

# **A bill on the regulations of the infant and baby food products marketing**

## **CHAPTER I THE GLOBAL PROVISIONS**

### Article 1

This decree is aimed to ensure the infants and babies an ideal diet for their growth and development by means of protecting the exclusive breastfeeding until the age of six months, then to encourage further breastfeeding up to the age of two years and over, and to introduce complementary foods from the age of six months.

### Article 2

This decree applies to the marketing of “target products” like preparations for infants which are also called infant formulas or industrial milk, series preparations which are also called 12 to 18 months infant formulas or series milk, other products which are marketed or presented as food or drinks for infants and/or babies. It also applies to the equipment that is used to prepare and administer them, to lollies and others as well as to the information and education related to infants’ and babies’ feeding.

### Article 3

For the purpose of this Decree, the following definitions are applied.

The words “**health officer**” are applied to anyone who works in a healthcare institution, as well as to students and trainers or any other person working there voluntarily and without reward.

The words “**authorised officer**” are applied to officials with the capacity of judiciary police officer and sworn-in officers of the fraud squad.

The words “**complementary food**” are applied to any food intended for the children aged six months up to twenty four months which is pre-packed, industrially manufactured and ready-made, or similarly presented, so that to complement mother’s milk, an infant preparation or series preparation.

The word “**marketing**” is applied to promoting, distributing, selling and advertising one of the target products that include public relations and information services.

The word “**distributor**” is applied to individual and legal entities who deal with marketing, wholesale or retailing, a target product.

The word “**sample**” is applied to unique specimens or a few quantities of a target product which are gratuitously provided.

The word “**packing**” is applied to the packaging of a target product intended for retail selling.

The words “**healthcare institution**” are applied to a public or private institution or organisation, or medical consulting offices, which directly or indirectly provide health cares. The words also include crèches, day-nurseries and other nursing institutions for infants or babies.

The word “**label**” is applied to any brand, sign that is figurative or descriptive, written, printed, stuck, graven, applied, marked, fixed or apparent in any form on the packing of a target product.

The word “**manufacturer**” is applied to any individual or legal entity who deals with manufacturing a target product, directly or through an agent or a person he controls or with whom he has entered into an agreement.

The word “**baby**” is applied to a child aged twelve up to full twenty four months.

The word “**logo**” is applied to the emblem, image or symbol to identify a manufacturer or a product.

The word “**brand**” is applied to a name given by the manufacturer to a product or a range of products.

The word “**infant**” is applied to a child aged zero up to full twelve months.

The words “**series preparation**” - also called series milk or 12 to 18 months infant milk - are applied to a milk product or a product that is similar to milk, of animal or vegetal origin, of industrial formula in compliance with the standard 156-1987 and any other standard of the “Codex Alimentarius” for series preparations, that is marketed or presented as ready-made for infants or babies of more than full six months.

The words “**infant preparation**” - also called infant milk - are applied to a milk product or a product that is similar to milk, of animal or vegetal origin, of industrial formula in compliance with the standard 72-1981 (amended 1983, 1985, 1987) and any other standard of the “Codex Alimentarius” for infant preparations, so that to meet by itself the infant’s nutritional needs from his birth and/or over his six first months, and include the products that keep meeting a part of the child’s feeding needs after his six first months.

The word “**prescribed**” or “**to be prescribed**” is applied to the provisions which are stipulated by the rules or written decisions to be adopted in pursuance of this Decree.

The words “**target product**” are applied to :

- a. infant preparations
- b. any other product that is marketed or presented as infant food up to the age of six months
- c. series preparations
- d. **complementary foods**
- e. feeding-bottles, teats, lollies
- f. and any other product the Minister in charge of Health declares, by proclaiming it in the Government Journal, as target product for the purpose of this Decree.

The words “**health professional**” are applied to a health officer who is holder of a professional diploma or an equivalence, such as practitioner doctors, nurses, midwives and medical assistants.

The word “**promotion**” is applied to any method for encouraging a person, directly or indirectly, to purchase a target product.

The word “**publicity**” means to encourage the purchase of a target product by means of the following, among others :

- a. publicity in the press and audio-visual aids : television, radio, cinema, internet, video, telephone
- b. publicity by means of bill-posters, advertisement boards and ads
- c. or publicity by means of pictures or models display.

The “**word**” lolly is applied to an artificial teat given to babies for sucking.

## CHAPTER II THE COMMERCIAL PROMOTION

### Article 4

The commercial promotion of a target product is prohibited. The proscribed promotion methods include the following, without being limited to :

1. publicity
2. sale techniques like price, presents, special displays, discount vouchers, free gifts, discounts, special sales, sales at a loss, coupled sales, and
3. providing anybody with a sample.

### Article 5

Unless in conformity with the Chapter IV of this Decree, it is prohibited :

1. to give or distribute information or education equipment on infant or baby feeding, or
2. to deal with educational activities in matters of infant or baby feeding
3. to deal with the promotion of complementary foods but on the following conditions :
  - a. all promotions of a complementary food should highlight in a showy manner the exclusive breastfeeding importance over six (6) months and to continue it with a complement of other foods until two (2) years and over, and
  - b. a promotion should not use any text or image that gives the impression that these products are for infants under six (6) months),
  - c. such a promotion practice should not occur in a healthcare institution, no media publicity and promotion

## Article 6

Manufacturers and distributors are not allowed, acting directly or through another person :

1. To give or provide a health officer or a healthcare institution with any quantity of a target product at a lower price than the wholesale cost or, failing that, at less than eighty percent of the retail selling price.
  - a. The paragraph 1 of this article does not apply to donations or selling at reduced prices of the target products to an orphanage or other welfare work institution and which are then exclusively aimed at infants or babies who do not have mother's milk at their disposal. The involved orphanages or other welfare work institutions should then submit a written request to the donors and which should be certified and approved by the **Control Committee**. The donor should inform the Control Committee of each donation. The donations should be provided as long as the beneficiaries need them.
  - b. Notwithstanding this Article, the Health Ministry can purchase target products at a reduced price in case of disasters or for welfare work programmes. The Ministry of Health should then make sure that the infant preparations are exclusively used or distributed among the babies who should be fed with mother's milk substitutes (WHO, A39/8, Add. 1, Geneva, April 1986). Distributions should be then provided as long as the involved infants are in need.

2. To give or distribute in a healthcare institution equipment, services or materiel or articles like pens, calendars, bill-posters, notepads, growth curves or toys.
3. To give or offer presents, contributions, financial aids or any gain to a health officer or professional health associations.
4. To finance or organise events, contests, counselling services and campaigns relating to pregnancy, birth, feeding of infant or baby or related persons.
5. To remunerate or award their employees or fix selling quotas for these products considering the target products sales volume.
6. Notwithstanding the paragraphs 2, 3, 4 and 5, the donations of equipment, scholarships and funding for scientific information exchanges are permissible after the Control Committee's approval following request from the part of a healthcare institution, a health officer or a professional health association. The Control Committee should make sure that the donations of equipment, scholarships and funding for scientific information exchanges are not granted with an objective to promote a target product. Such donations should comply with the provisions of Article ...

## Article 7

1. Health officers are not allowed :
  - a. To receive from manufacturers or distributors or any other person acting on his behalf, presents, financial

aids or financial gains or others of any value but as allowed by the Article 6, Paragraph 6.

b. To receive or give samples of a target product.

2. In case that a health officer has to demonstrate the use of an infant preparation, he has to do it only for an individual mother or members of her family. Then, the health officer should clearly explain them the risks of using infant preparations and to make them know the other information that is stated in Chapter IV.

## **CHAPTER III THE LABELLING**

### **Section 1**

#### **The prohibitions as far as the target products labelling is concerned**

##### Article 8

Manufacturers and distributors are not allowed to market a target product if its packing or label bears a photo, a drawing or any other graphic representation of infants, animals, feeding bottles or other representations or texts that could idealised the use of the product nor to use it for donation.

##### Article 9

Manufacturers and distributors are not allowed to market a target product nor use it for donation if the label is not written in Malagasy and French and/or English.

##### Article 10



Manufacturers and distributors are not allowed to market and make a donation of a target product if its packing or label does not bear - in a clear and showy manner, easy to read and understand - the following information :

1. the correct method for preparation and use of the target product, written and with drawings which are easy to understand ;
2. the full age, that is written in figures and from which the product is recommended. Regarding series preparations and complementary foods, the recommended age should not be below six months ;
3. a warning on the risks for the health of a bad preparation and use of the product before the recommended age ;
4. the ingredients which are used ;
5. the nutritional composition of the product, including nutrients content
6. the required conditions of storing before and after the pack opening, in consideration of the climatic conditions ;
7. the number of batch, the official authorisation reference, the manufacturing date and the expiry date of the product,
8. the name and address of the product manufacturer or distributor ;
9. and any other prescribed information.

### Article 11

Manufacturers and distributors are not allowed to market and make a donation of a target product if its packing or label suggests the existing relation between the product or one of its components with health, including the physiological role of a food regarding body growth, development or normal functions.

## **Section 2**

## **The prohibitions as far as the labelling of infant preparations and series preparations is concerned**

### Article 12

Manufacturers and distributors are not allowed to use as donation and market an infant preparation or a series preparation if the product packing or label does not meet, apart from the requirements stated in the above-mentioned articles 8 to 11, the following conditions.

1. To bear the words “IMPORTANT NOTICE” that is to be followed immediately by the statement that “This product does not substitute on no account for mother’s milk, the ideal food to ensure the infants and babies growth and smooth development. The mother’s milk protects against diarrhoea and other diseases”. This statement should be readable indeed and highlighted, written in bold character which size is at least 50% of the brand characters and, on no account, lower than two millimetres height. The statement should be uniform for all the manufacturers ;
2. To bear a notice according to which the product should be used only on a health professional’s prescription who will recommend its necessity and explain the correct instructions ;
3. To bear the statement that using a cup and spoon is more important than a feeding bottle
4. To bear a notice that infant and series formulas could be micro-organisms-infected during manufacture or preparation, and the importance to throw away any leftover after each feeding ;
5. To include a list of the recommended quantities in the preparation instructions and explain that leftovers should be thrown away ;

6. Not to compare infant and series preparations with mother's milk, not to use the words "suitable for infants", "humanised" or any other similar expressions ;
7. And not to use texts likely to discourage breastfeeding.

### **Section 3**

#### **The prohibition as far as the labelling of sweetened condensed milk is concerned**

##### Article 13

The sweetened condensed milk is not suitable for infant feeding, as a principal ingredient for a preparation. Consequently, the label of this product has to bear the expressions : "This product is not suitable for infants".

### **Section 4**

#### **The prohibitions as far as labelling of feeding bottles and teats is concerned**

##### Article 14

Manufacturers and distributors are not allowed to market feeding bottles or teats if the product packing or label does not meet, apart from the requirements of the above-mentioned Articles 8 and 9, the following conditions.

1. To bear the words "IMPORTANT NOTICE" that is to be followed immediately by the statement that "This product could harm the baby's health. It is better to use a cup and spoon". A statement that should be readable indeed and highlighted, written in bold characters which size is at least the third of the brand characters and, on no account, lower than two millimetres height. The statement should be uniform for all the manufacturers ;

2. To include written and illustrated instructions for the product cleaning and sterilisation ;
3. To bear a notice of the importance to comply carefully with the cleaning and sterilisation instructions ;
4. To show the manufacturer's or distributor's name and address.

## **Section 5**

### **The prohibitions as far as lollies labelling is concerned**

#### Article 15

Manufacturers and distributors are not allowed to market lollies if the product packing or label does not meet, apart from the requirements of the above-mentioned Articles 8 and 9, the following conditions.

1. To bear the words "IMPORTANT NOTICE" that is to be followed immediately by the statement that "A lolly could harm breastfeeding and harms the baby's health". A statement that should be readable indeed and highlighted, written in bold characters which size is at least the third of the brand characters and, on no account, lower than two millimetres height. The statement should be uniform for all the manufacturers ;
2. To include written and illustrated instructions for the lolly cleaning, sterilisation and preservation ;
3. To show the manufacturer's or distributor's name and address.

## **CHAPTER IV INFORMATION, EDUCATION AND COMMUNICATION**

**Section 1**  
**Information, education and communication**  
**medium/equipment**

Chapter 16

Any information and education medium/equipment related to infant and/or baby's feeding :

1. should not give the impression or make believe that a target product is equivalent to, comparable to or better than mother's milk ;
2. should only include exact and updated information and should not use pictures or texts likely to encourage the use of infant preparations or series preparations, feeding bottles, teats or lollies ;
3. should not bear the brand or logo of a target product, a target product manufacturer or distributor. This provision does not apply to the information as regards the target products which are provided to health professionals and pharmacists that is stated by the Article 18 terms and conditions of this Decree ;
4. should be written in Malagasy and French/or English ;
5. should explain in a clear and readable manner each of the following elements :
  - a. the advantages and superiority of breastfeeding,
  - b. the benefits of the exclusive breastfeeding up to the age of six months then completed with other foods till the age of two years or over,
  - c. the preparation for an exclusive and extended breastfeeding,
  - d. the difficulty to go back on the decision not to breastfeed,
  - e. the importance of introducing complementary foods from the age of six months,

- f. the harmful effects of any bottle-feeding or an early introduction of foods or other drinks on breastfeeding, and
- g. the benefits of using local ingredients to prepare complementary foods at home.

### Article 17

Any information and education medium/equipment on infant and/or baby feeding which deals with infant preparations or series preparations feeding should include - apart from the requirements which are stated in Article 16 - the following :

1. the instructions for a good preparation and use of the product, including the cleaning and sterilisation tools,
2. the feeding of infant with a cup and spoon,
3. the risks of bottle-feeding and a bad preparation of the product, and
4. the higher cost of using the product compared to breastfeeding for infant's foods according to the recommended quantities.

## **Section 2**

### **Equipment for information on target products which are designed to health professionals**

### Article 18

1. Manufacturers and distributors could provide health professionals and pharmacists with all information on the target product only following the latter's request and if the information is limited to the following, to be presented in a clear, showy and easy to read manner, without image or drawing :

- a. the advantages and superiority of breastfeeding,
- b. the benefits of the exclusive breastfeeding up to the age of six months, then completed with other foods till the age of two years or over,
- c. the product composition,
- d. the product analysis,
- e. the instructions and contraindications,
- f. the scientific references on which the information statements are based,
- g. the method for preparation and correct use of the product includes the importance of using a cup and spoon instead of a feeding-bottle,
- h. the full age from which the product is recommended,
- i. a warning on the risks for the health of a bad preparation and the use of the product before the recommended age,
- j. the required conditions of storing before and after the pack opening, in consideration of the climatic conditions,
- k. the product average quantity to feed infant aged zero up to six months when the information deals with an infant preparation,
- l. the average quantity to feed infant aged six months and over when the information deals with series preparations,
- m. the name and address of the product manufacturer or distributor.

2. The equipment involved in this article should not be of the general public access

### Article 19

Anyone producing or distributing the medium/equipment for information, education and communication which is described in

this Chapter should submit related copies to the Control Committee in conformity with the prescribed procedures.

## **CHAPTER V AUTHORISATION FOR TARGET PRODUCTS**

### Article 20

- It is imperative that all imported or manufactured target products should get an authorisation of the Ministers in charge of Commerce and Health before their market entry or distribution throughout the country
- It is imperative that all imported or manufactured target products should get an authorisation of the Ministers in charge of Commerce and Health one (1) year after publication of this Decree in the Government Journal at the latest
- The Ministry for Commerce sets in the Government Journal the date beyond which it is impossible for non authorised target products to be imported, manufactured or sold throughout the country.

### Article 21

The authorisation certificate is granted only to the target products that meet the applicable standards regarding food products quality with the conformity of each of their labels to the conditions stated in Chapter III of this Decree.

## **CHAPTER VI THE ADMINISTRATION**



### Article 22

A committee to control the promotion of foods for infants and babies, feeding bottles, teats, lollies and other target products will be set up at the national and regional levels through an inter-ministerial order within six months from the publication date of this Decree in the Government Journal.

## **CHAPTER VII INFRINGEMENTS AND SANCTIONS**

### **Section 1 Infringements**

#### Article 23

Infringements of this Decree provisions that the authorised officers of the Ministry for Economy, Planning, Private Sector and Commerce notice at all levels will be subject of an official report.

#### Article 24

The official report should be drawn up - otherwise invalid - within fifteen days after the date of the findings it states. It is jointly signed by the administration representatives and those of the opposing party who will get a copy of the report. If they declare that they can not sign it, a related written indication is made at the bottom of the report. The original of the official report is sent to the Health Minister and a copy to the Minister for Commerce as well as the Control Committee.

### **Section 2 Sanctions**

#### Article 25

In case of infringements of this Decree provisions, the Control Committee can pronounce a summons to the offender. It can also give this offender notice to put an end to the noticed violation to a rule within a period he will fix.

#### Article 26

If the offender does not conform to the formal notice he has got, the Control Committee can pronounce, after a contradictory procedure, the following sanctions :

1. a pecuniary sanction,
2. an order to put an end to the involved product selling,
3. withdrawal of the authorisation certificate

#### Article 27

If the offender does not conform to the Article 27 provisions and/or in case of a repeat offence, the Commerce Minister will ordain, on the Health Minister's request, the temporary or definitive withdrawal of the trading approval.

#### Article 28

When a health professional is acknowledged to be guilty of breaking a provision of this Decree, the Health Minister can recommend the administration on which the offender depends to sue him to the disciplinary committee, and in case of a repeat offence, a withdrawal of his authorisation to carry out the profession.

#### Article 29

Any offender of any provision of the Articles 4, 5, 6 and 7 of this Decree Chapter II is punished with 6 months to 5 years imprisonment and fined with Ariary 200.000 to 2.000.000 or only one of these two sanctions.

#### Article 30

Any offender of any provision of Chapter II is punished with 6 months to 5 years imprisonment and fined with Ariary 300.000 to 3.000.000 or only one of these two sanctions.

#### Article 31

Anyone being condemned after infringement for the purpose of Article 29 or 30 and a repeat offence for the purpose of these articles is punished with 6 months to 5 years and fined with Ariary 300.000 to 3.000.000 or only one of these two sanctions.

#### Article 32

When infringements are likely qualified as penal, the Health Minister and/or the Ministry in charge of Commerce send the related official report to the territorial Public Prosecutor involved.

#### Article 33

He can appeal to the Court involved within a period of 30 days from the verdict date.

## **CHAPTER VIII THE FINAL PROVISIONS**

#### Article 34

The implementation and control of this Decree will be subject, if necessary, of a decree providing for the enforcement of ministerial or inter-ministerial orders.

#### Article 35

All previous and contrary provisions to this Decree's are and keep being abrogated.

#### Article 36

This Decree will come into force from its publication in the Government Journal of the Madagascar Republic.

Article 37

The Minister of National Defence, the State Seals Master/Minister of Justice, the Minister for Health, Family Planning and Social Protection, the Minister of Telecommunications, Posts and Communication, the Minister for Economy, Planning, Private Sector and Commerce are responsible, as far as they are concerned, of this Decree implementation that will be published in the Government Journal of the Madagascar Republic.