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Statutory Instrument 46 of 1998.

[CAP. 15:09

Public Health (Breast-milk Substitutes and Infant Nutrition) Regulations, 1998

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GENERAL

IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 74 of the Public Health Act [*Chapter 15:09*], made the following regulations:—

PART I

PRELIMINARY

Title and date of commencement

1. (1) These regulations may be cited as the Public Health (Breast-milk Substitutes and Infant Nutrition) Regulations, 1998.

(3) These regulations shall come into operation on the 1st May, 1998.

Interpretation

2. In these regulations—

"advertising" means the making of any representation whatsoever, whether for the purpose of promoting, directly, or indirectly including the exhibition of pictures or models for the purpose of promoting, the sale or disposal of a designated product;

"baby" means an infant under the age of twelve months;

"breast-milk substitute" means any food or drink designed for babies and is marketed or otherwise represented as a partial or total replacement for human breast-milk, whether or not it is suitable for that purpose;

"committee" means the Infants Nutrition Committee appointed in terms of section 3;

"complementary food" means any food, whether manufactured or otherwise produced, that is marketed or otherwise represented as a complement to human breast-milk or breast-milk substitutes when either becomes insufficient to satisfy the nutritional requirements of a young child;

"container" means anything in or by which any designated product is covered, enclosed or packaged for sale as a retail unit;

"designated product" means any—

(i) infant formula; or

(ii) follow-up formula, beverage, milk and other food for consumption by babies and young children whether industrially formulated or otherwise; or

(iii) any other product marketed or otherwise represented as being suitable for feeding babies and young children; or

(iv) feeding article; or

(v) articles generally known as pacifiers; or

(vi) other product which the Minister may, from time to time, declare to be a designated poduct;

"distributor" means any person engaged in the business of marketing, importing, retail selling or providing informational or public relations services in relation to any designated product;

"exclusive breast-feeding" means the giving of nothing but human breast-milk to a baby under the age of six months;

"feeding bottle" means any utensil whatsoever which is intended for the feeding of babies and young children artificially and "bottle feeding" shall be construed accordingly;

"follow-up formula" means any industrially formulated milk or milk-like product intended for babies over the age of six months and young children;

"health-care facility"—

(a) means any public or private institution or organization engaged directly or indirectly in the provision of health-care or health-care education; and

(b) includes pharmacies, day-care centres, nurseries or other facilities for the care of babies and young children;

"health worker" means any person working or training in any health-care facility;

"infant formula" means any animal milk or other milk like products, including follow-up formula, industrially formulated for consumption by babies under the age of six months;

"informational or educational material on babies and young child nutrition" means any document, film, recording or other article which contains or provides instruction or purported instruction on the feeding of babies and young children;

"inspector" means a person appointed in terms of section 5 of the Public Health Act;

"label" means any brand, tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise that appears on or is otherwise attached to a container of a designated product;

"manufacturer" means a person engaged in the business of manufacturing a designated product whether directly or indirectly;

"marketing", in relation to a designated product, means any method of introducing or selling the designated product, including promoting, distributing, advertising, distribution of samples or providing public relations and informational services;

"monitor" means conduct or carry out any exercise necessary to reveal any fact or situation pertaining to any designated product;

"pacifier" means any artificial teat also known as a "dummy" designed for sucking by babies and young children;

"publish" includes distribute, display, exhibit, broadcast or televise;

"promotion" means any direct or indirect method of introducing a designated product or encouraging any person to buy or use a designated product;

"sample" means a single or small quantity of a designated product provided at a cost or free of charge;

"sell" includes—

(a) offer, keep, posses, expose, display, transmit, consign, convey or deliver for sale;

(b) authorize, direct or allow a sale;

(c) barter, exchange, supply or dispose of for any consideration, whether direct or indirect;

"young child" means an infant between the ages of twelve and sixty months.

PART II

INFANTS NUTRITION COMMITTEE

Appointment and membership of Committee

3. (1) There shall be a committee, to be known as the Infants Nutrition Committee, consisting of thirteen members appointed by the Minister of whom—

(a) subject to subsection (2), five shall be appointed to represent health workers employed by the State, mission and or local authority health facilities;

(b) one shall be appointed to represent health workers in private practice; and

(c) one shall be appointed to represent voluntary associations engaged in activities associated with the nutrition, health or welfare of infants; and

(d) three shall be appointed to represent manufacturers and distributors of designated products; and

(e) one shall be appointed to represent the Ministry responsible for information; and

(f) one shall be appointed to represent the Standards Association of Zimbabwe; and

(g) one shall be appointed to represent the Consumer Council of Zimbabwe.

(2) Among the members appointed in terms of paragraph (a) of subsection (1), one shall be an environmental health practitioner, one shall be a health education officer, one shall be a nutritionist, one shall be a paediatrician and one shall be a nurse.

(3) Members of the Committee shall be appointed for a period of three years and on such conditions as the Minister may fix at the time of their appointment.

(4) A member of the Committee shall cease to be a member—

(a) after giving the Minister such notice of his intention to resign as may be fixed in his conditions of appointment or after giving such other period of notice as he and the Minister may jointly agree; or

(b) upon the Minister requiring him to vacate his office on the ground that—

(i) he has conducted himself in a manner that renders him unsuitable as a member; or

(ii) he has failed to comply with any condition of his office fixed on his appointment as a member; or

(iii) he has ceased to represent the interests he was appointed to represent; or

(iv) he has become physically or mentally incapable of efficiently performing his functions as a member.

Functions of Committee

4. The functions of the Committee shall be—

(a) to advise the Minister on the policies for the promotion and protection of breast-feeding;

(b) to advise the Minister on the development of informational and educational materials and programmes for the promotion and protection of baby and young child feeding;

(c) to advise the Minister on the general policy to be adopted in relation to lactation management and curricula for students in the health professions;

(d) to advise and report to the Minister on matters relating to the feeding and health of babies and young children;

(e) to review reports of contraventions or other matters concerning these regulations and to report to the Minister;

(f) to advise the Minister on action to be taken in terms of these regulations against any person found to be contravening these regulations; or

(g) to monitor the enforcement of these regulations; and

(h) to cause the conducting of any research on matters relating to infant nutrition; and

(i) to examine and screen informational and educational materials and labels in terms of sections 11 and 13 and to recommend appropriate action to be taken in relation thereto; and

(j) to perform any other function in relation to infant nutrition and health-care imposed on the Committee by the Minister.

Chairman, vice-chairman of and secretary to Committee

5. (1) The Minister shall designate one member of the Committee to be chairman of the Committee and another member to be vice-chairman.

(2) Subject to subsections (3) and (4), the chairman shall preside at all meetings of the Committee.

(3) The Nutrition Unit in the Ministry of Health and Child Welfare shall provide secretarial services to the Committee.

(4) Whenever the chairman is for any reason unable to perform any of his functions as chairman, the vice-chairman shall perform such functions in his place.

(5) If at any meeting of the Committee the chairman and vice-chairman are both absent, the members present shall elect one of their number to preside at that meeting.

Meetings and procedure of Committee

6. (1) The Committee shall hold its first meeting on such date and at such place as the Minister shall fix, and thereafter, subject to this section, the Committee shall meet for the dispatch of its business and adjourn, close and otherwise regulate its meetings and procedure as it thinks fit.

(2) The Committee shall meet at least four times a year.

(3) The chairman of the Committee may at any time and shall, at the request in writing of no fewer than three members of the Committee, convene a special meeting of the Committee, which meeting he shall convene for a date not sooner than seven days nor later than thirty days after receipt of the request.

(4) A majority of the members of the Committee shall constitute a quorum for a meeting.

(5) All things authorized or required to be done by the Committee may be decided by a majority vote at a meeting of the Committee at which a quorum is present.

(6) At all meetings of the Committee every member present shall have one vote on each question before the Committee and, in the event of an equality of votes, the chairman shall have a casting vote in addition to a deliberative vote.

(7) Any proposal circulated among all members of the Committee and agreed to by a majority of all members shall be of the same effect as a resolution passed at a duly constituted meeting of the Committee and shall be incorporated into the minutes of the next succeeding meeting of the Committee:

Provided that, if any member requires that the proposal be placed before a meeting of the Committee, this subsection shall not apply to the proposal.

Subcommittees of Committee

7. (1) For the better exercise of its functions, the Committee may establish one or more subcommittees to which it may delegate such of its functions as the Committee may think fit, and may at anytime amend or revoke any such delegation.

(2) The Committee—

(a) shall appoint to any subcommittee established in terms of subsection (1) at least one member of the Committee, who shall be chairman of the subcommittee; and

(b) may appoint as members of any subcommittee established in terms of subsection (1), persons who are not members of the Committee on such conditions as the Committee, with the approval of the Minister, may fix.

(3) The procedure of a subcommittee established in terms of subsection (1) shall be fixed by the Committee.

Validity of decisions and acts of Committee and subcommittees

8. No decision or act of the Committee or of a subcommittee established in terms of subsection (1) of section 7 shall be invalid soley because—

(a) insufficient members had been appointed to the Committee or subcommittee, as the case may be; or

(b) a person who was not a member of the Committee or subcommittee, as the case may be, acted as a member;

when the decision was taken or the act was done or authorized.

PART III

EDUCATION AND INFORMATION CONCERNING INFANT NUTRITION

Education and instruction regarding babies and young child nutrition

9. (1) Subject to section 10, no manufacturer or distributor of a designated product shall employ any person to provide pregnant women or mothers of babies and young children or any other member of the public with education or instruction regarding—

(a) the use of a designated product; or

(b) the nutrition of babies and young children generally.

Restriction on publication of informational or educational material on baby and young child nutrition

10. (1) No manufacturer or distributor of a designated product shall publish or cause or permit to be published any informational or educational material on baby and young child nutrition—

(a) unless the material has been approved by the Committee in terms of section 11; and

(b) where the material has been so approved, except in accordance with any conditions imposed by the Committee in terms of section 11.

(2) No health worker shall publish to any pregnant woman or mother of a baby or young child and any other member of the public any informational or educational material on any designated product.

Screening of advertisement, informational or educational material on baby and young child nutrition

11. (1) Any person who wishes the Committee to approve any advertisement, informational or educational material on baby and young child nutrition may apply in writing for such approval to the Committee at the offices of the Nutrition Unit of the Ministry of Health and Child Welfare and shall submit with his application the material concerned or, where appropriate, a sample or copy thereof.

(2) Within thirty days after receiving an application in terms of subsection (1), the Committee shall examine the material concerned and may—

(a) approve it, either absolutely or subject to conditions; or

(b) refuse to approve it;

and shall notify the applicant in writing of its decision and, where it has refused to approve the material, of its reasons.

(3) The Committee shall not approve any advertisement, informational or educational material on baby and young child nutrition in terms of subsection (2) unless it is satisfied—

(a) that it includes clear and accurate information on the following matters—

(i) the importance, benefits and superiority of breast-feeding; and

(ii) maternal nutrition; and

(iii) the preparation for and maintenance of breast-feeding; and

(iv) the adverse effects on breast-feeding of introducing bottle-feeding; and

(v) the difficulty of reversing the decision not to breast-feed even for a short period; and

(vi) the proper use of designated products; and

(vii) the adverse effects of the use of pacifiers on breast-feeding;

and

(b) that it does not use any pictures of infants; and

(c) that it does not use any other pictures or text which may idealize the use of a designated product and discourage breast-feeding; and

(d) if the material referred to in subsection (1) deals with the use of infant formula or any other food or drink which requires a feeding bottle, that it includes clear and accurate information on—

(i) the instructions for the proper preparation and use of the product including the cleaning and sterilisation of feeding utensils; and

(ii) the approximate total current financial cost o feeding a baby on the designated product for a period of at least six months; and

(iii) the health and other hazards of bottle-feeding; and

(iv) the health and other hazards of improper prepara tion of the product; and

(v) how to feed infants from a cup;

and

(e) if the material referred to in subsection (1) includes th topic of feeding babies and young children with comple mentary foods, that it includes clear and accurate infor mation on—

(i) the instructions for the proper preparation and us of the product including the cleaning an sterilisation of feeding utensils; and

(ii) the approximate total current financial cost c feeding an infant on the designated product for period of at least six months; and

(iii) the health and other hazards of bottle-feeding; an

(iv) the health and other hazards of improper prepar tion of the product;

(v) how to feed infants from a cup; and

(vi) the health and other hazards of introducing compl mentary foods too early or too late; and

(vii) the fact that complementary foods can easily b prepared at home using foods normally consume by the family;

and

(f) where the material is intended to be published for use b health workers, that it is restricted to scientific ar factual information; and

(g) the material referred to in subsection (1) shall not mal any reference to a proprietary product in such material

(4) Where the Committee has refused to approve any adve tisement informational or educational material on infant nutrition terms of subsection (2), the applicant may at any time resubmit tl material to the Committee, having made such alterations to tl material as he considers necessary to secure the Committee's appprov

PART IV

LABELLING OF DESIGNATED PRODUCTS

Labels of designated products to be approved

12. (1) No person shall market any designated product unless : label thereof has been approved by the Committee in terms of :tion 13.

(2) Subsection (1) shall not apply in relation to any desig- ed product which was manufactured and covered, enclosed or :ked in its container before the date of commencement of these ;ulations.

(3) In any prosecution for an offence in terms of subsection , the burden of proving that the designated product concerned was nufactured and covered, enclosed or packed in its container before date of commencement of these regulations shall lie upon the 'son charged.

Screening of labels by Committee

13. (1) Any person who wishes the Committee to approve any el may apply in writing for such approval to the Committee at the ices of the Nutrition Unit of the Ministry of Health and Child :lfare, and shall submit with his application a specimen of the label ıcerned.

(2) Within thirty days after receiving an application in terms subsection (1), the Committee shall examine the label concerned l may—

(a) approve it, either absolutely or subject to conditions; or

(b) refuse to approve it;

l shall notify the applicant in writing of its decision and, where it : refused to approve a label, of its reasons.

(3) The Committee shall not, in terms of subsection (2), ›rove the label of a designated product unless—

(a) it is as simple and as clear as possible in Shona, English and Ndebele; and

(b) the Committee is satisfied that it provides sufficient information about the appropriate use of the product and that it does not discourage breast-feeding; and

(c) the Committee is satisfied that the label adequately specifies—

(i) the ingredients used; and

(ii) the composition and nutrient content or analysis of the product; and

(iii) the storage conditions required for the product; and

(iv) the batch number; and

(v) the date before which the product should be consumed under specified storage conditions and presented in manner stipulated in accordance with the Foods and Foods Standard Act [*Chapter 15:04*]; and

(vi) that the designated product is supplementary to breast-milk; and

(vii) the appropriate age of introduction; and

(viii) prominently and in bold, conspicuous, non-serif characters of not less than ten-point size, in black against a white background, that "Breast-milk is the best food for your baby. It protects against diarrhoea and other illnesses."; and

(ix) the manufacturer's name and physical address;

and

(d) in the case of a designated product which does not meet all the requirements for infant formula but which can be modified to do so, the Committee is satisfied—

(i) that the label carries a clear and adequate warning that the unmodified product should not be the sole source of nourishment for a baby; and

(ii) where the label carries instructions for modifying the product into infant formula or other breast-milk substitute, the label complies with the requirements specified for labels of infant formula or other breast-milk substitutes;

and

(e) in the case of a cereal marketed as a complementary food, the label carries an exhortation to continue breast-feeding a child as long as possible; and

(f) the Committee is satisfied that—

(i) the label, or the portion thereof that bears the matter specified in subparagraph (ii) will be printed on the container or will not be easily separable therefrom; and

(ii) the following matter is clearly printed in black against a white background on the label and in an understandable form—

A. the words "Important Notice" in bold characters of not less than ten-point size in black against a white background; and

B. a statement on the superiority of breast-feeding; and

C. a statement that the designated product should be used only after seeking the advice of a health worker as to the need for and proper use of the product; and

D. instructions for its proper preparations; and

E. a warning concerning the health and other hazards of improper preparations;

and

(iii) the label does not bear pictures of infants; and

(iv) the terms "humanized", "maternalized" and similar terms are not used; and

(v) having regard to the designated product concerned, the label bears, as may be appropriate, a prominent notice in bold, conspicuous, non-serif characters of not less than eight-point size black against a white background stating "To avoid illness of your baby, follow the preparation instructions carefully. Do not use more or less quantities than indicated. Cup feeding is safer than bottle feeding. If you use a feeding bottle, your baby may reject the breast." and

(vi) in the case of infant formula, the label indicates the number of containers necessary to feed a baby during the first six months of life exclusively on the infant;

and

(g) in the case of feeding articles and pacifiers, the label bears a notice in bold conspicuous characters of not less than eight-point size in black against a white background stating, as may be appropriate that "The use of a feeding bottle/feeding cup/pacifier interfers with breast-feeding.".

Appeals against decisions of Committee

14. (1) Any person who is aggrieved by a refusal of the Committee or by any conditions imposed by the Committe in terms of section 11 may appeal in writing to the Minister within thirty days of being notified by the Committee of its decision.

(2) On any appeal being made to him in terms of subsection (1), the Minister, after making such inquiry into the matter as he thinks necessary, may—

(a) uphold the decision appealed against; or

(b) set aside the decision appealed against in whole or in part and make such decision in its place as he thinks appropriate;

and any such decision of the Minister shall, for the purposes of these regulations, be deemed to be the decision of the Committee.

(3) The decision of the Minister in terms of subsection (2) shall be made within ninety days of the date of the appeal.

Requirements for labels of sweetened condensed milk, and dried skimmed milk, evaporated milk, whole cows milk or low fat milk

15. (1) No person shall market any sweetened condensed milk, dried skimmed milk, evaporated milk, whole cows milk or low fat milk the label of which contains purported instructions or how to modify the milk concerned for use as—

(a) an infant food; or

(b) as an ingredient of infant formula.

(2) The label of every container of—

(a) any sweetened, condensed, dried, skimmed, evaporated or low fat, milk shall bear a notice, as specified in the Schedule, in eighteen-point bold upper case non-serif characters in black against a white background and inside borders stating "Unfit for babies";

(b) any whole cow's milk shall bear a notice, as specified in the Schedule, in eighteen-point bold characters inside borders stating "Unfit for babies unless modified in accordance with the advice of a health practitioner or a nutritionist.".

(3) This section shall be additional to, and not in substitution for the requirements of any other enactment relating to the labelling of food and dairy produce.

PART V

ADVERTISING OF DESIGNATED PRODUCTS

Prohibition of general advertising of designated products

16. (1) Subject to subsections (2) and (3), no person shall publish or cause to be published any advertisement for any designated product in such a manner that the public or any section thereof is likely to see, read or hear such advertisement.

(2) Nothing in subsection (1) shall prevent—

(a) the distribution or sale, in the ordinary course of business by persons who are not manufacturers or distributors of designated products, of magazines and periodical publications which are published outside Zimbabwe and which contain advertisements for designated products:

Provided that no person shall import magazines or periodical publications for the purposes of advertising; or

(b) the publication of any advertisement, informational or educational material on infant nutrition that has been approved by the Committee in terms of section 11; or

(c) the marketing of designated products in accordance with these regulations.

(3) Where it appears to the Committee that no adverse consequences may arise from the advertisement of a designated product in a form approved by the committee, the Committee may recommend to the Minister that the advertisement may be published as approved.

Prohibition of sales promotions of designated products

17. (1) No distributor of a designated product shall—

(a) display the designated product to customers in a manner or place other than the manner in which or place where he normally displays his merchandise for sale; or

(b) provide customers with coupons or other documents allowing them a discount on the purchase price of the designated product; or

(c) sell the designated product to the public at a price that is lower than eighty *per centum* of the cost to him of purchasing or manufacturing the designated product; or

(d) provide any designated product free of charge or at a reduced price to customers who purchase any other product; or

(e) engage in any other activity designed to increase the sales of the designated product.

(2) No person shall distribute for sale, sell, stock or exhibit for sale any designated product—

(a) which has expired; or

(b) in a container other than its original container.

Prohibition of promotion of designated products within health care facilities or by health workers

18. (1) No person shall, within any health-care facility

(a) publish any advertisement for a designated product; or

(b) display any placard or poster depicting or intended to promote a designated product.

(2) No manufacturer or distributor of a designated product shall offer or give to any health worker, or to any member of the family of a health worker, any gift or benefit, financial or material inducement of any description, including pens, calendars, posters, note pads, growth charts or toys for the purpose of inducing the health worker to promote the designated product.

(3) No manufacturer or distributor of a designated product shall donate designated products and other articles, utensils, equipment or services to any health-care facility except with the approval of the Secretary.

(4) No person in charge of a health-care facility shall employ any other person or cause or permit any other person to be employed in the health-care facilities on duties which bring such other person into direct contact with babies and young children, pregnant women or mothers of babies and young children, if the salary or wages of such other person are paid, wholly or partly, by a manufacturer or distributor of a designated product.

(5) Any offer of a sample, gift, donation or other benefit made to a health worker or health-care facility in contravention of these regulations shall be reported to the Committee in writing.

(6) The onus of proving that any donation or benefit was not given for the purpose of promoting or inducing the use of a designated product shall lie with the distributor or manufacturer.

PART VI

DONATIONS, SAMPLES AND SPECIAL OFFERS OF DESIGNATED PRODUCTS

Restriction on donations, samples and reduced-price sales of designated products

19. (1) Subject to subsection (2), no manufacturer or distributor of a designated product shall supply to any person or cause or permit to be supplied to any person---

(a) any quantity of the designated product; or

(b) any utensil or article which is likely to promote bottle-feeding or the use of the designated product;

free of charge or at a price lower than eighty *per centum* price at which he normally sells the designated product, utensil or article.

(2) Subsection (1) shall not prevent a manufacturer or distributor supplying samples of any designated product, utensil or article at the time the product is launched—

(a) to an institution or organization for the purpose of professional analysis, evaluation or research; or

(b) to a distributor of the designated product, utensil or article concerned or to a person who is about to become such a distributor; or

(c) to any person in accordance with the written permission of the Secretary granted in terms of section 21.

Restriction on giving of samples of designated products by health workers

20. (1) Subject to subsection (2), no health worker shall supply, free of charge, any designated product to any pregnant woman or mother of an infant or to any member of the family of such woman or mother for her use.

(2) Subsection (1) shall not prevent a health worker supplying any designated product—

(a) in accordance with any health-care scheme conducted by or with the approval of the Ministry; or

(b) in accordance with any written permission of the Secretary granted in terms of section 21.

Power of Secretary to permit donation and supply of designated products and utensils

21. (1) Subject to this section, the Secretary may, in writing permit any manufacturer, distributor or health worker to supply any designated product, utensil or article, the supply of which would otherwise be prohibited by section 19 or 20.

(2) The Secretary shall not grant permission in terms of subsection (1) for—

(a) the supply of any donation of a breast-milk substitute or complementary food unless he is satisfied that—

(i) the supply of the breast-milk substitute or complementary food is necessitated by a medical condition of the infant or mother;

(ii) the breast-milk substitute or complementary food is to be fed to orphaned infants, infants in orphanages, abandoned infants during disaster or other relief operations; or

(iii) the breast-milk substitute or complementary food is intended for infants in cases of multiple births;

(b) the supply of any utensil or article unless he is sastified that the utensil or article does not bear the proprietary or brand name of any designated product.

(3) Where permission has been granted for the donation of any breast-milk substitute or complementary food in respect of an infant who is not within a health-care facility—

(a) the supplies shall be for so long as the infant requires them; and

(b) the care providers of the infants shall receive appropriate training to prevent the health hazards from improper use of the products.

(4) The Secretary may impose such written conditions as he thinks fit on any permission granted in terms of subsection (1).

(5) The Secretary may at any time for good cause, after giving any person concerned an opportunity to make representations thereon —

(a) amend any term or condition of any permission granted in terms of subsection (1); or

(b) revoke any permission granted in terms of subsection (1)

(6) The Secretary shall inform the Committee before granting or revoking any permission or imposing or amending any condition in terms of this section.

(7) The Secretary may in writing delegate any of his functions under this section to the District Medical Officer of Health, the Provincial Medical Officer of Health or any other medical officer of health designated by him.

PART VII

MARKETING PERSONNEL

Restriction on access to pregnant women and mothers of babies and young children

22. (1) No person who is employed by a manufacturer or distributor of a designated product and whose duties as such an employee involve marketing the designated product shall—

(a) in any health-care facility, seek or obtain access to any pregnant woman or mother of a baby or young child for the purpose of supplying her with or encouraging her to use the designated product; or

(b) instruct any pregnant woman or mother of a baby or young child in any matter relating to the nutrition or feeding of infants, for the purpose of supplying her with or encouraging her to use the designated product; or

(c) solicit any pregnant woman or mother of a baby or young child anywhere to use the designated product:

(2) In any prosecution for an offence in terms of subsection (1), if it is proved that an employee of a manufacturer or distributor of a designated product—

(a) in any one day—

(i) had access in any one health-care facility to three or more women who were either pregnant or are mothers of babies or young children; or

(ii) gave instruction in any matter relating to the nutrition or feeding of babies to three or more women who were either pregnant or mothers of babies;

it shall be presumed until the contrary is shown that his duties involved the marketing of the designated product and that he obtained the access or gave the instruction, as the case may be, for the purpose of supplying the women with or encouraging them to use the designated product;

(b) solicited any pregnant woman or mother of a baby or young child to use the designated product concerned, it shall be presumed until the contrary is shown that his duties involved marketing the designated product.

Prohibition of bonuses and quotas in relation to sales of designated products

23. (1) No manufacturer or distributor of a designated product shall pay to any employee whose duties involve marketing the designated product—

(a) remuneration which varies directly according to the volume of sales of the designated product; or

(b) any bonus or similar incentive calculated directly according to the volume of sales of the designated product.

(2) No manufacturer or distributor of a designated product shall require any employee, as a condition of his continued employment in the same post, to sell a specified minimum quantity or value of the designated product.

PART VIII

QUALITY STANDARDS

Standards of quality of breast-milk substitutes and complementary goods

24. (1) No person shall manufacture or market any breast-milk substitute or complementary food unless it complies with the applicable standards recommended—

(a) by the Codex Alimentarius Commission; or

(b) in the Codex Code of Hygienic Practice for foods for Infants and Young Children;

in relation to such breast-milk substitute or complementary food.

(2) The Secretary shall ensure that copies of documents containing all applicable standards referred to in subsection (1) are kept at the offices of the Ministry of Health and Child Welfare and are available for inspection there by any person, free of charge, during office hours.

(3) In any prosecution for an offence in terms of subsection (1), any document which purports to have been certified by the Secretary and to set out applicable standardas referred to in subsection (1) shall be admissible on its production by any person and be *prima facie* proof of the matters contained in it.

Requirements of Part to be additional to those of other enactments

25. The requirements of this Part shall be additional to, and not in substitution for, the requirements of any other enactment relating to the quality of food and dairy produce.

PART IX

INVESTIGATORY POWERS

Powers of entry, search, seizure and prohibition

26. Whenever there are reasonable grounds for believing that such action is necessary for the prevention, detection or investigation of an offence in terms of these regulations or for the seizure of property which is the subject-matter of or evidence relating to such an offence, an inspector, or police officer, or customs officer may—

(a) enter upon, inspect or search any premises or place;

(b) open and examine any package or receptacle in or upon any premises or place;

(c) inspect and make copies from any store, record, book, document or account in or upon any premises or place;

(d) require the owner or occupier of any premises or place to produce or make available to him for inspection any store, record, book, document or account in or upon the premises or place;

(e) take from any premises or place, a representative sample of any designated product as he considers necessary for the purposes of testing, examination or analysis;

(f) remove any designated product from any premises or place to some other place and detain it there under due and proper care;

(g) issue and deliver to any person who has custody of any designated product or, if such person is for any reason not available, place on or by the designated product in a conspicuous place a notice prohibiting the manufacturer, marketing or disposal of the designated product or its removal from any premises.

Return of detained products and withdrawal of prohibition against manufacturer or marketing

27. (1) An inspector, police officer, or customs officer who has detained any designated product in terms of paragraph (f) of section 26 or who has issued a notice in terms of paragraph (g) of that section, or any person acting on his behalf, may at any time—

(a) return the designated product to the premises or place from which it was removed or, if that is impracticable,

to such other convenient place as he may fix after consulting the person from whom he took the designated product; or

(b) withdraw the notice by giving notice in writing to the owner of the designated product concerned or to the person in whose custody it was found.

(2) If within thirty days from the date on which—

(a) any designated product was detained in terms of paragraph (f) of section 26; or

(b) a notice was issued in terms of paragraph (g) of section 26;

a summons in respect of a prosecution for an offence in terms of these regulations has not been issued—

(i) the designated product shall be returned to the premises or place from which it was removed or, if that is impracticable, to such other convenient place as the inspector or police officer concerned, or any other person acting on his behalf, may fix after consulting the person from whom he took the designated product; or

(ii) the notice be deemed to have been withdrawn; as the case may be.

Power of Secretary to obtain particulars of designated products

28. (1) The Secretary, in consultation with the Committee, may order any manufacturer or distributor of a designated product to provide the Secretary, within such period as may be specified in the order, with such particulars as he may so specify relating to the composition, use and marketing of the designated product.

(2) Without prejudice to the generality of subsection (1), an order made in terms of that subsection may require particulars to be furnished relating to—

(a) the composition of the designated product or any ingredient thereof;

(b) the manner in which the designated product is used or is intended to be used;

(c) the labelling of the designated product;

(d) the volume of sales within Zimbabwe of the designated product;

(e) the duties of marketing personnel and the manner in which they are remunerated;

(f) any investigation or inquiries carried out by or to the knowledge of the person to whom the order is given to determine whether and to what extent the designated product affects health.

(3) Neither the Secretary nor any person employed in the Ministry of Health and Child Welfare shall disclose to any person who is not employed in the Ministry any particulars furnished in terms of an order made in terms of subsection (1) or any information relating to an individual person or business obtained by means of such particulars without the consent of the person who supplied the particulars.

Power of Secretary to require analysis of samples

29. (1) The Secretary may order any manufacturer or distributor of a designated product to submit, at such intervals as the Secretary may specify, samples of the designated product to an analyst named by the Secretary in the order.

(2) The cost of analysing any sample submitted to an analyst in terms of subsection (1) shall be met by the Minister out of funds voted for the purpose by Act of Parliament.

Powers to be additional to those conferred by other enactments

30. The powers conferred by this Part shall be additional to any powers conferred on inspectors, police officers, customs officers, the Secretary or any other person in terms of any other enactment.

PART X

GENERAL

Promotion of breast-feeding

31. The owner or manager of a health-care facility shall—

(a) take measures to encourage and protect breast-feeding and shall ensure that all health workers employed at the health-care facility are familiar with these regulations;

(b) eliminate any practice, including pre-lacteal feeding, which directly or indirectly retards the initiation and continuation of breast-feeding.

Inspectors and monitors

32. (1) Every health worker and members of the Committee shall be monitors for the purposes of these regulations.

(2) The Minister may appoint as inspectors such other persons, whether or not they are members of the Public Service, as he thinks necessary for the proper enforcement of these regulations.

(3) The Secretary shall furnish every person appointed as an inspector in terms of subsection (2) with a letter of appointment.

(4) Every inspector appointed in terms of subsection (2) shall, when exercising any function in terms of these regulations and on demand by any person affected by such exercise, exhibit his letter of appointment.

Presumptions

33. In any prosecution for an offence in terms of these regulations—

(a) if it is proved that any designated product was found in or upon any premises or place used for the manufacture or sale of goods, it shall be presumed, until the contrary is proved, that the designated product was there in order to be marketed;

(b) if it is proved that any designated product was found in a sealed container, the person who appears, from any label appearing on or attached to or packed with the container, to have manufactured or distributed the designated product shall be presumed, until the contrary is proved, to have manufactured or distributed the designated product, as the case may be.

Offences and penalties

34. (1) Any person who—

(a) contravenes sections 9, 10, 12, 15, 16, 17, 18, 19, 20, 22, 23, subsection (1) of section 24 or subsection (3) of section 28; or

(b) resists, hinders or obstructs an inspector in the performance of his functions in terms of these regulations; or

(c) manufactures, markets, disposes of or removes any designated product in contravention of a notice issued by an inspector or police officer in terms of paragraph (g) of section 26; or

(d) fails or refuses to furnish the Secretary with any particulars required by him in terms of section 28; or

(e) fails or refuses to submit a sample for analysis when required to do so by the Secretary in terms of section 29;

shall be guilty of an offence and liable—

(i) on a first conviction, to a fine not exceeding one thousand dollars or to imprisonment for a period not exceeding six months or both such fine and such imprisonment;

(ii) on a second or subsequent conviction, to a fine not exceeding two thousand dollars or to imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

Repeals

35. The Public Health (Breast-milk Substitues and Infant Nutrition) Regulations, 1997, published in Statutory Instrument 163 of 1997, the Public Health (Breast-milk Substitutes and Infant Nutrition) (Amendment) Regulations, 1997 (No. 1), published in Statutory Instument 188 of 1997 and the Public Health (Breast-milk Substitutes and Infant Nutrition) (Amendment) Regulations, 1997 (No. 2), published in Statutory Instrument 230 of 1997, are repealed.

SCHEDULE (*Sections 13 and 15*)

FORM OF LABELS

PART I

SECTION 13 LABELS

1. Form of labels referred to in section 13 (3) (c) (viii)—

Breast-milk is the best food for your baby.
It protects against diarrhoea and other illnesses.

2. Form of label referred to in section 13 (3) (f) (v)—

To avoid illness of your baby, follow the preparation instructions carefully. Do not use more or less quantities than indicated. Cup-feeding is safer than bottle-feeding. If you use a bottle, your baby may reject the breast.

3. Form of label referred to in section 13 (3) (g)—

The use of a feeding bottle/feeding cup/pacifier interferes with breast-feeding.

PART II

SECTION 15 LABELS

1. Labels on containers of sweetened, condensed, dried, skimmed, evaporated and low fat milk (section 15 (2) (a))

UNFIT FOR BABIES

2. Labels on containers of whole cow's milk (section 15 (2) (b))

UNFIT FOR BABIES

Unless modified in accordance with the advice of a health practitioner or nutritionist.

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