MALAWI

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GOVERNMENT NOTICE No. 8

PUBLIC HEALTH ACT

(CAP. 34:01)

PUBLIC HEALTH (MARKETING OF INFANT AND YOUNG CHILD FOODS) RULES, 2004

ARRANGEMENT OF RULES

RULE

IN EXERCISE of the powers conferred by section 143 of the Public Health Act, I, YUSUF HUSSEIN MWAWA, Minister of Health and Population make the following Rules—

PART I—PRELIMINARY

Citation and commencement

1. These Rules may be cited as the Public Health (Marketing of Infant and Young Child Foods) Rules, 2004, and shall come into force ninety (90) days after publication.

Application

2. The Rules shall be applicable in the whole country and shall affect all breast-milk substitutes and other designated products whether locally made or imported and the practices related thereto, including their quality, availability and information concerning their use.

Interpretation

3. In these Rules, unless the context otherwise requires—

"advertising" means to make any representation for the purpose of promoting directly or indirectly sell of a designated product and includes every form of advertising or information dissemination by—

(*a*) written publications, television, radio, film, video or telephone;

(*b*) display of signs, billboards, notices or goods;

(*c*) exhibition of pictures or models;

(*d*) e-mail and internet; or

(*e*) any other means;

"Advisory Committee" means a Committee set up under rule 7;

"complimentary food" means any food suitable or presented as suitable addition to breast-milk, infant formula or follow-up formula;

"container" means any form of packaging of product for sale as a retail unit, including wrappers;

"designated product" includes—

(*a*) infant formula including special formulas for premature babies and those with metabolic diseases;

(*b*) any other food or milk marketed or otherwise presented as suitable for feeding infants for the first six (6) months of life;

(*c*) feeding bottles, teats, pacifiers, cups with spouts and similar receptacles; and

(*d*) such other products as the Minister may, from time to time, declare to be designated products for purposes of these Rules by notice in the *Gazette*;

"distributor" means a person engaged in the business, whether wholesale or retail, of marketing any designated product and includes any person engaged in the business of providing information, or public relations services in relation to any designated product;

"follow-up formula" means an animal or vegetable-based milk product intended for infants and young children older than six (6) months and industrially formulated in accordance with Malawi standards or in the absence of such standards, in accordance with standards elaborated by the Codex Alimentarius Commission;

"health care facility" means a public or private institution, non-governmental organization or private practitioner engaged directly or indirectly in the provision of health care or in health care education, day-care centres, nurseries or other infant-care facilities;

"health professional" includes a medical practitioner, nurse, clinical officer, midwife, dietician, nutritionist and environmental health officer;

"health worker" includes a person working, or in training to work in a health care facility, whether professional or non-professional including voluntary unpaid workers;

"infant" means a child from birth up to the age of twelve (12) months;

"infant formula" includes an animal or vegetable-based milk product; industrially formulated in accordance with Malawi standards, or in the absence of such standards, in accordance with standards elaborated by the Codex Alimentarius Commission, to satisfy some or all of the nutritional requirements of infants up to the age of six (6) months;

"Inspector" means a person appointed as an inspector under rule 15;

"label" includes a tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, attached or otherwise appearing on or displayed near a container of a designated product;

"manufacturer" means a person engaged in the business of producing a designated product whether directly, or through an agent, controlled by or under an agreement;

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

"pacifier" means an artificial teat for babies to suck, also referred to as a "dummy";

"sample" means a single or small quantity of a designated product provided without cost;

"young child" means a person from the age of twelve (12) months up to the age of three years (36 months).

Objective

4. These Rules intend to ensure safe and adequate nutrition for infants and young children by—

(*a*) promoting, protecting and supporting exclusive breast-feeding for six (6) months and breast-feeding with adequate complementation with locally available foods up to about two (2) years or beyond; and

(*b*) regulating the marketing of designated products.

PART II—ADMINISTRATION

Implementation

5.—(1) The Minister shall be responsible for the implementation of these Rules.

(2) The Minister shall, when necessary, call upon other ministries to ensure the proper implementation of these Rules.

Powers and functions of the Minister

6. For the purpose of implementing these Rules, the Minister shall have the following powers and functions—

(*a*) to call for consultations with Government agencies and other interested parties to ensure implementation and strict compliance with the provisions of these Rules;

(*b*) to ensure the enforcement of these Rules; and

(*c*) to exercise such other powers and functions as may be necessary for or incidental to the attainment of the purposes and objectives of these Rules.

Advisory Committee

7.—(1) There shall be an Advisory Committee which shall be responsible for the promotion, protection and support of breast-feeding.

(2) The Advisory Committee shall consist of the following members—

(*a*) the Minister of Health or his representative who shall be the *ex officio* chairman;

(*b*) two representatives from the Ministry of Health and Population responsible for nutrition, food and hygiene;

(*c*) two persons representing non-governmental organizations in the field of child welfare and development, infant nutrition or consumer protection;

(*d*) a representative from Malawi Bureau of Standards;

(*e*) the Secretary for Commerce and Industry or his designated representative;

(*f*) the Secretary for Ministry of Justice or his designated representative; and

(*g*) the Secretary for Gender and Community Services or his designated representative.

(3) No person shall be appointed a member of the Advisory Committee who has any direct or indirect financial interest in any designated product.

(4) The Minister shall appoint the members of the Advisory Committee within thirty (30) days after these Rules come into force.

(5) The members of the Advisory Committee other than the *ex officio* members, shall hold office for a term of three (3) years and shall be eligible for re-appointment for one more term.

Vacation of member

8.—(1) The office of a member of the Advisory Committee, other than an *ex officio* member shall be vacated—

(*a*) upon the expiry of the period of his appointment;

(*b*) upon his death;

(*c*) upon notice in writing to the Minister of his intention to resign his office;

(*d*) if a member acquires direct or indirect financial interest in any designated product; or

(*e*) if he is absent, without valid reasons, from three (3) consecutive meetings of the Advisory Committee of which he has had notice.

(2) A vacancy shall be filled in the same manner as the original appointment for the remaining unexpired term.

Invited persons

9. The Advisory Committee may invite any person to attend any deliberations of the Committee but such person shall not be entitled to vote on any matter at any meeting of the Advisory Committee.

Sub-committees of the Advisory Committee

10. The Advisory Committee may establish sub-committees to carry out any special or general functions determined by the Advisory Committee.

Administration of the Advisory Committee

11.—(1) The Minister shall appoint, within his Ministry, a secretary to the Advisory Committee and such other officers as he deems necessary for the purposes of the implementation of these Rules.

(2) The Secretary shall—

(*a*) convene meetings of the Advisory Committee at the direction of the Chairman;

(*b*) maintain minutes of the meetings; and

(*c*) perform such other duties as may be directed by the Advisory Committee.

Meetings of the Advisory Committee

12.—(1) The Advisory Committee shall meet as often as it deems necessary, but not less than twice a year at such time and place as the Secretary shall indicate.

(2) Five (5) members of the Advisory Committee shall constitute a quorum for a meeting.

(3) At any meeting the decision for the Advisory Committee on any matter shall be that of the majority of the members present and voting at that meeting and in the event of an equality of votes, the Chairman or the person presiding shall have a casting vote in addition to his deliberate vote.

(4) The Advisory Committee may make such other administrative rules as may be required for its proper functioning.

(5) An extraordinary meeting of the Advisory Committee—

(*a*) may be convened by the Chairman at anytime; and

(*b*) shall be convened by the Chairman within seven (7) days after receipt by him of a request in writing signed by not less than three (3) members of the Advisory Committee and specifying the purpose for which the meeting is to be convened.

Powers and functions of the Advisory Committee

13. The Advisory Committee shall have the following powers and functions—

(*a*) to review reports of violation or other matters concerning these Rules;

(*b*) to issue instructions to inspectors on what actions to be taken, or take such other actions, as the case may be, against any person found violating the provisions of these Rules;

(*c*) to examine and approve materials submitted in accordance with rule 21 (4) and recommend appropriate actions to be taken in the case of a violation of Part V; and

(*d*) such other powers and functions, as are conferred on it by the provisions of these Rules.

PART III—REGISTRATION AND INSPECTION

Registration of designated products

14.—(1) (*a*) Every manufacturer, importer, wholesaler or retailer of designated products shall apply annually to the Ministry for registration as a manufacturer, importer, wholesaler or retailer of designated products; and

(*b*) the application for registration shall be accompanied by non-refundable registration fees specified in the Schedule hereto.

(2) The Minister shall, by notice in the *Gazette*, specify the date prohibiting the importation, manufacturing or sale of any designated product that is not registered.

(3) A person applying for registration as a manufacturer, importer, wholesaler or retailer of a designated product shall furnish such information and samples as specified in the registration form.

(4) Once the registration has been approved, a Certificate of Registration shall be issued by the Ministry.

(5) No Certificate of Registration shall be granted unless the designated product is—

(*a*) in accordance with the Malawi Standards, or in the absence of such standards, in accordance with standards elaborated by the Codex Alimentarius Commission; and

(*b*) every label of designated product is in accordance with the requirements of Part VI of these Rules.

Inspectors

15.—(1) The Minister shall appoint such persons as he sees fit, who have the prescribed qualifications, to be inspectors for the purposes of these Rules within such limits as may be assigned to them respectively:

Provided that no person who has any direct or indirect financial interest in any designated product shall not be appointed as an inspector.

Powers of Inspectors

16. An Inspector may—

(*a*) inspect any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted;

(*b*) inspect all relevant records and documents related to designated products; and

(*c*) exercise such other relevant powers.

Procedure for inspection

17.—(1) Inspectors shall inspect, as regularly as possible but in any case not less than four (4) times a year, the premises which are used as a factory, warehouse, distribution or selling point of any breast-milk substitute or other designated product.

(2) After each inspection, the Inspector shall submit a report including any kind of violation of these Rules and recommendations to the Minister and seek instructions as to the action to be taken in respect of such violation.

PART IV—PROHIBITIONS

Sale, etc., of designated product

18. No person shall distribute for sale, sell, stock or exhibit for sale any designated product that—

(*a*) is not in compliance with these Rules;

(*b*) has reached its expiration date; or

(*c*) is not in its original container.

Promotion prohibited

19.—(1) No manufacturer or distributor shall promote any designated product.

(2) Prohibited promotional practices include—

(*a*) advertising;

(*b*) sales devices including but not limited to rebates, special sales, discount coupons, prizes and gifts;

(*c*) the giving of one or more samples of a designated product to any person;

(*d*) distribution of any information or educational material regarding infant or young child feeding, except in accordance with these Rules; and

(*e*) direct or indirect contact between marketing personnel and members of the public in furtherance of or for the purposes of their business.

(3) For the purposes of this rule, "promote" means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.

Prohibition of donations gifts, etc.

20.—(1) (*a*) No manufacturer or distributor shall donate or sell at lower than eighty (80) per cent of retail price any quantity of a designated product to a health care facility:

Provided that such donations or low-price sales may be offered to orphanages or institutions devoted exclusively to caring for abandoned children; and

(*b*) when such donations or low-priced sales are made, they shall be in a quantity sufficient to feed the infants concerned for a period of at least six (6) months.

(2) No manufacturer or distributor shall donate to or distribute within a health care facility materials, other than those specified in subrule (1) of this rule.

(3)—(*a*) No manufacturer or distributor of any designated product shall offer any gifts to a health worker, including but not limited to pens, calendars, posters, note pads, growth charts or toys;

(*b*) a manufacturer or distributor of any designated product may make contribution to a health worker for the purpose of funding the health worker's attendance at meetings, seminars, conferences, continuing education courses, or giving fellowships, study grants or for similar purposes:

Provided that the manufacturer or distributor informs the Advisory Committee and the institution to which the health worker is affiliated of the contribution; and

(*c*) manufacturers or distributors shall not make direct contributions to individual health workers for such purposes.

(4)—(*a*) No manufacturer or distributor shall fund research by a health worker, including clinical research on a designated product, unless such research conforms to a protocol that has been approved by the Advisory Committee;

(*b*) the disclosure should include the source of funding and the name of the recipient of the research grant; and

(*c*) any publication resulting from such research must include a statement disclosing the source of funding.

(5) No manufacturer or distributor shall provide payments to any personnel employed within a health care facility.

PART V—INFORMATION AND EDUCATION

Information and education about infant feeding

21.—(1) Information or educational materials, whether written, audio or visual, on the topic of infant and young child feeding shall—

(*a*) clearly and conspicuously explain each of the following points—

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

(ii) how to prepare for and maintain breast-feeding including maternal nutrition;

(iii) how and why early introduction of complementary foods interferes with breast-feeding;

(iv) how and why bottle-feeding interferes with breast-feeding;

(v) why it is difficult to return to breast-feeding after a period of bottle-feeding even if limited to a few feeds; and

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

(*b*) contain only factual and current information and shall not use any pictures or text that discourage breast-feeding;

(*c*) be written in English and Chichewa; and

(*d*) not make reference to the brand name of any designated product nor contain the name or logo of any manufacturer or distributor of the designated product, except by way of designating a copyright:

Provided that this paragraph shall not be applicable to information about designated products intended for health professionals.

(2) If the material referred to in subrule (1) includes the topic of feeding infants with infant formula or any other food or drink by feeding bottle, it must also include the following points—

(*a*) instructions for the proper preparation and use of the product including cleaning and sterilization of feeding utensils;

(*b*) the approximate financial cost of feeding an infant with the product for a period of six (6) months;

(*c*) the health hazards of bottle-feeding;

(*d*) the health hazards of improper preparation of the product; and

(*e*) how to feed infants with a cup.

(3) If the material referred to in subrule (1) includes the topic of feeding infants with complementary foods it must also explain the following points—

(*a*) the health hazards of introducing complementary foods before six (6) months or late; and

(*b*) that complementary foods can easily be prepared at home using local ingredients.

(4) Any person who produces or distributes any material referred to in this Part shall submit copies to the Advisory Committee.

PART VI—LABELS ON DESIGNATED PRODUCTS

Labels of designated products

22. The label of every designated product shall—

(*a*) not contain any text that may tend to discourage breast-feeding;

(*b*) contain the following notice, on the front, in bold and conspicuous characters, not less than 50 per cent the size of the largest words on the label and not more than 2 mm in height: "BREAST-MILK IS THE BEST FOOD FOR YOUR BABY";

(*c*) contain instructions for appropriate preparation in words and in easily understood graphics;

(*d*) indicate the age for which the product is recommended;

(*e*) explain clearly the health hazards of introducing the product prior to the recommended age;

(*f*) be written in Chichewa and English;

(*g*) indicate the ingredients, specifying the origin of any milk product, the composition and analysis of the product, the required storage conditions, the batch number, the date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;

(*h*) contain the name and address of the manufacturer and the distributor; and

(*i*) be in distinct characters and contrasting colour to the back ground.

(2) The label of every container of infant formula, in addition to the requirements specified in subrule (1) of this rule shall—

(*a*) not use the terms "humanized" or such similar terms nor contain any comparison with breast-milk;

(*b*) contain the following notice in bold characters no less than 1.5 mm in height:

"FOLLOW THE PREPARATION INSTRUCTIONS CAREFULLY OR YOUR BABY MAY BECOME ILL OR MALNOURISHED";

(*c*) not show any photographs of an infant or child, drawings or other graphics representation other than for illustrating method of preparation and, in no case, shall depict a feeding bottle; and

(*d*) in the case of infant formula, indicate the number of containers required to feed the infant during the first six (6) months of life.

(3) The label of every container of the following products in powder or liquid form shall contain the following notices in characters no less than 2 mm in height—

(*a*) skimmed or condensed milk:

"THIS PRODUCT SHOULD NOT BE USED TO FEED AN INFANT OR A YOUNG CHILD";

(*b*) standardized milk:

"THIS PRODUCT SHOULD NOT BE USED AS THE SOLE SOURCE OF NUTRITION FOR AN INFANT OR ANY YOUNG CHILD";

(*c*) whole cow's milk:

"THIS PRODUCT SHOULD NOT BE USED AS THE SOLE SOURCE OF NUTRITION FOR AN INFANT OR A YOUNG CHILD, UNLESS ADVISED BY A MEDICAL PRACTITIONER OR A NUTRITIONIST".

(4) The label of containers of every bottle and teat shall, in addition to the requirements specified in subrule (1) in paragraphs (*a*), (*d*), (*e*), (*f*), (*h*) and (*i*) of this rule contain—

(*a*) "YOUR BABY MAY BECOME ILL BY USING A FEEDING BOTTLE, FEEDING WITH A CUP IS MUCH SAFER, FOLLOW THE PREPARATION INSTRUCTIONS CAREFULLY"; and

(*b*) instructions for proper cleaning and sterilization in words and in easily understood graphics.

(5) The label of every pacifier shall contain the following notice in characters no less than 2 mm in height—

"WARNING: USE OF A PACIFIER CAN INTERFERE WITH BREAST-FEEDING".

Promotion of breast-feeding

23.—(1) Heads of health facilities, national and local health authorities shall take measures—

(*a*) to promote, protect and support breast-feeding;

(*b*) to promote these Rules; and

(*c*) to give information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all of the information specified in Part V.

(2) Health workers shall promote, protect and support breast-feeding and know the provisions of these Rules, particularly the information specified in Part V.

(3) Health workers shall work to eliminate practices that directly or indirectly retard the initiation and continuation of breast-feeding, such as prelacteal feeds.

Promotions

24. Health workers shall not—

(*a*) accept any gift or benefit, financial or otherwise of whatever value from a manufacturer or distributor;

(*b*) accept nor give samples of designated products from or to any person, except in accordance with the provision of these Rules; and

(*c*) promote, in any way, any designated product.

Written report

25. A health worker shall submit a written report to the head of a health facility, regarding any offer they receive of a sample or gift or other benefit from a manufacturer or distributor or any contravention of the provisions of these Rules and the head of the facility shall in turn report the matter to the Advisory Committee.

PART VIII—PENALTIES, PROCEDURES

Penalties

26.—(1) Any person who contravenes the provisions of these Rules commits an offence and shall upon conviction be liable to a fine of K2,000 and to imprisonment for six (6) months.

(2) Any person convicted of an offence under subrule (1) and who is again convicted of an offence under that subrule shall be liable to a fine of not less than K2,000 and to imprisonment for six (6) months.

Suspension or cancellation of Certificate of Registration

27.—(1) The Minister shall have the power to make cease and desist orders upon receiving a report from an Inspector or the Advisory Committee of a violation of the provisions of these Rules.

(2) Where a person contravenes any of the provisions of these Rules the Minister may, upon written recommendation of the Advisory Committee and after giving the person an opportunity to be heard, suspend or cancel any Certificate of Registration issued to that person pursuant to these Rules.

Appeal

28. Any person aggrieved by the decision of the Minister may apply to the High Court for judicial review within thirty-five (35) days after the decision is made.

Strict liability for officers directors, etc.

29. Where the person, guilty of an offence under these Rules is a corporation, company, partnership, firm, etc., or other association, every director, officer, partner and employee of the corporation, company, partnership, firm or other association, shall also be liable for that offence unless he proves that the offence was committed without his knowledge or consent.

Institution of prosecution

30. The Minister may refer a matter to the Director of Public Prosecutions for prosecution where the contravention of these Rules constitutes a criminal offence.

Public enforcement

31.—(1) Any person has the right to lodge a formal complaint to the Advisory Committee which may recommend that proceedings be instituted against any person relating to a violation of any provision that constitutes an offence under these Rules.

(2) Any person has the right to commence an action for damages in a court of law against any manufacturer or distributor or other person for any harm suffered as a result of violation of any provision that constitutes an offence under these Rules.

SCHEDULE

REGISTRATION FEES

	Category	*Amount to be paid annually* K t
1.	Manufacturers, importers or wholesalers	5,000 00
2.	Retailers	1,000 00

Made this 4th day of July, 2003.

Y. H. MWAWA
Minister of Health and Population

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