

Decree No 31-96 establishing the Implementing Regulation for the Law on Promotion, Teaching and Dissemination of Breastfeeding.

JOAQUIN BALAGUER
President of the Dominican Republic

Number: 31-96

WHEREAS on 19 September 1995 the Executive Power promulgated Law No 8-95, declaring Promotion, Teaching and Dissemination of Breastfeeding a National Priority and regulating the marketing of infant formulas;

WHEREAS it is necessary to regulate the implementation of said law, so as to ensure its enforcement and to contribute more effectively to the optimum nutrition of children, regulating modalities and approved practices of marketing of breastmilk substitutes, complementary foods and infant formulas;

WHEREAS it is appropriate to clarify the responsibilities of the institutions, persons and groups involved in the implementation of said law, as well as assigning specific tasks to a legal body that will monitor compliance with the law and regulations;

WHEREAS on 22 November 1994, the Department for Public Health and Social Welfare (SESPAS) set up the National Breastfeeding Committee, established its goals and specific objectives, its role, the functions of its Executive Secretary and its General Coordinator, as well as other aspects of its operations;

WHEREAS, in the light of experience at home and abroad, it appears that such rules need to be reviewed, updated and acquire legal force, so as to guarantee the full achievement of the goals of the law on breastfeeding and marketing of infant formula;

WHEREAS said law, referring to sanctions for violations of its provisions, in Article 14, states that "they shall be subject to the penalties established in the regulation for implementation of this law";

CONSIDERING Articles 144 and 151 of the Public Health Code of the Dominican Republic and its references to mother and child health care;

CONSIDERING Articles 94 and 192 to 212 of the Public Health Code of the Dominican Republic, dealing with breaches and sanctions;

BY VIRTUE of the powers conferred on me in Article 3 of the Constitution of the Republic,

[I hereby decree]

**REGULATION FOR THE IMPLEMENTATION OF THE LAW ON
PROMOTION, TEACHING AND DISSEMINATION OF BREASTFEEDING**

Article 1: This regulation provides for the implementation of Law No 8-95 which makes the Promotion, Teaching and Dissemination of Breastfeeding a National Priority and Regulates the Marketing of Infant Formula.

I. DUTIES

Article 2: The Department for Public Health and Social Welfare (SESPAS) shall be the institution responsible for implementing and enforcing Law No 8-95 on promotion, teaching and dissemination of breastfeeding and marketing of infant formula and this regulation.

Article 3: Health workers responsible, in particular, for the nutrition of mothers and infants, shall bear the duty of informing and instructing mothers about the need for and the benefits of breastfeeding, about the disadvantages of early weaning and the health hazards of replacing breastfeeding by artificial feeding or of the incorrect use of complementary foods.

Article 4: Directors of public or private health institutions shall take the steps necessary to protect, promote and support breastfeeding and to implement the pertinent provisions of the law and of this regulation. They shall, furthermore, instruct their health workers on their responsibilities under the law and regulation.

Article 5: Charitable associations, such as non-governmental organizations (NGOs), mothers' groups and similar groupings, shall be banned from promoting, directly or indirectly, any designated products, except with written authorization of the Department for Public Health and Social Welfare (SESPAS), through the National Breastfeeding Committee.

II. NATIONAL BREASTFEEDING COMMITTEE

Article 6: The National Breastfeeding Committee shall be chaired by the State Secretary for Public Health and Social Welfare (SESPAS) or his representative and shall be composed of the following members:

- (a) A General Coordinator who shall be an expert in breastfeeding and shall chair meetings in the absence of the State Secretary for Public Health and Social Welfare;
- (b) A representative of the Department of Industry and Trade;
- (c) A representative of the Department of Education, Arts and Culture;
- (d) A representative of the Department of Telecommunications;
- (e) The Coordinator of the National Breastfeeding Programme of SESPAS;
- (f) A representative of the Dominican Medical Association (AMD);
- (g) The president of the Dominican Paediatrics Association;
- (h) The president of the Dominican Society of Gynaecology and Obstetrics;
- (i) A representative of the Family Integration Centre (CIF); and
- (j) Any other person that the State Secretary for Public Health and Social Welfare may appoint as a member of the Committee.

PROVISO: None of the persons appointed shall have any direct or indirect financial interest in any designated product.

Article 7: The National Breastfeeding Committee shall have the following objectives and general attributions:

- (a) To establish the necessary measures to protect and promote breastfeeding, ensuring adequate use of infant formulas, when needed, on the basis of appropriate information and by regulating the modalities of marketing and distribution of designated products, their quality and availability and information about their use, following guidelines set by the National Breastfeeding Programme;
- (b) To coordinate, with public and private institutions, programmes and projects to promote adequate breastfeeding;
- (c) To promote research into breastfeeding;
- (d) To promote the introduction of nutrition and breastfeeding in the curriculae and study plans of preschool, primary, secondary and higher education institutions, as well as in non-formal education;
- (e) To disseminate and monitor compliance with laws and regulations that encourage breastfeeding and to propose changes to them when appropriate; and
- (f) To advise the Department for Public Health and Social Welfare (SESPAS), the Dominican Social Security Institute (IDSS), the Military Medical Corps of the Department of the Armed Forces, the State Sugar Council and other institutions concerned, in the development and dissemination of their plans and programmes for the promotion of breastfeeding.

Article 8: The National Breastfeeding Committee shall have the following specific objectives and powers:

- (a) To consider requests for donations of designated products, as well as equipment and information or educational materials referring to designated products, that manufacturers or distributors shall submit to the Department for Public Health and Social Welfare (SESPAS) and grant or deny approval on the basis of the provisions of laws and regulations dealing with breastfeeding;
- (b) To advise the Department for Public Health and Social Welfare (SESPAS) on:
 - Development of a national strategy for human resources training programmes in breastfeeding and health;
 - Communication and information to the general public on the protection, promotion and support of breastfeeding;
 - Production and dissemination of information and educational materials on infant feeding with particular emphasis on breastfeeding;
 - Implementation, dissemination and publicity of the laws and regulations covering breastfeeding;
 - Research into breastfeeding;
- (c) To consider denunciations of violations of laws and regulations supporting breastfeeding and to make recommendations accordingly;
- (d) To examine, amend and approve any printed material produced by manufacturers or distributors of infant foods before its publication and dissemination;
- (e) To support the implementation of the National Breastfeeding Programme of the Department for Public Health and Social Welfare (SESPAS) and other institutions involved;

- (f) To coordinate efforts of international aid agencies with the Dominican Government to work towards the achievement of the objectives of the law which makes the promotion, teaching and dissemination of breastfeeding a national priority;
- (g) To carry out monitoring exercises every two years, covering all aspects of Law No 8-95 and this regulation and to inform the State Secretary for Public Health and Social Welfare of their conclusions and recommendations;
- (h) To advise the State Secretary for Labour on the adoption of measures aimed at supporting working mothers, so that they may successfully combine work with pregnancy and breastfeeding;
- (i) To periodically evaluate the status of breastfeeding and infant feeding practices among the urban and rural population, through surveys and/or studies, and to continually review national and international bibliography on the subject;
- (j) To encourage health professionals to adopt a positive attitude towards breastfeeding.

Article 9: The National Breastfeeding Committee shall be permanent and may call, when necessary, on national and international technical assistance and cooperation for the review, development and implementation of programme activities, and may invite foreign or national experts to attend its meetings for that purpose.

Article 10: The Coordinator General of the National Breastfeeding Committee shall act as the Executive Secretary of the Committee and shall have the following functions:

- (a) To liaise between the Committee and other public or private bodies to develop and bring up to the Committee pertinent policy proposals;
- (b) To ensure that the Committee's policies, plans and programmes are implemented by various public and private bodies in the country;
- (c) To motivate and to monitor, directly or through a representative, the manufacturers of designated products and the national health care system, regarding [the fulfillment of] their responsibilities under the laws and regulations to protect and promote breastfeeding, identifying any violations and promoting the enforcement of the laws and regulations;
- (d) To act with due authorization on behalf of the Committee in negotiations with national and international funding agencies aimed at obtaining funds;
- (e) To be the spokesman of the Committee, issuing opinions about breastfeeding; in his absence he may be represented in this function by any other member of the Committee appointed by the Coordinator, after notification to the State Secretary for Public Health and Social Welfare;
- (f) To act as ex-officio member on any subcommittee that may be set up;
- (g) To call meetings of the Committee, to file its minutes and to implement its resolutions in the area of his competence;
- (h) To report to the Committee on all programmed activities [carried out], at the latest in the first week of November each year.

PROVISO: The Department for Public Health and Social Welfare (SESPAS) shall provide support to the Coordinator General in obtaining the human, logistic and financial resources necessary for the fulfillment of the Committee's role and tasks.

Article 11: The National Breastfeeding Committee shall set up subcommittees as deemed necessary for the fulfillment of its objectives and appoint their members. Members may be proposed by their institution or organisation. The Committee shall be entitled to accept or reject proposed candidates and to request their replacement by the head of the respective organisation.

PROVISO: The organisations represented in one or more subcommittees shall be the same that are part of the National Breastfeeding Committee.

PROVISO II: The National Breastfeeding Committee shall assign specific tasks and mandates to each subcommittee and shall set the deadline by when they shall submit their respective reports.

Article 12: Before distribution to consumers, any industrialized infant food shall be registered with the Food Control Division of the Department for Public Health and Social Welfare (SESPAS). Registration shall be granted upon: (a) Presentation of favourable results of tests by the National Laboratory Dr. Defillo of SEPAS, and (b) Presentation of a favourable opinion by the National Breastfeeding Committee.

PROVISO: Prohibited promotional and advertising practices include the placing or display of infant formula in supermarkets or other commercial outlets on the same shelves where other products, not suitable for infants, such as full-cream milks, formulas of basic nutrients and other non-milk products are placed or displayed.

refer law 11

* Article 13: **Promotions and Advertisements.** Any oral or visual promotion directly or indirectly related to breastmilk substitutes, complementary foods, infant formula, designated products, feeding bottles, teats, pacifiers (dummies), nipple shields and breast pumps, in addition to complying with the requirements established by the Dominican Standard NORDOM 53 on Labelling of Packaged Foods, shall require the approval of the National Breastfeeding Committee and the Food Control Division of SESPAS.

Article 14: **Labels.** Labels of breastmilk substitutes, complementary foods, infant formula, designated products, feeding bottles, teats, pacifiers (dummies), nipple shields and breast pumps, shall comply with the requirements established by the Dominican Standard NORDOM 53 on Labelling of Packaged Foods. They shall, furthermore, contain the following information:

- (a) A statement on the superiority of breastfeeding, with the following wording "*Breastmilk is the best food for your infant*", printed in bold and color characters of no less than 5mm height;
- (b) The ingredients used, in decreasing quantitative content;
- (c) The composition and analysis of the product;
- (d) The required storage conditions, batch number and date before which the product is to be consumed;
- (f) Instructions for its preparation, cleanliness to be observed and the age of the child for whom the product is suitable.

PROVISO: Labels shall not contain pictures of breastfeeding infants, text, drawings or illustrations that may, directly or indirectly, create a belief that the product is equivalent or superior to breastmilk or may idealize the use of a feeding bottle.

Article 15: **Donations.** Any donation of any of the products listed in Article 14 above shall require the approval of the National Breastfeeding Committee, after having been examined by the Food Control Division and been submitted to official laboratory tests.

III. COMPETENCE, PROCEDURES AND SANCTIONS

Article 16: The Department for Public Health and Social Welfare, through its technical food control division, shall be authorized to receive and investigate any violations of the laws and regulations dealing with breastfeeding.

The National Breastfeeding Committee shall appoint one of its members or a delegate to be present when sanitary inspections of manufacturers or distributors of industrialized infant foods are carried out.

Article 17: Any violations of the provisions of Law No 8-95 declaring the promotion, teaching and dissemination of breastfeeding a national priority and of its regulations shall be considered a breach of health [regulations] and shall be sanctioned in accordance with the procedures established in Articles 192 to 212 of the Health Code relating to health violations and sanctions.

Article 18: Specific sanctions applicable to health violations relating to breastfeeding. Notwithstanding any sanctions established by Articles 198 to 212 of the Health Code, breaches or violations of the laws and regulations dealing with breastfeeding shall be sanctioned administratively by the State Secretary for Public Health and Social Welfare, according to the seriousness and frequency of sanctions, in the following progressive manner:

- (a) Written admonestation or warning;
- (b) Temporary suspension of the marketing [licence] of the incriminated product or products, up to a period of thirty days;
- (c) Definitive suspension of the marketing [licence] of the incriminated product or products; and
- (d) If the defendant is a health worker, temporary suspension from work without pay, or cancellation of the employment contract without liability for the employer.

Article 19: Notwithstanding the sanctions established in Article 18 above, any breastmilk substitute, complementary food, infant formula, designated product, feeding bottle, teat, pacifier (dummy), nipple shield or breast pump that does not comply with the provisions of Law No 8-95 and its regulation shall immediately be withdrawn from circulation by the Food Control Division of the Department for Public Health and Social Welfare and shall be confiscated, if it is harmful to health, and, if necessary, shall immediately be destroyed, without any obligation of compensation. Furthermore, in accordance with Articles 94 and 201 of the Health Code, any commercial outlets or industrial establishments in which health violations of the legal and regulatory provisions on breastfeeding have been confirmed shall be immediately closed without further procedures.

Article 20: Law No 8-95 and this regulation shall supersede any provisions that run counter to breastfeeding.

Article 21: This regulation shall be sent to the Department for Public Health and Social Welfare for necessary action.

DONE in Santo Domingo de Guzman, National District, Capital of the Dominican Republic, on the twentieth (20th) day of the month of January of nineteen hundred ninety six, year 152 of Independence and year 133 of Restauration.

Joaquín Balaguer