

**Republic of Niger**  
**Ministry of Public Health**  
**Family Health Department**

**Arrêté No 00215 MSP/DSF of 27 July 1998 on**  
**Regulation of Marketing of Breastmilk Substitutes**

**The Minister of Public Health**

**Considering:**

The Constitution of 12 May 1996,  
Decree No 93-13 of 2 March 1993 adopting a Public Health Code,  
Decree No 97-002 of 10 January 1997 on pharmacy regulation,  
Decree No 93-172/PRN/MSP of 3 December 1993 on the attributions of the Minister of Public Health,  
Decree No 93-173/PRN/MPS of 6 August 1997 on implementation modalities of Decree No 97-002 of 10 January 1997 on pharmacy regulation,  
Decree No 97-301/PRN/MSP of 8 August 1997 on the attributions of the Minister of Commerce and Industry,  
Decree No 97-417/PRN of 1 December 1997 on the appointment of members of the Government,  
Decree No 049/MS/CAB of 29 April 1994 on the organization and attributions of the Family Health Department,  
The International Code of Marketing of Breastmilk Substitutes adopted by the 34<sup>th</sup> World Health Assembly on 20 May 1981

**DECREES**

**CHAPTER I**  
**Aim and Scope**

Art. 1 - The aim of this Decree is to protect infant health by the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

Art. 2 – 1. This Decree aims to set the conditions for marketing of these products:

- Breastmilk substitutes,
- Bottles and teats.

It also aims to control the quality of these products at the stages of manufacture, importation and marketing.

Art. 3 - For the purposes of this Decree:

1. **Breastmilk substitute** means any food marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.
2. **Complementary** food means any food, whether manufactured or locally prepared, suitable as a complement to breastmilk or to infant formula, from 4 to 6 months onward.
3. **Infant formula** means a breastmilk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age.
4. **Infant** means a baby from 0 to 12 months of age.
5. **Marketing** means any form of promotion, distribution, sale or advertising of a product.
6. **Health worker** means a person working in a component of a health care system, whether professional or non-professional, including voluntary, unpaid workers.
7. **Health care system** means governmental, nongovernmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It does not include pharmacies or other established sales outlets.

## **CHAPTER II** **Marketing Conditions**

### **SECTION 1: PROMOTION AND ADVERTISING**

Art. 4 – Promotional sales or reduced price sales of above products shall not be used to restrict competition. The decree does not cover complementary foods unless they are presented as suitable to partially or totally replace breastmilk. Therefore, the provisions on advertising and other promotional activities are not applicable to complementary foods.

Art. 5 – All types of advertising for breastmilk substitutes, feeding bottles and teats shall be prohibited throughout the national territory.

Art. 6 – Any representation of an infant or other illustration that may idealize artificial feeding shall be banned in the health care system **and other public places**.

Art. 7 – Manufacturers and distributors shall not provide, directly or indirectly, to health workers, to parents or members of their families, samples of products within the scope of this Decree.

2. They shall not donate to health care units or to health workers any equipment that refers to products under the scope of this Decree. The same shall apply to any material or gadget, including those intended for information and education.
3. However, in case of need, the Ministry of Public Health shall make specific agreements with manufacturers or distributors for them to provide donations of such products to recognized welfare institutions.

Art. 8 – Manufacturers and distributors shall not offer scholarships to health workers, nor offer to pay their costs of participation in a conference, or fund any research on infant feeding without prior approval from the Ministry of Public Health.

## **SECTION 2: PRODUCT QUALITY**

Art. 9 – The importation, local production, distribution and/or sale of any new product under the scope of this Decree shall require prior authorization from the Ministry of Public Health and must conform to the provisions of marketing regulations.

Art. 10 – Authorization prior to sale of any new product in the country shall be delivered only after a health inspection of the place of manufacture and/or storage, laboratory analysis paid by the manufacturer or importer at the request of the Ministry of Public Health, showing that the results thereof satisfy the standards for infant and young child foods.

Art. 11 –

1. Each batch of a product imported or locally manufactured shall be accompanied by a quality certificate issued by the competent authorities of the country of origin, certifying the safety of the product and conformity to existing standards.
2. A copy of said certificate shall be given to the Ministry of Public Health by the manufacturer or importer before the landing of imported goods and within 15 days after production for foods locally manufactured.

Art. 12 – The Ministry of Public Health shall have the right to perform unannounced or periodic quality controls of products under the scope of this Decree.

Art. 13 – The expiry date of imported breastmilk substitutes must be at least one year from the date of landing in the country.

## **CHAPTER III** **Labeling, Information and Education**

### **SECTION 1 – LABELING**

Art. 14 – Labels of products under the scope of this Decree shall include the following points:

- a) Brand name
- b) Composition of the product
- c) Quantity of the product (in volume or net weight)
- d) Instructions for use
- e) Method of conservation
- f) Name and address of the manufacturer
- g) Batch number

- h) Date of manufacture and expiry with embossed code or marked with indelible ink on the packaging
  - i) Precautions to avoid contamination of infant formula intended to feed infants
  - j) Age in months as of which the product may be used. For complementary foods this age cannot be below 4 months.
2. Labels of breastmilk substitutes must have a statement of the superiority of breastfeeding over artificial feeding.

Art. 15 – The use of words such as “humanized”, “maternalized” or similar is prohibited on labels.

## **SECTION 2 – INFORMATION AND EDUCATION**

Art. 16 – Information provided by manufacturers or distributors about products under the scope of this Decree shall be strictly scientific and not misleading nor shall it give the impression that artificial feeding and the use of substitutes is better than breastfeeding.

Art. 17 - Informational and educational materials, whether written or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children shall contain clear information on the advantages and the superiority of breastfeeding.

Art. 18 – Manufacturers and distributors of products under the scope of this Decree shall participate in education and information of the public dealing with promotion and protection of breastfeeding, in collaboration with health care services.

Art. 19 – Health authorities and health workers, at all levels, shall encourage, protect and support breastfeeding and promote the principles of this Decree.

## **CHAPTER IV** **Violations and Sanctions**

Art. 20 –

1. Violations of the provisions of this Decree shall be registered in writing by health and sanitation agents of the Ministry of Public Health, or by inspectors of the Ministry of Trade, duly mandated to do so. The enforcement officers may impound the goods subject of a violation.
2. The written record of violations must be established within 15 days of discovering the facts it describes; otherwise it shall be null and void. The record must be signed by representatives of the government and the accused party who receives a copy. Should the latter refuse to sign, this must be recorded at the end of the record.

3. The original of the record is sent to the Minister of Public Health with copy to the Minister of Trade.

Art. 21 –

1. In the case of a violation of the provisions of this Decree, the Minister of Public Health may:
  - seize and/or destroy the product;
  - reject the product or oblige the importer to re-export it.
2. He may also order a temporary or definitive suspension of the sales authorization [of products].
3. At the request of the Minister of Public Health, the Minister for Trade shall order the temporary removal of the importer from the register of traders. If a violation is likely to be classified as a crime, the Minister of Public Health or the Minister for Trade shall transmit the record of infringement to the Public Prosecutor.

Art. 22 - Violations of this Decree are investigated and confirmed by any agent of the state entitled to do so in other subjects. They are punished in accordance with laws and regulations.

## **CHAPTER V**

### **OTHER PROVISIONS**

Art. 23 – A committee for monitoring and evaluation of the implementation of this Decree shall be established in the Ministry for Public Health. The organization and operations of said committee shall be determined by regulation.

Art. 24 – Manufacturers and distributors of products under the scope of this Decree shall have a period of six months from the date of its signature to conform to the new rules.

Art. 25 – The implementation of the provisions of this Decree shall be the responsibility of the Secretary General of the Ministry of Public Health, Secretary General of the Ministry of Trade, the Director of Family Health, the Director of Commerce, Interior Service and Competition, the Director of Health and Sanitation, each within his field of competence.

Art. 26 – This Decree shall come into force on the date of its signature and be published in the Official Gazette of the Republic, and communicate to whom necessary.

(Signed) **Minister of Public Health, Lt. Col. Illo Almoustapha**

Copies:

MSP/CAB	1	UNICEF	1	GAPAIN	1
MC	1	DPSA	1	CHRONO	1
WHO	1	DPHL	1		

T.N. This law is based on the International Code exclusively. It does not include the subsequent WHA resolutions. It is quite limited. It has the very vague definition of breastmilk substitutes (verbatim from the Code). Following text speaks of “produits visés”, i.e. designated products: substitutes and bottles and teats. It still uses the old definition of infant formula as suitable for infants up to 4 to 6 months. (But there is also a definition for infant 0-12 months!)

And, importantly, it says that complementary foods are those given to infants aged 4 to 6 months in addition to breastmilk or formula. It expressly excludes complementary foods from the provisions on promotion and advertising, unless they are presented as breastmilk substitutes.

It expressly orders manufacturers and distributors to participate in education of the public on promotion of breastfeeding, something that should be avoided.

There is an interesting provision, maybe unintended, that bans representations of infants or other illustrations that may idealize artificial feeding in the health care system **and other public places**. This can mean that a representation of an infant idealizes bottle-feeding and that the famous happy baby pictures are banned from shops, pharmacies, road hoardings, magazines, etc.

ICDC is in possession of 6 draft decrees and draft regulations which have slightly more up-to-date text but no evidence that any of these were adopted. All seem to be drafted around 2005.