complementary foods for infants;
- (6) Feeding bottles and teats;
- (7) Nutritional supplements for pregnant and lactating women; and
- (8) Such other product as the Maldives Food and Drug Authority (MFDA) may, declare to be a “designated product” for purposes of this regulations.

#### **Section 4. Definitions**

For the purpose of this regulation:

- (1) “Advertise” means to make any representation by any means whatsoever for the purpose of promoting the sale or disposal of a designated product, including but not limited to
  - (a) written publication, television, radio, film, video, electronic transmission, Internet or telephone;
  - (b) display of signs, posters, billboards or notices;
  - (c) exhibition of pictures or models;
  - (d) special displays in stores; or in public places.
- (2) “Complementary food” means any food suitable or represented as suitable as an addition to breastmilk, after the age of six months, infant formula with the aim of adapting gradually to the common family foods.
- (3) “Container” means any form of packaging of a designated product for sale as a retail unit.
- (4) “Designated product” means as defined in Section 3 above.
- (5) “Distributor” means a person, corporation or other entity engaged in the business, whether wholesale or retail, of marketing any designated product, and includes any person providing product public relations or information services in relation to any designated product.
- (6) “Follow- up” or “Follow-on” means a liquid or powder product of animal or vegetable origin, formulated industrially in accordance with the Codex Alimentarius Standard for Follow-up , and used to replace breastmilk for infants and young children above six months of age.
- (7) “Complementary food” means a liquid, powder, puree or cereal-based product and animal or vegetable origin, formulated industrially in accordance with the Codex Alimentarius Standard for infant food, and used for feeding infants and young children above six months of age.

- (8) “Health care facility” means a public or private institution or organization or private practitioner engaged directly or indirectly in the provision of health care or in health care education. It also includes pharmacies, chemist shops and drug stores, and day-care centres, nurseries and other infant-care facilities.
- (9) “Health professional” means a health worker with a professional degree, diploma or license, such as a medical practitioner, nurse, community/family health worker, midwife, pharmacist or such other person as may be specified.
- (10) “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.
- (11) “Importer” means a person, corporation or other entity engaged in the business of importing a product included in the scope of these regulations.
- (12) “Infant” means a person 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 the Codex Alimentarius Standard for infant formula, to feed infants during the first six months of life, and intended to partially or totally replace breastmilk and to satisfy the nutritional requirements of infants in this age bracket.
- (14) “Label” means any tag, mark, pictorial or other descriptive matter, written, printed, stamped, stencilled, marked, engraved, embossed, attached or otherwise appearing on or inside a container of a designated product.
- (15) “Low-cost supplies” means quantities of a designated product at a cost less than the wholesale price or below 80% of the retail price.
- (16) “Manufacturer” means a person, corporation or other entity engaged in the business of manufacturing a designated product, whether directly, or through an agent, or through a person controlled by or under an agreement with it.
- (17) “Market” means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.
- (18) “Nutritional supplement for pregnant and lactating women” means a milk or milk-like product of animal or vegetable origin marketed or otherwise represented as suitable for pregnant and/or breastfeeding mothers to support growth and overall development of the foetus and/or to support the quantity and nutritional quality of breastmilk.
- (19) “Pacifier” means an artificial teat for an infant to suck on, without the purpose of providing food, liquids or medicine. It is also referred to as a “dummy.”

- (20) “Promote” means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.
- (21) “Sample” means a single or small quantity of a designated product provided without cost.
- (22) “Special formula” means infant formulas manufactured and marketed for premature or low-birth weight infants or for infants with lactose intolerance, carbohydrate intolerance or other physiological, pathological or metabolic disorders.
- (23) “Teat” means the part of the feeding bottle from which the baby sucks the food or liquid.
- (24) “Young child” means a person from the age of 12 months up to the age of three years (36 months).

## **CHAPTER II PROHIBITIONS**

### **Section 5. Sale of a designated product**

- (1) No person shall distribute for sale, sell, stock for sale or exhibit for sale any designated product that
- (a) is not registered according to these regulations or is not in accordance with the conditions of its registration;
  - (b) is not in its original container;
  - (c) has reached its expiry date, in the case of food products.

### **Section 6. Promotion**

- (1) A manufacturer, distributor or importer shall not him or herself, or by any other person on his or her behalf, promote any designated product referred to in Section 3, point 1, 2, 3, 4, 5, 6, 7,8, by any means of communication, including but not limited to
- (a) advertising;
  - (b) sales devices aimed at increasing retail sales, such as special displays, stocking on shelves facing windows and/or entrances, rebates, special sales, sales linked to products not covered by this regulations, discount coupons, tie-in sales, prizes and gifts;
  - (c) giving of one or more samples, directly or indirectly, to any person;

- (d) donation or distribution of any informational and educational material on feeding of infants and young children and on maternal nutrition, the nutritional adequacy of breastmilk and the ability of mothers to breastfeed, except in accordance with this Regulation .
  - (e) distribution to members of the public of any gifts of articles or utensils that may promote the use of a designated product indicated in this regulations.
  - (f) direct or indirect contact of any kind between marketing personnel and members of the public including but not limited to sponsorship of events, contests, telephone counselling lines or campaigns related to reproductive health, pregnancy, childbirth, infant and young child feeding or related topics for the purpose of promoting a designated product indicated in this regulations.
- (2) A manufacturer, distributor, or importer shall not him or herself, or by any other person on his or her behalf, promote any designated product to health workers or health care facilities. In addition to the requirements of paragraph 1 of this Section, prohibited promotional practices include, but are not limited to
- (a) distribution of free or low-cost supplies or samples of any designated product to a health worker or a health care facility;
  - (b) donation to or distribution within a health care facility of equipment or services that contain the name or logo of a designated product or of a manufacturer or distributor of a designated product or otherwise refer to or may promote the use of a designated product;
  - (c) donation to or distribution within a health care facility of materials, including but not limited to pens, calendars, posters, note pads, physician's pads, growth charts and toys, that contain the name or logo of a designated product or of a manufacturer or distributor of a designated product or otherwise refer to or may promote the use of a designated product;
  - (d) provision or offer, direct or indirect, of any gift, contribution or benefit to a health worker or any member of his or her family or to associations or organisations of health workers or to health care facilities, including but not limited to fellowships, research grants, funding for meetings, seminars, workshops, continuing education courses or conferences or other formal or informal education programs, or for upgrading the health care facility in any way.
  - (e) provision of mothercraft nurses or other such persons to health care facilities.
- (3) A manufacturer, distributor, or importer shall not, in addition to the requirements of paragraphs 1 and 2 of this Section,
- (a) Fix the remuneration of any of his or her employees or give any commission to such employees on the basis of the volume of sale of the

designated products referred to in Section 3, paragraphs 1, 2, 3, 5 and 6 above by such employees.

- (b) Engage his or her employees in the performance of any educational functions that relate to infant or young child feeding or maternal nutrition.

(4) A health care facility shall not

- (a) solicit, purchase or accept any free or low-cost supplies or samples of any designated product;
- (b) accept, distribute, display or permit to be displayed in its premises any placards, posters, gifts, equipment and materials that bear the name or logo of a designated product or of a manufacturer, distributor, or importer of a designated product or otherwise refer to or may promote the use or sale of a designated product;
- (c) promote in any way the use or sale of a designated product;

(5) A health worker shall not

- (a) accept or permit any family member to accept any gift, contribution or benefit, financial or in kind, including but not limited to fellowships, research grants, funding for meetings, seminars, continuing education courses, workshops or conferences or other formal or informal education programs, from any manufacturer, distributor, or importer of any designated product, or any person on their behalf;
- (b) accept from or give samples of designated products to any person;
- (c) distribute or give to persons other than health professionals the technical-scientific materials provided by manufacturers, distributors, or importers, as provided for in Chapter IV of this regulations;
- (d) demonstrate the use of infant formula and feeding bottles, 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 hazards of the use of these designated products as well as the other information required by Chapter IV;
- (e) promote in any way the use or sale of a designated product.

## **Section 7. Labeling of Designated Products**

- (1) A manufacturer, distributor, or importer shall not offer for sale or sell a designated product if the container or label affixed to it includes any photographs, illustrations or other graphic representations other than for showing the correct method of preparing and using the product, and in no case shall use photographs, illustrations or graphic representations of infants, young children, mothers, mothers with infants and/or young children, humanized figures or characters of

any kind, storybook or cartoon characters or animals, and other characters and animals, feeding bottles and teats that may promote the use of such items.

- (2) A manufacturer, distributor, or importer shall not offer for sale or sell a designated product, other than a feeding bottle, teat or pacifier, unless the container or label affixed to it indicates in a clear, conspicuous and easily readable manner, in Dhivehi, the following particulars:
- (a) instructions for appropriate preparation and use in words and in easily understood graphics, and in no way promotes the use of a feeding bottle;
  - (b) the ingredients used, specifying the origin of any milk or milk-like product;
  - (c) the composition and nutritional analysis;
  - (d) the required storage conditions both before and after opening, taking into account climatic conditions;
  - (e) the batch number;
  - (f) the dates of manufacture and expiry;
  - (g) the name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the designated product shall be declared;
  - (h) such other particulars as may be prescribed.
- (3) A manufacturer, distributor, or importer shall not offer for sale or sell infant formula or follow-up formula if the container and/or label affixed to it
- (a) uses names or expressions such as “maternalised,” maternalised milk,” “humanised,” “humanised milk,” “breastmilk substitute” or similar ones that may suggest a similarity between the product and breastmilk;
  - (b) uses any text that may tend to discourage breastfeeding or suggest that breastmilk is inadequate in some way or undermine a mother’s confidence in her ability to breastfeed her baby;
  - (c) promotes the product or other products of the same and/or another company in any way;
  - (d) promotes the baby-food company or manufacturer or distributor, using phrases such as “baby-feeding experts” or other similar phrases or expressions, or in any other way;
  - (e) implies in any way that the product has World Health Organization or any other international or national organization or association endorsement;
  - (f) provides mailing and/or e-mail addresses or telephone numbers for the purpose of promoting or distributing informational or educational materials on infant and young child feeding or on maternal nutrition, including but not limited to club memberships for mothers, infants or young children, or family members;
  - (g) offers free gifts or provides free gifts inside the container.
  - (h) 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.

- (4) A manufacturer, distributor, or importer shall not offer for sale or sell infant formula unless the container or label affixed to it, in addition to the requirements of sub-sections 1, 2 and 3 of this Section, conforms to the following:
- (a) contains on the front side, in a conspicuous and easily readable manner, in Dhivehi, in contrasting colour of a size not less than one-third the size of the characters in the product name, the statement :
    - i. **“IMPORTANT NOTICE: BREASTFEEDING IS BEST.**
    - ii. **MOTHER’S MILK IS THE IDEAL FOOD FOR HEALTHY GROWTH AND DEVELOPMENT OF INFANTS AND YOUNG CHILDREN.**
    - iii. **BREAST MILK PROTECTS AGAINST DIARRHEA AND OTHER ILLNESSES”**
  - (b) contains text and graphic representation illustrating the method of preparation using a feeding cup;
  - (c) contains immediately below the instructions for preparation and use, in a conspicuous and easily readable manner, in Dhivehi, in contrasting colour of a size not less than one-third the size of the characters in the product name, the words :
    - i. **“WARNING: IT IS IMPORTANT FOR YOUR BABY’S HEALTH THAT YOU FOLLOW ALL PREPARATION INSTRUCTIONS CAREFULLY.**
    - ii. **IF YOU USE A FEEDING BOTTLE, YOUR BABY MAY REFUSE TO FEED FROM THE BREAST.**
    - iii. **IT IS MORE HYGIENIC TO FEED FROM A CUP.”**
  - (d) includes a feeding chart in the preparation instructions and states 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.
- (5) A manufacturer, distributor or importer shall not offer for sale or sell follow-up formula unless the container or label affixed to it, in addition to the requirements of paragraphs 1, 2 and 3 of this Section, conforms to the following:
- (a) contains on the front side, in a conspicuous and easily readable manner, in Dhivehi, in contrasting colour of a size not less than one-third the size of the characters in the product name, the words in capital letters

- i. **“IMPORTANT NOTICE: THIS PRODUCT IS NOT SUITABLE FOR INFANTS UNDER 6 MONTHS OLD.**
    - ii. **BREASTFEEDING PROTECTS INFANTS AND YOUNG CHILDREN AGAINST DIARRHEA AND OTHER ILLNESSES**
    - iii. **IT IS RECOMMENDED TO BREAST FEED UP TO 2 YEARS OLD OR BEYOND.”**
  - (b) contains text and graphic representation illustrating the method of preparation using a feeding cup;
  - (c) contains immediately below the instructions for preparation and use, in a conspicuous and easily readable manner, in Dhivehi, in a contrasting colour of a size not less than one-third the size of the characters in the product name, the words in capital letters
    - i. **“WARNING: IT IS IMPORTANT FOR YOUR BABY’S HEALTH THAT YOU FOLLOW ALL PREPARATION INSTRUCTIONS CAREFULLY.**
    - ii. **IF YOU USE A FEEDING BOTTLE, YOUR BABY MAY REFUSE TO FEED FROM THE BREAST**
    - iii. **IT IS MORE HYGIENIC TO FEED FROM A CUP THAN A FEEDING BOTTLE.”**
  - (d) contains a warning about the health hazards of introducing the product prior to the recommended age;
  - (e) includes a feeding chart in the preparation instructions and states 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.
- (6) A manufacturer, distributor or importer shall not offer for sale or sell any other product, whether milk-based or not, that is marketed or otherwise represented as suitable for feeding infants and young children, including but not limited to cereal-based foods, jarred vegetable and fruit purees, and juices, teas and other beverages, unless the container or label affixed to it, in addition to the requirements of paragraphs 1 and 2 of this Section, conforms to the following:
- (a) contains on the front side, in a conspicuous and easily readable manner, in Dhivehi, in contrasting colour of a size not less than one-third the size of the characters in the product name, the words in capital letters
    - i. **“IMPORTANT NOTICE: THIS PRODUCT IS NOT SUITABLE FOR INFANTS UNDER 6 MONTHS OLD.**
    - ii. **BREASTFEEDING PROTECTS INFANTS AND YOUNG CHILDREN AGAINST DIARRHEA AND OTHER ILLNESSES**
    - iii. **BREAST FEEDING IS RECOMMENDED FOR UP TO ATLEAST 2 YEARS.”**
  - (b) contains all text in Dhivehi;

- (c) states on the front side of the container or label the age after which the product is recommended in numeric figures;
  - (d) contains a warning about the health hazards of improper preparation and of introducing the product prior to the recommended age;
  - (e) does not claim that the product has “good home-made tastes” or any other terms or expressions that offer a comparison between the product and food prepared at home from local and/or raw ingredients;
  - (f) does not use any text that may tend to discourage breastfeeding or suggest a comparison with breastmilk;
  - (g) does not promote the product or other products of the same and/or another company, including any designated product;
  - (h) does not promote the baby-food company or manufacturer or distributor, using phrases such as “baby-feeding experts” or other similar phrases or expressions, or in any other way;
  - (i) does not imply in any way that the product has World Health Organization, or any other international or national organization or association endorsement;
  - (j) does not provide mailing and/or e-mail addresses or telephone numbers for the purpose of promoting or distributing informational or educational materials on infant and young child feeding, including but not limited to club memberships for mothers;
  - (k) does not offer free gifts or provides free gifts inside the container.
- (7) A manufacturer, distributor or importer shall not offer for sale or sell a **feeding bottle** unless the package or label affixed to it is in compliance to the requirements of this regulation.

### CHAPTER III HEALTH WORKER RESPONSIBILITIES

#### **Section 8. 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 these regulations, and shall give information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all of the information specified in Chapter IV.
- 2) Health workers and their associates shall encourage, support and protect breastfeeding. They are expected to know the provisions of these regulations, particularly the information specified in Chapter IV.

- 3) Health workers shall work to eliminate practices that directly or indirectly retard the initiation, exclusive breastfeeding 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 these regulations.

## **CHAPTER IV INFORMATION AND EDUCATION**

### **Section 9. Informational and educational materials about infant feeding**

Informational and 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 Dhivehi.
- 3) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breast milk or breastfeeding;
- 4) not contain the 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 authorized by this regulations; and
- 5) clearly and conspicuously explain each of the following points:
  - a) the benefits of and superiority of breastfeeding;
  - b) the value of exclusive breastfeeding for about 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 after completion 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 10. Informational and educational materials about infant formula, follow-up formula or feeding bottles**

If the material referred to in section 9 includes the topic of feeding infants with infant formula, follow-up formula or any other food or drink by feeding bottle, it must also include the following points:

- 1) instructions for the preparation and use of the product including cleaning and sterilization of feeding utensils;
- 2) how to feed infants with a cup;
- 3) the health hazards 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 11. Product information for health professionals**

Information material about designated products may be given to health professionals if such material

- 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 this regulations.

### **Section 12. Submission of materials to Advisory Board**

Any person who produces or distributes any materials referred to in this Chapter shall submit copies to the Food and Drug Authority according to their regulation as shall be prescribed.

## **CHAPTER V ADMINISTRATION**

### **Section 13. Implementation**

- 1) The Maldives Food and Drug Authority (MFDA) is principally responsible for the implementation of this regulation.
- 2) The Maldives Food and Drug Authority (MFDA) shall, when necessary, call upon other ministries to ensure the implementation of this regulation.
- 3) For the purpose of implementing this regulations, the Maldives Food and Drug Authority (FDA) has the following powers and functions:

- a) Formulate a National Advisory Board
- b) to promulgate such rules as are necessary or proper for the implementation of this regulations and the accomplishment of its purpose and objectives.
- c) to call for consultations with government agencies and other interested parties to ensure implementation and strict compliance with the provisions of this regulations and the rules promulgated hereunder;
- d) to cause the enforcement of this regulations; and
- e) to exercise such other powers and functions that may be necessary for or incidental to the attainment of the purpose and objectives of this regulations.

**Section 14. National Advisory Board for the promotion and Protection of Breastfeeding**

- 1) There shall be a National Advisory Board under Maldives Food and Drug Authority (MFDA) for the Promotion and Protection of Breastfeeding to be composed of the following members:
  - a) Maldives Food and Drug Authority (MFDA)
  - b) Head of Department of Public Health
  - c) Representative from the Ministry of Education
  - d) Representative from the Ministry of Legal Reform, Information and Arts
  - e) Representative from the Ministry of Economic Development and Trade
  - f) Representative from Faculty of Health Sciences
  - g) Representative from Department of Medical Services
  - h) Representative from IGMH (Indira Gandhi Memorial Hospital) and other private Hospitals
  - i) Representative from a related NGO
  - j) Consumers

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

- 2) The Maldives Food and Drug Authority (MFDA) 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 re-nomination.
- 4) Any member of the Advisory Board may, at any time, resign his/her office by writing to the Minister. A vacancy shall be filled in the same manner as the original appointment for the balance of 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 matters set before it.

## **Section 15. Administration of the Board**

- 1) The Maldives Food and Drug Authority (MFDA) shall appoint the Secretary of the Advisory Board and such other officers as he or she deems necessary to carry out the purpose of this regulation.
- 2) The Maldives Food and Drug Authority (MFDA) Advisory Board shall appoint staff necessary to carry out its functions.
- 3) The Advisory Board shall meet as often as it deems necessary, but not less than once at every ninety days 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) Half the number of members in 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 16. Powers and functions of the Advisory Board**

- 1) The Advisory Board has the following powers and functions:
  - a) to advise the Maldives Food and Drug Authority (MFDA) and the 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 Maldives Food and Drug Authority (MFDA) on designing a National strategy for developing communication and public education programmes for the promotion of breastfeeding; informational 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 regulations; curricula for students in the health professions that include lactation management and to ensure widespread distribution of and publicity concerning this regulations, in a method as may be prescribed;
  - d) to review reports of violations or other matters concerning this regulations;
  - 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 regulation.
  - f) to scrutinize materials submitted in accordance with Section 12 and recommend appropriate actions to be taken in the case of violation of Chapter 4; 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 regulations and as may be prescribed.

### **Section 17. Registration of designated products**

- 1) The Ministry of Health shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.
- 2) The Maldives Food and Drug Authority (MFDA) shall, by notification in the official media, 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 has been approved, a Certificate of Registration shall be issued.
- 5) No Certificate or Registration will be granted unless the designated product is in accordance with the Maldives Food and Drug Authority (MFDA) food quality standards and has a label which is in accordance with the requirements contained in Chapter II of these regulations.

### **Section 18. Inspectors**

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

### **Section 19. 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, and advertised or otherwise promoted against the standards set in Section 20 and report it to the Advisory Board;
  - b) any violation of this regulation shall be reported to Advisory Board;
  - c) follow the advice and instructions of the Advisory Board in performing their tasks.

### **Section 20. Procedure for inspectors**

- 1) Inspectors shall carry out the inspections as prescribed by the Advisory Board.



- 2) After each inspection, the inspector shall submit a report including any finding of a violation of this regulation, to the Advisory Board and any action to be taken against those identified in the report will be decided on by the Advisory Board.

### **Section 21. Penalties**

- 1) Maldives Food and Drug Authority has the right to fine an amount of not less than MRf. 10,000/- for the first time who violates/contravenes the provisions of section 5,6(1), 6(2), 6(3), and 7 , and the rules made under it.
- 2) Maldives Food and Drug Authority has the right to fine any person having been convicted of an offence under section 21(1) for the second time, of an amount between MRf.10,000/- and MRf.100,000/-.
- 3) Maldives Food and Drug Authority has the right to fine any person who violates/contravenes the provisions of any other sections and the rules made under it, shall be punishable with fine which may extend up to MRf. 10,000/- .

### **Section 22. Cease and desist orders, etc**

The MFDA 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 Regulation promulgated pursuant thereto.

### **Section 23. Certificate of registration may be suspended or revoked**

Where any person has been found to have contravened any of the provisions of this regulations pursuant thereto, MFDA 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 regulation.

### **Section 24. Professional license may be suspended or revoked**

Where any health professional has been found to have contravened any provision of this Regulation pursuant thereto, MFDA may recommend to the relevant authority the suspension or revocation of any license for the practice of that persons profession.

### **Section 25. License, permit or authority may be suspended or revoked**

Where any distributor or importer has been found to have contravened any provision of this Regulation pursuant thereto, MFDA may recommend to the relevant authority the suspension or revocation of any license for sale or import.

## **Section 26. 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 Regulations made pursuant thereto. It is the responsibility of the Advisory Board to act on reports and advice on necessary action.
- 2) Any person has the right to seek for compensation of damages from manufacturer or distributor or other person for any harm suffered as a result to a violation of any provision that constitutes an offence under this Regulation made pursuant thereto.

## **Section 27 : Power to amend the Regulation**

MFDA shall have the Power to make amendments at any time suitable and required in changing circumstances.