

THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) BILL, 2012

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THE BREAST MILK SUBSTITUTES (REGULATION AND CONTROL) BILL, 2012

A Bill for

AN Act of Parliament to provide for appropriate marketing and distribution of breast milk substitutes; to provide for safe and adequate nutrition for infants through the promotion of breastfeeding and proper use of breast milk substitutes, where necessary, and for connected purposes

ENACTED by Parliament of Kenya, as follows—

PART I—PRELIMINARY

Short title and commencement.

1. This Act may be cited as the Breast milk Substitutes (Regulation and Control) Act, 2012 and shall come into operation on such date as the Cabinet Secretary may, by notice in the Gazette, appoint.

Interpretation.

2. (1) In this Act, unless the context otherwise requires—

"advertising" means to make a representation by any means for the purposes of directly or indirectly promoting the sale or use of a designated or complementary food product, including —

- (a) written publication, a television or radio broadcast, film or electronic transmission, including the internet, video or telephone;
- (b) displays, signs, symbols, colours, billboards or notices; or
- (c) exhibition of pictures or models;

"authorised officer" means a person appointed under section 11;

"breast milk substitute" means an food that is marketed, or otherwise represented, as a partial or total replacement of breast milk, whether suitable for that purpose or not;

"Cabinet Secretary" means the Cabinet Secretary for the time being responsible for matters relating to public health;

"Codex Alimentarius Commission" means the Joint Food Standards Programme of the Food and Agriculture Organisation of the United Nations and the World Health Organisation;

"Codex Alimentarius Standard" means the latest version of the relevant Codex Standard as issued by the Codex Alimentarius Commission;

"Committee" means the National Committee on Infant and Young Child Feeding established under section 4 (1);

"complementary food product" means any food suitable or presented as a suitable complement to breast milk, for infants from the age of six months up to the age of twenty-four months;

"designated product" means—

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- (a) any food or drink designed for infants marketed or otherwise represented to be a partial or total replacement of breast milk, whether or not it is suitable for that purpose;
- (b) feeding bottles;
- (c) teats;
- (d) infant formula;
- (e) follow-up formula for infants or children between the age of six months to twenty- four months;
- (f) products marketed or otherwise represented as being suitable for feeding infants of up to the age of six months;
- (g) breast milk fortifiers;
- (h) pacifiers;
- (i) cups with spout; or
- (j) any other product the Cabinet Secretary may, by a notice in the Gazette, declare to be a designated product.

"distributor" means a person engaged in the business of supplying a designated product, whether by wholesale or retail means;

"follow-up formula" means milk or a milk-like product industrially formulated and marketed or otherwise represented as suitable for an infant from the age of six months or a young child and includes follow-up formulas for special medical or nutritional purposes;

"gift" includes a free sample of a designated product, meals and refreshments, diaries, stationery, air ticket, holiday trip, calendars, stickers, growth charts, prescription pads, cot tags or tongue depressors;

"health worker" means a person providing, or undergoing training to provide health services, whether professional or non-professional, and includes a volunteer;

"health-care facility" means a public or private institution or organization engaged directly or indirectly in the provision of health care or health promotion;

"infant" means a child from birth upto the age of twelve months;

"infant formula" means milk or a milk-like product of animal or plant origin, formulated industrially in accordance with the Codex *Alimentarius* Standard for Infant Formula, to satisfy the nutritional requirements of up to six months of age and includes all infant formula for special medical or nutritional purposes;

"indirect contact" includes contact through television and radio, telephone or internet help lines, mother and baby clubs or baby competitions;

"marketing" means any method of introducing or selling of a designated or complimentary product, -and includes promotion, distribution, advertising, public relations, information services and distribution of samples;

"manufacture" means the processing of a designated product and includes the packaging, distribution or importation of a designated or complementary product for sale in Kenya;

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"manufacturer" means a person or corporation or other entity, in public or private sector, engaged in the business of manufacturing a designated or complementary product, whether directly or through an agent, or a person controlled by or under an agreement with the manufacturer;

"package" means a box, carton or tin, or a wrapping of any kind, in which a designated or complementary food product is customarily sold by a wholesale or retail unit;

"publish" means to show, broadcast, televise, display, exhibit or distribute a designated or complementary food product;

"social welfare institution" means a public or private organization engaged, directly or indirectly, in providing social welfare for infants or young children, but does not include a health care facility;

"sample" means a single or any quantity of a designated product provided at no cost; and

"young child" means a child between the age of six months to thirty six months.

(2) Despite subsection (1), until after the first elections under the Constitution, references in this Act to the expression "Cabinet Secretary" shall be construed to mean "Minister".

Act to bind the Government.

3. This Act shall be binding to the Government.

PART II- ESTABLISHMENT ANF FUNCTIONS OF THE NATIONAL COMMITTEE ON INFANT AND YOUNG CHILD FEEDING

Establishment of Committee.

4. (1) The Cabinet Secretary shall establish a committee to be known as the National Committee on Infant and Young Child Feeding.

(2) The Committee shall consist of—

- (a) the Director of Public Health, who shall be the Chairperson;
- (b) the Director of Nutrition and Dietetic Services;
- (c) the Director of the Kenya Bureau of Standards or his representative;
- (d) the Director of the Kenya Medical Research Institute or his representative;
- (e) the Director of a national hospital or his representative;
- (f) the Registrar of the Nursing Council of Kenya or his representative;
- (g) the Chairperson of the Kenya Paediatric Association or his representative;
- (h) the Chairperson of an institution representing nutritionists or his representative;
- (i) a representative nominated by each of the following bodies and appointed by the Cabinet Secretary -
 - (i) private health institutions;
 - (ii) non-governmental organizations with national mandate on infant and young child feeding;

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- (j) three co-opted members with relevant expertise in infant and young child feeding, appointed by the Cabinet Secretary.
- (3) The Director of Nutrition and Dietetic Services shall be the Secretary to the Committee.
- (4) A member of the Committee appointed under subsection (2) (i) shall hold office for a term of three years but shall be eligible for re-appointment for one further term of three years.
- (5) The Cabinet Secretary shall provide such public officers as may be necessary for the proper and efficient discharge of the functions of the Committee under this Act.
- (6) A member of the Committee shall not have direct or indirect interest in the manufacturing, distribution, marketing, advertisement or promotion of a designated or complimentary food product, and where a member has such interest, that member shall disclose, in writing, the nature of interest and shall cease to be a member of the Committee.
- (7) A member who fails to disclose his interest in accordance with subsection (5) commits an offence and shall be liable, upon conviction, to a fine not exceeding one hundred thousand shillings or a term of imprisonment not exceeding three years, or to both.
- (8) The Committee may establish sub-committees consisting of its members to deal with such matters as the Committee may specify.
- (9) The expenses of the Committee shall be met out of funds provided by Parliament for that purpose.
- (10) The conduct of the meetings of the Committee shall be in accordance with the Schedule.

Functions of the Committee.

5. (1) The functions of the Committee shall be to—

- (a) advise the Cabinet Secretary on the policy to be adopted in relation to the production, manufacture, sale, advertising, promotion and use of designated or complementary food products;
 - (b) participate in the formulation of, and recommend the regulations to be made under this Act; and
 - (c) perform any other functions as may, from time to time, be assigned by the Cabinet Secretary.
- (2) The Committee may, by resolution either generally or in any particular case, delegate to any of the sub-committees established under section 4(5), the exercise of any of its powers or the performance of any of its functions or duties under this Act.

PART III- ADVERTISEMENT, PROMOTION, LABELLING OF PACKAGES AND EDUCATIONAL AND INFORMATIONAL MATERIALS

Prohibition on advertisement and promotion

6. (1) A person shall not advertise or promote or cause to be advertised or promoted a designated or complementary food product.
- (2) For the purposes of this section, promotion includes—
- (a) a direct or indirect method of introducing a designated or complementary food product or encouraging the buying or use of the products;

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- (b) the use of sale devices including special discounts, special displays, competitions with prizes, tie-in sales, provision of premiums and rebates, discount coupons, loss leaders, giving of gifts and free samples to mothers to promote sales;
 - (c) a direct or indirect contact between marketing personnel and members of the public in furtherance of, or for the purpose of promoting business of a designated or complementary food product;
 - (d) electronic communications including internet, website and electronic mail encouraging the buying or use of the products;
 - (e) the distribution of promotional items including clothing, stationery, household utensils or items that refer to a designated or complementary food product or the brand name of the product;
 - (f) practices or communication in any form which create, or may create, any association with a designated or complementary food product.
- (3) For the purposes of subsection (1), a person promotes or causes to be promoted or engages in promotional activities of a designated or complementary food product if that person—
- (a) publishes or causes to be published an advertisement for a designated or complementary food product;
 - (b) distributes or causes to be distributed any information or educational material relating to infant and child feeding;
 - (c) distributes or causes to be distributed, or donates or causes to be donated, or sells or causes to be sold a designated or complementary food product in a social welfare institution, an orphanage or a health facility;
 - (d) engages persons whose duties involve marketing of a designated or complementary food product-
 - (i) remuneration which varies according to the volume of sale of designated or complementary food product; or
 - (ii) bonuses or similar incentives calculated directly according to the volume of sales of the designated or complementary food product.
 - (e) displays to the material which refers directly or indirectly to a designated or complementary food product;
 - (f) distributes materials to health workers which directly or indirectly refers to a designated or complementary food product;
 - (g) offers a gift or a benefit or inducement including fellowship, study grant, funding for attendance of meetings, seminars, continuing education or conferences to a health worker or a member of his family;
 - (h) directly or indirectly provides any support, financial or otherwise to the general public or a health worker for the purposes of promoting a designated or complementary food product;
 - (i) funds any research carried out by a health worker in infant and young child health;
 - (j) employs a person to provide to health workers in health care facilities, pregnant women or mothers of infants and young children or any other person, with education or instructions regarding infant and young child health; or

(k) sponsors, facilitates or finances an event, contest, telephone counselling line or campaign directed to pregnant women, mothers of infants or their families.

Power of the Cabinet Secretary to permit donations.

7. (1) Despite section 6(3)(c) and subject to subsection (2) of this section, the Cabinet Secretary or his representative may, in writing, permit any manufacturer, distributor or health worker to supply any designated or complementary food product to an orphanage or social welfare institution.

(2) The Cabinet Secretary or his representative shall not grant permission for the supply of any donation of any designated or complementary food product to an orphanage or social welfare institution unless the Cabinet Secretary or his representative is satisfied that—

(a) the label on the package carrying designated or complementary food product does not bear the proprietary or brand name of a designated product; and

(b) the infant care providers have or shall receive appropriate training to prevent any health hazards occurring from improper use.

Health worker or proprietor not to accept gifts.

8. A health worker or a proprietor shall not—

(a) accept from a manufacturer or a distributor of a designated or complementary food product -

(i) a gift;

(ii) financial assistance;

(iii) fellowship, scholarship, research grant, study tour, funding for meetings and conferences, seminars or continuing education courses; or

(iv) sample of a designated or complementary food product;

(b) distribute or display a designated or complementary food product; or

(c) demonstrate the use of a designated or complementary food product to mothers or members of their families unless in such special cases of need as may be determined by the Cabinet Secretary or his representative, in writing.

Labelling of packages

9. The package of a designated or complementary food product shall contain notices, warnings and necessary information with respect to promotion of breastfeeding and proper use of breast milk substitutes in the wording, size and manner prescribed by the Cabinet Secretary.

Educational and informational materials to be approved by Cabinet Secretary.

10. (1) Subject to subsection (2), a person shall not publish or cause or permit to be published any informational or educational material on infant and young child feeding unless the material has been approved by the Cabinet Secretary or his representative, in writing.

(2) Subsection (1) shall not apply to research articles and public presentations which disclose the financier, sponsor or facilitator thereof and which do not contain any advertisement or promotion of a designated or complementary food product in any manner.

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(3) The Cabinet Secretary shall make Regulations prescribing the procedures and requirements for the approval of informational and educational material under subsection (1).

PART IV—ENFORCEMENT

Appointment of authorised persons.

11. (1) The Cabinet Secretary may, from time to time, by notice in the Gazette, appoint any person or a class of persons to be authorized officers for the purposes of this Act.

(2) The Cabinet Secretary shall issue a certificate of appointment to every person appointed as an authorised officer under this section.

(3) In addition to authorised officers appointed under subsection (1) —

(a) public health officers appointed under the Public Health Act; and

(b) any other person upon whom written law vests functions of maintenance of law and order, shall be deemed to be authorized officers for the purposes of this Act.

Places authorised officers may enter.

12. (1) For the purposes of enforcing this Act, an authorised officer may, at any reasonable time, enter any place in which the officer believes on reasonable grounds that—

(a) a designated or complementary food product is or has been produced, manufactured, stored, packaged, sold or used;

(b) there is anything used in the production, manufacture, testing, packaging, promotion or sale of a designated or complementary food product in the place;

(c) there is information relating to the production, manufacture, testing, packaging, promotion or sale of a designated or complementary food product;

(d) any person is in any way contravening the provisions of this Act.

(2) An authorised officer who wishes to enter any premises under this section shall, if required, produce for inspection, by the person who is or appears to be in charge of the premises, the certificate issued under section 11(2).

Powers of authorised officers.

13. In carrying out an inspection in any place under section 12, an authorised officer may—

(a) examine a designated or complementary food product or anything referred to in section 12;

(b) require any person in charge of such a place to produce for inspection, in the manner and form requested by the officer, a designated or complementary food product;

(c) open or require any person in charge of such a place to open any container or package found in a place where the officer believes on reasonable grounds contains a designated or complementary food product;

(d) take or require any person in charge of such a place to produce samples of a designated or complementary food product;

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(e) conduct any test, analyse or examine a designated or complementary food product or document relating thereto; or

(f) require any person found in the place to produce for inspection or copying any written or electronic information that is relevant to the administration or enforcement of this Act.

Entry of dwelling place.

14. An authorised officer shall not enter a dwelling place except with the consent of the occupant or under authority of a warrant issued under section 15.

Authority to issue warrant.

15. (1) Upon an *ex-parte* application, a judge of the High Court, may issue a warrant authorizing an authorised officer named in the warrant to enter and inspect a dwelling place, subject to any conditions specified in the warrant, if the judge is satisfied by a statement on oath that—

(a) the dwelling place is a place referred to in section 14;

(b) entry into the dwelling place is necessary for the administration or enforcement of this Act;

(c) the occupant does not consent to the entry or that the entry has been refused or there are reasonable grounds for believing that it will be refused.

(2) An authorised officer named in the warrant issued under subsection (1) shall enter a dwelling place between six o'clock in the forenoon and six o'clock in the afternoon of any day of the week.

Use of force

16. An authorised officer executing a warrant issued under section 15 shall not use force unless such officer is accompanied by a police officer and the use of reasonable force is specifically authorised in the warrant.

Certificate of analysis.

17. An authorised officer shall, after analysing or examining a designated or complementary food product, prepare a certificate or report setting out the results of analysis or examination.

Assistance of authorised officers.

18. The owner, person in charge or any person found in a place that is being inspected shall—

(a) provide all reasonable assistance to enable the authorised officer to carry out his duties under this Act;

(b) furnish the authorized officer with such information as the officer may reasonably require for the purpose for which entry into the place has been made.

Obstruction of authorised officer.

19. A person shall not obstruct or hinder, or knowingly make a false or misleading statement to an authorised officer who is carrying out duties under this Act.

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Seizure of product, etc.

20. During an inspection under "this Act, an authorised officer may seize any designated or complementary food product or thing by means of which or in relation to which the officer believes, on reasonable grounds, that this Act has been contravened and take full inventory of all the items seized.

Storage and removal of seized product.

21. An authorised officer may direct that any designated or complementary food product or thing seized be kept or stored in the place where it was seized or that it be removed to another place.

Interference with seized product or thing.

22. Unless authorised by an authorised officer, a person shall not remove, alter or interfere in any manner with any designated or complementary food product or other thing seized.

Restoration of seized product or thing.

23. Any person from whom a designated or complementary food product or a thing has been seized may, within sixty days after the date of seizure, apply to the High Court for an order of restoration.

Order for restoration.

24. The High Court may order that a designated or complementary food product or a thing be restored immediately to the applicant if, on hearing both the parties to the application, the court is satisfied that—

- (a) the applicant is entitled to possession of the designated or complementary food product or the thing seized; and
- (b) the designated or complementary food product or thing seized is not and will not be required as evidence in any proceedings in respect of an offence under this Act.

Order of later restoration.

25. (1) Where upon hearing an application made under section 23 the court is satisfied that the applicant is entitled to possession of the designated or complementary food product or the thing seized but is not satisfied with respect to the matters mentioned in section 24(b), the court may order that the designated or complementary food product or a thing seized be restored to the applicant on the—

- (a) expiration of one hundred and eighty days from the date of seizure if no proceedings in respect of an offence under this Act have been commenced before that time; or
- (b) final conclusion of any such proceedings under this Act.

(2) An order for restoration shall not be made under this section where a designated or complementary food product or a thing has been forfeited by consent under section 26.

Forfeiture of product.

26. Where—

- (a) no application has been made under section 23, or an application has been made but on the hearing of such application no order for restoration is made;

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(b) a person has been convicted of an offence under this Act in respect of which a designated product or a thing has been seized under this Act;

(c) an officer has seized a designated product or a thing and the owner or the person in whose possession it was, at the time of seizure, consents in writing to its forfeiture,

a designate or complementary food product or a thing shall be forfeited to the State and may be destroyed or disposed in such manner as the Cabinet Secretary may direct.

PART V—MISCELLANEOUS

Offences and penalties.

27. (1) A person who commits an offence for which no penalty has been specifically provided for, shall on conviction be liable to a fine not exceeding one million shillings or a term of imprisonment not exceeding three years, or to both.

(2) Where an offence is committed by a body corporate or other association of individuals, a director, partner or any other person concerned in, or acting or purporting to act in the management of *i/s* affairs commits an offence unless that person proves that—

(a) the act or omission constituting the offence took place without his knowledge; or

(b) he took reasonable steps to prevent the commission of the offence.

Regulations and Orders.

28. (1) The Cabinet Secretary may, in consultation with the Committee, make Regulations generally for the better carrying out of the objects of the Act, and in particular, for prescribing—

(a) the wording, size and manner of notices, warnings and information required under section 9; and

(b) the procedures and requirements under which informational or educational material may be approved under section 10(3); and

(c) any other thing that is required by this Act to be prescribed.

(2) The Cabinet Secretary may, by order, permit a person or class of persons to use specified signs, symbols, colours, billboards or notices associated with a designated or complementary food product in the promotion or advertisement of other goods not connected with a designated or complementary food product but health care facilities or health workers shall not be used in the promotion.

SCHEDULE

(s. 4(6))

(1) The Committee shall meet for the discharge of its functions at least four times in a year at such time and place as the Chairperson shall, from time to time, determine.

(2) The Chairperson or in his absence, the Vice- Chairperson or in absence of both, a person elected from amongst the members of the Committee, shall preside at the meetings of the Committee.

(3) The quorum at any meeting of the Committee shall be one- third of the members.

(4) A decision of the Committee on any matter shall be by consensus and where there is no consensus, by a simple majority of the members present and voting.

(5) At any meeting of the Committee, each member shall have one vote and in the event of a tie of votes, the Chairperson shall have a casting vote.

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(6) The Committee may request any person to attend its meetings for the purposes of its deliberations, but that person shall have no right to vote.

(7) Subject to this Act, the Committee shall regulate its meetings and proceedings in such manner as it deems fit.

MEMORANDUM OF OBJECTS AND REASONS

The principal object of this Bill is to provide for appropriate marketing and distribution of breast milk substitutes, safe and adequate nutrition for infants, through the promotion of breast feeding and proper use of breast milk substitutes, where necessary.

PART I provides for preliminary matters.

PART II (Clauses 4-5) provides for the establishment and functions of a National Standing Committee.

PART III (Clauses 6-10) contains provisions for restriction on advertisement, promotion, packaging and educational and information material.

Clause 7 gives the Cabinet Secretary powers to permit manufacturers, distributors and health workers to supply designated or complementary food products to orphanages and social welfare institutions where certain conditions are met.

Clause 9 makes provisions for the labelling of packages.

Clause 10 provides for restriction on educational and informational materials. It prohibits a person from publishing or causing to be published any informational or educational material on infant and young feeding unless approved, in writing.

PART IV (Clauses 11-26) contains enforcement mechanism and lays down powers and procedures of enforcement officers in execution of provisions of the Bill once it becomes an Act.

PART V (Clauses 27-28) contains miscellaneous provisions.

Clause 27 provides for the penalties for various offences under the Bill once it becomes an Act while clause 28 gives the Cabinet Secretary powers to make Regulations.

The enactment of the Bill shall occasion additional expenditure of public funds which shall be provided for through the estimates.

Dated the 2nd August, 2012.

BETH MUGO,
Minister for Public Health and Sanitation.