**THE FOOD AND DRUGS ACT.**

Statutory Instrument 278—1.

**The Food and Drugs (Marketing of Infant and Young Child Foods) Regulations.**

**Arrangement of Regulations.**

**THE FOOD AND DRUGS ACT.**

Statutory Instrument 278—1.

**The Food and Drugs (Marketing of Infant and Young Child Foods) Regulations.**

*(Under section 41 of the Food and Drugs Act.)*

## 1. Citation.

These Regulations may be cited as the Food and Drugs (Marketing of Infant and Young Child Foods) Regulations.

## 2. Interpretation.

In these Regulations, unless the context otherwise requires—

(a) "advertisement" means a representation to the public, for the purpose of promoting directly or indirectly the sale or disposal of a prescribed product and includes every form of advertising, whether—
  (i) by written publication, television, radio, film, electronic transmission, video or telephone;
  (ii) by display of signs, billboards and notices;
  (iii) by exhibition of pictures or models;
  (iv) by pictorial displays, discount coupons, premiums, special sales and the like; or
  (v) advertising by any other means;

(b) "chairperson" means the chairperson of the committee appointed under regulation 3 of these Regulations;

(c) "committee" means the Infant and Young Child Nutrition Committee established under regulation 3 of these Regulations;

(d) "complementary food" means food whether manufactured or locally prepared, suitable or represented as suitable as a complement to breast milk or to infant formula when either becomes insufficient to satisfy the nutritional requirements of an infant or young child;

(e) "container" means any form of packaging of a prescribed product for distribution or sale as a retail unit, including wrappers;

(f) "distributor" means a person, corporation or any other entity in the public or private sector engaged in the business, whether

directly or indirectly, of marketing at the wholesale or retail level, a prescribed product;

(g) "follow-up formula" means a milk or milklike product of animal or vegetable origin industrially formulated in accordance with the standards of the Uganda National Bureau of Standards, to satisfy some or all of the nutritional requirements of infants;

(h) "health care system" means a governmental or nongovernmental or private hospital, clinic, institution, organisation or individual engaged directly or indirectly in providing health care to the public; daycare centres, nurseries or other infant care facilities; established pharmacies and drug shops and other sales outlets;

(i) "health worker" means a person who works in, or is training to work in, any component of the health care system, whether governmental or nongovernmental and whether paid or voluntary;

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

(k) "infant formula" means a milk or milklike product of animal or vegetable origin industrially formulated in accordance with the standards of the Uganda National Bureau of Standards, to satisfy some or all of the nutritional requirements of infants;

(l) "inspector" means an inspector appointed under regulation 9 of these Regulations;

(m) "label" means a tag, brand, mark, pictorial or other descriptive matter written, printed, stenciled, marked, embossed or impressed on or attached or otherwise appearing on or displayed near a container of a prescribed product;

(n) "manufacturer" means a person, company or other entity engaged in the business of manufacturing a prescribed product whether through an agent or a person controlled by or under an agreement with the manufacturer;

(o) "marketing" means any method of introducing or selling a prescribed product, including but not limited to promotion, distribution, advertising, public relations, information services and distribution of samples;

(p) "Minister" means the Minister responsible for health;

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

(r) "prescribed product" means a product prescribed in the First Schedule to these Regulations;

(s) "promotion" means a direct or indirect method of introducing a prescribed product or of encouraging a person to buy a prescribed

product;

(t) "publication" means the communication of matters by a person or his or her agent to the public or to a section of the public;

(u) "sample" means a single or small quantity of a prescribed product provided free of charge;

(v) "supplies" means quantities of a prescribed product provided free or at low cost for use over an extended period for a social purpose;

(w) "young child" means a child from the age of twelve months up to the age of five years (60 months).

**3. Establishment of Infant and Young Child Nutrition Committee.**

(1) There is established within the Ministry responsible for health, the Infant and Young Child Nutrition Committee, in these Regulations referred to as the committee.

(2) The committee shall consist of the following members appointed by the Minister—

(a) the commissioner for health services (nutrition) in the Ministry responsible for health;

(b) one member from the department of obstetrics and gyneacology of any university in Uganda;

(c) one member from the department of paediatrics of any university in Uganda;

(d) one member representing the women's umbrella organisation of the Catholic Church of Uganda;

(e) one member representing the women's umbrella organisation of the Muslim community in Uganda;

(f) one member representing the women's umbrella organisation of the Mothers' Union of Uganda;

(g) one member representing the National Association of Women of Uganda (NAWOU); and

(h) two members with wide experience in matters of infant and young child nutrition.

(3) The chairperson shall be appointed by the Minister from among the members of the committee on the recommendation of the committee.

(4) The committee shall have a secretary who shall be appointed by the Minister on the recommendation of the committee.

**4. Tenure of office of members.**

(1) The members of the committee shall hold office for three years and are eligible for reappointment.

(2) A member may at any time, by writing, resign his or her membership or may be removed by the Minister—

(a) for inability to perform the functions of his or her office on the ground of infirmity of body or mind or any other cause; or

(b) for misbehaviour.

**5. Functions of the committee.**

The functions of the committee are—

(a) to advise the Minister from time to time as to the products to be declared prescribed products under these Regulations;

(b) to advise the Food and Nutrition Council on infant and young child nutrition;

(c) to devise strategies to promote, encourage and protect breast feeding and infant and young child nutrition;

(d) to formulate infant and young child nutrition policy;

(e) to establish programmes for the education of health workers and the community on all aspects of breast feeding and on infant and young child nutrition;

(f) to monitor and report on any development in breast feeding and on infant and young child nutrition;

(g) to publish and censor information relating to infant and young child nutrition;

(h) to monitor compliance with these Regulations;

(i) to recommend to the Ministry responsible for trade, the issuing of licences in accordance with regulation 8 of these Regulations;

(j) to sanction information, education and communication materials and equipment from manufacturers or distributors of prescribed products for use within the health care system;

(k) to promote and support research into infant and young child nutrition;

(l) to advise the Minister on designing a national strategy for developing communication and public education programmes for—

(i) the promotion of breastfeeding;

(ii) information and educational materials on infant and young child feeding;
(iii) continuing education for health workers on lactation management; and
(iv) training curricula on infant and young child care in primary and secondary schools and health institutions; and

(m) to compile and review reports of violations of these Regulations made by an inspector under regulation 11 of these Regulations and make recommendations for appropriate action to be taken.

**6. Meetings of the committee.**

(1) The committee shall meet for the dispatch of business at least four times in a year at such times and places as the chairperson shall determine.

(2) The chairperson shall also summon a special meeting of the committee upon a request made by not less than seven members of the committee.

(3) One-half of the members of the committee shall form a quorum at any meeting of the committee.

(4) The chairperson shall preside at all meetings of the committee, and in his or her absence a member elected by the members present from among their number shall preside.

(5) A question proposed at any meeting of the committee shall be determined by a simple majority of votes of members present and voting; and where there is an equality of votes, the person presiding at the meeting shall have a second or casting vote.

(6) The committee may co-opt any person who is not a member to attend any of its meetings as an adviser, and that person may speak on any matter in relation to which his or her advice is sought but shall not have the right to vote on any matter coming for decision before the meeting.

(7) Subject to subregulations (1) to (6) of this regulation, the committee may regulate its own procedure.

**7. Remuneration of members.**

Members of the committee and also persons co-opted at any meeting of the committee may be paid such sitting, subsistence or other allowances and at such rates as the Minister may determine.

**8. No marketing without licence.**

(1) A person shall not engage in the marketing or distribution of a prescribed product unless he or she holds a valid licence issued by the Ministry responsible for trade.

(2) Recommendation for issuing a licence under this regulation shall be in Form 2 of the Second Schedule to these Regulations and shall be made to the chairperson who shall present the recommendation to the committee for consideration.

(3) An application under this regulation shall be in Form 1 of the Second Schedule to these Regulations.

(4) The committee shall cause the names of all licensees under these Regulations to be published once every year in the Gazette.

(5) A licence issued under this regulation shall remain in force for one year beginning on the day when it comes into force and may be renewed.

(6) A licence issued under this regulation may be revoked or suspended at any time.

(7) A register of licensed persons shall be maintained at the office of the committee.

**9. Inspectors.**

(1) The Minister shall appoint such persons as he or she sees fit, having the prescribed qualifications, including but not limited to health inspectors under the Food and Drugs Act, inspectors under the Uganda National Bureau of Standards Act and officers of the Uganda Revenue Authority, to be inspectors for the purposes of these Regulations within such local limits as he or she may assign to them respectively.

(2) Any person who has any direct or indirect financial interest in any prescribed product shall not be appointed as an inspector for the purposes of

these Regulations.

**10. Powers of inspectors.**

An inspector may, within the local limits for which he or she is appointed—

(a) inspect any premises where any prescribed product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted, and all relevant records; and

(b) exercise such other powers as may be prescribed by the Minister.

**11. Procedure for inspectors.**

(1) An inspector shall inspect the premises not less than the number of times prescribed.

(2) After each inspection, the inspector shall submit a report including any finding of a violation under these Regulations to the committee and seek instructions as to the action to be taken in respect of the contravention.



**12. Prohibition of distribution of supplies.**

A manufacturer or distributor or any person whose functions involve the marketing of a prescribed product shall not directly or indirectly—

(a) offer or provide to an expectant mother or to a parent or caretaker of an infant or young child any article or utensil that is likely to promote the buying or use of a prescribed product;

(b) give gifts to any person of any samples of free and low-cost supplies of a prescribed product; or

(c) supply to a health worker for financial benefit samples of a prescribed product, free equipment or utensils for the preparation of a prescribed product.

**13. Employment of manufacturers' or distributors' agents.**

A health care system shall not employ or permit the services of professional service personnel or similar personnel provided by manufacturers or distributors of a prescribed product or whose services are paid for by manufacturers or distributors.

**14. Prohibition of promotion of prescribed product.**

(1) No manufacturer or distributor shall promote to the public any prescribed product.

(2) The practices prohibited by subregulation (1) of this regulation in respect of the promotion of infant formula or food include—

(a) advertising;

(b) sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss leaders, tie-in sales, prizes or gifts;

(c) giving one or more samples of a prescribed product to any person;

(d) donation or distribution of any information or educational material regarding infant or young child feeding, except in accordance with regulation 17 of these Regulations and such other requirements as may be prescribed by the committee; and

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

**15. Prohibition of donation of prescribed product.**

(1) A manufacturer or distributor shall not donate or sell at lower than 80 percent of the retail price any quantity of a prescribed product to a health care facility, except that such donations or low-priced sales may be made to orphanages or institutions devoted exclusively to caring for abandoned children.

(2) A donation or low-priced sale made under subregulation (1) of this regulation shall be in a quantity sufficient to feed the infants or young children for at least six months.

(3) A manufacturer or distributor shall not donate directly or indirectly any equipment or services to a health care facility.

(4) A manufacturer or distributor shall not offer or give any gift to a health worker.

(5) A manufacturer or distributor shall not provide payments to any personnel employed in a health care facility.

**16. Prohibition of donation of equipment, study grants, etc.**

A manufacturer or distributor shall not himself or herself or by any other person on his or her behalf—

(a) donate or distribute within a health care facility or to a health worker, equipment or services or materials including but not limited to pens, calendars, posters, notepads, growth charts and toys, which may promote the use of a prescribed product;

(b) offer or give any gift, contribution or benefit to a health worker or associations of health workers including but not limited to fellowships, study grants, research grants or funding for attendance of meetings, seminars, continuing education courses or conferences; except that a manufacturer or distributor may make contributions to a nationally recognised trust fund under the management of the Ministry responsible for health for those purposes; or

(c) sponsor events, contests or campaigns aimed at pregnant or lactating women, parents of infants or young children or members of their families, nor sponsor events, contests or campaigns related to fertility, pregnancy, childbirth, infant or young child feeding or related topics.

**17. Censoring of information and educational materials.**

(1) All information and educational materials on infant and young child nutrition intended for use by families and any person in the field of infant and young child nutrition shall, before publication, be submitted to the committee for its approval.

(2) Information or educational materials, whether written, audio or visual, on the topic of infant and young child nutrition shall—

(a) clearly and conspicuously explain—

(i) the importance, benefits and superiority of breastfeeding to both mother and child;

(ii) how to prepare for and maintain breastfeeding, including maternal nutrition;

(iii) how and why bottlefeeding interferes with breastfeeding;

(iv) how and why early introduction of complementary foods interferes with breastfeeding;

(v) why it is difficult to return to breastfeeding after a period of bottlefeeding, even if limited to a few feeds;

(vi) the adverse effects of the use of pacifiers on breastfeeding;

(b) contain only factual and current information and shall not use any picture or text that discourages breastfeeding; and

(c) not make reference to the brand name of any prescribed product nor contain the name or logo of any manufacturer or distributor of a prescribed product, except by way of designating a copyright; except that this paragraph shall not apply to information about prescribed products intended for health professionals.

(3) Any material referred to in subregulation (2) of this regulation on the topic of feeding infants with infant formula or any other food or drink by feeding bottle shall include—

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

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

(c) the health hazards of bottlefeeding;

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

(e) how to feed infants with a cup and a spoon.

(4) If the material referred to in subregulation (2) of this regulation includes the topic of feeding infants with complementary foods, 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 local ingredients.

(5) Any person who produces or distributes any materials referred to in this regulation shall submit copies to the committee according to procedures prescribed by the committee.

(6) No prescribed product or information relating to a prescribed product, except materials approved by the committee under this regulation, shall be displayed in any hospital, clinic, pharmacy or other sales outlet.

(7) Information on the use of a prescribed product may be provided to health workers and to the community by a manufacturer or distributor of a prescribed product, but that information shall be restricted to scientific and factual matters prescribed by the committee and, in particular, the

information shall emphasize the superiority of breastmilk over the prescribed product.

**18. Education on infant and young child feeding.**

(1) Every head of a health care facility and national and local health authority shall give information and advice to health workers regarding their responsibilities and, in particular, ensure that health workers are familiar with all matters relating to information and education on infant and young child nutrition.

(2) A health worker shall encourage, support and protect breastfeeding and shall work to eliminate practices that directly or indirectly retard the initiation and continuation of breastfeeding, such as the use of pre-lacteal feeds.

(3) A health worker shall give education on feeding with prescribed products or complementary foods to mothers of infants and young children in respect of whom the infant formula or complementary food is prescribed by the health worker.

(4) The information under subregulation (3) of this regulation shall include clear explanations on the hazards of improper or inappropriate preparation and use of the prescribed product in English and at least one local language.



**19. Labelling.**

(1) No manufacturer or distributor shall label, package, treat, process or offer for sale or sell a prescribed product in a manner that is false, deceptive, misleading or likely to create an erroneous impression of the character, value, quantity, composition, merit or safety of the product.

(2) The label of a prescribed product shall—

(a) not contain any text that may tend to discourage breastfeeding;

(b) contain the following notice, on the front, in bold and conspicuous characters, not less than 50 percent of the size of the largest words on the label and not less than 2 mm. in height:

"BREASTFEEDING IS BEST FOR YOUR BABY.
IT PROTECTS AGAINST DIARRHOEA AND OTHER ILLNESSES";

(c) contain instructions for appropriate preparation in words and in easily understood graphics;
(d) indicate the age for which the product is recommended, according to rules prescribed by the committee;
(e) explain clearly the health hazards of introducing the product before the recommended age;
(f) be written in English and at least one local language;
(g) indicate the ingredients, specifying the origin of any milk product, the composition and analysis of the product, the required storage conditions and the batch number, the date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions; and
(h) contain the name and address of the manufacturer and the distributor.

(3) The label of every container of infant formula, in addition to the requirements of subregulation (1) of this regulation, shall—
(a) not use the terms "maternalised", "humanised" or their equivalent, nor contain any comparison with breastmilk;
(b) contain the following notice in bold characters not less than 1.5 mm. in height:
"FOLLOW THE PREPARATION INSTRUCTIONS CAREFULLY OR YOUR BABY MAY BECOME ILL. DO NOT USE MORE OR LESS THAN THE QUANTITIES INDICATED. USE A CUP OR SPOON FOR FEEDING. AVOID BOTTLES AND CUPS WITH SPOUTS.";
(c) not show any photographs, drawings or other graphic representations other than for illustrating methods of preparation and, in no case, shall depict a feeding bottle;
(d) indicate the number of containers necessary to feed the infant during the first six months of life; and
(e) indicate the number of feeds in the container and the number of days for which the container will last, depending on the age of the infant.

(4) The label of every container of the following products in powder or liquid form shall contain the following notices in characters not less than 2 mm. in height—
(a) skimmed or condensed milk:
"THIS PRODUCT SHOULD NOT BE USED TO

FEED INFANTS BELOW 12 MONTHS OF AGE. FOLLOW THE PREPARATION INSTRUCTIONS CAREFULLY.";

(b) low-fat standard milk:

"THIS PRODUCT SHOULD NOT BE USED AS THE SOLE SOURCE OF NUTRITION FOR INFANTS BELOW 12 MONTHS OF AGE.";

and

(c) whole cow's milk:

"THIS PRODUCT SHOULD NOT BE USED AS THE SOLE SOURCE OF NUTRITION FOR INFANTS BELOW 12 MONTHS OF AGE".

(5) The label of every bottle and teat shall, in addition to the requirements of subregulation (1) of this regulation, contain—

(a) the following notice in characters not less than 2 mm. in height:

"YOUR BABY MAY BECOME ILL BY USING A FEEDING BOTTLE. FOLLOW THE PREPARATION INSTRUCTIONS CAREFULLY."; and

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

(6) The label of every pacifier shall contain the following notice in characters not less than 2 mm. in height:

"WARNING: USE OF A PACIFIER CAN INTERFERE WITH BREASTFEEDING."

**20. Minimum standards.**

A prescribed product, when offered for sale or distribution, shall comply with the standards specified by the Uganda National Bureau of Standards under section 15 of the Uganda National Bureau of Standards Act and any other written law in Uganda.

**21. Offences and penalties.**

(1) A person who contravenes regulation 8, 12, 13, 14, 15, 16, 19 or 20 of these Regulations commits an offence and is liable on conviction, unless otherwise specified in the Act, to a fine not exceeding three thousand shillings or to imprisonment for a term not exceeding three months or both.

(2) The court convicting a person of an offence under these Regulations may, in addition to the penalty prescribed in subregulation (1) of this regulation, order the confiscation of all or part of the commodity or utensil which is the subject matter of the offence, and that commodity or utensil shall be disposed of in such manner as the court may direct.

(3) Where an offence under these Regulations is committed by a servant in the course of his or her employment, or by an agent in the course of his or her agency, and it is proved that it was committed with the authority, consent, knowledge or connivance of the principal, the principal is guilty of the same offence and is liable to the same penalty.

**22. Cease and desist orders.**

The Minister shall have the power to make cease and desist orders upon receiving a report from an inspector or the committee of a violation of these Regulations.

**23. Public enforcement.**

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

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

*First Schedule.*

reg. 2.

**Prescribed products.**

1. Infant formula
2. Follow-up formula
3. Complementary foods—
   (a) baby soya
   (b) maize flour
   (c) millet flour
   (d) sorghum flour

(e) nkejje powder

4. Feeding bottles
5. Feeding teats
6. Pacifiers
7. Cups with spouts
8. Nipple shields
9. Sterilising solution for cleaning bottles, teats, pacifiers and cups with spouts

*Second Schedule.*

reg. 8(3).

**Forms.**

Form 1.

Application for a Licence to Market Prescribed Products.

*The Food and Drugs (Marketing of Infant and Young Child Foods) Regulations.*

To: The Chairperson
Infant and Young Child Nutrition Committee
Ministry responsible for Health
P.O. Box 8, Entebbe

I/We, _____
of _____ *(address)*,
apply for a licence to market infant and young child products as prescribed under the First Schedule to the Food and Drugs (Marketing of Infant and Young Child Foods) Regulations.

Prescribed products

| | |
|---|---|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

| | |
|---|---|
| _____ | _____ |
| Date | Applicant |

reg. 8(2).

Form 2.

Recommendation for Issuing Licence.

*The Food and Drugs (Marketing of Infant and Young Child Foods) Regulations.*

I recommend the issuing of a licence to:

Mr./Mrs./Ms._____

of_____ *(address)*

to market the following prescribed products:

Prescribed products

| | |
|---|---|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

| | |
|---|---|
| _____ | _____ |
| Date | Chairperson |

_____

**History:** S.I. 76/1997.



**Cross Reference**

Uganda National Bureau of Standards Act, Cap. 327.

_____