

REPUBLIC OF MOZAMBIQUE

MINISTRY OF HEALTH
NATIONAL HEALTH DEPARTMENT

Code of Marketing of Breastmilk Substitutes

T. N. This does not appear to be a law. In the 25 May 2005 draft there were the words “Decree No. ...” and it listed the names of the Minister of Health and the President of the Republic who decreed the Code as law. All that has disappeared in this later Nov 2005 version.

Article 18 and others mention “after the publication of this Code in the Official Gazette of the Republic of Mozambique”, but nowhere in this text does it show or mention that it was published in the Official Gazette (Boletím da República).

It is a very complete and good implementation of the International Code and subsequent relevant WHO resolutions. It clearly states what is permissible and what is not, the role and responsibilities of health workers and of manufacturers, distributors and their agents. It enumerates sanctions for violations or non-fulfilment of duties, and states who decides and who applies such sanctions.

In that sense, it is both the Law and the Regulation for implementation of the Law.

Has it been passed through parliament or decreed? Has it been published in the Official Gazette of the Republic of Mozambique?

WHEREAS:

1. Exclusive breastfeeding for the first six months of life and gradual introduction of appropriate locally available foods from that age on, while continuing to breastfeed up to 24 months or more, are two essential steps to prevent malnutrition among children, to raise their ability to resist infections and to reduce morbidity and mortality caused by diarrheal diseases.
2. Protecting the health and nutrition of children during the first three years of life is of crucial importance for their future health and development.
3. Breastmilk substitutes should only be used in very special circumstances and be prescribed by qualified health workers.
4. Unfortunately, in many countries, particularly in Africa and other developing regions, aggressive marketing sometimes using misleading advertising, by companies that manufacture and market breastmilk substitutes, has led many mothers to abandon the age-old healthy African tradition of breastfeeding and prompted them to go for early and inappropriate weaning.
5. The World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) for almost three decades have insistently recommended to Member States that they should strongly promote breastfeeding and disseminate its virtues and that they adopt national codes of marketing of breastmilk substitutes that regulate the marketing of this type of products and impose strict standards, so as to shield their populations from such marketing and advertising practices that are so harmful to public health.
6. In 1978 and 1980 the World Health Assembly adopted resolutions urging Member States to "regulate the inappropriate sale and marketing of infant foods that could be used to replace breastmilk." Under the joint leadership of those two organisations, an International Code of Marketing of Breastmilk Substitutes was drafted and was adopted by the 34th World Health Assembly (Resolution WHA34.22 of 21 May 1981). Since that historic resolution, the World Health Assembly has regularly approved new resolutions to continue persuading Member States to intensify their efforts to promote breastfeeding and to integrate into their internal legislation the concepts of the International Code. In 1997 the International Code Documentation Centre (ICDC) prepared a "Model Code" to facilitate the task of countries of incorporating the International Code in their respective legislation.
7. Mozambique has systematically voted in favour of all those resolutions and supported all international initiatives in this field, without, however, having adopted a national code until this time. Indeed, during the first twelve years of independence, our centrally planned economy protected the country from potentially harmful advertising and marketing practices. The switch in political and economic orientation towards an open market economy has gradually exposed Mozambican mothers to those marketing practices and put our children at risk.
8. The government is making a concerted effort to improve public health in general and in particular that of Mozambican children, and therefore adopting a national code on marketing of breastmilk substitutes has become urgent.

Code of Marketing of Breastmilk Substitutes

CHAPTER I

Objectives, Scope and Definitions

ARTICLE 1

Objectives

The objectives of this Code are:

1. To contribute to the safe and appropriate nutrition of infants, safeguarding them from the risks of not being breastfed or from early inappropriate weaning, by protecting and effectively promoting the healthy age-old African tradition of breastfeeding, and ensuring the correct and appropriate use of breastmilk substitutes on the basis of scientifically adequate information, only and exclusively when they are needed.
2. To control and regulate the marketing, distribution, advertising and sale of breastmilk substitutes and complements, as well as artefacts used for the feeding of such substitutes and complements.

ARTICLE 2

Scope

This Code shall apply to the marketing and related practices of the following products, whether imported or manufactured in the country:

1. **Infant formula** and other milk-based and non-milk-based products, whether liquid, semi-liquid, in powder or other form, pasteurized, sterilized, natural or modified, when marketed or otherwise presented as suitable to be used as a partial or total replacement of breastmilk.
2. **Follow-up formulas** and other complementary foods used for weaning, such as purees, soups, fruits, deserts, milks, milk-derivatives and other drinks, milk-based or not.
3. **Feeding bottles** and closed cups with pout or straw sold or presented for use as recipients to feed liquid or semi-liquid products listed above.
4. **Teats and dummies.**
5. Products that must not be used to feed infants (condensed milk, skimmed or partially skimmed milk, full milk), even when modified for that purpose.
6. Any other products, which the Minister of Health may designate by ministerial decision.

ARTICLE 3

Definitions

For purposes of this decree only, the following definitions shall apply: [listed in the original Portuguese language order]

1. **Marketing agent:** Any person whose functions include participating in any stage of marketing of a product under the scope of this Code.
2. **Complementary food:** Any ready-to-use manufactured food or a homemade preparation suitable or presented as suitable to complement breastmilk or infant formula or follow-up formula when any of these are insufficient to satisfy the nutritional needs of infants. Such food is also called “weaning food” or “breastmilk supplement”.
3. **Free sample:** A unit or small quantity of a product provided free of charge.
4. **Feeding bottle:** A container used to feed infants or other children water, milk and other liquid or semi-liquid products used as infant formula, follow-up formula and/or as complementary food. A teat to allow the child to suck tops a feeding bottle.
5. **Dummy:** An object made of a malleable material, usually plastic, that imitates the shape of a teat, to allow children to suck between meals. A dummy usually has a ring that serves to hold it without touching the part that the child sucks.
6. **Marketing:** A set of activities aimed at the promotion, distribution, sale, propaganda or advertising of products under the scope of this Code, including public relations and information services.
7. **Distributor:** An individual, company or other private or public entity directly or indirectly involved in the wholesale or retail marketing of a product under the scope of this Code.
8. **Donation:** Free gift of a product in quantities above those qualified as “sample”.
9. **Packaging:** See “Container”.
10. **Manufacturer:** An individual, company or other private or public entity involved in the manufacture of a product or of products under the scope of this Code, whether directly or through an agent or a person under his control or under contract.
11. **Infant formula:** A milk, milk derivative or a product or mixture of products of animal or plant origin, that is formulated according to the applicable Mozambican Standards or, in their absence, the applicable Codex Alimentarius Standards, that claims to satisfy the nutritional needs of infants from birth up to 6 months of age, as a replacement of breastmilk. Infant formula can also be prepared at home, in which case it is called “homemade preparation”.
12. **Follow-up formula:** A milk, milk derivative or a product or mixture of products of animal or plant origin, that is formulated according to the applicable Mozambican Standards or, in their absence, the applicable Codex Alimentarius Standards, marketed or otherwise presented as suitable to feed infants or children up to three

years old (weaning food). Follow-up formula can also be prepared at home, in which case it is called “homemade preparation”.

13. **Infant:** A child up to the age of one year.
14. **Standard:** A document prepared by consensus and approved by a recognized body that provides rules, guidelines or specifications for common and repeated use, for activities or their results, guaranteeing an optimum level of organisation within a given context.
15. **Mozambican Standard:** A document prepared by consensus and approved by the National Institute for Standardisation and Quality (INNOQ) of the Republic of Mozambique, that provides rules, guidelines or specifications for common and repeated use, for activities or their results, guaranteeing an optimum level of organisation within a given context.
16. **Marketing staff:** Any professional whose functions involve the marketing of products within the scope of this Code (sales person, promoter, demonstrator, sales agent or representative).
17. **Health professional:** A health sector worker with basic, medium or higher technical training recognized by the Ministry of Health, who works in healthcare facilities of the National Healthcare System or in those of the private sector.
18. **Promotion:** The use of any method to encourage a person directly or indirectly to purchase or use a product or products within the scope of this Code.
19. **Advertising:** The presentation of products within the scope of this Code by any means with the purpose of promoting their sale or distribution, including but not limited to i) writing, television, radio, cinema, video, electronic or telephone transmission; ii) exhibition of posters, hoardings, billboards or announcements; iii) exhibition of paintings or models; iv) direct or indirect contact with health professionals, mothers, pregnant women and their families and with the general public; or, v) samples, gifts, presents, donations or special price sales.
20. **Container or packaging:** Any kind of packaging of a product within the scope of this Code as a normal retail unit of said product, including its wrapping.
21. **Label:** Any marker, sticker, figure, illustration or other graphic indication, written, printed, mimeographed, stamped or engraved on the container of a product under the scope of this Code or attached to it.
22. **Health care system:** The ensemble of health institutions, entities or services and health professionals, in the public and (for-profit or non-profit) private sector directly or indirectly involved in health care for the people.
23. **Breastmilk substitute:** Any food marketed or otherwise presented as a partial or total replacement of breastmilk, whether suitable for the purpose or not.
24. **Supplies:** Quantities of a product provided for use over an extended period of time, free of charge or at low price, for social purposes, including distribution to families in need, to cover requirements that their economic capacity cannot satisfy.
25. **Teat:** An artificial pout or other device, usually made of a soft material, for infants and other children to suck out the contents of a feeding bottle.

26. **Health worker:** Any person working in a unit of the National Healthcare System or belonging to the (for-profit or non-profit) private sector, whether a professional or not, including unpaid voluntary workers.
27. **Infant care unit:** Any nursery, crèche, Kindergarten, day-care centre or other institution that provides any type of care to children up to the age of three years.

CHAPTER II

Promotion and Advertising

Article 4

Commercial Promotion

1. Manufacturers and distributors, acting themselves or through another person, shall not promote or advertise any products within the scope of this Code at a point of sale, in any part of the healthcare system or any other place. The banned promotional practices include but are not limited to:
 - a. Advertising in any form;
 - b. Sales tactics such as special exhibits, discount coupons, prizes, discounts, special sales, sales baits, linked sales, gifts or presents;
 - c. Delivery or distribution to any person of one or more samples of a product within the scope of this Code;
 - d. Delivery or distribution of information or educational materials about feeding of infants or other children or [providing] education related to the feeding of infants or other children.
2. The provisions of subparagraph b) above shall not restrict the establishment of pricing policies and practices intended to provide products within the scope of this Code at lower prices on a long-term basis.
3. Marketing staff shall, furthermore, not have any direct or indirect contact in their professional capacity with pregnant women, mothers of infants and/or pre-school age children and, in particular, shall not give them any information, educational or other materials.
4. Manufacturers and distributors shall, however, be authorized to provide information on products within the scope of this Code to higher-level health professionals, provided such information is restricted to concrete scientific matters relating to technical aspects and methods of use of products under the scope of this Code and is in conformity with the provisions of Chapter VII of this Code.
5. Violations of the provisions of paragraphs 1 and 3 of this Article shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 5

Promotional Donations

1. Notwithstanding the provisions of Article 6 below, manufacturers and distributors acting on their own behalf or through another person shall not:
 - a. Donate to health workers or to any component of the healthcare system or provide to them at a price lower than the retail price, if it is known or, where such a retail price does not exist, at a price lower than 80% of the wholesale price, any quantity of a product under the scope of this Code.
 - b. Donate or distribute in any component of the healthcare system any equipment or devices or other materials (including but not limited to pens, calendars, posters, note blocks, growth charts, key holders, caps, T-shirts, pins, stickers and toys) that refer to the use of products under the scope of this Code or that could promote their use.
 - d. Offer or give any present, benefit or contribution to health workers or their associations, including but not limited to fellowships, subsidies for research or meetings, seminars, ongoing education courses or conferences.
 - e. Sponsor events, competitions, telephone services for counselling or campaigns aimed at lactating women, parents of babies or children under 3 years of age or their families which, directly or indirectly, refer to fertility, pregnancy, birth, infant and young child feeding or to related matters.
 - f. Include the sales volume of products under the scope of this Code in the calculation of the main or accessory remuneration (bonus, subsidies, commissions) of their staff, or set sales quotas for products under the scope of this Code.
2. Violations of the provisions of the preceding paragraph shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.
3. Notwithstanding the provisions of paragraph 1 of this Article, the Minister of Health may exceptionally accept donations from manufacturers and distributors of products under the scope of this Code, which shall be distributed exclusively by health units of the National Healthcare Service.
4. Similarly, manufacturers and distributors of products under the scope of this Code, acting on their own behalf or through another person, may make donations or low-priced sales of their products to social institutions or organizations, such as childcare facilities, crèches and orphanages for their own exclusive use or for distribution controlled by them to families of infants who, on the basis of a prescription from a qualified health professional, may have justified reason to be fed with breastmilk substitutes. Such donations or low-priced sales do not, however, carry the prior authorization of the Minister of Health.
5. Violations of the provisions of the preceding paragraph shall be punishable by a fine equivalent to 5 minimum monthly salaries in case of a first violation, of 20 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 4 months in case of more than one relapse.

6. Products donated or sold at low price in accordance with paragraphs 3 and 4 above may bear the name or logo of the donating company, but not any inscription that might be contrary to the provisions of this Code.

ARTICLE 6

Donations for Research

1. Manufacturers and distributors of products under the scope of this Code may donate appropriate quantities of a product or products for the sole purpose of scientific research done in a health institution, provided the beneficiary institution requests such a donation in writing after having obtained the prior authorization from the Minister of Health.
2. The request for ministerial approval shall contain a detailed explanation of the purposes of the research and the reasons for the request of donation and shall be accompanied by the research protocol.

CHAPTER III

Labelling of products under the scope of this Code

ARTICLE 7

General requirements for containers and labels of all products under the scope of this Code

1. The messages on containers and/or labels of products under the scope of this Code shall be written in Portuguese language and shall be clear, easily readable and understandable, so that they leave no margin for doubt.
2. Violations of the provisions of the preceding paragraph shall be punishable by a fine equivalent to 5 minimum monthly salaries in case of a first violation, of 20 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 4 months in case of more than one relapse.
3. Containers and labels of products under the scope of this Code shall contain only the written or graphic information strictly necessary for the preparation and appropriate use of the product. The inclusion of photographs, pictures or other graphic representations of infants and/or children or any reference or suggestion that may, directly or indirectly discourage breastfeeding shall be strictly forbidden.
4. Violations of the provisions of the preceding paragraph shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration in case of more than one relapse.
5. Messages shall be printed or embossed on the container itself or on a label that cannot be easily removed from it.
6. Violations of the provisions of the preceding paragraph shall be punishable by a fine equivalent to 5 minimum monthly salaries in case of a first violation, of 20 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 4 months in case of more than one relapse.

ARTICLE 8

Compulsory content on containers and labels

1. Messages on containers and/or labels of products under the scope of this Code, with the exception of feeding bottles, teats and dummies, shall include the following items:

- a) Instructions for preparation and appropriate use [of the product] in easily understandable words and pictures;
- b) Age, in numbers, from which the use of the product is recommended;
- c) A warning about the health risks of incorrect preparation and of using the product before the recommended age;
- d) A list of ingredients, in decreasing order of their proportion in the product, by weight or volume, specifying the origin of milk products used;
- e) The chemical composition and nutritional analysis of the product;
- f) The net weight of product in the container;
- g) The storage conditions required before and after opening the container, taking into account the climate conditions;
- h) Batch number, date of manufacture and expiry date for consumption, taking into account climate and storage conditions;
- i) Name and address of the manufacturer or the local distributor; and
- j) Other requirements of standards or regulations that may be applicable.

2. Violations of the provisions of the preceding paragraph shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 9

Labelling of Infant Formulas

1. In addition to the items listed in paragraph 1 of the preceding article, containers and/or labels of infant formulas shall include, in a prominent space and in an easily visible and readable form, the following items:

- a) The words “IMPORTANT NOTICE” in capital letters, followed by *“Breastfeeding is the best. Breastmilk is the ideal food for healthy growth and development of infants and other children. It protects them from diarrhoea and other diseases.”* in letters of at least one third of the font size of the name of the product and not less than 2 mm in height.
- b) The word “WARNING” followed by *“Before deciding to supplement or to replace breastfeeding by this product, consult a health professional. It is important for the health of your baby that you carefully follow all the preparation instructions. If you*

use a feeding bottle, your baby may no longer want to suckle from the breast. It is safer to give foods to baby with a spoon.” in letters of at least one third of the font size of the name of the product and not less than 1.5 mm in height.

- c) A feeding chart in the preparation instructions and the following words: *“If formula is left in the feeding bottle, it must be discarded.”*
2. Containers and/or labels of infant formulas shall not include expressions such as “maternalized” or “humanized” or similar ones, or make any comparisons with breastmilk.
3. Violations of the provisions of paragraphs 1 and 2 of this article shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 10

Labelling of Follow-up Formulas

1. In addition to the items listed in paragraph 1 of Article 8, containers and/or labels of follow-up formulas and complementary foods shall include, in a prominent space and in an easily visible and readable form, the following items:
- a) An “IMPORTANT NOTICE” exactly the same and with the same text, same prominence and same font size as prescribed in subparagraph a) paragraph 1 of the preceding article.
- b) A “WARNING” with the same prominence and font size as that prescribed in subparagraph b) of paragraph 1 of the preceding article, with the following text: *“Before deciding to supplement or to replace breastfeeding by this product, consult a health professional. It is important for the health of your baby that you carefully follow all the preparation instructions. It is safer to give foods to baby with a spoon.”*
- c) A clear prominent statement that *“This product shall not be used to feed babies less than six months old”*.
- d) A feeding chart in the preparation instructions and the following words: *“If formula is left in the feeding bottle, it must be discarded.”*
2. Containers and/or labels of follow-up formulas shall not include expressions such as “maternalized” or “humanized” or similar ones, or make any comparisons with breastmilk.

3. Violations of the provisions of paragraphs 1 and 2 of this article shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 11

Labelling of condensed, skimmed, partially skimmed and whole milks

1. Labels of condensed or skimmed milks shall include, in a prominent space and in an easily visible and readable form, in letters of at least one third of the font size of the name of the product and not less than 2 mm high, a WARNING stating: *“This product must not be used to feed babies.”*
2. Indications on the labels of sweetened condensed milks to the effect that they can be modified to feed infants shall be expressly banned.
3. Containers and/or labels of partially skimmed and whole milks shall include, in a prominent space and in an easily visible and readable form, in letters of at least one third of the font size of the name of the product and not less than 2 mm high, a WARNING stating: *“This product must not be used as the only source of nutrition for children under 3 years.”*
4. Provided that they comply with the provisions of paragraphs 1 and 3 of this article, condensed, skimmed, partially skimmed and whole milks shall not be covered by the other provisions of this Code.
5. Violations of the provisions of paragraphs 1, 2 and 3 of this article shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 12

Labelling of products modified so as to be suitable to feed children less than 3 years old

1. Food products which do not meet all the requirements of an infant food, but which can be modified to do so, shall carry on the label or the container a WARNING stating, *“The unmodified product is not suitable for babies.”*
2. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 13

Labelling of feeding bottles and teats

1. In addition to complying with the provisions of Article 7, containers and/or labels of feeding bottles and teats shall include, in a prominent space and in an easily visible and readable form, the following items:
 - a) An “IMPORTANT NOTICE” exactly the same and with the same text, same prominence and same font size as prescribed in subparagraph a) paragraph 1 of Article 9.
 - b) A “WARNING” with the same prominence and font size as that prescribed in subparagraph b) of paragraph 1 of Article 9, with the following text: *“It is important for the health of your baby that you carefully follow all the preparation instructions. If you use a feeding bottle, your baby may no longer want to suckle from the breast. It is safer to give foods to baby with a spoon.”*
 - c) A “WARNING” with the same prominence and font size as that prescribed in subparagraph b) of paragraph 1 of Article 9, with the following text: *“Children must not be left alone to feed from a bottle for long periods.”*
 - d) Instructions for cleaning and sterilizing feeding bottles and teats, using words and drawings or other forms of graphic representation.
 - e) The name and address of the manufacturer or the local distributor and the place of production.
2. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 14

Labelling of dummies

1. In addition to complying with the provisions of Article 7, containers and/or labels of dummies shall include, in a prominent space and in an easily visible and readable form, the following items:
 - a) An “IMPORTANT NOTICE” exactly the same and with the same text, same prominence and same font size as prescribed in subparagraph a) paragraph 1 of Article 9, with the following text: *“The use of dummies can interfere with breastfeeding.”*
 - b) Instructions for cleaning and sterilizing feeding bottles and teats, using words and drawings or other forms of graphic representation.
 - c) The name and address of the manufacturer or the local distributor and the place of production.
3. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 5 minimum monthly salaries in case of a first

violation, of 20 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 4 months, in case of more than one relapse.

CHAPTER IV

Storage and sale of products under the scope of this Code

ARTICLE 15

Storage conditions

1. Storage of products under the scope of this Code shall abide by the rules and conditions established or to be established for each type of these products.
2. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 16

Conditions of sale

1. The sale, exhibition for sale, storage and any other form of marketing of products under the scope of this Code shall be allowed only to manufacturers and distributors registered [with the appropriate authority] according to the terms of Chapter VIII of this Code.
2. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 17

Sales of expired products

1. Products under the scope of this Code, with the exception of feeding bottles, teats and dummies that are exhibited for sale shall have a clear indication of their consumption expiry date.
2. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.
3. The sale or exhibition for sale of products under the scope of this Code for which the expiry date has passed shall be strictly banned.

4. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

CHAPTER V

Technical standards for products under the scope of this Code

ARTICLE 18

Conformity with national and international standards

1. The quality of food products is crucial for the health of infants and other children. Products under the scope of this Code shall comply with the applicable Mozambican standards or, in their absence, with those of the Codex Alimentarius and other pertinent international organizations.
2. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.
3. The National Institute for Standardization and Quality (INNOQ) shall identify the international standards applicable to products under the scope of this Code, as well as the appropriate testing methods to verify their conformity, within a period of 12 months after the publication of this Code in the Official Gazette of the Republic of Mozambique.
4. The National Institute for Standardization and Quality (INNOQ) shall prepare and approve national standards for the products under the scope of this Code, within a period of 24 months after the publication of this Code in the Official Gazette of the Republic of Mozambique.
5. The National Institute for Standardization and Quality (INNOQ) shall develop a system for assessing the conformity of products under the scope of this Code.

ARTICLE 19

Sale of intact containers only, to avoid product deterioration

1. To avoid quality deterioration, adulteration or contamination, the sale or exhibition for sale of a product under the scope of this Code in [quantities or] dosages different from those of the original container that indicate that the container was opened or fragmented, as well as the distribution of products in cups, spoons, boxes or other recipients that are not the original container, shall be strictly forbidden.
2. Violations of the provisions of the foregoing paragraph of this article shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of

activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

CHAPTER VI

Duties of health workers

ARTICLE 20

Special responsibilities of leaders

1. The leaders of the health sector at central, provincial and district level shall use all means to promote the implementation of this Code and take measures to encourage, support, promote, value and protect breastfeeding and shall provide information and advice to other health workers about their duties and responsibilities and, especially, ensure that they are familiar with this Code, in particular with the provisions of Chapters VI and VII.
2. Leaders of the health sector shall furthermore ensure that health workers who are their subordinates assume their responsibilities and fulfil their duties.
3. The non-fulfilment of the provisions of the two preceding paragraphs shall incur disciplinary sanctions.

ARTICLE 21

Promotion of breastfeeding

1. All health workers shall encourage, support, promote, value and protect breastfeeding and disseminate its advantages and superiority over artificial feeding. They shall furthermore be bound to know this Code and in particular the provisions of Chapters VI and VII.
2. Health professionals especially shall act to eliminate any practices that directly or indirectly interfere with the initiation and continuation of breastfeeding.
3. The non-fulfilment of the provisions of the two preceding paragraphs shall incur disciplinary sanctions.

ARTICLE 22

Banned practices

1. Health workers and their trade unions or associations shall be expressly banned from:
 - a) Accepting any sample, gift, contribution or benefit, financial or other, whatever its value, from manufacturers and distributors of products under the scope of this Code or from any person acting on their behalf;
 - b) Accepting or offering samples of products under the scope of this Code to pregnant women, lactating women, mothers of infants or children of pre-school age, to members of their families or to any other person;

- c) Demonstrate the use of infant formulas or follow-up formulas, except to mothers or family members of children with very special needs for whom such products have been prescribed by a qualified health professional. In such cases, the health professional shall also provide a very clear explanation of the risks of using infant formulas or follow-up formulas, as well as such other information as prescribed by this Code.
2. Violations of the provisions of the preceding paragraph shall incur disciplinary sanctions (which may range from a registered reprimand to expulsion) for the health worker or health workers and for the trade unions or associations responsible for such violations. Such violations shall also carry sanctions for the manufacturers, distributors or other persons acting for them that may have instigated a health worker to commit such a violation. In such cases a violation shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 23

Obligation to communicate

1. Health workers and trade unions or associations of health workers who are the target of attempts by manufacturers or distributors of products under the scope of this Code, or any person acting on their behalf, to provide, in violation of the provisions of the preceding article, samples, donations, gifts, contributions or benefits, financial or other, or to make demonstrations of the use of products under the scope of this Code, or to commit any other violation of the provisions of this Code, shall be obliged to report such incidents, in writing, to their hierarchic superiors who shall take the appropriate measures and, in turn, shall pass such information on to the National Advisory Board established under Chapter IX of this Code.
2. Failure to communicate such attempts of violation referred to in the preceding paragraph shall incur disciplinary sanctions (which may range from a registered reprimand to expulsion) for the health worker or health workers and for the trade unions or associations responsible for such failures.
3. Manufacturers and distributors or other persons acting on their behalf responsible for violations that have been reported shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 24

Prior approval of donations and benefits for health professionals and their trade unions or associations

1. Any contribution from manufacturers or distributors of products under the scope of this Code or from any person acting on their behalf for health professionals or their trade unions or associations, such as travel or study fellowships, grants for scientific research or for participation at scientific and/or professional conferences, shall be channelled through the Ministry of Health and does not have prior approval of the Minister of Health.
2. Violations of the provisions of the preceding paragraph shall incur disciplinary sanctions (which may range from a registered reprimand to expulsion) for the health worker or health workers and for the trade unions or associations responsible for such violations. Such violations shall also carry sanctions for the manufacturers, distributors or other persons acting for them that have made such illicit donations. In such cases a violation shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

CHAPTER VII

Information and education

ARTICLE 25

Information and education of mothers and the general public

1. The Ministry of Health shall have the duty and responsibility of promoting breastfeeding and formulating policies and strategies on infant feeding that are consistent with the objectives and content of this Code. It shall ensure that families and the community at large have access to objective and consistent information on appropriate methods of feeding infants and children less than 3 years. Such information shall be disseminated not only by the central bodies of the Ministry of Health but also by the provincial and district health divisions who shall be responsible for their generalized circulation, possibly in cooperation with NGOs and other recognized institutions.
2. Information and educational materials on infant feeding, whether written or audio visual, intended for the general public and especially pregnant women and mothers of infants and children under 3 years shall be written in Portuguese language or in local Mozambican languages and shall be clear, easily readable and understandable, so as not to leave margin for any doubts.
3. Information and educational materials shall contain correct and up-to-date information and shall not contain photographs, pictures or other forms of graphic representations of infants and/or children, or any reference or suggestion that might, directly or indirectly, discourage breastfeeding. Such materials shall never give the

impression or lead to believe that any of the products under the scope of this Code is equivalent or comparable to breastmilk and, even less, that it could be superior.

4. Information and educational materials shall not contain the name or brand of any product under the scope of this Code or of a manufacturer or distributor of any product under the scope of this Code.
5. Information and educational materials shall contain clear information on the following items:
 - a) The enormous benefits, advantages and superiority of breastfeeding;
 - b) The value of exclusive breastfeeding for the first six months and of continuing breastfeeding up to two years or more;
 - c) How to initiate and to maintain exclusive breastfeeding and ensure its continuation;
 - d) The difficulty of going back to breastfeeding after a short period of bottle feeding or even just interruption of breastfeeding, even if for a short time only;
 - e) The importance of introducing complementary foods from the age of six months approximately;
 - f) How and why the introduction of bottle feeding or the early introduction of complementary foods jeopardizes breastfeeding;
 - g) That complementary food can easily be prepared at home using local ingredients.
6. Health professionals who are held responsible for non-compliance with the provisions above shall incur disciplinary sanctions.

ARTICLE 26

Information and education on infant formulas and follow-up formulas

1. When materials referred to in the preceding article contain information about the use of infant or follow-up formulas or about any other food or liquid that could be fed with a feeding bottle, it shall also include the following items:
 - a. Instructions for the correct preparation and use of the product, including cleaning and sterilizing utensils used;
 - b. Instructions on how to feed infants with a spoon;
 - c. The health risks of bottle feeding and of inappropriate preparation of the product;
 - d. The approximate financial cost of feeding an infant with the product in the recommended quantities.
2. Health professionals who are held responsible for non-compliance with the provisions above shall incur disciplinary sanctions.

ARTICLE 27

Information and education of health professionals

1. The Ministry of Health shall have the obligation to provide health professionals with training, information and the appropriate technical guidance on the products under the scope of this Code and to disseminate specific guidelines to ensure compliance with the provisions of this Code by all health workers.
2. Manufacturers and distributors of products under the scope of this Code may provide technical and scientific information about their products to leaders of the health sector at central level and to higher-level health professionals, and only to them, provided such information is restricted to concrete technical and scientific aspects and to the methods of using said products and makes no reference to equivalence or superiority of artificial feeding or the use of bottle feeding in relation to breastfeeding.
3. The information referred to in the preceding paragraph shall not be accompanied by the provision of samples or other materials (including but not limited to pens, calendars, posters, note blocks, growth charts, key holders, caps, T-shirts, pins, stickers or toys).
4. Such information shall furthermore not be provided with any kind of financial or material inducement, or any nature.
5. Violations of any of the provisions of paragraphs 2, 3 and 4 of this article shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 28

Approval of information and educational materials by the Advisory Board

1. All the information and educational materials referred to in the two preceding articles shall be submitted for approval by the National Advisory Board for the Promotion and Protection of Breastfeeding established under Chapter IX, before being distributed.
2. Health professionals who are held responsible for non-compliance with the provisions above shall incur disciplinary sanctions.

CHAPTER VIII

Use of facilities of the National Health Care System

ARTICLE 29

Prohibition to use the National Health Care System for purposes contrary to this Code

1. The use of the National Health Care System and of institutions for the exhibition or exposition of products under the scope of this Code or for affixing or leaving posters or advertising materials of such products or for the distribution of materials provided by manufacturers shall be banned.
2. Violations of the provisions of the preceding paragraph shall incur disciplinary sanctions (which may range from a registered reprimand to expulsion) for the health worker or health workers responsible for such violations. Such violations shall also carry sanctions for the manufacturers, distributors or other persons acting for them that have instigated health workers to commit such violations. In such cases violations shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.

ARTICLE 30

Responsibility for demonstrations within the facilities of the National Health Care Service

1. In cases where there is a justified [technical] reason for the use of breastmilk substitutes, demonstrations of the preparation and use of these products in front of mothers or other members of the families of children who need such products shall be done exclusively by health professionals and never by any person directly or indirectly connected to manufacturers and distributors of said products.
2. Violations of the provisions of the preceding paragraph shall lead to punishment of the marketing agents and the manufacturers and/or distributors on whose orders they have acted. Such violations shall be punishable by a fine equivalent to 15 minimum monthly salaries in case of a first violation, of 40 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.
3. Such violations shall also incur a disciplinary sanction (which may range from a registered reprimand to expulsion) for the health worker or health workers and those responsible for the health care unit who may have permitted such a violation to occur.

CHAPTER IX

Implementation and management

ARTICLE 31

Responsibility for implementation and compliance with this Code

1. The Ministry of Health is the main agency responsible for the implementation of this Code and for ensuring compliance with its provisions and shall count on the collaboration of the Ministry of Industry and Trade in all aspects related to issues of marketing. Whenever necessary, the Ministry of Health shall request the cooperation of other parts of the State apparatus to ensure implementation of and compliance with this Code.
2. It shall be the responsibility of the Ministry of Health, in collaboration with the Ministry of Trade and Industry where necessary, to regulate implementation of this Code by ministerial decrees.

ARTICLE 32

National Advisory Board for the Promotion and Protection of Breastfeeding

1. The National Advisory Board for the Promotion and Protection of Breastfeeding shall hereby be established.
2. The National Advisory Board for the Promotion and Protection of Breastfeeding shall be chaired by the Minister of Health and have as Vice Chairman the Deputy Minister of Health. In the absence of the Chairman the Vice Chairman shall chair the National Advisory Board for the Promotion and Protection of Breastfeeding.
3. In addition to the Chairman and Vice Chairman, the National Advisory Board for the Promotion and Protection of Breastfeeding shall have as members the following by virtue of the functions:
 - a. the Deputy Minister for Industry and Trade
 - b. the National Director of Health
 - c. the National Director of Trade
 - d. the Director of the National Institute for Standardization and Quality (INNOQ)
 - e. the Assistant National Director of Health, in charge of the Community Health Area, who shall be the Secretary of the Board
 - f. the National Director for Women's Affairs
 - g. the National Director for Social Action
 - h. the Director of the National Institute for Educational Development
 - i. the Chairman of the National Council for Social Communication
 - j. the Director of the Office of Information under the Prime Minister's Office
 - k. the Head of the Nutrition Division of the Ministry of Health, who shall assist the Secretary of the Board

- l. the Head of the Infant Health Division of the Ministry of Health
 - m. the Head of the Education for Public Health Department of the Ministry of Health.
4. In addition to the members by virtue of their functions, the Minister of Health shall appoint ten more members, specifically paediatricians, nutritionists, leaders or higher staff of NGOs and cooperation agencies that have a particular interest in breastfeeding, leaders of professional associations of health workers, journalists and other experts in communication sciences, who shall serve in their personal capacity. The Minister for Industry and Trade, in turn, shall appoint three other members and the Minister for Planning and Finance another two members, who shall also serve in their personal capacity.
5. The appointments listed in the preceding paragraph shall be for a term of three years that can be renewed. Such appointments shall be made by ministerial order published in the Official Gazette of the Republic of Mozambique, within 90 days of the date of publication of this Code in the Official Gazette.
6. The Minister of Health and the Deputy Minister for Industry and Trade may invite national or foreign experts to participate as observers in meetings of the National Advisory Board for the Promotion and Protection of Breastfeeding.

ARTICLE 33

Conflict of interests

1. Membership in the National Advisory Board for the Promotion and Protection of Breastfeeding is incompatible with the holding of financial or other interests, whether directly or indirectly, in the manufacture or distribution of any of the products under the scope of this Code.
2. Therefore, any member of the National Advisory Board for the Promotion and Protection of Breastfeeding, whether member by virtue of functions or serving in a personal capacity, who holds financial or other interests, directly or indirectly, in the manufacture or distribution of any of the products under the scope of this Code shall immediately declare this, so that s/he may be replaced in such a function.
3. Violations of the above two paragraphs shall be deemed corruption and punished by law.

Article 34

Attributions of the National Advisory Board for the Promotion and Protection of Breastfeeding

The National Advisory Board for the Promotion and Protection of Breastfeeding shall:

- a) Advise the Government in general and the Ministers of Health and of Industry and Trade in particular on the national policy for the promotion and protection of breastfeeding;

- b) Advise the Ministers of Health and of Industry and Trade on the implementation of this Code, specifically regarding:
- The definition of the national strategy to develop communication and education programmes to promote breastfeeding;
 - The preparation of information and educational materials and guidelines and recommendations on feeding of infants and young children under 3 years;
 - The planning of ongoing training programmes for health professionals;
 - The approval of training curricula for health professionals in matters covered by this Code;
 - The dissemination of this Code and promotion [of its objectives] through various means;
 - Any other matter related to this Code.
- c) Examine the information and educational materials submitted to it in accordance with Article 27 and recommend appropriate action, including disciplinary measures, when justified;
- d) Elicit information about possible violations of this Code and examine such information and reports, and take the necessary measures, including recommending applicable sanctions if appropriate;
- e) Issue instructions to inspectors on the actions to be taken, or initiate such actions, depending on the case, against any person who violates or attempts to violate the provisions of this Code or any regulations issued in pursuance of it;
- f) Establish provincial committees and expert committees to carry out functions of this Board, and designate experts to carry out studies on issues resulting from the implementation of this Code;
- g) Give opinions on any matters that may be submitted to it, within the framework of the objectives of this Code, by the Minister of Health and the Minister of Industry and Trade.

ARTICLE 35

Start of operations of the National Advisory Board for the Promotion and Protection of Breastfeeding

The National Advisory Board for the Promotion and Protection of Breastfeeding shall start operations as soon as its members in their personal capacity have taken up their positions, which shall occur not later than 150 days after the publication of this Code in the Official Gazette of the Republic of Mozambique. The start of operations of the National Advisory Board for the Promotion and Protection of Breastfeeding even before most of the provisions of the Code have entered into force is very important to advise the Minister of Health and the Minister of Industry and Trade on measures to be taken in preparation for the entry into force of all of the provisions of the Code.

ARTICLE 36

Registration of products under the scope of this Code

1. Manufacturers and distributors or other agents who intent to be involved in the sale, exhibition for sale, storage and any other form of marketing of products under the scope of this Code shall register with the Ministry of Health which for the purpose shall establish a registry of manufacturers and distributors and issue certificates of registration to approved manufacturers and distributors.
2. Manufacturers and distributors or their agents shall furthermore submit to the Ministry of Health for prior registration each one of the products that they intend to market and, for this purpose, present complete documentation on said products, the manufacturing process, packaging, containers, labelling and, where applicable, provide samples of products for laboratory analysis, so as to ascertain that the marketing of such products shall proceed according to the provisions of this Code and to existing standards. The Ministry of Health shall establish its own mechanism to register products under the scope of this Code and shall issue certificates of registration to products that comply with the requirements of this Code.
3. After the entry into force of this Code in its entirety, the importation or national manufacture of products under the scope of this Code that have not been registered in accordance with the preceding paragraph shall not be permitted.
4. Violations of the provisions of the preceding paragraphs of this article shall be punishable by a fine equivalent to 10 minimum monthly salaries in case of a first violation, of 30 minimum monthly salaries in case of relapse and by suspension of activities for 1 to 3 months or even cancellation of the product registration, in case of more than one relapse.
5. It shall be the responsibility of the Ministry of Industry and Trade and of the National Customs Department to promote and control implementation of the provisions of paragraph 3 of this article.

ARTICLE 37

Inspection and inspectors

1. The Ministers of Health and of Industry and Trade shall determine, by joint ministerial decree, who shall be competent to carry out inspections, who shall apply fines and who shall decide on suspension of activities or on cancellation of a registration.
2. The conflict of interest provisions referred to in Article 33 of this Code shall equally apply to officials who are appointed as inspectors or who are competent to exercise the functions of inspectors. Therefore, if any such official holds financial or other interests directly or indirectly in the manufacture or distribution of any of the products under the scope of this Code, s/he shall proceed as prescribed in paragraph 2 of said article.
3. The Ministers of Health and of Industry and Trade shall determine, by joint ministerial decree, the procedures to be followed for inspections (to ascertain compliance with the regulations) and for the application of sanctions.

ARTICLE 38

Register of sanctions

The Minister of Health shall establish a system of registry of sanctions applied which shall contain the names and titles of violators (individuals and juridical persons), the nature of each violation, the mitigating or aggravating circumstances of any violations, in particular whether it is a first violation or a relapse, the sanctions applied and any other elements deemed appropriate.

[T.N. The date that appeared on the draft - Maputo, 25 May 2005 – has been removed but there is no indication at the end of this Code that it was decreed, by whom, in what form and when.]

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