

THE MARKETING OF BREAST MILK SUBSTITUTES
(Decree of the Minister of Health no. 237/MENKES/SK/IV/1997
dated April 10, 1997)

Considering :

- a. that breast milk is the best and most suitable food for the healthy growth and development of infants and children, its use must therefore be protected and promoted;
- b. that the provision of breast milk exclusively to infants up to the age of 4 months, which shall be continued until the age of 2 years with the provision of food additional to breast milk, must be conducted well and correctly, in an effort to promote the quality of the Indonesian people;
- c. that the use of breast milk substitutes which are considerably produced, promoted and distributed must be conducted well and correctly as its incorrect use shall do harm to health;
- d. that the regulation of breast milk substitute stipulated in Decree of the Minister of Health No. 240/MNEKES/PER/V/1985 needs to be adjusted to the development and policies in the framework of promoting the use of breast milk;
- e. that in connection with letters a, b, c, and d above, a regulation on the marketing of breast milk substitutes needs to be stipulated;

In view of :

1. Law No. 23/1992 on health affairs (Statute Book No. 100/1992, Supplement to Statute Book No. 3495);
2. Government Regulation No. 32/1996 on health personnel (Statue Book No. 49/1996, Supplement to Statute Book No. 3637);

D E C I D E S

To stipulate : **THE DECREE OF THE MINISTER OF HEALTH ON THE MARKETING OF BREAST MILK SUBSTITUTES**

CHAPTER I
GENERAL PROVISIONS
Article 1

Referred to in this decree as :

- a. A breast milk substitute shall be a food product which is marketed or which is stated in another way as food for infants and shall be used as breast milk substitute, either wholly or in part.

- b. Food additional to breast milk shall be a food product which is marketed or which is stated in another way as food for infants aged over 4 months to fulfil their nutritional needs in addition to breast milk.
- c. Infant formula milk shall be a food product the formula of which is intended to fulfil and infant's need for nutrition from its birth up to the time when it is aged between 4 and 6 months in accordance with its physical characteristics.
- d. Follow-up/on formula milk shall be a food product of which the formula is intended for infants after the age of 6 months.
- e. A baby shall be a child aged between 0 and 12 months.
- f. A bottle shall be a special container with which breast milk substitute is given to an infant.
- g. A nipple shall be the cover part of a milk bottle made of rubber or another suitable substance, which shall function as a complement to a milk bottle.
- h. Marketing shall be the promotion, distribution, sales and advertising of a product.
- i. Promotion shall be all kinds of activities in an effort to introduce and sell a products.

Article 2

Marketed breast milk substitutes shall encompass :

- 1. a. Infant formula milk
 - b. Follow-up/on formula milk
 - c. Food additional to breast milk provided in a bottle with a nipple
2. The instruments for the use of breast milk substitute shall be a bottle and a nipple.

CHAPTER II DISTRIBUTION

Article 3

- (1) Breast milk substitutes may be distributed after a registration approval has been obtained from the Director General of Food and Drug Control.
- (2) The registration approval as meant in sub-article (1) shall also apply to foreign products.

Article 4

- (1) Breast milk substitutes must fulfill their quality requirements.

- (2) The bottle and the nipple used for the provision of breast milk substitute must fulfill the quality requirement.

Article 5

The quality requirements as meant in Article 4 sub-articles (1) and (2) shall be set pursuant to the prevailing laws.

CHAPTER III

LABEL

Article 6

The label on a breast milk substitute must comply with the stipulation on labelling pursuant to the prevailing laws.

Article 7

The label on infant formula milk must mention :

- a. The name of the product : "infant milk", infant formula milk", or "infant formula".
- b. A statement mentioning the superiority of breast milk and stating that infant formula milk shall be used only on the advice of health personnel.
- c. A direction about how to prepare and use it.
- d. A statement that if infant formula milk is not used in accordance with the direction it will do harm to the health of the infant.
- e. Expiry date.
- f. Direction about how to store and how to store after the container is opened.
- g. Nutritional content.
- h. An explanation of the signs indicating when infant formula milk is no longer good and cannot be given to infants.
- i. Imprinted clear name and address of the importer.
- j. The protein sources used in a descending order weight, placed close to the name of the product.
- k. Special requirements for products for infants needing special nutritional requirements.
- l. Information that an infant aged 6 months must be given food additional to breast milk.

- m. Inscription reading "with iron substance" for products containing an iron substance of not less than 1 mg of iron (Fe) per 100 calories.
- n. Other information which may be mentioned on each kind stipulated on the standard.

Article 8

The label on further formula must mention :

- a. The name "follow-up formula milk", "follow-up formula" or "follow-on formula".
- b. The sources of protein used in a descending order of weights, placed close to the name of the product.
- c. Inscription reading "with milk as the basic material" shall be used only if 90% of the protein comes from milk.
- d. Inscription reading "not suitable for infants aged less than 6 months".
- e. A statement that infants and children given follow-up/on formula milk shall also be given food additional to breast milk.
- f. Direction about its preparation and use.
- g. The expiry date.
- h. Direction about storage and storage after the container is opened.
- i. Nutritional content.
- j. An explanation of the signs indicating that the follow-up/on formula milk is no longer good and shall not be given to infants.
- k. Imprinted clear name and address of the importer.
- l. Other information which may be mentioned on each kind stipulated on the standard.

Article 9

The label on the food additional to breast milk must mention :

- a. The name of the product
- b. Nutritional content
- c. Direction of its preparation, use and handling.
- d. The expiry date.
- e. Direction of storage and storage after the container is opened.
- f. An explanation of the signs indicating that the said product is no longer good and shall not be given to infants.

- g. Imprinted clear name and address of the importer.
- h. Direction that dilution must be done with milk or infant formula milk if the product contains less than 15% of protein and less than 75% of caseine.
- i. Direction that dilution can be done with water or milk or infant formula milk if the product contains over than 15% of protein.
- j. Direction that the product is used for infants aged over 4 months.

Article 10

- (1) An advertisement on follow-up/on formula milk must mention the superiority of breast milk and an inscription reading "not suitable for infants aged less than 6 months".
- (2) An advertisement on food additional to breast milk must that the product is given only to infants aged over 4 months.

CHAPTER IV PROHIBITION Article 11

- (1) It is prohibited to import and distribute breast milk substitutes, bottles and nipples which are not registered with the Directorate General of Food and Drug Control.
- (2) It is prohibited to mention on the label of infant formula milk and follow-up/on formula milk :
 - a. The picture of an infant
 - b. The picture or inscription stating that the product can be used as breast milk substitute.
 - c. An inscription of "of the same quality as that of breast milk" or other inscription of the same meaning.
 - d. The picture of a bottle and a nipple
 - e. A sentence or a picture or another thing which discourages a mother from breastfeeding.
- (3) It is prohibited to advertise infant formula milk other than in the medical science media already approved by the Minister.
- (4) It is prohibited to advertise follow-up/on infant milk using a trade mark with the characteristics resembling the trade mark of infant formula milk, other than in the medical science media already approved by the Minister.

CHAPTER V INFORMATION AND EDUCATION Article 12

- (1) Information and education about infant formula milk and follow-up/on infant milk provided to medical personnel must be scientific and objective.

- (2) Equipment to provide information can bear the company's name and logo but not trade name.
- (3) The information and education material shall give priority to the benefits of mother's milk and the method of the good and correct breast feeding / lactation management as well as disadvantages to mothers and infants in case no breast feeding is made.

CHAPTER VII
PROMOTION
Article 13

- (1) Health service facilities shall be prohibited for the promotion of infant and follow up formula milk promotion.
- (2) Health service facilities shall be prohibited to provide services in the health area with funds made available by a business company in exchange for the promotion of infant formula milk and follow-up/on formula milk.
- (3) Health service facilities shall be prohibited to receive samples or donation in the form of infant formula milk and follow-up/on formula milk for routine or research purposes.

The sample or donation can be given only in an emergency with the approval of the head of a local regional office of the Ministry of Health.

- (4) Health service facilities and medical personnel shall be prohibited to request for or receive from a business company anything which may open up and opportunity for promotion of infant formula milk and follow-up/on formula milk.

CHAPTER VII
MARKETING
Article 14

- (1) A business company shall be prohibited to undertake the following activities :
 - a. Giving free samples or something in whatever form to health service facilities and pregnant women or delivering mothers, or
 - b. Selling, offering or door-to-door selling, or
 - c. Giving a discount or a bonus or something in whatever form for the purchase of breast milk substitute as an attraction from the seller, or
 - d. Using medical personnel to provide information about breast milk substitute to the community

- (2) Employees of a business company as meant in sub-article (1) shall be prohibited to put on dress or other identity to make them look like doctors, midwives, nurses or officers at health service facilities.

CHAPTER VIII
FOSTERING AND SUPERVISION
Article 15

Fostering of and supervision over the implementation of this decree shall be undertaken by the Director General of Food and Drug Control, the Director General of Community Health Development and the Director General of Medical Services in accordance with their respective tasks and functions.

Article 16

To implement on-the-field supervision over the enforcement of this stipulation, every supervising officer shall have to carry a letter of instruction from the government agencies as meant in Article 15.

Article 17

Supervision over the implementation of the marketing of breast milk substitutes shall be coordinated by the Director General of Food and Drug Control.

Article 18

The Director General of Food and Drug Control, the Director General of Community Health Development and the Director General of Medical Services shall separately or jointly stipulate directives for the enforcement of this decree.

CHAPTER IX
SANCTIONS
Article 19

Violation against the provisions in this decree shall be subject to administrative sanctions from oral warning up to license revocation pursuant to the prevailing laws.

CHAPTER X
TRANSITIONAL PROVISION
Article 20

Stipulations for the enforcement of the Regulation of the Minister of Health No. 240/MENKES/PER/V/1985 on breast milk substitutes shall remain valid as long as these stipulations do not contradict the provisions stipulated in this decree or as long as they have not been revoked because of the new provisions.

CHAPTER XI
CLOSING
Article 21

With the enforcement of this Ministerial Decree, Regulation of the Minister of Health No. 240/MENKES/PER/V/1985 on breast milk substitutes shall be declared null and void.

Article 22

Companies already producing, importing and distributing breast milk substitutes at the time of the issuance of this decree shall be allowed 24 (twenty-four) months to fulfill these provisions.

Article 23

This decree shall take effect as from the date of stipulation.
For public cognizance, this decree shall be promulgated by publishing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta
On April 10, 1997
THE MINSITER OF HEALTH

Signed

Prof. Dr. Sujudi

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