

Mother's Milk Substitutes (Control of Sale and Distribution) Act, 2049 (1992)

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Act No. 39 of 2049 (1992)

An Act Made to Provide for the Control of Sale and Distribution of Mother's Milk Substitutes

Preamble: Whereas, it is expedient to provide for safe and adequate nutrition to the infant by protecting and promoting the breastfeeding and regulating the mother's milk substitutes as well as the sale and distribution of infant foods;

Now, therefore, be it enacted by Parliament in the twenty-first year of the reign of His Majesty King Birendra Bir Bikram Shah Dev.

1. **Short title, extent and commencement:** (1) This Act may be called as the "Mother's Milk Substitutes (Control of Sale and Distribution) Act, 2049 (1992)."

(2) This Act shall come into force on such date as Government of Nepal may, by a notification in the Nepal Gazette, appoint.[∇]

2. **Definitions:** In this Act, Unless the subject or the context otherwise requires:

- (a) "Mother's milk substitute" means any food marketed or otherwise distributed as a partial or total replacement for mother's milk.
- (b) "Container" means any kind of package in which any product is placed for sale or distribution in a retail unit and this expression also includes a wrapper.
- (c) "Committee" means the Breastfeeding Protection and Promotion Committee formed under section 4.
- (d) "Product" means any of the following things:
 - (1) mother's milk substitute,
 - (2) any kind of such milk marketed or otherwise distributed as is

[∇] This Act came into force on 2051.11.15 (27 Feb.1995) by a notification published in the Nepal Gazettee.

- suitable for feeding to the infant, with or without any conversion in such milk,
- (3) any other such food or beverage marketed or otherwise distributed as is suitable for feeding to the infant,
 - (4) milk bottle and nipple.
- (e) "Distributor" means a person involved in the sale and distribution of any product by wholesale or retail and this expression also includes a person involved in the process of public relation services or information related with any process.
 - (f) "Health care system" means a governmental, non-governmental or private institution or organization or person engaged directly or indirectly in health care activities, and this expression also includes a nursery and other child care institution.
 - (g) "Medical practitioner" means a doctor, registered nurse, nutrition expert or such other person as may be specified by Government of Nepal on a notification in the Nepal Gazette.
 - (h) "Health worker" means a person who is working in a health care system or a trainee to work in that system and engaged in health care activities for remuneration or otherwise.
 - (i) "infant" means a baby below the age of twelve months.
 - (j) "infant formula (*balsutra*)" means an mother's milk substitute which is so prepared in conformity with the prevailing Nepalese standards which is suitable to the physical structure of the infants from four to six months of age and with a view to the fulfillment of the general nutritional requirement of such infant.
 - (k) "Label" means a tag, symbol, picture or other descriptive matter written, printed, lithographed, marked, embossed, included or otherwise displayed on a container containing a product.
 - (l) "Manufacturer" means a person who is directly or through an agent or an

agreement or through a person controlled under an agreement involved in the production or manufacturing business.

- (m) "sale or distribution" means the marketing or selling of such product, inclusive of any act related with the promotion, distribution, advertisement, sample distribution, public relation and information service of such product.
- (n) "Sample" means one unit or small quantity of a product to be provided for free of cost.
- (o) "Complementary food" means such appropriate food substance as to be used as a complementary substance in cases where the mother's milk or mother's milk substitute is inadequate to meet the nutritional requirement of the infant.
- (p) "Ministry" means the Ministry of Health, the Government of the Nepal.
- (q) "Prescribed" or "as prescribed" means prescribed or as prescribed in the Rules framed under this Act.

3. **Implementation and supervision:** (1) The Ministry shall have the main responsibility to enforce and implement this Act.

(2) The Ministry may, as per necessity, obtain assistance of other Ministries in order to ensure the implementation of this Act.

(3) The functions and powers of the Ministry shall be as follows, for purposes of the implementation of this Act:

- (a) To issue Rules to implement this Act,
- (b) To hold consultations with governmental and nongovernmental bodies to ensure the implementation and full compliance of this Act and the Rules issued under this Act,
- (c) To enforce this Act,
- (d) To perform similar other functions that are required to attain, or incidental to the attainment of, the objectives of this Act.

4. **Breastfeeding protection and promotion committee:** (1) The Government of Nepal shall form a Breastfeeding Protection and Promotion Committee to

supervise whether this Act is being complied with, to protect and promote the breastfeeding and to control the sale and distribution of the product.

(2) The committee shall consist of the following members:

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| (a) | Secretary, Ministry of Health | Chairperson |
| (b) | Representative (Gazetted first class), Ministry of Industries | Member |
| (c) | Representative (Gazetted first class), Ministry of Supplies | Member |
| (d) | Representative (Gazetted first class), Ministry of Commerce | Member |
| (e) | Representative (Gazetted first class), Ministry of Education and Culture | Member |
| (f) | Representative (Gazetted first class), Ministry of Labor and Social welfare | Member |
| (g) | Representative, Nepal Pediatrician Association | Member |
| (h) | Representative, Nepal Chamber of Commerce and Industries | Member |
| (i) | Two persons nominated by the committee from amongst the renowned persons engaged in the maternal and child health sector | Member |
| (j) | Renowned nutritional expert nominated by the Government of Nepal | Member |
| (k) | One nominated by the Government of Nepal from amongst the mothers having experiences related with the child care and maintenance | Member |
| (l) | A person designated by the Government of Nepal | Member secretary |

(3) The tenure of office of the nominated members shall be of two years; and they may be re-nominated as determined by the committee.

(4) The committee may invite any native or foreign expert to attend its meeting as an observer.

(5) Government of Nepal may, by a notification in the Nepal Gazette, make alteration in the members of the committee.

5. **Meeting of committee:** (1) The member secretary shall, at the direction of the chairperson, call a meeting of the committee.

(2) The presence of two-thirds members of the committee at the meeting shall be deemed to constitute a quorum for the meeting.

(3) A majority opinion of the attending members on a matter presented to the meeting of the committee shall be deemed as a decision of the committee.

(4) The member secretary shall authenticate the decision of the committee.

(5) The other procedures on the meeting of the committee shall be as determined by the committee on its own.

6. **Functions, duties and powers of committee:** The functions, duties and powers of the committee shall be as follows, subject to the approved policies of the Government of Nepal:

- (a) To supervise, as prescribed, the compliance with this Act,
- (b) To make recommendation for making investigation and instituting a case against the manufacturer, distributor or health worker who violates the provisions of this Act,
- (c) To consider a request for the provision of any product as a grant, and accept or reject such request, as prescribed,
- (d) To consider a request made by the health workers to obtain assistance from manufacturers or distributors for research works, scholarships, participation in professional symposia or conferences or for holding such symposia or conferences, and accept or reject such request, as prescribed,
- (e) To review the labels submitted by the manufacturers and distributors and approve those labels which are in conformity with the provisions of this Act,

- (f) To coordinate the activities related with the publicity of information and educational materials on infant food,
- (g) To formulate a national policy for the protection and promotion of breastfeeding,
- (h) To form sub-committees, as per necessity, for purposes of implementation, supervision and control.

7. **Information and education on infant food:** (1) The Ministry may, on advice of the committee, give approval to publicize any information and educational materials related with the infant food.

(2) Every information and education material, in written or audio or visual form, dealing with the infant food shall include clear information relating to the following matters:

- (a) The benefits and superiority of breastfeeding,
- (b) The preparation for and the continuation of breastfeeding including mother's nutrition,
- (c) The harmful effects on breastfeeding due to the partial adoption of bottle feeding or complementary food feeding,
- (d) The difficulties in reverting to breastfeeding after a period of feeding by mother's milk substitute.

(3) The information and educational material containing the matters of feeding a complementary food or mother's milk substitute to the infants shall also make the following matters clear, in addition to the matters as referred to in Sub-section (2):

- (a) proper use of mother's milk substitutes,
- (b) expenditures to be incurred in feeding mother's milk substitutes in comparison with the expenditures to be incurred in breastfeeding to infants,
- (c) the health hazards of improper use of mother's milk substitutes, improper food and feeding bottles,

- (d) methods of feeding infants with a cup or spoon,
- (e) methods of preparing complementary food at home.

(4) The information and education material shall contain correct and usual information only; and no picture or statement of a nature to discourage breastfeeding or encourage bottle-feeding habit.

8. Health care system and health worker: (1)The chiefs of health care systems and national and local health officials shall adopt proper measures to promote the principles of this Act, protect and encourage breastfeeding and give proper information and advice to the health workers about their responsibilities.

Information as to all the matters contained in section 7 shall certainly be given to the health workers.

(2) The health workers shall protect, promote and encourage breastfeeding. They shall have knowledge of the provisions of this Act; particularly the matters contained in section 7, and implement them to the extent possible.

(3) The health workers shall not allow any act inhibiting the commencement and expansion of breastfeeding, whether directly or indirectly.

(4) No health worker shall accept any financial or in-kind gift in any manner for a manufacturer or distributor.

(5) No health worker shall give a sample of a product to any person.

(6) No health worker shall promote the product in any manner.

(7) If a health worker gets information that any manufacturer or distributor intends to give any gift or other financial facility or that any person has violated any other provision of this Act, the health worker shall give a report thereof in writing to the chief of his/ her organization; and the chief shall also give information thereof to the committee.

9. Acts prohibited from being done by manufacturer and

distributor: (1) No manufacturer or distributor shall make an advertisement in the following manner:

- (a) promoting any product,
- (b) giving an impression or creating a belief that the feeding of mother's milk substitutes is equivalent to, or better than, mother's milk.

(2) For purposes of this section, "advertisement" includes any advertisement made as follows:

- (a) by any publication or television, radio, film, video or telephone,
- (b) by a symbol, billboard, notice or exhibition of goods,
- (c) by exhibition of pictures or miniatures,
- (d) in any other manner.

(3) Notwithstanding anything contained in Sub-section (1), those publications reaching the medical practitioners only may contain an advertisement of a product.

Provided that, such advertisement shall be limited only to the factual and scientific matters and shall not be of such a nature as to give an impression or create a belief that the feeding of mother's milk substitutes is equivalent to, or better than, mother's milk. Such advertisement shall include the information as referred to in Section 7.

(4) No manufacturer or distributor shall give or distribute samples of product to any person.

(5) No manufacturer or distributor shall promote any product in the health care system.

(6) For purposes of this section, "promotion" means to introduce a product to any person or make any person acquainted with a product in any manner including the following manner:

- (a) by making advertisement,

- (b) by using a book, pamphlet or poster as well as printed material containing the name or logo of the manufacturer or distributor or the name, logo, graphic or other miniature of a proprietary product,
- (c) by giving or distributing, free of cost or at nominal price, any matter containing the name or logo of the manufacturer or distributor or the name, logo, graphic or other miniature of a proprietary product,
- (d) by demonstrating products, or
- (e) in any other manner.

(7) Except in cases where a health care system or another institution or organization makes a request for a grant or contribution from a manufacturer or distributor in the prescribed format and the committee approves the request as prescribed, no product shall be provided or donated to the health care system or institution or organization.

(8) No manufacturer or distributor shall make contact with the general public in the health care system to increase own business or for such purpose.

(9) No manufacturer or distributor shall donate any equipment or goods to the health care system without obtaining the approval of the committee.

(10) No manufacturer or distributor shall present any gift or cause any financial or other benefits to a health worker.

(11) Except in cases where a manufacturer or distributor or health worker makes a request in the prescribed format and the committee approves such request as prescribed, no scholarship or research grant shall be given to the health worker nor shall such amount as required to organize a professional symposium or conference or as required for the health worker to participate in the symposium or conference be provided to the health worker.

10. Certification of product: (1) Prior to the marketing of any product other than a feeding bottle and nipple in Nepal, its manufacturer or distributor shall get the product tested by the Central Food Laboratory and obtain certification.

(2) In the case of a product already marketed in Nepal, its manufacturer or distributor shall obtain certification from the Central Food Laboratory no later than ninety days after the date of commencement of this Act.

(3) The manufacturer or distributor shall, for purposes of Sub-sections (1) and (2), make an application, accompanied by a sample of product and the required fee, to the Central Food Laboratory, in the prescribed format.

11. Labeling: (1) Prior to the marketing of any product in Nepal, its manufacturer or distributor shall submit a label of such product, along with the application, as prescribed, to the committee for its approval.

(2) In the case of a product already marketed in Nepal, its manufacturer or distributor shall obtain approval of the committee for the label of such product no later than ninety days after the date of commencement of this Act.

(3) The label of a product shall be prepared in such a manner as to give necessary information about the proper uses of the product and not to discourage breastfeeding.

(4) No label or container of a product shall have any picture, drawing or other miniature other than a graphic describing the manufacturing process.

(5) The label of product shall contain the name and address of its manufacturer and of its distributor, wherever possible.

(6) Every container of an mother's milk substitute or any other milk substance falling within the purview of this Act or label affixed thereto shall indicate, in a clear, conspicuous and in an easily understandable manner, a statement containing all the following particulars in the Nepalese language:

- (a) the words "important notice" or similar other matters,
- (b) a statement that mother's milk is best for infants,
- (c) a statement that a product should be used only on the advice of a health worker as to the need for its use and the method of its use,
- (d) the instructions for its appropriate preparation in easily understandable graphs or words, and

(e) the quantity of a mother's milk substitute or other milk substance required to properly feed an infant each month.

(7) The word "humanized" or "materialized" or any other similar word shall not be used.

(8) The label of, or any thing affixed to the outer part of a container of, a such milk that does not meet all nutritional requirements of an infant formula but can be converted for that purpose shall contain a warning that the product is not the sole source of nourishment of an infant and that the product should not be used or fed to infants without on the advice of a health worker.

(9) The label of a sweetened condensed milk shall contain a clear and conspicuous warning that it should not be used for infant feeding.

(10) The label of a product other than a milk bottle or nipple shall also contain the following matters:

- (a) the ingredients used,
- (b) the composition or analysis of product,
- (c) the storage conditions required,
- (d) the batch number, storage condition, date of its manufacture and the date before which it is to be consumed, taking in account the climatic conditions.

(11) The label of a feeding bottle or nipple shall also contain the name and address of the manufacturer and distributor as well as the statements that mother's milk is the best milk for infants and that it is safer to feed with a pot or spoon than with a bottle.

12. Standard: (1) A product shall conform to the standards specified or recommended by the Nepal Bureau of Standards when it is manufactured, sold or otherwise distributed.

(2) The central food laboratory shall have the powers to test whether a product marketed in Nepal is fit for consumption by a human being.

(3) No product which does not conform to the standards in the country

of its manufacture shall be sold in Nepal.

(4) No product of which expiry date has expired shall be marketed, sold or distributed.

(5) Any product, other than a feeding bottle and nipple, shall be sold only in its original container in order to prevent quality deterioration, adulteration and contamination.

13. Inspection: (1) The Ministry may, on recommendation of the committee, appoint the inspectors in the required number in order to inspect and inquire into whether the manufacturer, distributor, health care system and health worker have observed this Act or the Rules framed under this Act and take necessary action or may, with the approval of the concerned body of Government of Nepal, designate any employees to act as inspector.

(2) The inspector appointed or designated under Sub-section (10) shall inspect and inquire into, as prescribed, whether the manufacturer, distributor, health care system and health worker have observed this Act or the Rules framed under this Act and submit a report thereof to the committee.

14. Powers to suspend or cancel license, permit or authorization: If, based on the report submitted by the inspector under Sub-section (2) of Section 13, it appears that any manufacturer, distributor, health care system or health worker have not observed this Act or the Rules framed under this Act, the Ministry may, on recommendation of the committee, write to the concerned body to suspend or cancel the license, permit or authorization which they have obtained from the Government of Nepal or any other body.

15. Functions and powers of inspector: The functions and powers of the inspector, other than those mentioned in this Act, shall be as prescribed.

16. Penalties: (1) A health worker who violates Sub-sections (4), (5) or (6) of Section 8 shall be punished with a fine not exceeding One Thousand Rupees or with imprisonment for a term not exceeding one month or with both.

(2) A manufacturer or distributor who violates Sub-sections (1), (4), (5), (7), (8), (9), (10) or (11) of Section 9 shall be punished with a fine not exceeding Ten Thousand Rupees or with imprisonment for a term not exceeding three months or with both.

(3) A manufacturer or distributor who violates Section 10 or 11 shall be punished with a fine not exceeding Fifteen Thousand Rupees or with imprisonment for a term not exceeding four months or with both.

(4) A person who violates the provisions of this Act, other than those contained in Sub-sections (1), (2) or (3), or the Rules framed under this Act shall be punished with a fine not exceeding Two Thousand Rupees or with imprisonment for a term not exceeding one month or with both, according to the gravity of the offense.

(5) The court may, while awarding punishment to any person for the commission of any offense under this Section, also order that offender to pay compensation in a sum from Twenty Five Thousand to One Hundred Thousand Rupees to the person aggrieved from such offense or to his/her successor.

17. Liability of firm or body corporate: If any firm or body corporate violates this Act or the Rules framed under this Act, in the case of a firm, its owner or partner, and in the case of a body corporate, the chief administrative officer carrying out the functions of that body, shall be liable to the punishment as referred to in section 16.

18. Government to be the plaintiff : Government of Nepal shall be plaintiff in the cases of under this Act.

19. Investigation and filing of case: (1) The inspector shall investigate a case related with an offense punishable under this Act and, after completion of such investigation, file a case in the District Court.

(2) In investigating and filing the case pursuant to sub-section (1), the inspector may seek advice of the government attorney. After the filing of the case, the government attorney shall plead the case.

20. **Powers to frame Rules:** Government of Nepal may frame necessary Rules in order to implement the objectives of this Act.