MARKETING OF FOODS FOR INFANTS AND YOUNG CHILDREN REGULATIONS

(under section 13(1)) (17th June, 2005) ARRANGEMENT OF REGULATIONS

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S.I. 37, 2005, S.I. 55, 2006.

PART I

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Preliminary (regs 1-3)

1. Citation and commencement

These Regulations may be cited as the Marketing of Foods for Infants and Young Children Regulations, and shall come into operation on publication, with the exception of the parts of regulations 11, 12, and 15 relating to labelling in Setswana, which shall come into operation on the 1st July, 2007.

2. Interpretation

In these regulations, unless the context otherwise requires—

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

"complementary food" means any food suitable for use to complement breast milk or infant formula or follow-up formula;

"container" means any packaging of foods for infants and young children and other designated products for delivery as a single unit and includes wrappers;

"designated products" includes—

- (a) infant formula;
- (b) formulas for special medical purposes intended for infants;
- (c) follow-up formula;
- (d) complementary foods;
- (e) beverages for infants and young children;
- (f) any product marketed or otherwise presented as suitable for feeding infants and young children:
- (g) feeding bottles;
- (h) teats;
- (i) pacifiers or dummies;
- (j) breast pumps;
- (k) cups with spouts or similar receptacles for feeding infants and young children; and
- (1) such other products as the Minister may, by notice published in the *Gazette*, designate.

"distributor" means a person engaged in the business, whether wholesale or retail, of marketing or distribution or sale of foods for infants and young children or any designated products, and includes any person engaged in the business of providing information, or public relations services in relation to foods for infants and young children or designated products;

"foods for infants and young children" means a group of food products distributed, marketed or otherwise represented as suitable for infants and young children including—

- (a) infant formula;
- (b) formulas for special medical purposes intended for infants;
- (c) follow-up formula;
- (d) complementary foods;
- (e) any other product marketed or otherwise represented as suitable for feeding infants and young children;

"follow-up formula" sometimes referred to as "follow-on formula", means milk or a milk-like product of animal or vegetable origin industrially formulated in accordance with such regulations as the Minister may make and, in the absence of such regulations, in accordance with the Codex Standard for follow-up formula, distributed, marketed or otherwise represented as suitable for infants older than six months of age and young children;

"formula for special medical purposes intended for infants" means infant formula which is specially manufactured to satisfy the nutritional requirements of infants during the first months of life up to the introduction of complementary feeding when medically indicated;

"gift" includes designated product, meals and refreshments, diaries, stationery,

calendars, cot tags, stickers, growth charts, prescription pads, tongue depressors or any free item of whatever value:

"health care facility" means any governmental, non-governmental or private institution or organisation engaged, directly or indirectly, in health care for mothers, infants, young children, pregnant women, and includes private practice, nurseries or childcare institutions; but does not include social welfare institutions;

"health worker" means any person working or training to work in a health care facility, whether or not that person is a professional or non-professional and includes voluntary or unpaid workers:

"infant" means a person from birth up to the age of 12 months;

"infant formula" means milk or a milk like product of animal or vegetable origin formulated industrially in accordance with such regulations as the Minister may make and, in the absence of such regulations, in accordance with the Codex Standard for infant formula intended to satisfy the nutritional requirements of infants from birth, and includes formula for special medical purposes;

"manufacturer" means any person, corporation or other entity engaged, directly or indirectly, in the business of manufacturing food for infants and young children and other designated products;

"marketing" means promoting, distributing, selling, or advertising a designated product and includes product public relations and information services, including the use of professional service representatives such as mother craft nurses, or any person acting on behalf of a manufacturer or distributor;

"monitor" means a person appointed by the Permanent Secretary to carry out any exercise necessary to reveal contravention of these Regulations;

"promote" has the meaning assigned to it under regulation 8(1);

"sample" means a single or a small quantity of a food for infants and young children or a designated product provided without cost;

"social welfare institution" means any governmental or non-governmental organisation engaged, directly or indirectly, in providing for the social welfare of infants and young children, but does not include health care facilities;

"tie-in sales" means the sale of any designated product that is linked to a purchase of any other product including a designated product; and

"young child" means a person aged between 12 months and three years.

3. Application

These Regulations apply to the marketing, and practices related thereto, of foods for infants and young children and other designated products, when imported into, marketed, distributed, sold or manufactured in Botswana.

PART II

Monitoring, Inspection, Stocking, etc. (regs 4-7)

4. Designation of monitors

- (1) The Permanent Secretary may designate, as monitors, such number of persons he or she considers appropriate, who have undergone training on monitoring of violations of the International Code of the Marketing of Breastmilk Subsitutes and these Regulations.
- (2) The Permanent Secretary shall issue to any person designated as a monitor, a letter of appointment and the monitor shall have such letter in his or her possession when performing any function in terms of these Regulations.

5. Duties of monitors

- (1) A monitor in exercise of his or her duties shall investigate, observe and record information regarding the marketing practices of manufacturers and distributors at any points of sale, health care facilities, border posts and offices, through media, institutions and elsewhere.
 - (2) A monitor may for the purpose of monitoring violations of these Regulations enter, at

any time, any premises which are used for dealing in foods for infants and young children or other designated products and may—

- (a) require any person in the premises to furnish any information including documents in his or her possession as the monitor may require;
- (b) caution the person on the premises regarding any violations of these Regulations;
- (c) seize any goods, or promotional materials or documents where the goods or promotional material or documents in question contravene these Regulations.
- (3) A monitor shall, after monitoring under subregulation (1), submit a report in writing, in relation to his or her findings to the Board.
- (4) In any proceedings under these Regulations, a report signed by a monitor shall be accepted as *prima facie* evidence of the facts stated therein.
- (5) No monitor shall have any direct or indirect commercial interest in infant and young child feeding.
- (6) A monitor, acting in accordance with these Regulations, shall if required by any person, provide proof of his or her authority.
- (7) An owner, occupier or person in charge of any premises entered by a monitor shall give to the monitor all reasonable assistance and shall furnish him or her with such information as the monitor may reasonably require.
- (8) No person may obstruct or impede a monitor in the course of performance of his or her duties.
- (9) No person may knowingly make any false or misleading statement, either verbally or in writing, to any monitor engaged in carrying out his or her duties.

6. Duties of authorized officers

- (1) An authorised officer shall implement these Regulations under the powers vested on him or her by the provisions of section 6 of the Food Control Act.
- (2) No authorised officer shall have any direct or indirect commercial interest in infant and young child feeding.

7. Conditions for stocking, etc., foods for infants and young children or other designated products

- (1) No person shall stock, distribute, sell or exhibit any foods for infants and young children which have expired or are beyond their shelf life.
- (2) No person shall stock, distribute, sell or exhibit any foods for infants and young children or other designated products which are not in their original containers.
- (3) A container of foods for infants and young children, for sale or distribution, shall be free from dents or any other form of damage and shall be kept—
 - (a) in a cool and dry place;
 - (b) at least 50 cm from the floor; and
 - (c) in a hygienic manner.

PART III

Prohibition against Promotion, Advertising, etc. (regs 8-9)

8. Promotion, advertisement, etc., prohibited

- (1) For the purposes of this regulation, "promote" includes—
- (a) any direct or indirect method of introducing a designated product or encouraging the buying or use of a designated product;
- (b) sale devices such as rebates, special displays to promote sales, tie-in sales, loss leaders, grant of rewards, discount coupons, premiums, special sales, prizes, gifts and giving of samples to mothers;
- (c) direct or indirect contact between marketing personnel and members of the public in furtherance of or for the purpose of promoting the business of designated products and indirect contact includes television and radio, telephone or internet help lines, mother and baby clubs and baby competitions;

- (d) electronic communication including website, internet and electronic mail;
- (e) promotional items such as clothing, stationery or items that refer to a designated product or to a brand name of a designated product;
- (f) outdoor advertisements such as billboards;
- (g) placard and newspaper or magazine inserts;
- (h) practices that create an association between a manufacturer or distributor and breastfeeding.
 - (2) No person shall—
- (a) promote or cause to be promoted, foods for infants and young children or other designated products;
- (b) engage in promotional activities of any designated product;
- (c) publish or cause to be published any advertisement for any designated product;
- (d) advertise or cause to be advertised any designated product.
 - (3) No manufacturer or distributor shall—
- (a) distribute or cause to be distributed any information or educational material relating to infant or young children nutrition or feeding, except in accordance with these regulations.
- (b) offer or give or cause to be offered or given, any benefit to a health worker, including, fellowships, study grants, funding for attendance of meetings, seminars, continuing education or conferences;
- (c) fund any research, clinical or otherwise, carried out by any health worker on any designated product, except in accordance with a protocol approved by the relevant authority in writing;
- (d) directly or indirectly, provide any support, financial or otherwise, to any health worker;
- (e) employ any person to provide to health workers in health care facilities, pregnant women or mothers of infants and young children or any person with education or instructions regarding the use of a designated product;
- (f) sell, donate or distribute or cause to be sold, donated or distributed in a health care facility, any—
 - (i) equipment, materials or any other services with any reference to any designated products or contain the name or logo of any manufacturer or distributor of any designated product,
 - (ii) foods for infants and young children or other designated products at a price lower than the published wholesale price or in the absence of such price, lower than 80 per cent of the retail price.
- (g) calculate a bonus payment based on the volume of sales of any designated product; or
- (h) set a quota for the sale of any designated product as a sales incentive.
- (4) Notwithstanding the provisions of subregulation (3)(a), manufacturers and distributors may give information about designated products to health professionals if such information is restricted to scientific and factual matters regarding the technical aspects and methods of use of designated products, and in accordance with regulations 15 and 16.
- (5) Subregulation 3(f)(ii) shall not apply where a donation or low price sale is made to an orphanage or other social welfare institution for infants who have to be fed on designated products and shall not prevent the Government from procuring foods for infants and young children, for its feeding programme or for social welfare purposes, at the lowest possible price through bidding procedures.
- (6) Donations or low price sales made to orphanages or other social welfare institutions, whether for use in the institutions or for distribution outside them, as provided for under subregulation (5) should be sustained once started and should continue as long the beneficiaries need them.
 - (7) Manufacturers shall not make donations as referred to in subregulation (5) or set low

price sales as sales inducements.

(8) Marketing personnel in their business capacity shall not seek direct or indirect contact of any kind with pregnant women, or with caregivers, or mothers of infants and young children intended to further commercial interests.

9. Health workers prohibited from promoting, etc., foods for infants and young children

- (1) Health workers shall—
- (a) promote and support breast-feeding, unless medically indicated;
- (b) keep a records register of contraventions of the provisions of these Regulations by manufacturers or distributors in their respective health care facilities; and
- (c) provide the records under subregulation (1)(b) to monitors and authorized officers.
 - (2) Health workers shall not—
- (a) accept from manufacturers or distributors any of the following offers:
 - (i) gift,
 - (ii) financial assistance,
 - (iii) fellowships, study tours, research grants, funding for attendance of conferences,
 - (iv) samples of foods for infants and young children or other designated products, or
 - (v) quantities of foods for infants and young children or other designated products at a price lower than the published wholesale price, or in the absence of such price, lower than 80% of the retail price; or
- (b) display foods for infants and young children or other designated products.
 - (3) Subregulation (2) shall not apply to—
- (a) research activities approved by the health research authority in writing; or
- (b) quantities of foods for infants and young children or other designated products for social welfare purposes provided under the Government feeding programmes and in terms of such guidelines as the Board may from time to time approve.

PART IV

Labelling, Warning, Preparation, etc. (regs 10-14)

10-12. ...13. Labelling of other products sometimes used as foods for infants and young children

The label on any container of the following types of milk—

- (a) sweetened;
- (b) condensed:
- (c) evaporated;
- (d) dried:
- (e) skimmed;
- (f) low fat;
- (g) imitation milk-like dairy products; or
- (h) standardised milk

shall contain the following words in bold and conspicuous characters not less than 2mm in height—

"THIS PRODUCT IS NOT SUITABLE FOR FEEDING BABIES".

14. Labelling requirements for feeding bottles, etc.

- (1) A label, package or container of a feeding bottle or teat shall include, in simple written English and Setswana—
 - (a) a statement of the superiority of breast-milk for feeding infants;
 - (b) a statement that feeding with a cup is safer than bottle feeding;
 - (c) instruction for proper cleaning and sterilisation of feeding bottle and teat;
 - (d) a warning of potential health hazards of using feeding bottle especially if it is not properly sterilised;
 - (e) the need to follow preparation instructions carefully;

- (f) the name and address of manufacturer or distributor.
- (2) A label, package or container of a feeding bottle or teat shall not contain pictures of infants, women or infant toys nor any other picture or text or any symbol depicting a health advantage which idealises artificial feeding.
 - (3) A label of a dummy shall include, in simple written English and Setswana—
 - (a) a notice that the use of such dummy can interfere with breast-feeding;
 - (b) instructions for proper cleaning and sterilisation of the dummy;
 - (c) a warning on potential health hazards of using a dummy especially if it is not properly sterilised:
- (4) A label of a dummy shall not contain pictures of infants, women, animals or toys nor any other picture or text or any symbol depicting a health advantage which idealises artificial feeding over breast-feeding.
- (5) A label of a breast pump shall have written instructions in simple English and Setswana, for proper use, cleaning and sterilisation of the breast pump.

PART V

Information and Educational Materials (regs 15-16)

15. Information and educational materials on infants and young children feeding

- (1) Notwithstanding any other provision of these Regulations, no person shall, directly or indirectly, distribute any educational material or any information relating to infant or young child feeding in Botswana without the approval of the Board.
- (2) Any educational material or information, written, audio or visual, electronic or otherwise, relating to infant feeding shall explain—
 - (a) the importance, benefits and superiority of breast-feeding during the first two years of the life of a child:
 - (b) the value of exclusive breast-feeding for the first six months of life followed by sustained breast-feeding for at least the first two years of the life of a child;
 - (c) the preparation for and the continuance of breast-feeding;
 - (d) factual and current information and shall not use any pictures or text discouraging breast-feeding;
 - (e) how bottle-feeding interferes with breast-feeding;
 - (f) the difficulty in reverting to breast-feeding after a period of formula feeding; and
 - (g) how the early introduction of complementary foods interferes with breast-feeding.
- (3) The educational material or information referred to in subregulation (2) shall not make any reference to the brand name of food for infants and young children or any designated product or the name or logo of any manufacturer or distributor.

16. Information and educational materials on foods for infants and young children

- (1) Where the educational material or information referred to in regulation 15 includes the topic of the feeding of infants with infant formula or follow-up formula, it shall include:—
 - (a) instructions for the proper preparation and use of the product in question including the cleaning and sterilisation of feeding utensils;
 - (b) the health hazard of bottle-feeding and improper preparation of the product;
 - (c) the importance and proper instructions on cup feeding; and
 - (d) the approximate financial costs of the product in question if used in recommended quantities for a period of six months.
- (2) Where the material referred to in regulation 15 includes the topic of infant feeding with complementary food, it shall explain—
 - (a) the health hazards of introducing complementary foods too soon or too late; and
 - (b) that complementary foods can easily be prepared at home using indigenous ingredients.
- (3) Feeding with infant formula, follow-up formula or complementary foods whether manufactured or home prepared, shall be demonstrated only by health workers or other

community workers if necessary, and only to the mothers or family members who need to use it and the information given shall include a clear explanation of the hazards of improper use.

PART VI Offences and Penalties (regs 17-18)

17. Offences and penalties

- (1) A person who contravenes a provision of these Regulations commits an offence and is liable—
 - (a) for a first offence, to a fine not exceeding P1,000 or to imprisonment for a term not exceeding three months, and where the offence is a continuing offence, to an additional fine not exceeding P500 or imprisonment for a term not exceeding one month for each day on which the offence continues; and
 - (b) for a second or subsequent offence, to a fine not exceeding P5,000 or to imprisonment for a term not exceeding six months, and where the offence is a continuing offence, to an additional fine not exceeding P2,000 or imprisonment for a term not exceeding two months for each day on which the offence continues.
- (2) Notwithstanding the provisions of subregulation (1), the Board may recommend to the Minister, any other action to be taken against any manufacturer, distributor, health worker or other person who contravenes the provisions of these Regulations.
- (3) On the conviction of any person for an offence under these Regulations, the Minister may cancel, or suspend any licence issued to that person which is relevant to the offence committed.
- (4) Where a person has been convicted of an offence under these Regulations, the Minister may order that any article relevant to the offence be forfeited and that it be destroyed or otherwise disposed of, as the Minister considers appropriate.

18. Body corporate liability

Where an offence under these regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in such capacity, he or she as well as the body corporate, shall be guilty of an offence and liable to a fine not exceeding P1,000 or to imprisonment for a term not exceeding three months, or to both.