

The Law on Protection, Promotion and Support of Breastfeeding and Infant and Young Child Feeding, for the year 2005.

Pursuant to the provisions of the Interim Constitution of the Republic of Sudan, for the year 2005, the National Transitional Council passed the following law, which was signed by the President of the Republic:

Chapter I Name of the law and starting date of enforcement:

1. This law is called the Law on Protection, Promotion and Support of Breastfeeding and Infant and Young Child Feeding for the year 2005. It shall take effect starting the date of its signing.

Interpretation:

2. In this Law, unless the context otherwise requires, the words and phrases mentioned below shall have the meaning set forth in front of each:

Exclusive breastfeeding: means the sole dependence of the baby on mother's breast milk during the first six months of age, without any additional food or drink; not even water.

Breast-milk substitutes: means any food being traded as a total or partial replacement of breast milk, whether or not it would fit for the purpose.

Complementary food: means any processed or other food whether prepared inside or outside the house and whether is of animal or vegetable origin, used as food supplement to mother's breast milk, to provide for the nutritional needs of the baby.

Infant foods: means any foods prepared at home, from milk and dairy products.

The Product: means: Breast milk substitutes, Complementary food, Infant Foods, Teats or pacifiers, Any other products determined by the competent authorities, from time to time, for purposes of this Law, by means of an announcement published in the Official Gazette

The Distributor: means every natural or legal person who sets to the marketing and promotion of the product.

Health care facilities: means the governmental and non-governmental facilities or institutions engaged in, or providing the service of health care. This does not include pharmacies or drug stores.

Health workers: they are the personnel working at health care facilities, including volunteers and trainees.

label: means any sign, mark, description, writing or print, whether affixed to the product or written on it.

The Minister: means the Federal Minister of Health, or any person or entity that would act for him.

The Commission: means the advisory body composed under the provisions of Article (3a) of this Law.

Promotion: means advertising the product in various media and distribution of products and posters that refer to the concerned product, such as gifts or presents, as well as any publicity materials bearing the name of the product or the distributor. This also includes giving information or instructions on how to use the product (for sales purpose).

Inspector: means the inspector appointed under the provisions of Article (15) of this Law.

Sample: means any small amount of the product, given free of charge.

Pacifiers: means the artificial nipples made for babies and used to calm them.

Technical Committee: means the National Commission for Registration of Breast Milk Substitutes, which works in coordination with the Committee on Food Import and Registration of Foods, Department of Food Control.

Educational materials: printed and audio-visual materials intended to explain and demonstrate the material(s) or the product.

Chapter II National Commission and Membership

3. (a) A National Commission on Protection, Promotion and Support of Breastfeeding, shall be formed by the Federal Minister of Health, composed of the following members:

- The Minister or his designee, Chairman
- State-health Ministers or their designees
- Director of Child Health
- Representative of the National Nutrition Directorate
- Director of Integrated Management of Childhood Illness Programme
- Chief of Obstetrics and Gynecology
- Chief of Pediatrics
- National Council for Childhood
- Midwifery Superintendent
- Representative of the Federal Health Education Directorate
- Representative of the Federal Ministry of Education
- Representative of the Federal Ministry of Social Planning
- Representative of the Federal Ministry of Communications
- Federal Mass Media Specialist
- Representative of the Federal Ministry of Finance and National Economy
- Representative of voluntary organizations working in the field of breastfeeding protection
- Consumer Protection Association

Specifications:

(a) Any other members appointed on the recommendation of the National Commission.

(b) Term of membership is three years, renewable for one term or more.

(c) The post shall become vacant by resignation, or if the Minister directs to dismiss the member. The vacancy shall be filled in the same manner in which appointment was made, for the remainder of the term of membership.

(d) The Advisory Body may invite national or international experts to attend their meetings as observers. It may also form a technical committee(s), or appoint experts to submit detailed studies on any of the topics related to the purposes and objectives of this Law.

Supervisory Role of the Minister:

4a The Commission shall act under the supervision of the Minister, who will exercise the powers necessary to implement provisions of this Law. Without prejudice to the foregoing, the Minister shall have the authority to:

4b issue the rules and orders necessary to implement provisions of this Law.

4c consult with government agencies and other relevant actors to achieve the objectives and purposes of this Law

4d reconsider membership and composition of the Commission.

Authorities and Objectives of the Commission:

5. The Commission shall have the following objectives:

a) Development of national policies for protection, promotion and support of breastfeeding and infant and young child feeding.

b) The Commission may, with approval of the Minister, establish State-level committees with the same objectives and powers of the Advisory Body at the level of states.

c) Development of a national communication strategy for protection, promotion and support of breastfeeding and infant and young child feeding, as well as promotion of public awareness programmes, preparation of educational materials on infant feeding and qualifying and training health workers in the field of protection, promotion and support of breastfeeding.

d) Reviewing reports on the implementation of the provisions of this Law, or any other matters related thereto.

e) Issuance of necessary instructions to inspectors to take appropriate action against anyone who may violate this Law, or the regulations issued thereunder.

f) Reviewing the materials submitted under provisions of Article () and make recommendations for appropriate action.

g) Any other duties and tasks required to implement provisions of this Law.

h) Issuance of the administrative regulations needed for the Commission to undertake its role.

i) Ensuring that all products have been registered in accordance with the prescribed conditions and proper procedures.

j) Overseeing the configured ad hoc technical committee(s).

Management of the Advisory Body:

The Commission shall have a permanent office space at the Ministry of Health Headquarters, which would be determined by the Minister.

6. The Minister shall appoint a secretary for the Advisory Body. Decisions taken by the Commission shall be issued under the secretary's signature.

7. The Advisory Body shall appoint permanent staff to run its business, according to the budget that would be endorsed by the Minister.

8. The Commission shall hold regular monthly meetings. Chairman of the Commission may call for any emergency meeting as he may deem appropriate.

9. The secretary shall call for meetings, according to the Chairman's directives and shall take minutes of the meetings to be held by the Commission. He shall undertake any other tasks or duties assigned to him by the Advisory Body.

10. The Advisory Body shall have a quorum with the presence of absolute majority. If this proves infeasible on the first meeting, the subsequent meeting shall be considered legal upon the presence of any number of the members. Decisions shall be taken by the majority of the members to be present at any legal meeting.

Chapter III: Registration Registration of Products

11. The Minister shall determine the final date for importation, manufacture or sale of any product that is not registered, through an announcement published in the official newspapers.

12. The person who wishes to register a product must provide the required information, data and documents.

13. The product shall be registered when it becomes compatible with the specifications set for foods and when the data stated in the labels found consistent with the product and meets all the terms and conditions set forth in article 16, Chapter III of this Law.

14. Product registration certificate shall be issued after the registration has been authenticated.

15. Applications for registration are submitted to the technical committee concerned with children's foods.

Terms of Registration:

16. Without prejudice to any other conditions stipulated in the Law on Food Control, for the year 1973 and the regulations issued thereunder, or in any other law, the label to be submitted for registration must contain the following information:

- a) accurate instructions for preparation of the product, with illustrations on how to use and apply them, in drawing and in writing;
- b) indication of the age group for which the product is recommended, in accordance with the established rules;
- c) sufficient and clear explanation of the health hazards detriments ensuing from giving the product before reaching the prescribed age;
- d) be written in both Arabic and English;
- e) ingredients of the product;
- f) terms of shipping, storage and preservation;
- g) production and expiration dates;
- h) name and address of the producer;
- i) warning of the harms caused, in case of improper preparation of the product.

Label MUST NOT contain the following:

- a) any information encouraging the abandonment of breastfeeding;
- b) any pictures or graphics other than those explaining the way to prepare the product;
- c) any assimilation or likening to mother's milk, or any phrases suggestive of comparison with breastfeeding.

17. In addition to the conditions mentioned in Article 15 of this Law, label must contain the following:

- a) In the case of breast-milk substitutes, it should present, on the front side, the following statements, in noticeable and legible letters, size of which shall not be smaller than 50% of the largest words appearing in the product introductory information, but not less than 2mm in height:
“Exclusive breastfeeding during the first six months will ensure good health for your child”
“Continued breastfeeding for two years, together with complementary feeding is the best food for your child to protect him from all diseases”
- b) Label shall also contain the following statements, in boldface letters, not smaller than 15 mm in height:
“Follow the instructions carefully or else your child might get sick”
“Do not use a larger or lesser amount than the prescribed quantity”.
“Drinking in a cup is better for your child than drinking in a bottle. He may refuse breastfeeding if he gets used to the bottle”.
- c) If the product is an artificial teat, label is to contain the following statements, in letters not smaller than 2mm in height.

First:

“Using the bottle may make your child vulnerable to illness”

“Cup feeding is safer for your child”

“Follow preparation instructions thoroughly”

Second: It must also contain instructions for proper washing and disinfection in clear and legible words.

d) Product label of each pacifier must contain the following warning in letters not smaller than 2 mm in height: (Warning: using pacifiers impedes breastfeeding)

18. Product label of foods that can be used as infant foods, whether liquid or powder must contain the following statements as detailed below:

- a) for concentrated or skimmed milk; and low-fat milk (This product is not to be used as the sole source of nutrition for children under twelve months)
- b) for full-fat cow's milk: (This product is not to be used as the sole source of nutrition for children under twelve months, unless the doctor, or dietitian has so advised).

Chapter IV Inspection Appointment of Inspectors

The Minister shall appoint inspectors holding suitable qualifications to realize the purposes of this Law, each within his specified administrative limits.

Authority of Inspectors:

19. In addition to the authority granted to inspectors by the Law of Food Control and those stated in the Bylaw on Inspection, Sampling and Analysis, issued under the said law, inspector may:

- a) enter any place where an imported or manufactured product is being sold, stored, displayed for sale, advertised or promoted in any way. He may inspect the product, as well as all the records relevant thereto;
- b) institute criminal lawsuit should there be any violation of the provisions of this Law.

20. The inspector shall submit to the Advisory Commission a report on any violation of the provisions of this Law. The Commission shall issue their directives as to the actions to be taken concerning said violation.

Chapter V Promotion and Marketing

21. Approval of the Advisory Commission must be obtained before publishing or broadcasting advertisements or publicity materials for breast milk substitutes. Promoting advertisements shall, in no way, contain any text suggestive of ideality of the product or the preference thereof to breastfeeding.

22. Product manufacturers or distributors shall not promote any product in any of the following ways:

- a) all forms of special sale, which imply price reduction, discount or sale in installments;
- b) direct and indirect contact by marketing staff with customers, for purposes required by their business;
- c) giving one sample or more of the product to anyone.

Promotion at health care facilities:

23. Manufacturers or distributors are not allowed to: promote products at health care facilities, in any of the following ways:

- a) distribution of free materials or samples at health care facilities;
- b) direct involvement of health workers by means of gifts or presents for purposes of financing participation of health workers in meetings, seminars, training courses and scholarships. Such educational activities must be arranged through the Federal Ministry of Health;
- c) financing research projects conducted by health workers, which include clinical research on the concerned product, unless such projects are conducted under a protocol approved by a competent body. Financing of these projects is to be provided through the Advisory Commission and both the funding source and name of the researcher benefitting from this support must be known;
- d) offering payments to any health worker;
- e) presenting free samples to health workers, except for purposes of: Professional evaluation and Research projects conducted at hospitals or other health facilities
- f) presenting utensils, or offering services to health care facilities;
- g) presenting or selling, at less than 80% of the retail price, any quantity of the product to health workers, unless this giving, or sale at a lower price, is made for the benefit of orphanages or child-adoption institutions. In this case, a quantity sufficient to meet the needs of these children, for a period of not less than 6 months, must be provided.

Marketing:

24. It is not permitted for any person to distribute for sale, store or display for sale, any product, that is:

- a) not registered;
- b) not compatible with the established specifications and conditions of registration;
- c) expired;
- d) not in its original packaging;
- e) label lacks the necessary data and facts.

Chapter VI Information and Education

Educational Materials

25. Educational materials on infant feeding are to explain:

- a) importance, advantages and supremacy of breastfeeding over other alternatives;
- b) how to prepare for and maintain breastfeeding, to include maternal nutrition;
- c) how and why pacifiers impede breastfeeding;
- d) how and why early complementary foods impede breastfeeding;
- e) the negative effects of pacifiers on breastfeeding.

26. Educational materials are distributed upon a written approval from the competent authority.

27. Educational materials must fulfill the following requirements:

- a) contain facts and updated information and not to use any pictures or writings that may encourage the abandonment of breastfeeding.
- b) is written in both Arabic and English.
- c) not to indicate brand name of the product. It must not carry the name or logo of any manufacturer or distributor, except for purposes of copyright reservation. This paragraph, however, shall not apply to information of the concerned product, which is directed to health care professionals.

28. Without prejudice to the provisions of Articles 22, 23 and 24, educational materials, meant for bottle-fed infants, must include the following information:

- a) instructions for proper preparation of the product, to cover cleansing and disinfection of the utensils used;
- b) approximate cost of infant feeding for 6 months when using the product in question;
- c) health detriments for using pacifiers;
- d) health detriments for the improper preparation of the product;
- e) how to feed infants with a cup.

29. If the educational material covers topics on infant feeding with complementary foods, it must indicate the following:

- a) health detriments for introducing complementary foods at an early or late age;
- b) complementary food can be easily and conveniently prepared at home using locally available materials;
- c) individuals producing or distributing the materials referred to in this chapter, need to provide the Advisory Body with a copy thereof, as per the set procedures.

Chapter VII General Provisions Promoting Breastfeeding

30. Officials responsible for the management of health services, together with the national and local health authorities, must take the necessary measures needed to encourage and protect breastfeeding and to apply provisions of this Law.

31. Competent authorities shall provide health workers with information and shall delineate their duties and responsibilities. Health workers are to exert every effort to support breastfeeding.

32. Health workers are to abstain from:

- a) accepting any gift or benefit, in cash or in kind, irrespective of its value, from any manufacturer or distributor;
- b) accepting or giving any samples to anyone except in accordance with the provisions of this Law;
- c) promote any product.

32. Health workers shall be obligated to submit a written report to their immediate supervisors, who, in turn, shall submit to the Advisory Commission, a report explaining any offers made for health workers to accept any sample, gift or benefit from any distributor or manufacturer, or other violations of the provisions of this Law.