

**AN ACT MADE TO CONTROLL THE MARKETING OF BREASTMILK
SUBSTITUES**

PREAMBLE

Whereas it is expedient to promote and protect breastfeeding and to ensure safe and adequate nutrition for infants by regulating the marketing of certain infant foods including breastmilk substitutes,

Be it enacted by Parliament in the twenty first year of reign of His Majesty King Birendra Bir Bikram Shah Dev.

1. Short Title and Commencement :

- (1) This Act may be called the "Breastmilk Substitutes (Marketing Control) Act, 2049."
- (2) This Act shall come into force on such date as His Majesty's Government may, by a notification published in the Nepal Gazette, appoint.

2. Definitions :

Unless the subject or context otherwise requires, in this Act,

- (a) "Breastmilk substitute" means any food being marketed or otherwise represented as a partial or total replacement for breastmilk.
- (b) "Container" means any form of packaging of any products for sale as a retail unit, including wrappers.
- (c) "Committee" means the Committee for the Promotion and Protection of Breastfeeding constituted under Section 4.
- (d) "Products" means following matters :-
 - (1) a breastmilk substitute; ?
 - (2) any type of milk being marketed or otherwise represented as suitable for feeding infants with or without any modification;

- (3) any other food or beverage being marketed or otherwise represented as suitable for feeding infants or
- (4) feeding bottles and teats. ✓
- (e) "Distributor" means a person engaged in the business, whether wholesale or retail, of marketing any product and including any person engaged in the business of providing informational or public relations services in relation to any product.
- (f) "Health care facility" means a governmental, nongovernmental or private institution or organization or private practitioner engaged directly or indirectly in the provision of health care. It also includes nurseries and other child care institutions.
- (g) "Health professional" means a medical doctor, registered nurse or nutritionist or such other person as may be specified by His Majesty's Government by a notification published in the Nepal Gazette.
- (h) "Health worker" means a person working or in training to work in a health care facility, and engaged in providing health care including voluntary unpaid workers.
- yc. (i) "Infant" means a child up to the age of 12 months.
- (j) "Infant formula" means a breastmilk substitute formulated industrially in accordance with prevalent Nepalese standards to approximate the normal requirements of infants up to the age of four to six months and adapted to their physiological characteristics.
- (k) "Label" means any tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on container of product.
- (l) "Manufacturer" means a person engaged in the business of manufacturing the products whether directly, through an agent, or through a person controlled by or under an agreement.
- (m) "Marketing" means any method of introducing or selling the product, including promotion, distribution, advertising, distribution of samples, product public relations and product information services.
- (n) "Sample" means a single or small quantity of the product provided without cost.

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- (o) "Supplementary food" means any food suitable as an addition to breastmilk or to a breastmilk substitute when either becomes insufficient to satisfy the nutritional requirements of an infant.
 - (p) "Ministry" means Ministry of Health, His Majesty's Government of Nepal.
 - (q) "Prescribed" or "as prescribed" means prescribed or as prescribed in the rules made under this Act.

3. Implementation and Monitoring :

- ✓(1) The Ministry shall be principally responsible for the implementation and enforcement of this Act.
- ✓(2) The Ministry shall, when necessary, call upon other ministries to ensure the implementation of this Act.
- (3) For the purpose of implementing this Act, the Ministry shall have the following powers and functions :
 - (a) To promulgate such rules as are necessary for the implementation of this Act;
 - (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 thereunder;
 - (c) To cause the enforcement of this Act, and
 - (d) To exercise such other powers and functions that may be necessary for or incidental to the attainment of the objectives of this Act.

4. Committee for the Promotion and Protection of Breastfeeding :

- (1) For purposes of monitoring compliance with this Act and for the promotion and protection of breastfeeding and the control of the marketing of products, His Majesty's Government shall form a Committee for the Promotion and Protection of Breastfeeding.
- (2) The Committee shall be composed of the following members :
 - (a) Secretary, Ministry of Health - - Chairman

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| (b) | Representative (Gazetted First Class)
Ministry of Industry | - | - Member |
| (c) | Representative (Gazetted First Class)
Ministry of Supply | - | - 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 Labour and Social Welfare | - | - Member |
| (g) | Representative, Nepal Paediatric Society | - | - Member |
| (h) | Representative, Federation of Nepal Chambers
of Commerce and Industries | - | - Member |
| (i) | Two persons nominated by the Committee from
noted people working in the field of maternal and
child health | - | - Member |
| (j) | A noted nutritionist nominated by
His Majesty's Government | - | - Member |
| (k) | A person nominated by His Majesty's Government
from among the mothers experienced in the field of
upbringing and care of the Child. | - | - Member |
| (l) | A person designated by His Majesty's
Government | | -Member-Secretary |

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- (3) The nominated members shall serve for a term of two years and may be renominated as determined by the Committee.
- (4) The Committee may invite a national or foreign expert to take part in the meetings as an observer.
- (5) His Majesty's Government may, by a notification published in the Nepal Gazette, change the size and composition of the Committee.

5. Meetings of the Committee :

- (1) The Member Secretary shall convene meetings at the direction of the Chairman.
- (2) Two thirds of the members of the Committee shall constitute a quorum for a meeting.
- (3) A majority vote of the members present on any agenda of the meeting of the Committee shall be deemed to be the decision of the Committee.
- (4) Decisions of the Committee shall be attested by the Member Secretary.
- (5) Other procedures relating to meetings of the Committee shall be as determined by the Committee itself.

6. Functions Duties and Powers of the Committee :

The functions, duties and powers of the Committee shall, subject to the approved policy of His Majesty's Government, be as follows :-

- (a) To monitor compliance with this Act as may be prescribed;
- (b) To recommend investigation or initiation of cases against manufacturers, distributors or health workers found to be violating the provisions of this Act;
- (c) To consider requests for donations of any product and approve or deny such requests as prescribed;
- (d) To consider requests by health workers for funding from a manufacturer or distributor for research, fellowship, attendance at a professional meeting or conference or sponsorship of such a meeting or conference, and approve or deny such requests as prescribed;
- (e) To review labels of all products as they are submitted by manufacturers and distributors and approve such labels that comply with all relevant provisions of this Act;
- (f) To coordinate the dissemination of informational and educational materials on the topic of infant feeding, (g) To formulate national policy for the promotion and protection of breastfeeding and
- (h) To constitute the sub-committee as required for the purpose of implementing, supervising and controlling.

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7. Information and Education about Infant Feeding :

- (1) The Ministry with the advice of the Committee, shall give its approval for the dissemination of informational and educational materials on infant feeding.
- (2) Informational and educational materials, whether written, audio or visual, on the topic of infant feeding shall clearly and conspicuously explain each of the following points:-
- (a) The benefits and superiority of breastfeeding
 - (b) How to prepare for and maintain breastfeeding including maternal nutrition;
 - (c) How and why any introduction of bottle-feeding or early introduction of supplementary foods interferes with breastfeeding.
 - (d) Why it is difficult to return to breastfeeding after a period of bottle-feeding.
- (3) Informational and educational materials that include the topic of feeding infants with breastmilk substitutes or supplementary foods must explain, in addition to the information specified in subsection (2), the following points:-
- (a) The proper use of breastmilk substitutes;
 - (b) The approximate financial cost of feeding an infant with breastmilk substitutes as compared to the cost of breastfeeding;
 - (c) The health hazards of bottle-feeding, of improper preparation of breastmilk substitutes and of feeding with inappropriate foods;
 - (d) How to feed infants with a cup and spoon, and
 - (e) How to prepare supplementary foods at home.
- (4) Informational and educational materials shall contain only correct and current information and shall not use any pictures or text that encourage bottle-feeding or discourage breastfeeding.
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8. Health Care Facilities and Health Workers :

- 6.1
- (1) Heads of health care facilities and national and local health authorities shall take appropriate measures to encourage and protect breastfeeding and promote the principles of this Act, and shall give appropriate information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all of the information specified in Section 7.
- 7.1
- (2) Health workers shall encourage, support and protect breastfeeding. They are expected to know the provisions of this Act, particularly the information specified in Section 7, and to implement them when possible.
- (3) Health workers shall not do any work that directly or indirectly retard the initiation and continuation of breastfeeding.
- 7.3
- (4) Health workers shall not accept any financial or material gifts from a manufacturer or distributor.
- 7.4
- (5) Health workers shall not give samples of the products to any person.
- (6) Health workers shall not promote, in any way, any product.
- 7.5
- (7) Health workers shall make in writing a report to the head of his or her institution, who shall in turn report to the Committee, any offer of a gift or other financial benefit by a manufacturer or distributor or any other contravention of the provisions of this Act.

9. Manufacturers and Distributors - Prohibited Practices :

- 5.1
- (1) A manufacturer or distributor shall not put forth any advertisement that :
- (a) Promotes any product;
- (b) Implies or creates the belief that bottle-feeding is equivalent to or superior to breastfeeding.
- (2) For purposes of this section, advertisement includes every form of advertising whether :
- (a) In a publication, or by television, radio, film, video or telephone;
- (b) By display of signs, billboards, notices or goods;
- (c) By exhibition of pictures or models; or
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(d) In any other manner.

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(3) Notwithstanding anything contained in subsection (1), products may be advertised in publications that reach only health professionals,

Provided that, such advertisements must be limited to factual and scientific matters and must not create the belief that bottle-feeding is equivalent to or superior to breastfeeding. Such advertisements must include the information listed in Section 7.

(4) A manufacturer or distributor shall not supply or distribute samples of the products to any person.

(5) A manufacturer or distributor shall not promote any product within a health care facility.

(6) For purposes of this Section, promotion means any method of introducing or familiarizing a person with a product including by :

(a) Advertising;

✓ (b) The use of printed matter including books, pamphlets, or posters bearing the name, logo, graphic or other representation of a proprietary product or the name or logo of a manufacturer or distributor;

(c) Distribution or offer of any item for little or no cost, bearing the name, logo, graphic or other representation of a proprietary product or the name or logo of a manufacturer or distributor;

(d) Display of the products;

(e) Any other manner.

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(7) No manufacturer or distributor shall donate or provide at lower than retail price any quantity of the products to a health care facility or any other institution or organization unless such facility, institution or organization requests a donation on a form as prescribed and such request is approved by the Committee under such conditions as prescribed.

(8) No manufacturer or distributor shall in furtherance of or for the purposes of its business have contact with the general public within a health care facility.

(9) No manufacturer or distributor shall donate equipment or materials to a health care facility without the approval of the Committee.

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(10) No distributor or manufacturer shall offer or make to a health worker any gift or other benefit, financial or otherwise.

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(11) No manufacturer or distributor shall provide fellowships or research grants for health worker or shall sponsor a professional meeting or conference or fund the attendance of a health worker at such a professional meeting or conference unless such is requested on a form as prescribed and such request is approved by the Committee under such conditions as prescribed. # Sponsorship

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10. Certification of the Products :

- (1) Manufacturers or distributors must obtain a certification from the Central Food Laboratory approving any product, other than the feeding bottles and teats, before it may be sold in Nepal.
- (2) For any product, already being sold in Nepal, manufacturers or distributors must obtain a certification from the Central Food Laboratory within ninety days of the commencement of this Act.
- (3) For purpose of subsections (1) and (2) manufacturers or distributors must submit to the Central Food Laboratory an application along with a sample of the products in the form as prescribed and any fee that may be required.

11. Labelling :

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(1) Manufacturers or distributors shall submit the label of the products to the Committee for approval before the products may be sold in Nepal with an application as prescribed.
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(2) For any product already being sold in Nepal, manufacturers or distributors shall obtain the Committee's approval for the label of each product within ninety days of the commencement of this Act.
- 9.1
(3) Labels of the products shall be designed so as not to discourage breastfeeding and shall provide the necessary information about the appropriate use of the product.
- 9.2
(4) The label or container of the products shall not show any photographs, drawings or other representations other than graphics for illustrating methods of preparation. *
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(5) The label of the products must contain the name and address of the manufacturer and, when applicable, the distributor.

9.2
(6) Every container of a breastmilk substitute or other milk product within the scope of this Act must have a clear, conspicuous, and easily understood message printed on it or on a label that cannot become separated which shall be written in the Nepali language and shall include all of the following information:-

- (a) the words "Important Notice" or their equivalent;
- (b) a statement that breastmilk is the best milk for infants;
- (c) a statement that the product should not be used without the advice of health worker concerning the need and proper method for its use;
- (d) instructions for appropriate preparation in words and in easily understood graphics;
- (e) the quantity of the breastmilk substitute or other milk product that will be required to properly feed the infant each month.

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(7) The terms "maternalized", "humanized" or their equivalent shall not be used.

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(8) Any type of milk that does not meet all the nutritional requirements of an infant formula, but can be modified to do so, must contain on its label or on an insert that is visible from the outside of the container, a warning that the product alone should not be the sole source of the infant's nourishment and that it should not be used to feed infants except under the guidance of a health worker.

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

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(10) The label of products, other than the feeding bottles and teats, shall also state the following:

- (a) the ingredients;
- (b) the composition and analysis of the product;
- (c) the required storage conditions; and
- (d) the batch number and date before which the product is to be consumed, taking into account climatic and storage conditions.

- (11) The labels for bottles and teats shall state in addition to the name and address of the manufacturer and distributor, that breastmilk is the best milk for infants and that feeding with a cup and spoon is safer than bottle-feeding.

12. Quality :

- (1) The products shall, when manufactured, sold or otherwise distributed meet applicable standards fixed or recommended by the Nepal Bureau of Standard.
- (2) The Central Food Laboratory shall have the power to test any product sold in Nepal to determine whether it is fit for human use or consumption.
- (3) The products that do not meet the safety standards for use in the country of manufacture shall not be sold in Nepal
- (4) The products that have reached the expiration date shall not be marketed, sold or distributed.
- (5) To prevent quality deterioration, adulteration or contamination, the products, other than the feeding bottles and teats, shall be sold only in the original container.

13. Inspection :

- (1) For the purpose of taking necessary actions after inspection and enquiry about the compliance of this Act and rules made under this Act by the manufacturer, distributor, health care facilities and health worker, Ministry may, on recommendation of the Committee, appoint the inspectors in required number or designate the employees as inspector by obtaining the approval of the concerned bodies of His Majesty's Government.
- (2) The inspector, appointed or designated under subsection (1) shall, after inspection and enquiry about the compliance of this Act and the rules made under this Act by the manufacturer, distributor, health care facilities and health worker, submit a report thereof to the Committee.

14. License, Permit or Authority May be Suspended or Revoked :

In case it is found from the report submitted by the inspector pursuant to subsection (2) of Section 13 that provisions of this Act or the rules made under this Act has not been complied by any manufacturer, distributor, health care facilities or health worker, Ministry may, on recommendation of the

Committee, write to the concerned bodies to suspend or revoke any license, permit or authority obtained by them from His Majesty's Government or any other body.

15. Powers and Functions of an Inspector :

The powers and functions, other than those mentioned in this Act, of an inspector shall be as prescribed.

16. Penalties :

- (1) Any health worker who acts in contravention of subsection (4), (5) or (6) of Section 8 shall be penalized with a fine up to one thousand rupees or an imprisonment up to one month or both.
- (2) Any manufacturer or distributor who acts in contravention of the subsection (1), (4), (5), (7), (8), (9), (10) or (11) of Section 9 shall be penalized with a fine up to three thousand rupees or an imprisonment up to two months or both.
- (3) Any manufacturer or distributor who acts in contravention of Section 10 or 11 shall be penalized with a fine up to five thousand rupees or an imprisonment up to three months or both.
- (4) Any person who acts in contravention of other provisions of this Act other than those mentioned in the subsection (1), (2) or (3) or the rules made under this Act shall be penalized with a fine up to two thousand rupees or an imprisonment up to one month or both.
- (5) The Court may, while making decision to punish any person pursuant to this Section for any offence, make such person liable to pay an amount of compensation ranging from twenty five thousand rupees to one hundred thousand rupees to the person who has sustained the damage from such offence.

17. Responsibility of Firm or Corporate Body :

If any firm or corporate body contravenes the provisions of this Act or rules made under this Act the owner or partner of such firm or chief administrative officer responsible for the conduct of the business of such corporate body shall be penalized pursuant to Section 16.

18. Government to be Plaintiff :

His Majesty's Government shall be plaintiff in all the cases under this Act.

19. Investigation and Filing of the Case :

- (1) The inspector shall conduct the investigation of the case relating to an offence which may be penalized under this Act and file the case before the District Court on completion of the investigation work.
- (2) The inspector may seek the advice of the government lawyer on conduct of investigation and filing of the case. After the case is filed the government lawyer will plead the case .

20. Power to Frame Rules :

His Majesty's Government may frame necessary rules for implementing the objectives of this Act.