



# **LEGISLATION ON FOODS FOR INFANTS AND SMALL CHILDREN**

**FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS**

LEGISLATION ON FOODS FOR INFANTS  
AND SMALL CHILDREN

by

Randy Frances Kandel, Ph. D.

For the  
Legislation Branch  
Legal Office

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS  
Rome, 1983

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

M-82

ISBN 92-5-101487-6

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying or otherwise, without the prior permission of the copyright owner. Applications for such permission, with a statement of the purpose and extent of the reproduction, should be addressed to the Director, Publications Division, Food and Agriculture Organization of the United Nations, Via delle Terme di Caracalla, 00100 Rome, Italy.

© FAO 1983

FOREWORD

Increasing attention has been paid in recent years to the subject studied in these pages both among the general public and by national governments and international organizations.

The WHO International Code of Marketing of Breastmilk Substitutes in particular has focussed global attention on the need for developing legislation which will effectively safeguard nutritional health in infancy and childhood.

Special legislative attention to this area is important for several reasons. Nutritional health during the first year of life depends upon the feeding of breastmilk (or a nutritionally and hygienically adequate substitute) during the first months, followed by the timely introduction of adequate complementary foods. The improper use of proprietary infants' foods is a major cause of malnutrition which may result in death, disease, and mental retardation, while customary weaning foods are often nutritionally inadequate. Infants' and children's diets generally consist of a limited range of foodstuffs selected for them by parents or other caretakers who may lack nutritional knowledge.

There is a need, therefore, for legislation, based upon sound principles of child nutrition, which can appropriately regulate the development, quality, production, distribution and use of infants' and children's foods, and promote and protect breastfeeding. Effective national legislation can give force to the principles enunciated in recommended international standards and codes of practice and help to implement the right to adequate nutrition.

The purpose of this study is threefold: to provide summaries of selected national laws and regulations; to present a synthesis of the national and international legal contexts; and to offer main elements which may be relevant for the preparation of special legislation on foods for infants and small children.

The selection of countries for the inclusion of their laws and regulations in this study was determined, within the limits of the documentary material available in FAO's Legislation Branch, by geographic considerations and those of their legal systems - inclusion or exclusion representing no judgement whatsoever as to the values of any law in force under them.

This study was prepared by Ms. Randy Frances Kandel, Ph.D., and the opinions expressed here are the author's own and in no way commit FAO. By publishing them as they are the Organization wishes simply to contribute to that effort of reflexion and imagination which is demanded of the legislator in deciding between the options open to him in this particularly important field.

The necessary research was done mainly at FAO Headquarters, where the author had the benefit of the advice and opinions of the Animal Plant and Food Legislation Section of the Legislation Branch, Legal Office. It would nevertheless be appreciated if any omissions, or any statements based upon incomplete information, which may come to light were to be pointed out with a view to remedying them in any future edition.

Dante A. Caponera  
Chief, Legislation Branch



TABLE OF CONTENTS

	<u>Page</u>
The International Legal Context: Nutritional Rights in International Law	1
The National Legislative Context	2
The Nutritional and Socioeconomic Context	9
Adapting Legislation to the Social, Cultural, and Economic Context	15
Summary Statement of Legislation Surveyed	26
Argentina	31
Australia	34
Brazil	35
Canada	40
Colombia	46
Denmark	47
Italy	51
Kenya	54
Mexico	56
Netherlands	59
New Zeland	62
Papua New Guinea	64
Peru	66
Portugal	67
Sweden	70
Sri Lanka	73
Thailand	75
United States of America	81
Venezuela	83
Yugoslavia	85
European Economic Community	92
Main Elements and Provisions which are Relevant for the Preparation of Special Legislation on Foods for Infants and Small Children	93



## THE INTERNATIONAL LEGAL CONTEXT

### NUTRITIONAL RIGHTS IN INTERNATIONAL LAW

The right to adequate nutrition for infants and small children is implicit or explicit in numerous formal documents of international law 1/. The right is inherent in Articles 55 and 56 of the United Nations Charter which state, in the pertinent part, “All Members pledge themselves to take joint and separate action in cooperation with the Organization ... with a view to the creation of ... solutions of international economic, social, health and related problems” 2/.

That “Everyone has the right to a standard of living adequate for the health and well-being of his family, including food” is specifically proclaimed in Article 25(1) of the Universal Declaration of Human Rights 3/, one of the most widely cited documents in international law. The right is reaffirmed in Article 11(1) of the 1966 International Covenant on Economic, Social, and Cultural Rights. Article 11(2) of the Covenant further states:

The States Parties to the present Covenant, recognizing the fundamental right of everyone to be free from hunger, shall take, individually and through international co-operation, the measures, including specific programmes, which are needed:

- (a) To improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition and ...
- (b) Take into account the problems of both food-importing and food exporting countries to ensure an equitable distribution of world food supplies in relation to need 4/.

The basic right to food is recognized in numerous other declarations including the 1959 Declaration of the Rights of the Child (Principle 4) 5/; the Declaration on the Eradication of Hunger and Malnutrition 6/; and the resolutions adopted at the World Food Conference in 1974 7/. The WHO/UNICEF 1979 Statement on Infant and Young Child Feeding specifically affirmed “the right of every child and every pregnant and lactating mother to be adequately nourished” 8/.

---

1/ Proceeding of the American Academy of International Law, April 24, 1975. Remarks by J. Paust at 45-47; Remarks by V.P. Nanda at 55.

2/ UN CHART. art. 56 and art. 55(b).

3/ Universal Declaration of Human Rights. Approved by G.A. Res. 217A(III), GAOR III.1, UN Doc. A/810 at 71-77 (1948).

4/ International Covenant on Economic, Social, and Cultural Rights. Approved by G.A. Res. 2200 (IX), GAOR XXI Supp. (No. 16), UN Doc. A/6316 at 49-52 (1966).

5/ 1959 Declaration of the Rights of the Child.

6/ Declaration on the Eradication of Hunger and Malnutrition. Approved by G.A. Res. 3348 (XXIX) (1974).

7/ World Food Conference, Rome, Nov. 5-16, 1974.

8/ WHO/UNICEF Statement on Infant and Young Child Feeding, para. 6 (1979).

National food legislation and food control infrastructures can play a substantial part in facilitating the satisfaction of the basic right to adequate nutrition in infancy and childhood 1/. As stated in the FAO Recommended International Code of Ethics for the International Trade in Food, such legislation and infrastructures are not sufficiently developed, in many countries, to secure adequate protection 2/. There is a world need to implement nutritional rights by establishing or strengthening national legislation in this area.

#### NATIONAL, PROFESSIONAL AND INDUSTRIAL CODES OF ETHICS

The need to develop ethical marketing standards for the trade in infants' and children's foods, and to promote breast-feeding, has been recognized in numerous national and international professional and industrial codes which have set forth suggested guidelines. Among such codes are the "Code of professional ethics concerning regulated preparations and dietetic preparations for the nourishment of infants less than four months old" in France 3/; the "Code of Ethics and Professional Standards for Advertising, Product Information and Advisory Services for Infant Formula Products in Malaysia" 4/; the "Medical Standards for the Marketing of Infant Foods in Sweden" 5/; the summary statement on breastfeeding of the American Medical Association House of Delegates in the United States 6/; the International Council of Infant Food Industries' "Code of Ethics and Professional Standards for Advertising, Product Information and Advisory Services for Breast-milk Substitutes" 7/; the Abbot Laboratories "Code of Marketing Ethics for Developing Countries" 8/; and the Bristol-Myers Company International Division "Policies & Practices, Production, Labeling and Marketing of Infant Formula" 9/.

- 
- 1/ CODEX ALIMENTARIUS COMMISSION. Code of Ethics for International Trade in Food, Preamble, para (a). CAC/RCP 20 - 1979.
  - 2/ Ibidem at para. (e).
  - 3/ Code d'ethique professionnelle concernant les preparacions sous visa et les preparacions diététiques, destinés a l'allaitement des nourrissons de moins de 4 mois of the "Association Pour La Sauvegarde de L'Ethique Professionnelle des Fabricants et Distributeurs de Laits Infantiles". Paris (1979).
  - 4/ Code of Ethics and Professional Standards for Advertising, Product Information and Advisory Services for infant Formula Products in Malaysia; date 1 June 1979.
  - 5/ Medical Standards for the Marketing of Infant Foods in Sweden. 66 Acta Paediatrica Scandinavica 131 (1977).
  - 6/ AMA Emphasizes Importance of Breast-Feeding. Nutrition Notes (June 1979).
  - 7/ Code of Ethics and Professional Standards for Advertising, Product Information and Advisory Services for Breast-Milk Substitutes of the International Council of Infant Food Industries, reprinted in Marketing and Promotion of Infant Formula in Developing Nations, 1978; Hearings Before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, of the United States of America, 95th Cong., 2d. Sess. (hereinafter Senate Hearings) at 887-88 (1978).
  - 8/ Code of Marketing Ethics for Developing Countries of Abbott Laboratories/Ross Laboratories, reprinted in Senate Hearings at 204-07.
  - 9/ Policies & Practices, Production, Labeling, and Marketing of Infant Formulas of Bristol-Myers Company International Division, reprinted in Senate Hearings at 1436-38.

## INTERNATIONAL CODES OF ETHICS AND STANDARDS

International codes of ethics have also been developed, setting forth both legal principles and substantive guidelines and provisions. The FAO/WHO Codex Alimentarius Commission Code of Ethics for International Trade in Food (Art. 5.9) addresses the issues in substance and detail 1/. The International Code of Marketing of Breast-Milk Substitutes, adopted by the World Health Assembly in 1981, explicitly affirms “the right of every child and every pregnant and lactating woman to be adequately nourished as a means of attaining and maintaining health” 2/.

In addition, developed international norms such as the Codex Alimentarius Commission Recommended International Standards for Foods for Infants and Children 3/ and The Codex Alimentarius Commission Recommended International Code of Hygienic Practice for Foods for Infants and Children 4/ set forth precise standards concerning the quality and hygiene of specific products.

The harmonization of national standards with international standards for ingredients, hygiene and purity, packaging and labelling, and other matters pertinent to infants' and children's foods serves two purposes: (1) It helps ensure consumer protection because standards are in conformity with those determined by scientific and technical bodies having the requisite expertise; (2) it facilitates international trade by ensuring that those products which meet accepted standards can flow freely in the international marketplace 5/.

## RELATIONSHIP BETWEEN INTERNATIONAL NUTRITIONAL LAW AND NATIONAL LEGISLATION

While the basic principles of international nutritional law have been enunciated and reaffirmed, and specific guidelines and recommendations have been developed, much work remains to be done in incorporating them into binding effective legislation appropriate to the needs of individual countries.

International declarations, resolutions and codes lack the binding power of domestic law, unless countries specifically undertake to make them binding upon themselves. Even treaties and conventions, which are binding legal instruments, are generally not self-effectuating in signatory countries. Depending upon the legal and governmental system of the signatory country any or all of three steps may be necessary to convert an international legal instrument into domestic law. First, a process of ratification, by which the treaty is adopted by the national law-making body may be required. Second, enabling legislation may be required. Enabling legislation is general law, granting authority to the relevant law-making or regulatory body or entity to develop the specific provisions of domestic law to implement the international instrument. Third, specific, more detailed domestic laws or regulations may have to be developed, such as registration provisions, enforcement provisions, sanctions, and specific prescriptions and proscriptions, to give the international instrument practical meaning and enforceability domestically.

---

1/ See supra, note 9.

2/ Draft International Code of Marketing of Breastmilk Substitutes. Report by the Director-General. UN Doc. EB67/20 (1980).

3/ CODEX ALIMENTARIUS COMMISSION. Recommended International Standards for Foods for Infants and Children. UN Doc. CAC/RS 72/74-1976 (Rome, 1976).

4/ CODEX ALIMENTARIUS COMMISSION. Recommended International Code of Hygienic Practice For Food for Infants and Children. CAC/RCP 21-1979.

5/ Kimbrell, E.F., Food Composition Regulation and Codex Standards. Food, Drug and Cosmetic Law Journal at 145 (March 1978); See also, Gerard A., International Food Standards and National Laws. Food, Drug, and Cosmetic Law Journal at 281 (June 1978).

Even without incorporation into domestic law, however, international instruments serve two important purposes. First, they carry a power of moral persuasion on individual nations, especially those which are participants or signatories to them. As the principles become familiar, through repetition in successive instruments, and through adherence to them by increasingly large numbers of nations, they become part of the customary international law, developing a binding force by virtue of their widespread acceptability. Second, international instruments such as the International Code of Marketing of Breast-milk Substitutes, with detailed specific proscriptions and prescriptions, may serve as models and guidelines for the drafting of national legislation implementing the principles concerned.

## THE NATIONAL LEGISLATIVE CONTEXT

### The Need for Special Legislation

Many countries have comprehensive Food Acts. Typically, these acts include general provisions governing requirements, prohibitions, registration, monitoring and enforcement provisions, acceptable standards of mandatory and voluntary compliance, and general requirements on such matters as food labelling and food hygiene. Often such acts have specific regulatory provisions. The Act itself sets out broad principles, and the regulations contain detailed provisions governing the different categories of products coming under the jurisdiction of each set of regulations. Several comprehensive guides to the drafting of food laws exist, including the FAO/WHO Guidelines for Developing an Effective Food Control System, which includes an example of a general food law, and An Outline of Food Law: Structure, Principles and Main Provisions, by Alain Gerard. In countries having such Food Acts, certain aspects of legislation on foods for infants and small children, such as those dealing with quality, hygiene control, and labelling, may be suitably incorporated in the general Food Act.

It is important to emphasize, however, that the domain of necessary legislation shall be broader than that usually encompassed within a general Food Act. Food law is generally considered to serve three purposes: (a) protection of consumer health through the imposition of nutritional quality and hygienic standards; (b) protection of consumers against fraud and ensurance of fair dealing in the food trade through the imposition of sanctions for misrepresentation; and (c) facilitation of the food trade through the standardization of various requirements.

Food law is thus generally regarded as protective in character. The legislation suggested here, however, when adopted in conformity with the biological model, and other considerations discussed above, is such as to exert a positive, formative influence on the quality of infant and child nutrition by becoming a part of the context in which nutritional improvement takes place - and an element of the context carrying with it the force of sanction.

In addition, as the discussion above indicates, legislation facilitating proper infant and child nutrition may extend beyond the domain of what is normally considered food law to encompass areas of the law governing health care delivery systems, control of business and advertising, or labour law.

### Law, Regulation, or Code?

Several options are available in structuring laws dealing with infant and child nutrition. The first option is to draft specific and detailed legislation, governing all standards and requirements. While such laws have the virtue of completeness they present two major drawbacks. First, lawmakers may lack the requisite expertise to meaningfully establish specifications and details. Second, national political and

governmental processes may involve prolonged periods of discussion and deliberation prior to the passage of a new law. While such procedures may be advantageous where primarily legal considerations are involved, they may be unnecessarily inefficient where the modifications required in the law are merely those necessary to adapt the law to scientific and technical developments in infants' and children's food and nutrition.

A second option, therefore, is to follow the bifurcated pattern used in many Food Acts. In such a structure, the basic law or enabling act is adopted by the appropriate law-making body of the country. The act sets forth principles, and purposes, and basic standards of legal liability - and grants authority to elaborate the detailed technical specifications to an agency or department with the appropriate expertise. This entity then develops the specific regulations, frequently with the participation of concerned individuals, groups, or industries. Such a structure allows the regulations to be modified and up-dated as conditions and technical and scientific knowledge change by those directly concerned and having the appropriate expertise. In countries where the bureaucratic structure in the relevant areas is insufficiently developed, however, an excessively complicated regulatory system may prove detrimental to the efficacy of the law.

The third option is to design laws placing the responsibility for regulatory development with the professions or industries concerned. For examples, specific regulations concerning de-promotion of feeding with breast-milk substitutes, or instructions in proper breast-feeding may be delegated to health care institutions or the appropriate national organizations of health care professionals. The efficacy of such a system is, of course, related to the degree to which the profession and industry is organized and self-regulating within the country and the degree to which it is subject to licensing or other forms of legislative and judicial regulation.

A fourth option is to generate voluntary compliance with the principles and policies discussed above, through the legislative design of inducements and incentives such as educational opportunities, research grants and other financial and economic factors.

#### Whom Should the Law Regulate?

The efficacy of a law depends upon its enforceability as well as its prescriptions. It thus must be structured so as to be meaningfully policed through existing or feasible regulatory structures, and targeted to regulate those who may be meaningfully and practically subjected to legal process.

The most easily targeted persons for the placement of legal responsibility and liability are those who are already subject to legislative and regulatory licensing or supervision. Thus, responsibility for proper instruction in breast-feeding may most feasibly be placed upon physicians and other health care professionals working in licensed hospital facilities; and responsibility for the proper promotion of breast-milk substitutes and infants foods may be more easily placed upon manufacturers and distributors than small scale producers. The trade aspects of food encompass all processes from production or manufacture to final retail sale, including assembly, storage, transport, processing, export, import, distribution, promotion and advertising. Together these processes form an integrated system which significantly

impacts upon the quality and purchase of food products. Many national food legislation schemes choose one or more of these elements - typically the manufacturer or vendor, as the primary focus of regulatory legislation. In legislation on infants' and children's foods the focus may be the same or different from those appropriate in other areas of food law. In making this determination, there is a need to consider the entire food trade system, including intra-familial and international aspects and to create legal liability and responsibility in a fashion meaningful within the national context.

#### The parent or other purchaser

Typically, the domain of those “actively” affected by food law (that is, those upon whom the law imposes certain positive obligations or prohibitions) includes persons or entities engaged in the production, handling or sale of food. Purchasers are generally understood to be “passively” affected (that is, they may look to the law for effective legal protection against possible offences). In the case of infants' and children's foods, there are sound arguments for extending the domain of those actively affected to include purchasers: (1) The diets of infants and small children are generally selected for them by parents or other caretakers who bear a fiduciary responsibility; (2) Breast-milk substitutes, and to a lesser degree weaning foods, are “complete foods”, comprising the total dietary intake of individuals in the relevant developmental stages. Therefore special need exists to ensure that foods purchased comport with nutritional requirements; (3) Breast-milk substitutes and prepared weaning foods require sanitary conditions and accuracy of preparation to ensure a healthful, wholesome food product. Much of the hazard of such products comes from the improper use, by purchasers, of products which are hygienic and healthful at the point of manufacture or retail sale. This places a special burden upon the parent-caretaker.

Although purchaser/consumer liability is unusual in food legislation, it is a common element of the law on drugs and dangerous substances. There is good reason to consider its applicability to infants' and children's foods, in light of the special responsibility parent-caretakers bear for the nutritional health of children and the great dangers attendant upon misuse of formula and proprietary children's foods.

#### Import and Export Control

In the international trade in infants' and children's foods, the developed nations are primarily manufacturer-vendors and the developing nations are primarily purchaser-consumers. The Third World infant formula market is dominated by a small number of multinational corporations of Japanese, United States, or Western European origin. A decade of dialogue and activism over the high-powered marketing strategies of these corporations has culminated in the development of professional and industrial codes on ethical marketing. There is a need to ensure that imported infants' and children's food products satisfy nutritional needs. Despite the urgent, manifest need for regulation, there is currently a dearth of import control legislation and an almost total absence of export control legislation in the area. Generally, export control regulations are not established with the nutritional needs of importing countries in mind. Some food law schemes specifically exempt products destined for export from the need to comply with even domestic standards. The development of suitable import control legislation may safeguard national interests and further serve as a stimulus to exporting nations to devote legislative attention to conditions beyond their territorial limits. Ultimately, there is a need for effective legislation by both importing and exporting nations.

### Standards of Legal Liability

Food laws typically impose criminal sanctions, or governmentally enforced civil sanctions, upon violators. It may also be advisable to allow for a personal cause of action, providing redress for individuals through the courts.

In civil law countries, the conditions under which an individual may be liable for causing injury to another are specified within the law itself. In common law countries, personal redress is generally provided through the doctrines of the law of torts (“civil wrongs”). Tort law imposes liability for negligence. It may impose liability upon manufacturers, distributors or vendors of foods who fail to conform to the customary standards of the trade, with consequent injury to the purchaser or the consumer. Under the variation known as medical malpractice, liability may be imposed upon a physician who fails to properly inform or treat a patient in conformity with the standards of the profession. Tort liability doctrine may be invoked to provide redress for failure to properly instruct on breast-feeding, or for misinformation, improper sale or promotion of breast-milk substitutes and other infants' and children's foods.

While the law of torts requires a finding of negligence to hold a person or entity legally liable, two corollaries have been developed which impose stricter standards upon manufacturers and vendors. “Strict liability” imposes liability for products marketed in a “defective condition unreasonably dangerous to the purchaser or consumer”. Because a product may be considered defective if it does not meet nutritional standards, this legal doctrine may impose a positive duty upon manufacturers and distributors to modify and upgrade their products, and provide accurate information, to comport with new technical and scientific standards even where these have not been incorporated into prescriptive legislation.

The doctrine of “implied warranty” holds that a manufacturer or vendor of a product is considered to guarantee that the product is fit for its intended purposes. This embraces not only those purposes described on the label or in advertising but those which are foreseeable uses of the product. Thus, a food sold as, or expected to be used as, a children's food should be fit for its intended purpose.

Several legal writers have suggested liability in tort or strict product liability as appropriate legal doctrines under which to provide a legal remedy for improper sale or promotion of infants' and children's foods. Without specific implementing legislation, however, the problem remains jurisdictionally intractable because the home courts of formula corporations are rarely open, and never convenient, to poor Third World plaintiffs; and many of the most affected countries lack the legal infra-structures to provide adequate judicial remedies.

## THE NUTRITIONAL AND SOCIOECONOMIC CONTEXT

Legislative guidelines must be such as to foster the maximum nutritional status possible in all regions, and prevent abuses or misuses of products with negative nutritional and health consequences. The formulation of such guidelines requires an integration of nutritional knowledge with existing principles of food legislation adaptable to the socioeconomic conditions and food and nutrition policies of varying nations and regions. The most important factors to be considered in developing and improving legislation on infants' and children's foods are summarized below.

### THE NUTRITIONAL CONTEXT

Standards for ingredients, hygiene and purity must be established so as to comply with the nutritional needs of infants and small children in different developmental stages; and distribution must be regulated so that products reach their intended consumers and do not reach those for whom they may be harmful or inappropriate.

It is possible, for our purposes, to divide the nutritional needs of early childhood into three states: the early post-natal stage, the nursing stage, and the complementary food stage. These stages may be defined as follows:

1. The early post-natal stage is the period from birth through the first week of life. During the first few days of life, the infant's ideal diet is the immature human milk, colostrum, which is rich in maternal immunities. Nursing must be initiated during this period to successfully trigger maternal lactation.
2. The nursing stage is the period from the first week through, approximately, the fourth to sixth month of life. It is the period during which breastmilk is the ideal and complete food for almost all infants, adequate to meet all nutritional requirements, while supplying additional advantages including the transference of maternal immunities and the emotional fostering of the mother-child bond.
3. The complementary food stage is the period during which breastmilk is still an excellent, but no longer a complete, food for the infant and the diet should be supplemented with additional appropriate foods to ensure adequate growth and development. Gradually, as appropriate to the child's developmental needs, additional foods are introduced, and come to comprise the largest percentage of the child's diet. The complementary food stage ends when the child is fully weaned onto the normal family diet. The length of the complementary food stage depends upon numerous biological, sociocultural and economic considerations but encompasses, maximally, the period from four months through four years of age. A more detailed description of these three stages follows.

### THE EARLY POST-NATAL STAGE

Successful breastfeeding must be established during the first week after birth because lactation depends upon the presence of the maternal hormone prolactin. At the time of delivery, prolactin levels are approximately 20 times higher than in non-pregnant women. If the infant nurses, lactation is initiated through the "let-down" reflex and the prolactin level remains elevated for at least 15 months. If the infant does not nurse, the prolactin level declines sharply one week after birth, preventing lactation until the next child is born 1/. Once initiated, maternal milk supply increases with the increasing strength and duration of the infant's sucking. Less than 5% of all mothers are estimated to be unable to breastfeed adequately for physiological reasons 2/. However, the "let-down" reflex responds to psychological influences so that a supportive emotional environment is necessary for breast-feeding to continue successfully 3/.

In the first five days of life, the nursing infant feeds upon colostrum, a maternal secretion not approximated in commercial formulas. The primary function of colostrum is to transfer maternal anti-infective factors to the infant whose own immune system will not develop until the end of the first year. Colostrum is high in antibody - rich protein, especially secretory immunoglobulin A (SIgA) and lactoferrin. Secondly, colostrum may supply concentrated dosages of zinc and other nutrients and facilitate clearance of the meconium 4/. Gradually, during the early post-natal stage, as the infant nurses, colostrum changes into mature human breastmilk.

### THE NURSING STAGE

Nutritionists and other specialists in maternal and child health are today in general agreement in recommending unsupplemented breastmilk as the preferred diet for most infants from birth through the fourth to sixth month of life. Breastfeeding is superior to alternative methods in five ways: (1) nutritional characteristics, (2) immunological and anti-allergenic properties, (3) psychological effects (4) maternal health advantages, and (5) contraceptive properties.

Nutritional characteristics. Breastmilk contains an abundant supply of the nutrients needed for rapid growth and development of the brain and central nervous system: lactose, cystine, cholesterol, and specific patterns of polyenoic fatty acids 5/. The high lactose content plays an important role in maintaining electrolyte balance 6/. Additionally, cholesterol may be important in the synthesis of bile salts

---

1/ WHO/UNICEF. Background Paper Prepared for Meeting on Infant and Young Child Feeding at 6. UN Doc. FHE/ICF/79.3 (1979).

2/ Deem, H.M. and M. McGeorge. Breastfeeding. 57 New Zealand Medical Journal 539 (1958).

3/ Carballo, M., Social and Behavioral Aspects of Breast-Feeding. Journal of Biosocial Science, Supp. 4 at 57 (1977); Newton, N. and M. Newton, Lactation: Its Psychological Components In Modern Perspectives in Psycho-Obstetrics (ed. T.G. Howells), Edinburgh: 1972, Oliver & Boyd at 385-409.

4/ WHO/UNICEF. Background Paper Prepared for Meeting on Infant and Young Child Feeding at 6. UN Doc. FHE/ICF/79.3 (1979).

5/ Jelliffe, D.B. and E.F.P. Jelliffe, The uniqueness of human milk. 24 American Journal of Clinical Nutrition 101 (1971).

6/ WHO/UNICEF. Background Paper Prepared for Meeting on Infant and Young Child Feeding at 7. UN Doc. FHE/ICF/79.3 (1979).

and the development of cholesterol metabolizing enzymes, thus lowering serum cholesterol 1/. Copper, ascorbic acid, and vitamin E (needed for the synthesis of hemoglobin and red blood cells) are present in slightly higher quantities than in cow's milk 2/. The combination of nutrients in human milk and the interaction among them facilitates digestion and assimilation. For example, significantly more iron and calcium are absorbed from human than from cow's milk. The casein content is low resulting in a soft curd which makes emptying of the stomach easier. This, together with the rich supply of nucleotides, the distribution of amino-acids, and the possible protein-synthesizing effects of human milk all contribute to its extremely efficient utilization 3/.

Commercial formulas simulate human milk to a certain extent. However, because the exact nature and purpose of the more than 100 constituents of human milk has never been fully analysed 4/, formulas are, at best, second best. Formula feeding is significantly associated with undernutrition in the poor regions of the world 5/, and with overnutrition (PCM plus) in the affluent regions of the world 6/. Additional metabolic stresses associated with formula feeding include neonatal hypocalcemia, an excessive renal solute load, the early development of a taste for sucrose, and a predisposition to hypertension 7/.

Immunological and anti-allergenic properties. Breastmilk provides immunities to pathogens found in the living environment and in food, and to diseases to which the mother has been immunized. Through nursing, the infant acquires an individually specialized complex of immunities, uniquely adapted to protect it from particular infections in the birth and home ecology, which cannot be duplicated exactly through immunization. Because the infantile immune system develops slowly, such protection is critical.

Specific immunological factors found in breastmilk include both lymphocytes and immunoglobulin (SIgA). The SIgA antibodies of breastmilk provide protection for the infant's mucous membranes, through which most infections occur. SIgA antibodies found in breastmilk include those to neonatal sepsis, neonatal meningitis (E. coli strains); dysentery (Shigella and Salmonella), poliovirus, coxsackie, enterovirus, influenza A virus, and respiratory syncytial virus. Breastmilk also has virus-inhibiting properties which may be unrelated to antibodies 8/.

---

1/ Ibidem

2/ Committee on Nutrition, American Academy of Pediatrics, Commentary on Breastfeeding and Infant Formulas, Including Proposed Standards for Formulas. *57 Pediatrics* 278 (1976); M.A. Caliendo, *Nutrition and the World Food Crisis*, New York: 1979 (MacMillan) at 209 (hereinafter Caliendo)

3/ WHO/UNICEF. Background Paper Prepared for Meeting on Infant and Young Child Feeding at 7. UN Doc. FHE/ICF/79.3 (1979).

4/ Caliendo at 208, 210.

5/ Puffer, R.R. and C.V. Serrano, Pan American Health Organization Scientific Publication 262 (1973).

6/ Jelliffe, D.B. and E.F.P. Jelliffe, Human milk, nutrition, and the world resource crisis. *188 Science* 557 (1975); Neuman, C.G. and M. Alpaugh, Birthweight doubling time: A fresh look. *57 Pediatrics* 469 (1976).

7/ Caliendo at 210.

8/ WHO/UNICEF. Background Paper Prepared for Meeting on Infant and Young Child Feeding at 10-12. UN Doc. FHE/ICF/79.3 (1979).

The non-specific anti-infective factors in breastmilk include phagocytes, lactoferrin, lysozymes, lactoperoxidase, the complement factor, and “bifidus factors” (nitrogen-containing polysaccharides which help inhibit growth of Gram-negative bacteria and fungi in the stool) 1/.

Infections occur more rarely in breastfed than in bottlefed infants. When they do, clinical symptoms are rarer and less severe. Breastfeeding therefore plays a critical role in preventing nursery epidemics 2/.

Many allergists feel that artificially fed infants have a greater incidence of allergies, particularly eczema and milk-induced colitis 3/.

Psychological effects. Breastfeeding involves a close, physically active relationship between mother and child. Psychologists have determined that the nursing relationship fosters the development of synchronized responses between mother and child which awaken feelings of mutual love and facilitate and improve social interaction later and throughout life 4/.

Maternal health advantages. Breastfeeding stimulates production of the hormone oxytocin, involved in the involution of the uterus and stimulates uterine contractions that help reduce post-partum blood loss. Mothers who breastfeed have a decreased incidence of thromboembolism 5/. Carcinoma of the breast appears less frequently in communities where prolonged lactation is common and the longer period of amenorrhea allows the mother to conserve her iron stores 6/.

Contraceptive properties. Although, on an individual basis, breast-feeding is not adequate as the sole means of birth control, on a population level, it is a powerful and important contraceptive. The contraceptive effect results from a combination of hormonal mechanisms which delay the return of menstruation and ovulation, maternal nutritional status, and cultural taboos on sex during the breastfeeding period. Breastfeeding prolongs the birth interval by an average of four months in urban areas and an average of eight months in rural areas 7/. It is most important in rural developing regions where alternative methods are unavailable and where it may prolong the birth interval by as much as 15 months.

---

1/ Ibidem at 12-13.

2/ Gerrard, J.W., Breast-Feeding: Second Thoughts. 54. (No. 6) Pediatrics 757 (1974); Mata, L.J. and J.J. Urrutia, Intestinal colonization of breast-fed children in a rural area of low socioeconomic level. 176 Annals of the New York Academy of Science 93 (1971); Tassovatz, B. and A. Kotsich, Le lait de femme et son action de protection contre les infections intestinales chez le nouveau-né. 37 Annales Pediatr. 286 (1961).

3/ Jelliffe, D.B. and E.F.P. Jelliffe, The uniqueness of human milk. 24 American Journal of Clinical Nutrition 1013 (1971); Sartulli, T.V. et. al., Acute necrotizing enterocolitis in infancy: A review of 64 cases. 53 Pediatrics 115 (1974).

4/ Klaus, M.H., J.H. Kennell, et. al., Human maternal behavior at the first contact with her young. 46 Pediatrics 187 (1970); WHO/UNICEF. Background Paper Prepared for Meeting on Infant and Young Child Feeding at 14-15. UN Doc. FHE/ICF/79.3 (1979).

5/ Caliendo at 211.

6/ Jelliffe, D.B. and E.F.P. Jelliffe, The uniqueness of human milk. 24 American Journal of Clinical Nutrition 1013 (1971).

7/ WHO. Collaborative Study on Breastfeeding. Methods and Main Results of the First Phase of the Study. Preliminary Report at 43-53. UN Doc. MCH/79.3 (1979); WHO/UNICEF. Background Paper Prepared for Meeting on Infant and Young Child Feeding at 17. UN Doc. FHE/ICF/79.3 (1979).

Despite the considerations discussed above, nearly all infants can grow and develop well through bottle feeding with breastmilk substitutes provided these are properly manufactured, prepared and administered, meet nutritional and hygienic standards such as those established by the Codex Alimentarius Commission and are of a physical texture and composition that facilitates ingestion, digestion and assimilation. In individual cases, where mothers cannot, or choose not to, breastfeed for health, psychological, sociocultural or economic reasons, or where artificial feeding is indicated for reasons of infant health, formulas based upon cow or other animal milk, or vegetable foodstuffs, may be the preferred form of infant feeding.

#### THE COMPLEMENTARY FOOD STAGE

As a guideline nutritionists and other maternal and child health specialists recommend that complementary foods be introduced sometime between the fourth and sixth month of life. However, nutritional need for complementary foods depends not upon chronological age but upon the infant's level and rate of growth and development as indicated by, inter alia, the weight for age index 1/.

Variations in development are due primarily to (a) the infant's health status, which is affected by the overall environmental stress load including diarrheal, respiratory, and other infections; and (b) the quality and quantity of the maternal milk supply, which may be affected by the health, nutrition, and lifestyle of the mother 2/. In a context of health and affluence, breastmilk alone may be sufficient to sustain weight and length curves above the 25th percentile through the tenth month 3/, while, in a poorer context, breastfed infants may show evidence of a faltering weight gain as early as the fourth or fifth month 4/.

Unfortunately, it is frequently in the most needy contexts that nutritionally adequate complementary foods are least available. While the early introduction of proper weaning foods may be superior to prolonged, exclusive breastfeeding, the use of improper weaning foods may be much worse, leading to marasmus and death 5/.

Lactation may be improved by supplementing the maternal diet with inexpensive, readily available, high-carbohydrate foods whose protein/calorie ratio and physical texture make them unsuitable as complementary foods. The conversion of maternal caloric intake into mother's milk is a natural method of nutritional enrichment. However, even with nutritional supplementation of the maternal diet, indefinite prolongation of exclusive breastfeeding is detrimental to infant health. The critical "cut-off" point may occur as early as the fourth or fifth month where overall health status is low and ambient levels of infection are high, even when maternal milk supply remains constant for a longer period 6/.

---

1/ Scrimshaw, N. and B. Underwood, Timely and Appropriate Complementary Feeding of the Breastfed Infant - An Overview. 2 Food and Nutrition Bulletin 1970.

2/ Endozien, J.C., Malnutrition in Africa - need and basis for action, in Malnutrition is a problem in ecology (eds. P. Gyorgy and O.L. Kline Basel: Karger at 64 (1970).

3/ Ahn, C.H. and W.C. MacClean, Abstract, Growth of the Exclusively breast-fed infant. 33 American Journal of Clinical Nutrition 183 (1980).

4/ Lauber, E. and M. Reinhardt, Studies on the quality of breastmilk during 23 months of lactation in a rural community in the Ivory Coast. 32 American Journal of Clinical Nutrition 1159 (1979).

5/ International Advisory Group on Infant and Young Child Feeding, The Feeding of the Very Young: An approach to the Determination of Policies. A Report to The Nutrition Foundation, Inc. (October 1978). Newman, Marshall T., Nutritional Adaptation in Man, in Physiological Anthropology (ed A. Damon) N.Y.: Oxford Press at 210 (1975).

6/ See, Ahn, *supra*, note 49.

The issue is less one of establishing nutritional ideals than of optimizing the use of available dietary and economic resources. It requires research into the length of time for which infants in a given population can sustain adequate growth and development curves when exclusively receiving human milk from adequately nourished mothers; the most ecologically and economically feasible method of supplying additional calories; (when is it wiser to feed the mother? when is it wiser to feed the child?); and the existence of, or opportunity for developing, low cost, locally produced, high protein weaning foods.

As with the initiation of complementary feeding, the appropriate time for final weaning depends significantly on the quality of the weaning diet. Tuberous diets are especially protein poor. Grain based diets may be less so. Children weaned onto low protein/high carbohydrate diets may develop kwashiorkor and related forms of protein-calorie malnutrition which can lead to retardation of mental and physical development 1/. Such syndromes, formerly common in the developed world, and common today in the developing world, have been a major cause of the mortality peak during the second to third year of life 2/. As many as 50 to 80 of all preschool children in the developing countries may suffer from protein/calorie malnutrition of sufficient degree to cause retardation of physical and mental development 3/. Where enriched weaning foods are not widely used, the protein content of the family diet is of primary concern in determining the appropriate time for final weaning.

---

1/ Jelliffe, D.B., *Clinical Nutrition*, New York: Harper-Row at 102-102 (1962).

2/ Gordon, J.E. *et. al.*: The second year death rate in less developed countries 254 *American Journal of Medical Science* 357; Monckeberg, F., Factors conditioning malnutrition with special reference to Chile, *Advice for a volunteers program in Malnutrition is a Problem in Ecology* at 22.

3/ Edozien, J.C., *Malnutrition in Africa - need and basis for action*. In *Malnutrition is a Problem of Ecology* (eds. P. Gyorgy - O.L. Kline) Basel: Karger at 64 (1970).

## ADAPTING LEGISLATION TO THE SOCIAL, CULTURAL, AND ECONOMIC CONTEXT

### Patterns of Breast-feeding in Developing and Developed Countries

Recent decades have seen a global decline in breast-feeding. Although this trend is evident in almost all countries, both breast-feeding patterns and the problems created by the decline in breast-feeding show differences among countries at differing levels of socioeconomic development.

The prevalence and duration of breast-feeding are inversely correlated with socioeconomic status and degree of urbanization. As a global average, breast-feeding is least common among economically advantaged mothers, more common among the urban poor, and most common in rural groups. 1/ A recent cross-sectional study of 23,000 mother-infant pairs in fifteen countries, as part of the WHO Collaborative Study on Breast-feeding, revealed that the groups studied fell into three distinct categories. In the first category, which included most of the economically advantaged mothers, the prevalence of breast-feeding declined sharply with infant age; it was never higher than 50% at 6 months post partum. At the opposite extreme was the category comprised of most of the rural groups. In this category, 85% of the mothers were still breast-feeding at 6 months post partum. In the intermediate group, breast-feeding declined linearly with age up until 18 months. 2/

These data indicate a diffusion of the practice of feeding with breast-milk substitutes, from its origin among economically advantaged urbanites in the early decades of this century to poorer families and those living in more traditional communities. At least three channels of communication have conveyed ideas which have accelerated this trend.

First, and most difficult to control or to gauge, is the informal imitation of models of modernization by young mothers as part of a broader pattern of sociocultural change. 3/ This pattern includes a trend towards purchased rather than home-prepared foods, an increased influence of peer groups in comparison to older women in the community, an increased emphasis on the cosmetic value of the female breast, and an increased involvement of women in non-maternal roles. Anti-breast-feeding influences thus reach young mothers through the general educational ambience, including social networks and the mass media.

---

1/ Contemporary Patterns of Breast-feeding, Report on the WHO Collaborative Study on Breast-feeding, WHO, Geneva, 1981 at pg. 31.

2/ Ibidem at pgs. 32-36.

3/ Feeding the Preschool Child, Report of a PAG Ad Hoc Working Group FAO/WHO/UNICEF, New York 1971 at 18-19.

Second is the direct influence of the health care system and members of the health profession. For the past several decades, many maternity hospitals and clinics, and much of infant health care, has been geared to and has encouraged feeding with breast-milk substitutes. 1/

Third is commercial persuasion by the infant food industry, which has used both subtle and high-powered marketing techniques to promote artificial feeding, including direct marketing to consumers and promotion and distribution through the health care system. 2/

However, the WHO Collaborative study also revealed that breast-feeding is more frequent among economically advantaged mothers in the most developed countries than it is among economically advantaged mothers in developing countries. For example, the prevalence of breast-feeding by economically advantaged mothers in Guatemala and the Philippines was noticeably lower than in Hungary and Sweden. This suggests the possibility of an incipient reverse trend favoring increased breast-feeding, beginning especially in such countries as Hungary and Sweden, where information on proper breast-feeding forms a part of maternal-infant health care. 3/

Artificial feeding presents a health hazard in both developed and developing nations. Risk of infection is higher even in properly bottle fed infants than in those who are breastfed. In addition, infantile obesity, also called PCM plus, is a major infant health problem in affluent populations. Infantile obesity is most common among bottle-fed babies in communities where financial resources and sanitary conditions are adequate. In bottle feeding, the quantity and composition of formula are under the mother's control. If the mother encourages the child to eat excessively, obesity may result. In contrast, in breast-feeding, the volume of the mother's milk is regulated by the infant's sucking so that overeating is much less likely. 4/

Nonetheless it is among poor populations where scarce financial resources, unsanitary conditions, and lower educational attainment aggravate the inherent biological disadvantages of bottle feeding that the decline in breast-feeding continues to have the most serious consequences for infant health. It is among such populations that the decline in breast-feeding has been most dramatically correlated with both an increase in the infant mortality rate and a decrease in the age of infant death. 5/ In such populations, infant mortality curves now show peaks in the early months of life as well as the beginning of the weaning period.

---

1/ Ibidem at 19.

2/ Ibidem at 19-20.

3/ Contemporary Patterns of Breast-feeding, Report on the WHO Collaborative Study on Breast-feeding, WHO, Geneva 1981 at 153.

4/ Caliendo, Mary Alice, Nutrition and the World Food Crisis, New York: 1979 at 208; Jelliffe, D.B. and E.F.P. Jelliffe. Human milk, nutrition and the world food crisis. Science 188: 557-561 (1975).

5/ Sanjur, D.M.; Cravioto, L. Rosales, A. Van Veen: Infant feeding and weaning practices in a rural preindustrial setting. Acta Paediat. Scand. Suppl. 200: 10-43.

Such infant mortality results substantially from synergistic malnutrition-infection syndromes. The reasons for this are as follows. Proper bottle feeding requires (1) a sufficient amount of nutritionally adequate breast-milk substitute; (2) a sanitary water supply; (3) adequate facilities for sterilized preparation and cool storage, and (4) a parent or other caretaker educated in the proper preparation, storage and feeding of formula.<sup>1/</sup>

These conditions are difficult or impossible to attain in many communities. Particularly staggering is the prohibitive cost of formula for the poor. To illustrate, the cost of adequately feeding an infant on purchased commercially prepared formula for six months is equal to 70-100% of the per capita income in Ethiopia, 50-80% of the per capita income in India, and 15-40% of the per capita income in the Philippines.

To compensate for cost, parents are forced to (a) dilute formula beyond the point of nutritional adequacy; (b) substitute other fluids which resemble formula in appearance but lack comparable nutritional value; and (c) divert a significant percentage of the household food budget to the purchase of formula to the detriment of other family members.

Improperly formula-fed babies are at heightened risk of infection for three reasons: (1) Malnutrition lowers overall health status and depresses the immune system; (2) Bottle fed babies lack the complex of immunities normally transferred through breast-milk; (3) Contaminated water, spoiled formula, and unsanitary bottles and nipples introduce additional infection. These babies have more illnesses, especially diarrheal and respiratory diseases, more frequently, more severely, and at an earlier age than do their breast-fed counterparts.<sup>2/</sup> The presence of infection has an aggravating effect upon nutritional status. This, in turn, increases the infant's risk of supplementary infection, which further depresses nutritional status in a vicious synergism.

---

<sup>1/</sup> Caliendo, Mary Alice, Nutrition and the World Food Crisis New York: 1979 at 207.

<sup>2/</sup> Gyorgy P. and O.L. Kline (eds) Malnutrition is a Problem of Ecology. New York: S. Karger, 1970 pg. 30; Caliendo at 207; Feeding the Preschool Child, Report of a PAG Ad Hoc Working Group, FAO/WHO/UNICEF, New York 1971 at 17.

### Developing a Context to Support and Encourage Breast-feeding

Breast-feeding practices are obviously embedded in a matrix of social, cultural and economic forces, including interactions with the nuclear and extended family, and lifestyles of women apart from their roles as mothers. Most of these factors have been insufficiently studied to permit of generalizations and lie outside the domain where legislation may have any direct effect. Although lawmakers should devote attention to the specific sociocultural patterns of their communities, we consider here only those factors which may be most easily targeted by legislation.

The decision as to whether to breast-feed is often made in the immediate pre-natal period, and sucking must be properly established in the days following birth to continue successfully. The information, persuasion, instruction, and support which the mother receives during this period may be critical.

In communities where the majority of infants are delivered in hospitals or similar health-care facilities, and professional pre and post natal care is routine, a suitable context for breast-feeding may be created with relatively ease by placing emphasis on the following three factors. First, distribution, promotion and advice in favor of feeding with breast-milk substitutes should be minimized or eliminated except where medically necessary. Second, proper instruction and information about breast-feeding should be provided. Individual instruction or short courses for new mothers may be provided within the maternity hospital setting, and may advisably include both instruction in techniques and methods for dealing with psychological and social problems which may develop after the mother goes home. Because the mother's social network may significantly impact upon her decision to continue breast-feeding, where cultural patterns make it appropriate, instructional groups may also include the father and other members of the mother's nuclear or extended family. Other educational materials may also be developed. For example, prepared pamphlets, either written or pictographically illustrated, as appropriate to the level of parental literacy, may be provided to instruct and aid new mothers in the initiation of breast-feeding. Third, the structure of the physical environment of the child-birth setting may be crucial in the proper initiation of breast-feeding. Breast-feeding is facilitated when mother and infant are in regular twenty-four-hour-a-day contact so that on-demand feeding may evolve into a mutual accommodation of the habits of mother and child. Adequate privacy, as appropriate to the custom of the culture, for the mother to breast-feed with the modesty she desires is also essential. The requirements of maternal privacy and mother-infant contact may be met either within the hospital setting through "rooming-in" (housing mother and child in the same room), or by returning the mother to her own home relatively soon after delivery. Hospitals should also make accommodation for breast-feeding in situations where, for medical reasons, mother and infant must be separated in the days following delivery.

In communities where delivery does not generally take place in a health care facility, the childbirth environment is less susceptible of direct legislative control and it becomes more important for lawmakers to consider encouraging breast-feeding by directing attention to a broad range of factors in the maternal environment. These may include (1) control of advertising and marketing of breast-milk substitutes; (2) controlled distribution of breast-milk substitutes and accompanying utensils (such as bottles and teats) - so that they are available only upon prescription or only through health care facilities; (3) promotion of and education for breast-feeding through the mass media and educational institutions; (4) training of traditional midwives, extension workers, pharmacists and others to whom mothers normally turn for advice on health and infant care in the advantages of breast-feeding.

As the infant grows older, and the mother's routine returns to normal, a wider range of factors influence her decision and ability to continue breast-feeding. Providing continuing help with breast-feeding should be made a routine part of infant health care. Appropriate control of distribution, marketing, and promotion of breast-milk substitutes also continues to be important. Provision must be made to ensure that the resumed employment of the mother outside the home does not interfere with her ability to breast-feed. Among the most important considerations are (1) paid maternity leave, with provisions including protection against employment termination during the post-natal period; (2) regular nursing breaks for flexible work schedules to accommodate nursing mothers; and (3) infant care nurseries provided in the vicinity of the workplace.

In addition, continuation of nursing may be facilitated by providing an appropriate context during the hours which a woman spends neither at home nor at work. This is especially true in developed countries where social mores disfavor breast-feeding in public. For example, as part of the WHO Collaborative Study mothers were asked whether they preferred to breast-feed at home discreetly; at home without concern for privacy; or anywhere without concern for privacy. Half or more of the mothers in all the economically advantaged groups except in Ethiopia and Zaire preferred to breast-feed in privacy; while in most of the rural and urban-poor groups, a majority of mothers said they would breast-feed anywhere without regard to privacy.<sup>1/</sup> These data indicate that breast-feeding patterns might be meaningfully increased by the provision of private "breast-feeding" areas in public locations.

### International Law and Breast-feeding

Several instruments of international law contain provisions specifically directed at fostering environments and contexts conducive to breast-feeding. They may serve as guidelines, examples, standards and beginnings for the development of national legislation.

The International Code of Marketing of Breast-milk Substitutes, adopted by the World Health Assembly in 1981, is included as an appendix to this study. Article 5 of the Code governs the relationship between the general public and mothers to the marketing and promotion of breast-milk substitutes. It prohibits advertising to the general public (Art. 5.1); direct or indirect distribution of free samples of breast-milk substitutes to pregnant women, mothers or members of their families by manufacturers and distributors (Art. 5.2); prohibits point-of-purchase promotion, tie-in sales, loss-leaders and similar promotional devices (Art. 5.3); prohibits the distribution of utensils which may promote bottle feeding (Art. 5.4); and directs that marketing personnel, in their business capacity, should have no direct contact with pregnant women or mothers of infants and young children (Art. 5.5).

---

<sup>1/</sup> Contemporary Patterns of Breast-feeding, Report of the WHO Collaborative Study on Breast-feeding, WHO, Geneva, 1981 at 46.

Article 6 governs the relationship of breast-milk substitutes to the health care system. It prohibits promotion of breast-milk substitutes through health care facilities (Art. 6.2); display of products, placards or posters in health care facilities (Art. 6.3); and use by the health care system of “mothercraft nurses” and similar personnel, provided or paid for by manufacturers and distributors of breast-milk substitutes (Art. 6.4). It also mandates that demonstration of breast-milk substitutes should be made only by health workers and only to those who need to use the products (Art. 6.5); and that distribution of breast-milk substitutes should be made only to those who must be fed on them (Art. 6.6); and states that steps should be made to continue the supply of such donated products for as long as necessary (Art. 6.7).

Article 7 of the Code governs health workers. It states that health workers should encourage and protect breast-feeding (Art. 7.1); that information provided to health workers should be limited to scientific and factual matters (Art. 7.2); that no financial or material inducements to promote breast-milk substitutes should be made to health professionals (Art. 7.3); that health workers should not give out samples of breast-milk substitutes (Art. 7.4); and that manufacturers and distributors should disclose to the relevant institutions any contribution made to a health worker or on his behalf (Art. 7.5).

Article 8 of the Code governs persons employed by manufacturers and distributors. It provides that no bonuses or sales quotas should be established for the sale of breast-milk substitutes (Art. 8.1); and that sales personnel should not be used as health workers (Art. 8.2). Articles 9 and 10 of the Code govern labelling and quality, respectively.

Several of the ILO Conventions contain provisions ensuring the working mothers are able to continue breast-feeding through (1) paid maternity leaves including a pre and post partum period; (2) guarantees against employment termination during this period; (3) nursing breaks during the work day compensated as working hours; and (4) infant nurseries and creches in the vicinity of the workplace. For example, ILO Convention No. 103, Convention Concerning Maternity Protection (Revised 1952), applies to women employed in industrial undertakings and in non-industrial and agricultural occupations, including women wage earners working at home. Article 3.2 of the Convention provides for a period of paid maternity leave of at least 12 weeks, including a period of compulsory leave after confinement of at least six weeks, which may be extended for medically certified illness arising out of pregnancy. Article 4 provides that during this period a mother shall receive cash benefits sufficient for the full and healthy maintenance of herself and her child in accordance with a suitable standard of living; and that where such cash benefits are provided based on previous earnings, they should be at a rate of not less than 2/3 of the woman's previous earnings.

Article 5 provides that if a woman is nursing her child she shall be entitled to interrupt her work for this purpose at a time or times to be prescribed by national laws or regulations and that interruption of work for the purpose of nursing shall be counted as working hour and remunerated accordingly or as determined through collective bargaining agreements.

### Complementary Food Considerations

Although numerous nutritionally adequate and hygienic commercial “baby foods” are widely available, the weaning period continues to be a nutritional crisis point in many countries because of the high cost of weaning infants onto a nutritionally adequate diet. Facilitation of proper weaning presents a two-fold problem for lawmakers. On the one hand, legislation directed at commercial baby foods should be concerned with the scrupulous control of quality and hygiene which is appropriate to food law. Where financial factors raise the risk of inappropriate use of commercial baby foods, consideration should also be given to controls on marketing and distribution similar to those suggested above for breast-milk substitutes and to various forms of cost-subsidized food subsidy programs.

On the other hand, legislation directed towards commercial baby foods should be different from, and not interfere with, positive legislation directed towards the development and promotion of locally produced weaning foods. Development of adequate complementary foods through nutritional enrichment of local grains and tubers is a superior solution to the problem of protein calories malnutrition during the weaning years than importation or imitation of commercial “baby foods”. Local products are less expensive, can be prepared at home or on an artisanal scale, more closely approximate the taste of the foods that the child will eat later, and may represent a step towards achieving of national nutritional self-sufficiency. To date, some eighty such complementary foods have been developed, including Faffa in Ethiopia; Lukuni Phala in Malawi; Bennimix in Sierra Leone; and Kaset Infant Food in Thailand. The number of such products, and the distribution and use of existing products is not yet sufficiently widespread to meet the need. Legislative attention to complementary foods is, therefore, substantially a consideration of developing positive contexts, inducements and incentives to the development, production, distribution and sale of local complementary foods through structures and support systems appropriate for the country concerned.

## LABELLING EFFICACY AND LOW LITERACY RATES

Labels for breastmilk substitutes and proprietary infants' and children's foods pose special problems because they must communicate a large amount of technical information succinctly and effectively to ensure proper, safe product use. Much existing legislation solves the problem through comprehensive labelling provisions requiring full information on, inter alia, the intended use or user of the product; the names and quantities of all ingredients and additives; techniques for proper preparation, storage, and use of the product; date of expiration; and sufficient information on the manufacturer, importer, or distributor to enable liability to be fixed. Recently, statutes and codes have further suggested that labels for infant formula bear additional warnings against improper use or statements stressing the superiority of breastfeeding 1/.

Although scholars in the field have debated whether accuracy and completeness or consumer comprehensibility should be paramount in determining labelling requirements 2/, it is clear that a label cannot be effective if the purchaser cannot understand it 3/. Labelling requirements should therefore be established based on a reasoned determination of how the purchaser can best be made to understand what the purchaser needs to know to use the product safely and appropriately. Detailed scientific labelling may be the preferred means of protection where the majority of consumers are literate and formally educated. Labeling in an "appropriate language" provides additional assurance of purchaser understanding where imported products are marketed or where products are marketed among a group speaking a language or dialect different from the national language.

However, the "label loading" method is not immediately applicable to the needs of many poor, non-literate or poorly literate purchasers in the developing nations. Such purchasers may have a twofold problem: (1) They may need to learn more from the label to properly use the product, and (2) they may be able to understand less in written form. Recently, attempts have been made to develop pictographic, diagrammatic, and color-coded labels. Every effort should be made to extend and improve such labelling, including pre-market testing with intended purchasers.

However, because it is questionable whether pictures and diagrams can communicate sufficiently to teach an adult how to properly feed an infant or small child with proprietary foods, legislative attention should be devoted to combining labelling with additional means of purchaser information including (1) standardized verbal instructions for product purchasers; (2) standardized verbal instructions in electronic media promotion; (3) nutrition education; and (4) controlled and "prescription only" distribution of easily misused proprietary foods.

---

1/ See, for example, Peru, Ministerial Resolution No. 0041-80-SA/DS of 1 April 1980, Chapter I; International Code of Marketing of Breastmilk Substitutes, Article 4.2 - WHA 34.22.

2/ Compare, Brewer, J.N., Labeling and Advertising Trends; If it is in the labeling, Is it off our shoulders? Food, Drug and Cosmetic Law Journal at 631 (December 1979), and Gerard, A., An Outline of Food law at 51-53, Legislative Study No. 7, Rome, FAO: 1975.

3/ Gerard, A., An Outline of Food Law, Legislative Study No. 7, Rome, FAO: 1975.

### FOCI OF TRADE REGULATION

The trade aspects of food encompass all processes from production or manufacture to final retail sale, including assembly, storage, transport, processing, export, import, distribution, promotion, and advertising. Together, these processes form an integrated system which significantly impacts upon the quality and purchase price of food products <sup>1/</sup>. Many national schemes of food legislation choose one or more of these elements, typically the manufacturer or vendor, as the primary focus of regulatory legislation.

Effective legislation on infants' and children's foods requires a determination of the focus or foci of regulation appropriate to the country concerned. These foci may be the same as or different from those appropriate in other areas of food law. In making this determination, there is a need to consider the entire food trade system, including intrafamilial and international aspects. For a discussion of two such foci, which may prove to be of considerable importance but which are not presently emphasized in most food legislation, the reader is referred to the two subheadings: The parent or other purchaser, and Import and Export Control on page 8 of this study.

---

<sup>1/</sup> Food Marketing and Nutrition, V (No. 3) PAG Bulletin 2 (1975)

SUMMARIES OF LEGISLATION ON FOODS FOR INFANTS AND SMALL CHILDREN

List of Countries;

Argentina

Australia, State of South Australia

Brazil

Canada

Colombia

Denmark

Italy

Kenya

Mexico

Netherland

New Zealand

Papua New Guinea

Peru

Portugal

Sri Lanka

Sweden

Thailand

United States of America

Venezuela

Yugoslavia

also, European Economic Community -

List of Topics:

Purposes and Scope

Definitions

Ingredients

Hygiene and Purity

Packaging and Labeling

Advertising and Promotion

Control and Inspection

Import

Export

Measures to promote breast-feeding and implement nutritional policy

## SUMMARY STATEMENT OF LEGISLATION SURVEYED

This survey of national legislation on infants' and children's foods is intended to be representative, not exhaustive. Its purpose is twofold: (1) to provide an overview of legislation in this area; and (2) to suggest basic principles and guidelines which may be useful in improving, expanding, and developing legislation. Countries were selected so as to include, insofar as possible, a balanced geographical representation from among the nations having specific statutes and/or provisions on foods for infants and small children.

The countries included in the survey are; Argentina, Brazil, Canada, Colombia, Italy, Kenya, Mexico, the Netherlands, New Zealand, Papua New Guinea, Peru, Portugal, Sweden, Thailand, the United States, Venezuela, and Yugoslavia. Statutes were found to cover some or all of the following topics: definitions, ingredients, hygiene and purity, packaging and labeling, advertising and promotion, control and inspection, import, export, and measures to promote breast-feeding.

### DEFINITIONS

#### Definitions of age groups

Many legislative systems divide young children into two age groups, "infants" and "small children". Argentina, Canada, Mexico, Sweden, and Yugoslavia define "infants" as those up to or through the first year of life. In Argentina "small children" are defined as those between one and two years of age, while in Mexico and Yugoslavia, the category includes those up to three years of age. Brazil employs a three part system: infants, pre-school children, and school children up to age 14. Portugal and Venezuela use an alternative method. "Infants" and "small children", without specific age designation, are included within a broader category of "healthy persons under special physiological exigencies of nutrition", a category which, relevantly, also includes pregnant and lactating women.

#### Definitions of food products

Considerable variation exists in the definitions and legal descriptions of food products. Many legislative systems, including those of Argentina, Denmark, Portugal, Venezuela and Yugoslavia, classify foods for infants and small children within a broader category of "dietetic foods" or "foods for special dietary purposes", typically, this type of food is defined as that which is (1) distinguishable from the corresponding regular product by virtue of its composition or processing and (2) thereby fit or suitable for the dietary needs of a special category of person. The New Zealand Food and Drug Regulations refer to such products as "special purpose food", an apt term because, unlike the word "dietetic", it avoids any association with weight loss or metabolic disorder.

The Italian system of classification is outstanding in relating definitions to stages of nutritional development. It divides "foods for small children" into three categories: (1) those which substitute in whole or in part for mother's milk; (2) those which are used from the moment of weaning; and (3) those which are used to supplement the nourishment of the body during the first period of life.

Provisions defining particular foodstuffs and types of foodstuffs are numerous and differ too greatly among legislative systems to be described in general terms. The Canadian system classifies foods for infants and small children into four categories, roughly corresponding to the generic designations used by food manufacturers: infant formula, infant food, strained food, and junior food. The United States Infant Formula Act provides a comprehensive definition of "infant formula" as a food for infants which purports to be or is represented as being for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk. A Mexican regulation defines three types of corn cereal products with added chocolate or cocoa in terms of their proportions of specific constituent ingredients.

There is some combination, even within single statutes, of definitions based upon the product's actual fitness for purpose and definitions based upon the way the product is represented for sale. In general, definitions based upon nutritional and textural suitability are superior to those based upon labeling or contents because they may more easily serve as a vehicle for establishing nutritional standards.

### INGREDIENTS

Comprehensive mandatory standards for ingredients and quantities have not yet been widely adopted in national legislation. The laws of some countries, for example Yugoslavia, state in general terms that product contents should conform to the physiological needs of their intended consumers, without prescribing contents specifically. The laws of other countries, for example Argentina, state permissively that products "may" satisfy full nutritional requirements.

Standards for breastmilk substitutes and infant formulas are to be met with most frequently. Of the nations surveyed, Australia, State of South Australia, Canada, Denmark, Italy, the Netherlands, Sweden, Thailand, the United States and Yugoslavia have mandatory standards for such products. Compulsory standards for other children's foods are rare. Thailand has excellent, precise standards for weaning foods; Italy and Yugoslavia have extensive but more generally stated provisions; Mexico has specific standards for corn cereals with chocolate or cocoa; and Canada has established maximum limits for sodium chloride.

### HYGIENE AND PURITY

Nearly all nations surveyed have established extensive hygienic standards, and prohibitions of, or limitations on, the use of preservatives, antioxidants, other non-nutritive substances and pesticide residues. Such standards are contained either within the specific provisions on foods for infants and small children or within the general provisions of the various food codes.

Typically, however, these standards are controlled and enforced only at the point of production (as in Italy); at the point sale (as in Kenya); or, as appropriate, along the chain of commerce (as in Brazil). The Papua New Guinea Baby Feed Supplies (Control) Act and Regulation stand nearly alone in coping with the problem of hygiene and purity at the consumer level. Under the Act and Regulation it is a punishable offence to use baby bottles and teats without proper authorization. Such authorization can be granted only on the condition that the parent or caretaker has received and understood standardized directions in the proper use and cleaning of the items.

## LABELING

Labeling provisions are extensive for almost all countries surveyed. Typically required are: (1) the name of the product (Italy, Kenya, Mexico, New Zealand and Portugal); (2) the product's special purpose and the characteristics which make it so fit (Denmark, Italy, Kenya, New Zealand, Portugal, Sweden, Thailand, Venezuela and Yugoslavia); (3) the net contents by weight, mass, volume and/or caloric value (Argentina, Denmark, Canada, Italy, Kenya, Mexico, New Zealand, Portugal and Yugoslavia); (4) all or major ingredients or additives, often in descending quantitative order, and the amount of each, with greater or lesser degree of specificity (Australia, State of South Australia, Argentina, Canada, Denmark, Italy, Kenya, Mexico, the Netherlands, New Zealand, Peru, Portugal, Sweden, Thailand, Venezuela and Yugoslavia); (5) information enabling the manufacturer or distributor to be identified (Italy, Mexico, the Netherlands, New Zealand, Portugal, Thailand and Yugoslavia); and (6) an indication of product life through date of manufacture, date of sale, or expiration date (Denmark, Italy, the Netherlands, Portugal, Thailand, Venezuela and Yugoslavia).

Directions for proper preparation are required on the label in Australia, State of South Australia, Argentina, Canada, Denmark, the Netherlands, Portugal, Thailand, Venezuela, and Yugoslavia. Directions for hygienic use are required in Peru. Directions for proper storage are required in Canada, Portugal and Yugoslavia. The Venezuelan requirements are especially comprehensive. They include (a) instructions for the preservation of the unopened package; (b) information necessary to guarantee the integrity of the product from the moment of opening until use; (c) instructions for reconstituting the product; (d) instructions on the appropriate mode of use; and (e) a warning if it is not possible to preserve the product after opening or to preserve it in its original container.

Italy and Portugal prohibit curative claims and misleading statements on product labels. Argentina, New Zealand and Mexico require specific warnings for certain easily misused products. National language labeling is required in Italy, Kenya, Portugal, Thailand and Sweden. Standards of legibility, visibility, readability or indelibility are required in Argentina, Italy, Kenya, Mexico, and Thailand.

One major drawback of most existing labeling legislation is that it covers only the printed word, without consideration of photographs, illustrations, diagrams and other suggestive materials. In this regard, New Zealand offers an excellent model for expanding the concept of labeling, especially where pictographic and diagrammatic labels are used. Under the New Zealand Food and Drug Regulations, "label" is defined as any written, pictorial, or other descriptive matter appearing on or attached to the exterior of any package containing food. The Regulations further prohibit any misleading statement, word, brand, picture, or mark from appearing on any label.

## ADVERTISING AND PROMOTION

Regulations on advertising and promotion of foods for infants and small children are not extensively developed or frequently found in the legislation surveyed.

Colombia and Papua New Guinea have recently enacted laws regulating the advertising of infant formulas. Colombia excludes advertising discouraging breastfeeding or emphasizing the bottle in preference to the breast from health centres, health posts, and hospitals. The more stringent Papua New Guinea legislation proscribes publication

of any advertisement the intention or likely result of which is to encourage bottlefeeding the purchase of bottles or teats, or the purchase of milk and other products to be used in connection with bottles.

Peru and Papua New Guinea have established positive requirements for informational materials. In Peru, such materials must be developed by qualified, experienced personnel with due regard for the economic, educational and social background of purchasers and must be supplied, in sufficiency to meet demand, through various communications media. Such informational materials must explain the rules of hygiene and the need to use uncontaminated water, emphasize that human milk is the ideal infant food and avoid any statement that one product is superior to another. In Papua New Guinea, standardized instructions must be read and explained to purchasers by health workers before they can receive authorization to purchase baby bottles and teats.

Argentine, Italian, Portuguese and Venezuelan legislation on advertising extends generally to dietetic products. Italy, Portugal and Venezuela prohibit claims of curative properties and other misleading statements from consumer advertising, and Argentina requires that all information with respect to dietary products be intended primarily for medical professionals.

Peru limits other promotion of infant formulas: personnel who disseminate information may only distribute samples to health professionals and may receive remuneration for formula demonstrations only from producers, distributors and vendors of such products.

#### CONTROL AND INSPECTION

Control and inspection provisions are diverse, as appropriate to the varying administrative structures of the countries concerned. Three laws are particularly noteworthy for the emphasis they place on different points in the chain from manufacturer to consumer. Italy places emphasis upon the point of manufacture. Separate authorization must be obtained from the Minister of Health for the manufacture of each food product. Requests for authorization must include the analytical method of ingredient control, all documentation about the product's purpose and any new or rarely used substances it contains, and plans of production facilities, general services and utilities. Inspection may be required prior to the granting of authorization.

In the United States, manufacturers are similarly required to notify the Secretary of Health and Human Services prior to distributing new or altered products. The Secretary establishes quality control procedures, including periodic testing. Additionally, nonconforming products are subject to recall.

The Papua New Guinea legislation is unique in emphasizing control at the purchaser level. It is an offence, punishable by substantial fine, to use a baby bottle or teat without proper authorization, or to grant such authorization without being satisfied that the parent or other caretaker understands the proper care and use of the items.

#### IMPORT AND EXPORT

Import and export legislation on foods for infants and small children is poorly developed among the nations surveyed. Of the food importing nations, Kenya has extensive quality control of imports. If a product does not conform to the provisions of the Food, Drug and Chemical Substances Act and Regulations, to the satisfaction of an authorized officer, it may provisionally be brought into the country for purposes of

bringing it into conformity with requirements. If this is not done satisfactorily within three months, it must be removed from the country or else may face forfeiture to the government.

Standards for exported products are virtually non-existent. Argentina and Italy specifically exempt products destined for export from the need to comply with domestic standards if they meet the standards of the country of destination.

Sweden is exceptional in requiring that skim milk must be fortified with vitamin A, if exported to countries where hypovitaminosis A is a major nutritional problem. In the United States, the Secretary of Health and Human Services is authorized to make recommendations concerning action to be taken in regard to the export of infant formula which could not be legally marketed domestically.

#### Promotion of Breast-feeding

Laws and regulations specifically designed to promote breastfeeding are beginning to appear in national legislation. Colombia has issued directives for medical care from the pre-partum period through the infant's second year of life which include: (a) nipple strengthening exercises during pregnancy, (b) rooming-in and on-demand feeding during the puerperal period, (c) exclusive breastfeeding for four months, (d) introduction of complementary foods using a cup and spoons, and (e) continuing education in maternal and infant nutrition. Sweden has issued Instructions to maternity hospitals to ensure that neonates receive human breastmilk including (a) the provision of special nurse-midwives as breastfeeding instructors and supervisors and (b) the establishment of milk banks for the infants of mothers who cannot nurse.

## ARGENTINA

- Argentine Food Code (Código Alimentario Argentino), Law No. 18284, 18 July 1969 - Boletín Oficial de la República Argentina, 20 September 1979, No. 2262 p. 5-69.
- Decree No. 2126-30 June 1971 - Boletín Oficial de la República Argentina, 20 September 1971, No. 2262, 30 June 1971 (Covering infants and childrens foods).

### Purposes and Scope

The Code is designed to link food legislation to processes of nutritional and economic development. The Preamble states that the purpose of the Code is to unify national food legislation in order to (a) provide a solution to the country's very serious nutritional problems; (b) eliminate the heterogeneity of provincial norms which hamper the national distribution of food products, thereby restricting the growth of the national food market; (c) facilitate the free circulation of imported products which comply with the Codex Alimentarius Worldwide Standards; (d) improve the quality and prestige of Argentine exports; (e) stimulate the development of a coordinated food production industry; (f) stimulate the scientific and technological research in food production and the formation of food technology; and (g) stimulate the formation of establishments which will follow these provisions for the benefit of the entire country.

The Code covers all food, drinks and raw materials for these and all persons, firms, establishments, etc., which manufacture, process, distribute, sell, import or export foods, drinks, additives or raw materials for these (Articles I and II, Annex I). Its aim is to prevent all spoiled, contaminated, adulterated, or spurious food from being put into commerce.

The sections of the Code dealing with foods for infants and small children (primarily Chapter XVII of Decree No. 2126) define with specificity a particular group of consumers and a particular type of product and establish consumer protection through provisions on labeling and hygiene, but set only general and non-mandatory guidelines for nutritional composition.

### Definitions

Foods for infants and small children are defined as a special type of dietary food. (Chapter XVII of Decree No. 2126). Two age groups are defined: (1) "infants" (lactantes), meaning children from birth through the first year of life and (2) "small children" (niños en la primera infancia), meaning children from 1 year through 2 years of age. Food products for them should be of the following types: (1) liquid or powdered preparations of a composition suitable to substitute partially or totally for mother's milk; (2) preparations for use as general foods for healthy infants, that is, "modified milk"; and (3) preparations for adapting infants to the foods of small children. These foods include dietetic cereals, and preparations based on vegetables, meat, organ meats, eggs, fruit, etc., presented in the form of paste, powder, puree, etc. (Article 1.371).

“Modified milks” are defined as those which, by being subjected to special treatment, Or by the addition of different nutrients or partial substitution of nutrients, have been transformed in their physical properties or have been altered in the percentage relationship of the original constituents (Article 1.376). The law refers to the generic term leche maternizada. “Dietetic cereals” are defined as those products which are designed to adapt the infant to the diets of 1-2 year olds, which are generally made of cereal or vegetable flours, starches, or their derivatives (dextrose, maltose, etc.) in combination with other foods such as powdered milk, powdered eggs, edible fats, carbohydrates, minerals, vitamins, and special substances to render them more digestible.

#### Ingredients

Ingredients standards for foods for infants and small children are expressed in general terms. The composition of all general foodstuffs for these age groups and all transitional food preparations should be authorized by satisfactory information from at least three pediatric specialists belonging to the public health department or specially designated by it for this purpose (Article 1.374). All products: (a) should only contain ingredients suitable for children of the age for which the product is intended; (b) must be made from raw materials which meet maximum standards of quality; and (c) may contain the aggregation of nutrients in the quantity required to comply with the nutritional norms of children for the ages for which they are intended (Article 1.370). Special provisions concern the addition of acid to milk products. Milk products sold in powdered form, if acidified or containing acid, must not have an acid content greater than 1 g/100 millilitres, expressed in lactic acid (Article 1.376). All products for infants which contain added biological or lactic acid must state on the label the contents of the acid per 100 grams of product.

#### Hygiene and Purity

All products must be free from hormones and antibiotics, and practically free from pesticide residues. They must not contain artificial colouring agents, preservatives or synthetic antioxidants (Article 1.370). Modified milks sold in fluid form must be sterile (Article 1.376). Additionally, all products must conform to general standards for dietetic foods.

#### Packaging

All dietetic foods must be appropriately packaged at the factory and may not be divided up for retail sale (Article 1.342).

#### Labelling

Detailed provisions on labeling are provided. The raw ingredients used and their caloric value must be shown (Article 1.371). All foods for infants must show on the label the principle ingredients, quantitatively and qualitatively, including the contents of calcium, vitamin and vitamin D. Labels for products sold in solid form which must be prepared by dissolving in water or other appropriate medium must give directions for preparation and the percentage composition of the ready-to-consume product. All foods for infants and small children must state the method of preparation on the label (Article 1.375). Additionally, all foods for infants and small children should carry on the label the statement “Consult with physician” in well-placed, emphasized, easily seen and easily legible characters, not less than 2mm. high.

Advertising and Promotional Activities

All information with respect to the use of dietary products must be intended primarily for medical professionals (Article 1.342).

Export

Although imported and exported products must generally conform to the standards of the Code, it is permissible to export products which do not comply with the norms when (1) their production, manufacture, or division has been authorized for this purpose by the national health authority, (2) they satisfy the norms of the importing country and (3) they express clearly and completely on all packaging and requirements under (1) and (2).

## AUSTRALIA - STATE OF SOUTH AUSTRALIA

- The Food and Drug Regulations, 1978, Part 55 - Standard for Infants' Foods, (revoking Regulations of 27 August 1964)

### Purposes and Scope

The regulations establish ingredient, purity and comprehensive labeling requirements for infants' foods.

### Definitions

Infants' food is defined as any food described or sold as suitable for infants (55.1).

### Ingredients

Any food advertised, described or sold as suitable for infants under six months of age must not contain less than 2.1% fat, and 4.0% lactose, when prepared for use in accordance with the directions for an infant one month old (55.3). No infant food may contain more than 0.3% fibre (55.2). The energy standard for an infant one month of age is to be taken as 1675 kilojoules [55.4(e)].

### Hygiene and Purity

All infants' foods are to free of rancidity and contain no preservatives and no mineral substances insoluble in decinormal hydrochloric acid (55.2).

### Labeling

Labels of all foods advertised, described or sold as suitable for infants, except unsweetened condensed milk, must legibly and prominently state the following (55.4); (a) the date of packaging; (b) the source(s) of proteins and fats, and the nature of all carbohydrates; (c) the percentage composition of the food when prepared in accordance with instructions for a one month old infant; (d) exact directions for preparation, including a statement of the weight corresponding to the measure of the amount of food directed to be used; (e) a statement of the average amount of prepared food to be given to an infant at one time, and the proper number of feeding times per day; and (f) a statement of the nutrient and energy composition of the food, compared to human milk and average energy requirements, displayed as in the table below.

#### Composition of food for an infant aged one month

	human milk %	prepared food %
Proteins	1.5	--
Fat	3.5	--
Lactose	6.5	--
Ash	0.2	--

Food value, expressed in kilojoules, in one day's food: 1675 (approx.)

The above labeling requirements do not apply if the label states: "UNSUITABLE FOR INFANTS UNDER THE AGE OF SIX MONTHS" in standard type letters not less than 1.5mm. in height.

## BRAZIL

- Decree No. 112.486 of 20 October 1978 (extending the terms of Decree No. 12.342 of 27 September 1978 and revoking Decree No. 52.504 of 28 July 1970).

### Purposes and Scope

The Decree establishes Special Technical Standards and analytical methods for the microbiological hygiene and purity of foods for infants, pre-school children, and school children up to 14 years of age. It covers pre-packaged products offered for consumer sale and packaged and bulk products placed in the chain of commerce between producer and final purchaser.

### Definitions

Definitions necessary to understand the Standards are established as follows: (1) "unit" is the quantity of food or drink per container; (2) "lot" is a unit or group of units of the same nature, size, type and form presentation; (3) "shipment" is lot or combination of lots from the same responsible producer; (4) "sample size" or "n" is the number of containers or sample units that may represent the lot (for purposes of analysis); (5) "acceptability number" or "c" is the maximum number of defective units it is possible for the sample to contain and still be considered acceptable; (6) "m" is the amount, in grams, of an organism which marks the limit between a product of acceptable quality and a product of marginal quality; (7) "M" is the amount, in grams, of an organism which marks the limit between a product of marginal quality and a product of unacceptable quality.

Hygiene and Purity

Standards are as follows;

Products Ready-to-Consume with the Addition of Liquid

Microorganism	Sample Size “n”	Acceptability Number “c”	Contents per gram	
			“m”	“M”
total content of mesophilic bacteria $5.10^5$ (except for fermentation bacteria in foods obtained by fermentation)	5	1		$5.10^4$
Coliform bacteria	5	1	10	$10^2$
<u>E. coli</u>	5	0	Absent from 1 gram	
<u>B. cereus</u> (in foods for infants, 0-1 yr. of age)	5	1	10	$10^2$
<u>B. cereus</u> (in foods for children older than 1 year)	5	1	$10^2$	$10^3$
Yeasts & molds	5	1	$10^2$	$10^3$
Sulfur-reducing anaerobic organisms	—	—	—	—
Staphylococcus (+ coagulating)	5	0	Absent from 1 gram	
Salmonella	10	0	Absent from 250 grams	

Products Requiring Cooking, Prepared According to Directions

Microorganism	Sample Size “n”	Acceptability Number “c”	Contents per gram	
			“m”	“M”
total content of mesophilic bacteria $10^6$ (except for fermentation bacteria in foods obtained by fermentation)	5	1	$10^5$	
Coliform bacteria	5	1	$10^2$	$10^3$
<u>E. coli</u>	5	1	1	10
<u>B. cereus</u> (in foods for infants, 0-1 yr. of age)	5	1	10	$10^2$
<u>B. cereus</u> (in foods for children older than 1 year)	5	1	$10^3$	$10^4$
Yeasts & molds	5	1	$10^3$	$10^3$
Sulfur-reducing anaerobic organisms	5	1	10	$10^2$
Staphylococcus	5	1	1	10
Salmonella	10	0	Absent from 250 grams	

Ready-to-Consume Products

Microorganism	Sample Size “n”	Acceptability Number “c”	Contents per gram	
			“m”	“M”
total content of mesophilic bacteria $10^5$ (except for fermentation bacteria in foods obtained by fermentation)	5	1	$10^4$	
Coliform bacteria	5	1	$10^2$	$10^3$
<u>E. coli</u>	5	0	Absent from 1 gram	
<u>B. cereus</u> (in foods for infants, 0-1 yr. of age.)	5	1	10	$10^2$
<u>B. cereus</u> (in foods for children older than 1 year)	5	1	$10^2$	$10^3$
Yeasts & molds	5	1	$10^2$	$10^3$
Sulfur-reducing anaerobic organisms	5	1	1	10
Staphylococcus (+ coagulating)	5	0	Absent from 1 gram	
Salmonella	10	0	Absent from 250 grams	

After seven days incubation at 35° Centigrade, there should be no observable change in packaging or modification in the physical, chemical or organoleptic nature of the product. After such incubation, the total content of mesophilic bacteria, for products with a pH greater than 4.5 should be as follows: “n” = 5; “c” = 0; “m” = 10<sup>2</sup>. After incubation, the total content of mesophilic bacteria for products with a pH equal to or less than 4.5 should be as follows: “n” = 5; “c” = 0; “m” = 10<sup>3</sup>. In no case should sterilized milk products contain pathogens or toxins, or more than 10 aerobic germs per gram of product, after seven days incubation at 35° Centigrade.

#### Inspection and Control

The Decree establishes detailed procedures for testing. In particular, it provides for three types of analyses: (1) “Routine analysis” to be done on samples collected from commercial establishments; (2) “Analysis as indicated by lot or shipment” to be done on foods directed towards the consumer when reason exists to suspect the quality or quantity of the product; and (3) “Analysis to verify the Acceptability of the Lot or Shipment of Product” to be done whenever a purchaser demands that a vendor prove the quality of the product.

## CANADA

- Food and Drugs Act - Chapter F-27 of the Revised Statutes of Canada, 1970, as amended.
- Regulations concerning foods for infants and small children, Division 25-9 August 1978, B. 25.001 - B. 25.060, pgs. 73E - 73H.

### Purposes and Scope

The Food and Drugs Act integrally incorporates nutritional standards as well as consumer protection principles, with implementation and enforcement powers in both areas vested in the Governor in Council. The Act aims primarily at regulating food quality at the point of sale, with broad coverage and interpretation of advertising and labeling. The general provisions of the Act include (a) a comprehensive definition of food, as any article manufactured, sold or represented for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purposes whatever; (b) a simple and all-embracing definition of unsanitary conditions, as any conditions or circumstances which might contaminate a food, drug or cosmetic with dirt or filth or render the same injurious to health; and (c) an inclusive definition of advertisement as any representation, by any means whatever, for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device. This broad definition of advertisement brings within its scope all efforts at product promotion, whether oral, written, broadcast or pictorial, which may in any way influence either the sale or the disposal of a product.

The regulations concerning foods for infants and small children reflect the Act's major emphasis on nutritional quality, specifying detailed standards for ingredients as well as labeling requirements.

### Definitions

“Infant” “(bébé)” is defined as a person who is under the age of one year (B.25.001). Foods for infants and small children are divided into four categories, as follows, similar to the generic designations employed by food producing corporations.

“Infant formula” means a food that is sold, labelled or advertised as a substitute for human milk in meeting the nutritional requirements of infants with normal or special dietary needs and is of such consistency that, when ready to serve, it passes freely through a nursing bottle nipple (B.25.001). “Infant food” means a food that is sold, labelled or advertised for consumption by infants. “Strained food” means a food that is of a generally uniform particle size that does not require and does not encourage chewing before being swallowed. “Junior food” means a food that normally contains particles of a size to encourage chewing by infants, but may be readily swallowed by infants without chewing.

Ingredients

A. Infant formula: To be sold or advertised, infant formula must contain, as normally consumed:

- (i) not less than 3.3 grams of fat and not more than 6.0 grams of fat per 100 available kilocalories;
- (ii) not less than 500 milligrams linoleic acid in the form of a glyceride per 100 available kilocalories;
- (iii) not more than 1 kilocalorie from C22 Monoenoic Fatty Acids per 100 available kilocalories;
- (iv) not less than 1.8 grams of protein and not more than 4.9 grams of protein per 100 available kilocalories;
- (v) not less than 1.8 grams of protein of nutritional quality equivalent to casein as determined by the applicable official method, or such an amount and quality of protein, including those proteins to which amino acids are added, that, when the quality of the protein is expressed as a fraction of the quality of casein, the fraction will not be less than 85/100 and the product obtained by multiplying the fraction by the gram weight of the protein will not be less than 1.8, per 100 available kilocalories;
- (vi) not less than 12 milligrams of choline per 100 available kilocalories;

- (vii) a vitamin and mineral composition, per 100 available kilocalories, in conformity with the table below:

	Column I	Column II	Column III
Item No.	Vitamin or Mineral nutrient	Minimum amount per 100 available kilocalories	Maximum amount per 100 available kilocalories
B.1	Biotin	2 mcg	
F.1	Folic acid	4 mcg	---
N.1	Niacin	250 mcg	---
P.1	d-pantothenic acid	300 mcg	---
R.1	Riboflavin	60 mcg	---
T.1	Thiamine	40 mcg	---
T.2	Alpha-tocopherol	0.6 I.U.	---
V.1	Vitamin A	250 I.U.	500 I.U.
V.2	Vitamin B6	35 mcg	---
V.3	Vitamin B12	0.15 mcg	---
V.4	Vitamin C	8. mg	---
V.5	Vitamin D	40 I.U.	80 I.U.
V.6	Vitamin K1	8 mcg	---
C.1	Calcium	50 mg	---
C.2	Chloride	55 mg	150 mg
C.3	Copper	60 mg	---
L.1	Iodine	5 mcg	---
L.2	Iron	0.15 mg	---
M.1	Magnesium	6 mg	---
M.2	Manganese	5 mcg	---
P.2	Phosphorous	25 mg	---
P.3	Potassium	80 mg	200 mg
S.1	Sodium	20 mg	60 mg
Z.1	Zinc	0.5 mg	---

- (viii) a ratio of alpha-tocopherol to linoleic acid of not less than 0.6 International Units to one gram;
- (ix) a ratio of calcium to phosphorous of not less than 1.2 grams to one gram and not more than 2.0 grams to one gram; and
- (x) a ratio of vitamin B6 to protein of not less than 15 micrograms to one gram. (B. 25.052).

Additionally, infant formula may not contain added amino acids unless (a) the amino acids are required to improve the quality of the protein in the formula and are present in an amount not exceeding the minimum required for that purpose, or (b) the protein content of the formula is supplied by isolated amino acids or by protein hydrolysate, and only the L forms of the amino acids are used (B. 25.053).

A separate provision prescribes an approximate correspondence between infant formula and human milk as follows: No nutritive substance not listed above, may be added, unless the amount of that substance present in the infant formula, as normally consumed, is equal to the amount thereof normally contained in the same quantity of human milk. (B. 25.053).

Nutritional adequacy of infant formula is further assured by a specific prohibition against selling or advertising for sale an infant formula which, when prepared according to directions, requires the addition of a nutritive substance, other than water, or a source of carbohydrate, or both. (B. 25.050).

Modifications in the ingredient standards are allowed for infant formulas specifically represented as being for fat-modified, low amino-acid, low mineral, or low vitamin D diets (B. 25.054).

**B. Other foods for infants and small children;**

Regulation of ingredients for foods for infants and small children other than formula is less comprehensive. Sale or advertising of strained fruits, strained fruit juice, strained fruit drink and cereal, for infants, containing sodium chloride is prohibited. (B. 25.003). The permissible salt content for other types of foods is specified in the table below:

**SODIUM CONTENT IN INFANT FOODS**

Column I	Column II
Food	Total Sodium in grams per 100 grams of Food
1. Junior Desserts	0.10
2. Junior Meat, Junior Meat Dinners, Junior Dinners, Junior Breakfasts	0.25
3. Junior Vegetables, Junior Soups	0.20
4. Strained Desserts	0.05
5. Strained Meats, Strained Meat Dinners, Strained Dinners, strained Breakfasts	0.15
6. Strained Vegetables, Strained Soups	0.10

Where a food to which a vitamin has been added is represented as being solely for use in the feeding of children under two years of age, no person shall sell such food unless a reasonable daily intake of that food by a child under two years of age would result in the daily intake by the child of not less than: (a) in the case of vitamin A, 1,000 International Units; (b) in the case of thiamine, 0.4 milligrams; (c) in the case of riboflavin, 0.6 milligrams; (d) in the case of niacin or niacinamide, 4 milligrams; (e) in the case of pyridoxine, 0.6 milligrams; (f) in the case of ascorbic acid, 20 milligrams; (g) in the case of vitamin D, 300 international Units; and (h) in the case of vitamin E, 5 International Units (D. 01.010).

**Hygiene and Purity**

It is prohibited to sell or advertise foods containing additives except those listed in the attached table (Tables IV and X, B. 16.100); those used in bakery products for infants; citric acid, and soybean lecithin in rice cereal and dry cereals containing banana.

### Labeling

Infant formula labels must carry (1) the content of protein, fat, available carbohydrate, ash and, where present, crude fibre in grams per 100 grams or grams per 100 millilitres of the infant formula both as offered for sale and as ready-to-consume; (2) the caloric value expressed in calories per 100 grams or calories per 100 millilitres of the infant formula both as offered for sale and as ready-to-consume; (3) the quantity of biotin, folic acid, niacin, d-pantothenic acid, riboflavin, thiamine, alpha-tocopherol, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin K1, calcium chloride, copper, iodine, iron, magnesium, manganese, in milligrams or grams per 100 grams or per 100 millilitres of the infant formula both as offered for sale and as ready-to-consume; (4) the quantity of any added nutritive substance normally contained in human milk and not listed in the required ingredients in milligrams or grams per 100 grams, or milligrams or grams per 100 millilitres of infant formula both as offered for sale and as ready-to-consume; (5) the quantity of choline in milligrams per 100 grams, or milligrams per 100 millilitres of the infant formula both as offered for sale and as ready-to-consume (B. 25.056).

Labels must also contain adequate directions for the preparation and use of the product and its storage after the container has been opened [B. 25.056(e)]. The expiration date must be specified [B. 25.056(f)]. Additionally, it is not permitted to make claims with respect to the iron content of infant formula unless the formula contains at least 1 milligram of iron per 100 available kilocalories (B. 25.057).

Where a food to which no vitamin has been added is represented as being solely for use in the feeding of children under two years of age, a person may state on the label of the food the amount of any of the following vitamins that are present in the food, if a reasonable daily intake of that food by a child under two years of age would result in the daily intake by the child of not less than: (a) in the case of vitamin A, 600 International Units; (b) in the case of thiamine, 0.25 milligrams; (c) in the case of riboflavin, 0.4 milligrams; (d) in the case of niacin or niacinamide, 2.5 milligrams; (e) in the case of pyridoxine, 0.25 milligrams; and (f) in the case of ascorbic acid, 7.5 milligrams (D. 01.008).

Where a food to which no mineral nutrient has been added is represented as being solely for use in the feeding of children under two years of age, a person may state on the label of the food the amount of any of the following mineral nutrients that are present in the food, if a reasonable daily intake of that food by a child under two years of age would result in the daily intake by the child of not less than: (a) in the case of calcium, 150 milligrams; (b) in the case of phosphorus, 150 milligrams; (c) in the case of iron, 2 milligrams; and (d) in the case of iodine, 0.05 milligrams.

### Control and Inspection

The Director has power to demand evidence in regard to the expiration date of infant formula (B. 25.0580 and the fact that formula is nutritionally adequate to promote acceptable growth and development when consumed in accordance with directions for use [B. 25.059(4)].

### Export

The Provisions of the Canadian Act do not apply to any packaged products not manufactured or sold for consumption in Canada, provided that the package is marked in distinct overprinting with the word "Export" and a certificate has been issued that the package and its contents do not contravene any known legal requirement of the importing country (Food and Drugs Act, part II, Section 32).

## COLOMBIA

- Resolution No. 5532 of 9 July 1979 of the Minister of health adopting standards promotion of breast-feeding.

### Purposes and Scope

The Preamble recognizes that breast-feeding is best for children under two years of age; that health institutions have the responsibility for supporting and promoting breast-feeding. The Resolution establishes detailed directives for medical care, medical advice and maternal education during the pre-natal, puerperal and two-year post-natal period to be followed by hospital and health workers.

### Advertising and Promotion

Advertising discouraging breast-feeding or emphasizing the bottle in preference to the breast is excluded from health centres, health posts and hospitals [Article 2(3)].

### Breast-feeding

During the pre-natal period breast-feeding is encouraged through appropriate preparation of the breast and maternal education. Breasts of pregnant women are to be examined and women are to be taught exercises for lengthening and hardening of the nipples and, if appropriate, for correction of nipple abnormalities. Mothers are to be instructed in the advantages of breastfeeding and reminded of meeting additional nutritional requirements through increase in daily food intake. Individual and group education sessions on breast-feeding, using diverse educational techniques, are to be promoted. (Article 2).

During the puerperal period, breast-feeding is to be promoted as follows. The child is to be accommodated in the same room as the mother, breastfed immediately or within three hours after birth, and whenever required, day or night, thereafter. The mother's capacity for and confidence in breast-feeding is to be strengthened through drawing her attention to the need to consume liquids, informing her that feeding water, dextrose, or infant formula diminishes the supply of breastmilk, promoting education on techniques for initiating and continuing breast-feeding, and other appropriate measures. Diseases of the breast (other than cancer and serious systemic diseases as determined by a physician) are not to be considered as permanent contra-indications to breastfeeding. If the child and mother must be separated, maternal milk must be manually extracted to ensure continued production and, where it can be kept fresh and clean, it must be given to the infant (Article 3).

Breast-feeding (without additional vitamins, iron or water) is to be recommended exclusively through the fourth month. It is to continue through the end of the second year, with supplementary foods, fed by cup and spoon, introduced between the fourth and sixth month. [Article 3(h) and Article 4(a) and (d)].

Throughout the first two years of the child's life, maternal education is to continue, with special attention given to solving the mother's problems and questions. Information is to be obtained on how the child is fed and measures inhibiting or affecting milk production, and appropriate measures taken. Where family planning is sought, non-hormonal measures should be used whenever possible (Article 4).

## DENMARK

- Order No. 110 on maternalized milks (modermaelkserstatninger) - 19 March 1971 - Lovtidende for Kongeriget Danmark A, XIII, 16 April 1971\*
- Order No. 598 on foods for special dietary uses - 28 November 1978 - Lovtidende A, 15 December 1978.
- Order No. 617 on preserved milk products - 15 December 1977 - Lovtidende A, No. 58, 23 December 1977.

### PURPOSES AND SCOPE

The Order on maternalized milks promulgated pursuant to Law No. 93 of 1927 on preserved milk exports, to the Law on food products; and to Law No. 74 of 31 March 1936 on publicity about vitamins establishes ingredients, hygiene and purity standards; manufacturing, packaging, and labeling requirements, and administrative control procedures for breastmilk substitutes. Products covered by the Order are also subject to the relevant provisions of the Order on Foods for Special Dietary uses and the Order on Preserved Milk Products.

### DEFINITIONS

Foods for healthy infants and young children are considered to be “foods for special dietary uses”, defined as foods which on account of their particular composition or manner of production are clearly different from ordinary foods, are suitable for the indicated dietary use, and are traded in such a way that it is clear that they are intended for that use (No. 598). “Maternalized milks” are defined as milk products or modified milk products which indicate on their packaging, in advertisements, in texts, through illustrations, or in any other manner, that they are designed for or suitable for the diet of nursing babies as a substitute for mother's milk (Art. 1).

---

\* All citations are from this Order unless otherwise indicated in the text.

## INGREDIENTS

Maternalized milks must contain the following (Art. 5):

<u>Nutrient</u>	<u>Amount per 1000 kilocalories</u>
iron	at least 10 mg.
vitamin A	not less than 1000 I.U. not more than 3000 I.U.
vitamin D	not less than 600 I.U. not more than 900 I.U.
thiamine (vitamin B1)	at least 0.4 mg.
riboflavin (vitamin B2)	at least 0.6 mg.
pyroxidine (vitamin B6)	at least 1 mg.
niacin equivalents	at least 7 mg.
ascorbic acid	at least 50 mg.

---

The quantitative relationship among the naturally occurring milk constituents may be altered provided that the protein content corresponds to at least 20 g/1000 kilocalories [Art. 4(2)]. The natural milk fats may be partially replaced with non-hydrogenated vegetable fats, provided that the total fat content of the product is a maximum of 55 g/1000 kilocalories; that of linoleic acid is at least 3g/1000 kilocalories; and that of vitamin E corresponds to at least 1 mg. of Alpha tocopherol (the quantity indication corresponding to 1 free Alpha tocopherol) per gram of linoleic acid (Art. 7). All addition of niacin must result in nicotinic amide, not nicotinic acid [Art. 9(2)].

Maternalized milks must be manufactured from cow's milk (subjected to suitable thermal treatment) by the method of desiccation and pulverization or by another method suitable for the conservation of nutritional value [Art. 4(1)].

Cane sugar (sucrose), glucose, dextrin, maltose, lactulose, gluten-free starch, lactic acid and citric acid may be added if their nature and quantity are clearly stated on the label (Art. 6).

## HYGIENE AND PURITY

Maternalized milk manufactured by the process of desiccation and pulverization must satisfy the conditions fixed by the American Dry Milk Institute for milk powdered packaged in a gaseous medium, for fermented products without added vegetable fats, and for the contents of titratable acid (degree of acidity) and solubility [Art. 4(3)].

Neither maternalized milk nor its constituents may be treated with substances such as colouring agents, flavourings, or preservatives without the specific authorization of the Minister of Agriculture (Art. 8). All additives must be of the quality standards decreed in the Pharmacopoeia, if such exist [Art. 9(1)].

Microbiological standards are as follows:

1. The total number of germs (of foreign bacteria when products are acidified by bacteriological means) must not be greater than 10,000/g, as determined by the method prescribed by the Nordic Committee on Standards (Nordisk Metodikomit ) No. 27 of 1958) [Art. 10(1)].
2. The assay of coliform bacteria must be negative in the examination of 0.1 g. of powder by the methods prescribed by the Nordic Committee on Standards (Nordisk Metodikomit ) No. 44 of 1962 [Art. 10 (2)].
3. For haemolytic bacteria toxinogens requirements are as follows: Assay for B. cereus must be negative in the examination of 0.01 g of powder according to the method prescribed by the Nordic Committee on Standards (Nordisk Metodikomit , No. 67 of 1968); Staphylococcus aureus must not be assayed positive in a dispersion of 1 g in liquid, subsequently cultured on a solid substrate, according to the methods prescribed by the Nordic Committee on Standards (Nordisk Metodikomit  No. 66, of 1968) [Art. 10(3)].
4. Assay for sulphur-reducing Clostridium must be negative in the examination of 0.01 grams of powder, according to the method prescribed by the Nordic Committee on Standards (Nordisk Metodikomit , No. 56 of 1965).
5. Assay for salmonella must be negative in the examination of a 50 gram sample according to the method prescribed by the Nordic Committee on Standards (Nordisk Metodikomit , No. 71 of 1969) [Art. 10(5)].
6. For export products labelled “selected” or “specially intended for use as infant food” the total bacterial count for “foreign” bacteria, including those permitted in cultured milk, must not exceed 30 000 (Order No. 617, Chap. VI, Section 12).

#### PACKAGING AND LABELING

Labels for maternalized milk must bear the statement “infant formula” [Art. 11(1)]. If the product includes vegetable fats, they must state “contains vegetable fats” immediately next to the words “infant formula”, in characters of the same type, and the same colour, and at least half as big. The nature and composition of the fats, expressed in percentages, must also be stated [Art. 11(2)].

Labels must also state the following information in easily visible, easily legible, indelible characters: (a) the type and quantity of special ingredients or special manner of preparation which imparts to the food its particular dietary properties [Order No. 598, Section 3(2)]; (b) The energy content expressed in kilojoules or kilocalories, (Order No. 598, Section 3); (c) the net weight [Art. 11(3)]; (d) the composition of the product calculated per 100 grams, including proteins, carbohydrates, fatty materials, the total composition of mineral salts, and the composition of vitamins and mineral salts considered individually. Vitamins and minerals other than vitamin A, vitamin D, thiamine, riboflavin, pyroxidine, niacin, ascorbic acid, iron, sodium,

potassium, calcium and phosphorous may not be listed without the permission of the Minister of Agriculture (Art. 11(3)); (e) the expiration date or the time for which the manufacturer guarantees the preservation of the product, at a temperature between 20° and 22°C [Art. 11(3)]; (f) the method of use including the directions for dissolving the product in previously boiled water [Art. 11(3)]; the statement “From the end of two weeks, vitamin drops are to be given daily, as a vitamin supplement, in conformity with the directions indicated on the package of vitamins” [Art. 11(3)].

#### CONTROL AND INSPECTION

The manufacture for sale of infant formula may only be done in factories authorized by the Ministry of Agriculture for the manufacture of preserved milk products for export. Manufacturing may not begin until a declaration has been made (containing a precise specification of product composition, notably final fat content and method of manufacture) to the State Control Service for Milk Products, etc. The Minister of Agriculture may specify that special conditions, appropriate to the nature and composition of the product, be imposed. No modification in composition may be made without a declaration stating this to the State Control Service (Art. 3).

Fatty materials of vegetable origin used in the manufacture of infant formula must be stored until utilization in the area of the manufacturing plant; their purchase and use must be stated in the accounts of the business (Art. 12).

Control of compliance with the above regulations is exercised by the State Control Service for Milk Products, etc. The Service must have access to all places where such products are manufactured, sold, stored, delivered or dispatched and be able to demand the necessary documentation and sampling. Where special situations require, the Minister of Agriculture can make exceptions to the order (Art. 13).

#### IMPORT AND EXPORT

Where export conditions require, the Minister of Agriculture can make exceptions to the Order (Art. 13).

## ITALY

- Act No. 327 to regulate the Production and Sale of Foods for Small Children and Dietetic Products,
- Decree No. 578 of the President of the Republic - 30 May 1953 - Rule for the Execution of Act No. 327 - 29 March 1951 - on the control of production and sale of foods for small children and dietetic products - Gazzetta Ufficiale della Repubblica Italiana - 10 August 1953, No. 188, 1st part I, pp. 2958-2962.

### Purposes and Scope

The Act and the Decree establish nutritional, hygienic and purity standards for food products for small children, dietetic products, and the establishments which produce them. The primary emphasis is on control at the point of production, and detailed provisions are provided for registration and inspection of facilities.

### Definitions

“Foods for small children” are defined as those which substitute in whole or in part, for mother's milk, and those which are used from the moment of weaning, or with a view to supplementing the nourishment of the body during the first period of life. (Act No. 327, Sec. 1). Included among such foods are: “milk powder” which conforms to the regulatory provisions; “yeasted meal” (*farine diastatiche*), meaning those in which the starch is entirely transformed through the direct action of yeasts (Decree No. 578, Article 19); partially de-yeasted or dextrinated cereals; soluble and non-fermented milk protein derivatives; and cereals and foods conforming to the regulatory provisions (Decree No. 578, Chapter II, Article 16).

### Ingredients

Milk powders for use in foods for small children must be obtained from cow's milk which conforms in all respects to the hygienic standards for milk for direct human consumption (Decree No. 578, Chapter II, Article 17); although, exceptionally, with proper authorization it may be obtained from other animals (Article 18).

Milk powder may be partially or totally skimmed; contain added sucrose, lactose, glucose, maltose, malt glucose or a combination of these substances; and/or contain added lactic acid, citric acid, or their salts (Article 17). It may also contain lactic acid resulting from the partial transformation of lactose by selective fermentation. (Article 17). Milk powder must conform to the following requirements: (1) The solubility of non-acidified milk powder must be at least 96% unless stated otherwise on the label in easily visible characters; (2) the moisture content of powders obtained from skimmed milk must be 6% at most; the moisture content of powders obtained from whole or partially skimmed milk must be 4% at most; and the moisture content of powders obtained from acidified (partially skimmed or whole) milk must be 5% at most. (3) The content must be, at most, 40% of the raw product (Article 17).

The addition of starch to cereals in which at least 80% of the starch has been transformed into maltose or malt glucose is authorized in the proportion of at most 20% of the product (Article 19).

Cereals and foods for small children, intended for use as complementary or weaning foods must contain not less than 25% “yeasted meal” (farine diastasiche) or milk powder without added sugar, or other added protein derivatives obtained from milk fat; or some combination of these three constituting a proportion of, at least, 25% of the product (Article 20).

#### Hygiene and Purity

Milk powders must have a bacteriae count of, at most, 10,000 per gram. The bacteria count of powders obtained from acidified milk may be higher, provided the excess includes only fermentation bacteriae (Article 17). Primary and semi-processed materials and all substances intended for use in food preparation must be intact and sanitary (Article 14). All preservatives are prohibited, except where specially authorized by the High Commissioner and stated on the product label and accompanying materials (Article 11).

#### Packaging

Products must be sold in suitable, original packaging and sealed in a manner which guarantees the potency of the product (Article 9).

#### Labelling

The following information, written in easily visible characters, in the Italian language, must be on the outer panel of all packaging: (1) the name of the product; (2) a statement of the nature of the product; (3) the name, company name, address of the production plant and the production enterprise; (4) the final mode of use of the product; (5) the exact effective analytical composition of the product; (6) the net weight; (7) the date of manufacture and, in cases where the Minister of Health deems it necessary, the final date for the use of the product (Article 9). Cereals with added starch must indicate the quantity of starch added on the label (Article 19). The name and percentage of specially authorized preservatives must be stated in a visible manner, in typographic characters identical to those used for the other statements (Article 11). Informative leaflets accompanying the product may call attention to the use or action which is normally attributed to the product by virtue of its composition (Article 10).

It is prohibited to state on the label: (1) claims for curative or preventative properties or an efficacy superior to that which the product has; (2) testimonials, laudatory remarks, or such statements as “recommended by physicians” which may mislead the consumer; and (3) imprecise statements which may lead to doubt “of whatever nature, in whatever manner” about the product or its ingredients (Article 10).

#### Advertising and Promotional Activities

With the exception of statements contained in publications and printed matter for the medical profession, all curative or preventative claims for the product, testimonials, imprecise remarks, and other statements causing confusion in the mind of the consumer are prohibited in newspapers, magazines, radio and other sorts of publicity (Article 10).

### Control and Inspection

Separate authorization must be obtained from the Minister of Health for the manufacture of each food product for infants and small children. Requests for authorization must include (a) the analytical method of quantitative and qualitative control of ingredients; (b) all documentation demonstrating the product's purpose and a statement if it contains new or rarely used substances, and (c) plans of the production facilities and clear information about general services and utilities (Articles 1-3). The Minister of Health, with the aid of provincial medical and public health personnel, may inspect the premises requesting authorization and grant, deny, or delay such authorization (Articles 4-6). The public health authority may make inspections of all points in the production-distribution system (Article 26). The judicial authority is to be alerted when the results of the inspection indicate that (a) the product does not conform to the statements in relation to which authorization was granted; (b) the deviations of manufacturing or processing do not suffice to explain the variations established; (c) the product has lost the properties by reason of which it was authorized; or (d) the product is altered, adulterated, or falsified (Article 8). All personnel connected with the preparation and manipulation of foods for small children must have an annual, favorable, medical inspection (Article 29).

### Import

Imported products may not be put into commerce in Italy without previous authorization by the Minister of Health.

### Export

Foods for small children which do not conform to Italian regulations are authorized for production and sale for export, provided the interested enterprise is able to prove to the health authority that the products conform to the norms and usages of the country of destination.

## KENYA

- The Food, Drugs and Chemical Substances Act, Cap. 254 of the Laws of Kenya, Legal Notice No. 105, - Kenya Gazette Supplement No. 40, 1 July 1978, Legislative Supplement No. 27.
- The Food, Drugs, and Chemical Substances Regulations, Legal Notices 105, 106, 107, - Kenya Gazette Supplement No. 40, 1 July 1978, Legislative Supplement No. 27, (see especially Part II, 29 on baby foods).
- Legal Notice No. 55, 28 March 1979 - Kenya Gazette No. 14, 6 April 1979, legislative Supplement No. 18.

### Purposes and Scope

The Food, Drugs and Chemical Substances Act of Kenya is an adaptation of the Canadian Food and Drugs Act to the needs of an importing country. As in the Canadian Act, the general provisions consist of a set of definitions of key terms including: (a) “food component” (any substance which forms part of an ingredient); (b) “ingredient” (any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product); (c) “inner label” and; (d) “outer label”. Most of the provisions are concerned with standards of hygiene, regulation of additives, labeling, and import regulation. The specific provisions on baby foods are included within Part II (Labeling, Special Dietary Food and policy) of the Food Drugs and Chemical Substances (Food Labeling, Additives, and Standards) Regulations.

### Hygiene and Purity

It is prohibited to sell a food that is represented for use for babies if the food contains additives (other than ascorbic acid used in dry cereals containing banana or soyabean lecithin in rice cereals) unless special permission has been granted (Part II, Article 29).

### Labelling

Labeling provisions are precise, extensive and detailed. Two types of labels are defined as follows: (1) “inner label” means the label on or affixed to an immediate container of the product and (2) “outer label” means the label on, or affixed to, the outside package. Where both inner and outer labels are used in packaging, all required statements must appear on both (Part II, Article 8). All required statements must be readily discernable to the purchaser or consumer under the customary conditions of purchase and use, and clearly and prominently displayed on the label (Legal Notice No. 105, Article 7). Required information is deemed clearly and prominently displayed if all words comprising the common name of the product (as defined by Schedules included in the Act), other than articles, conjunctions, and prepositions, are identically displayed in identical type and all statements of net contents are in boldface type (Part II, Article 6).

The main panel of a food label must carry: (1) the brand name of the food, if any; (2) the common name of the food; and (3) in close proximity to the common name, a correct declaration of the net contents in terms of weight, volume or number in accordance with the usual practice in describing the food. Grouped together on any

panel of the label, must be the following: (a) a complete list of the acceptable common names of all ingredients and components of ingredients (Part II, Article 30) in descending order of their proportions, unless the quantity of each ingredient is stated in terms of percentages or proportionate composition and; (b) a declaration of permitted food colour and any artificial or imitation flavouring. One panel of the label must carry the name and address of the manufacturer, packer or distributor of the food (Part II, Article 4). Products packed in glass containers may, instead, carry the required information twice on the shoulder or upper part of the container in block lettering (Part II, Article 7). Imported products must state the country of origin on the label (Part II, Article 31).

Where a statement or claim implying a special dietary use is made on the label, the label must also carry a statement of the type of diet for which the food is recommended (Part II, Article 15). However, the reference, present in some other countries, to the requirement of a designation of the precise ingredients or characteristics which make the product suitable for its special purpose, is absent.

All required statements must appear on the label in the English language, in addition to any other languages used. The English language type size must be equivalent to, or greater than, the type size used for any other languages and shall be displayed on the main panel (Legal Notice NO. 105, Article 6). While the specification of English language labeling is clearly designed to facilitate consumer comprehension of the labeling of imported products, the Act makes no requirement that any information be in Swahili, the second national language of Kenya.

#### Advertising and Promotional Activities

No direct or indirect references to the Act or Regulations may be made in any advertisement for a food unless the reference is a specific requirement of the Regulations (Part II, Article 9). Where a statement or claim implying a special dietary use is made in advertising, a statement must be made of the type of diet for which the food is recommended (Part II, Article 15).

#### Import

Thorough and detailed consideration is given to the identification of the sources of imported products and the quality control of imports. "Lot or batch number" is defined as "any combination of letters or figures, or both, by which any food ... can be traced in manufacture or distribution (Legal Notice No. 105, Article 2). The "country of origin" is defined as that in which the final processing which affects the nature of the product is done (Part II, Article 31).

It is prohibited to import into Kenya any food product which is in violation of the Act or Regulations. Authorized officers are empowered to undertake examination of product samples; detailed provisions are provided on the identification of samples; and analytical reports on samples in violation are to be sent to the Commissioner of Customs and Excise and to the importer. A food product which is in violation may be provisionally imported for the purpose of bringing it into conformity with the requirements.

## MEXICO

- Official Mexican Standard NOM - F. 350 S. 1980, "Foods-Pre-cooked Cereal for Infants and Children - Corn Flour Flakes and/or Granulates with Chocolate" - 11 February 1980 - Diario Oficial No. 42, 20 February 1980.

### Purposes and Scope

One of the very few standards for children's foods not specifically marketed as breastmilk substitutes, complementary, weaning, or transitional foods, this standard covers ingredients, composition, hygiene, labeling, packaging and storage, inspection and control.

### Definitions

Two age groups are defined: (1) "infants" (infantes), meaning children less than 12 months of age; and (2) "small children" (niños de corta edad), meaning children more than 1 year old and less than three years old. (Appendices A. 1 and A. 2, respectively). "Corn flour flakes and/or granulates with chocolate" is defined as the food product obtained by cooking, drying and then milling wholesome, clean flour, free of teguments, obtained from corn kernels (Zea mays L.), with chocolate and/or cocoa, with or without the addition of nutrients, optional ingredients, and permitted food additives, that does not require additional cooking before consumption (Article 3). These cereals are further divided into three types as follows: (1) Type A - Simple, made only from maize flour with chocolate and/or cocoa, with or without the added nutrients; (2) Type B - Mixed, made from not less than 50% maize flour with chocolate and/or cocoa, plus flours of other cereals, with or without added nutrients; and (3) Type C - Combination, made from no less than 50% maize flour, with chocolate and/or cocoa and other optional ingredients, with or without added nutrients (Article 4).

### Ingredients

Type A - Simple must consist of maize flour and chocolate and/or cocoa, in a concentration between 6 and 10 grams per 100 grams of flour. Types B and C may contain other cereal flours in compositional formulas authorized by the Secretariat of Health and Welfare (Articles 5.6 - 5.7). Added salt is permitted to a maximum of 0.3% sodium (Article 5.7). Type C cereal may also contain whole or skimmed powdered milk, demineralized milk whey (suero de leche dismineralizado), malt extract, honey, sugar and other adequate comestible substances (Article 5.7).

Physical and chemical standards for Type A cereals are as follows:

<u>Specification</u>	<u>Values in %</u>	
	<u>minimum</u>	<u>maximum</u>
moisture		7.0
ash		5.0
protein (N x 6.5)	7.0	
ether extract	3.5	4.0
crude fibre	1.10	1.50

Specifications for Type B and Type C must be in accordance with compositional formulas approved by the Secretariat of Health and Welfare (Article 5.2). Colour, odour and flavour must be those characteristic of the product's composition. Texture must be that characteristic of the physical form and composition of the product (Article 5.1). Proteins, vitamins and/or minerals are permitted according to the limits established by the Secretariat of Health and Welfare (Article 5.9). The following flavourings are permitted: vanilla extract in necessary quantity; vanillin and ethylvanillin up to 5 milligrams per 100 grams of finished product (Article 5.8).

#### Hygiene and Purity

Food additives must be those permitted by the Secretariat of Health and Welfare for each of the three types (Article 5.8). The following emulsifiers are permitted: lecithin 1 and mono and diglycerides of fatty acids 1.5% (Article 5.8). The following antioxidants are permitted: mixture of tocopherols (300 milligrams per kilogram of fat), ascorbyl palmitate (200 milligrams per kilogram of fat), ascorbic acid, and sodium and potassium salts (50 milligrams per kilogram of fat).

All cereals must be free of insect fragments, hairs, rodent excreta, and other foreign materials and contaminants (Article 5.4). Pesticide residues must be within the limits authorized by the Secretariat of Agriculture and Water Resources and the Secretariat of Health and Welfare (Article 5.5).

Microbiological specifications for Type A cereals are as follows: (1) maximum count of aerobic mesophilic bacteria - 10000/g; (2) maximum count of fungi and yeasts - 50/g; (3) fecal coliform bacteria count in one gram - negative; (4) Salmonella in 25 grams - negative; (5) Staphylococcus aureus (positively coagulated) in one gram - negative; and (6) coliform organism count in one gram - negative. Type B and C cereals must meet the same standards with respect to the limits of fecal coliforms, Salmonella, Staphylococcus aureus and coliform organisms. Limits for aerobic mesophilic bacteria, fungi and yeasts must be authorized by the Secretariat of Health and Welfare (Article 5.3).

#### Packaging and Storage

Products must be packaged in resistant, sanitary materials that protect the product, prevent contamination, and do not alter the quality, odour, colour, taste or physical appearance. They must be stored in locations that meet the requisite hygienic standards (Article 8.2).

Labelling

Each package must carry a label or permanent impression, written in visible, legible, and indelible characters, with the following information: (1) name of the product; (2) brand name and/or factory symbol; (3) net contents, followed by the corresponding quantities expressed in grams or kilograms; (4) list of ingredients, in descending order of concentration; (5) if appropriate, additives and their function; (6) name, company name, and address of the manufacturing plant; (7) manufacturing lot number; (8) registration number; (9) nutritional information required by regulation; and (10) the statement "Made in Mexico". If the product contains chocolate and/or cocoa it must state the precautionary warning "This product is to be consumed only by children over 8 months of age".

Control and Inspection

Where inspection and analysis is necessary to ascertain conformity with the above provisions, the methods used must be those established by the Secretariat of Health and Welfare.

## NETHERLANDS

- Order of the Secretary of State for Public Health and Hygiene of 23 September 1976, General Directorate of Public health, Food Section No. 61412 (Stcrt. 189), "Ordinance on Complete Foods for Infants" (Made pursuant to Section 10 of the General Ordinance under the Commodities Act).

### Purposes and Scope

The Order establishes standards for ingredients, hygiene, packaging and labeling for complete foods for infants (breastmilk substitutes).

### Ingredients

Breastmilk substitutes must completely satisfy infant nutritional needs. It is permissible to add vitamin A (in the form of retinol or harmless retinol esters); vitamin D; vitamin E (in the form of D Alpha or D.L. Alpha tocopherol); vitamin C; vitamin B1; vitamin B2; niacin (in the form of amide of nicotinic acid); vitamin B6 (in the form of pyroxidine or pyridoxol chlorhydrate; folic acid; pantothenic acid; vitamin B12 (in the form of cyano-cobalamine); vitamin K1; biotin; iodine (in the form of potassium or sodium iodide); and other nutritive substantives in the proportions found in human milk. Proteins must be exclusively milk proteins. To lower the pH, lactic acid or lactic bacteria cultures producing exclusively the 1(+) acid may be added.

Ingredients must be present in the quantities specified below.

Amount per quantity of product

<u>Yielding 100 kilocalories</u>	<u>Minimum</u>	<u>Maximum</u>
protein (milk protein, with proportions of serial equivalent to that in cow's milk)	2 mg.	3 g.
lipids	4 mg.	6 mg.
glucides	9 g.	13 g.
linoleic acid	0.3 g.	2.5 g.
vitamin A (exclusive of carotene) (1 IU = 0.3 mgs. of retinol)	250 IU	500 IU
retinol	75 mg.	150 mg.
vitamin D (1 IU = 0.025 mgs. of calciferol)	60 IU	120 IU
calciferol	1.5 mg.	3 mg.

vitamin E, per 100 kcal	1 IU	
vitamin E, per gm of linoleic acid (1 IU = 0.67 mg. of D Alpha tocopherol = 0.74 mg. of acetate of D Alpha tocopherol)	1 IU	3 IU
ascorbic acid (lbs. mol. 176)	6 mg.	20 mg.
thiamin (lbs. mol. 265)	30 mg.	100 mg.
riboflavin (lbs. mol. 376)	60 mg.	240 mg.
niacin (free niacin, not including tryptophan) (lbs. mol. 122)	122 mg.	750 mg.
vitamin B6	40 mg.	100 mg.
folic acid (lbs. mol. 441)	5 mg.	20 mg.
D-pantothenic acid (lbs. mol. 219)	0.3 mg.	1.0 mg.
vitamin B12 (lbs. mol. 135)	0.15 mg.	0.5 mg.
vitamin K1 (lbs. mol. 451)	4 mg.	40 mg.
biotin (lbs. mol. 244)	0.5 mg.	5 mg.
ash	0.3 mg.	0.8 mg.
calcium	50 mg.	140 mg.
phosphorus	25 mg.	90 mg.
magnesium	6 mg.	12 mg.
iron	0.6 mg.	1.8 mg.
copper	40 mg.	80 mg.
zinc	0.5 mg.	1.0 mg.
manganese	5 mg.	50 mg.
sodium	20 mg.	60 mg.
potassium	75 mg.	150 mg.
chlorine	55 mg.	120 mg.

The ratio of calcium to phosphorus must be a minimum of 1.5 and a maximum of 2.5.

### Hygiene and Purity

The following additives are permitted per 100 ml of ready-to-consume product: 30 mg. of carrageenan (in liquid products); 0.2 g of lecithin; and 0.2 g of mono and diglycerides. All other colorings, artificial flavorings, antioxidants, preservatives, gelling agents, emulsifiers and stabilizers are prohibited.

Dry products must not contain more than 10,000 germs per gram and must be free of pathogenic microorganisms. There must be no observable Salmonella in 50 g of product; Staphilococcus aureus or enterobacteria in 1 g of product; or B. cereus in 0.01 g of product. Fermentation and mold must be less than 100 per gram of product.

Liquid products must conform to the requirements for the designation "sterilized" in the Ordinance on Milk (Commodities Act) 1974. The normal diluted product should contain 70 kilocalories per 100 ml and have an osmolarity not greater than 153 m.osmol/l by the Ziegler-Fomon Method (78 I. Pediat 561 - 1971).

### Packaging and Labelling

All labels must bear the following: (1) the name and address of the manufacturer, importer or vendor; (2) the statement "complete food for infants"; (3) the method of use; (4) the complete list of ingredients; (5) the quantity in grams of protein, glucides, lipids, linoleic acid, and ash per 100 grams of product, and per indicated quantity of ready-to-consume product; (6) the quantity of all vitamins and mineral salts and other nutritive substances listed above; (7) the final date of sale. Liquid products must state "sterilized". Labels may also state "The vitamin and mineral composition conforms to that established in the Ordinance on complete foods for infants".

## NEW ZEALAND

- The Food and Drug Regulations 1973. Serial No. 1973, 26 March 1973 (See especially Part II, 236 on infants' foods)

### Purposes and Scope

The Regulations control food quality through detailed specifications on proper labeling (including pictorial representations), packaging and use of all food additives (defined as including preservatives, antioxidants, colouring substances, non-nutritive sweeteners, flavouring substances, food conditioners, free-flowing agents, gaseous packaging agents, other non-nutritive substances, incidental constituents, and any material used in production or packaging that may become a component of or affect the characteristics of a food) (Part I, Reg. 2).

### Definitions

“Special-purpose food” is defined as a food named or described as particularly suitable for consumption by persons belonging to a particular class because it possesses or does not possess certain ingredients or properties specified in the name or description (Part II, Article 233). “Infants'food” is defined as special-purpose food that is particularly suitable for babies (Part II, Article 236). “Label” is defined as any written, pictorial, or other descriptive matter appearing on or attached to the exterior of any food or drug or any package containing such. “Written” includes printed, typewritten, painted, engraved, lithographed, or otherwise traced or copied (Part I, Reg. 2).

### Hygiene and Purity

Infants'food must not contain: (1) preservatives; (2) antioxidants; (3) artificial sweeteners; (4) artificial colouring substances; or (5) nitrates or nitrites (Part II, Article 236). If intended for sale frozen, it must be sterilized by heating immediately before freezing and retained in a frozen state until sold (Part II, Article 236). Additionally, any water, steam, or ice used must be clean and free from harmful contamination (Part I, Article 47).

### Labelling

Labels must carry the following information; (1) the common name of the food, or a description (other than the name of the food) sufficient to indicate the true nature of the food, or a description of the food containing the common name of its principal ingredients; (2) a statement of the net weight or volume or number of the contents of the package, whichever appropriate (Part I, Article 5); (3) a statement in descending order of quantities or proportions of the ingredients of which the food is composed, such statement being expressed either as a proportion of the whole contents of the package or as the amounts present in named units within the package; (4) adequate information to support the special suitability or nutritional qualities claimed (Part II, Article 233); and (5) the name and address of the manufacturer or seller, or of the owner of the rights of manufacture, or of the agent of any of them (Part I, Article 5).

Infants' food which is intended as the main food or as a milk replacement, and which, when prepared in accordance with directions, does not approximately conform to the composition of human milk, must carry, as the first line(s) of the label, the statement "THIS FOOD SHOULD NOT BE GIVEN TO INFANTS UNDER THE AGE OF 4 MONTHS, EXCEPT UNDER SKILLED SUPERVISION".

The following are prohibited on any written, pictorial or other descriptive matter appearing on, attached to, or supplied or displayed with the product: (1) any false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects or proportion of the product; (2) the word "pure", or "genuine" or any word of similar meaning unless the product is of the quality, strength, purity, or composition required by the Regulation; (3) the word "mock", "imitation", or "substitute" or any word of similar meaning, unless permitted by regulation (Part I, Article 8); and (4) no word descriptive of any disease or ailment, except the word "diabetic" (Part II, Article 233).

## PAPUA NEW GUINEA

- The Baby Feed Supplies (Control) Act, 1977. (No. 21 of 1977), 9 March 1977.
- The Baby Feed Supplies (Control) Regulation, 1977. Statutory Instrument No. 3 of 1977, 6 July 1977.

### Purposes and Scope

The Preamble to the Act states that its purpose is to restrict the right of freedom of expression conferred by the national Constitution so as to protect the public health from the bad consequences of unhygienic, inefficient, or wrong use of items connected with baby feeding. Designed to directly combat the infant health hazard of unsanitary and improper bottle feeding, the Act and Regulations make nursing bottles, nipples, and dummies (pacifiers) proscribed articles, to be used only upon written authorization, on penalty of fine. Authorization can only be granted by authorized medical professionals (such as physicians, medical assistants and registered nurses) who are satisfied that such would be in the infant's best interest and that the person to whom authorization is granted has received, and understands, directions on the proper use of the items. The Act and Regulation stand nearly alone in world legislation on infant nutrition, in controlling bottle feeding at the consumer level and in regulating the feeding equipment rather than the dietetic product.

### Definitions

“Proscribed article” is defined as (1) a baby's feeding bottle; (2) a bottle teat; and (3) a dummy (a teat of any shape and substance intended to be used for soothing babies or infants). “Proscribed advertisement” is defined as an advertisement the intention or result of which is to encourage: (1) the bottle feeding of babies; (2) the purchase or use of proscribed articles; or (3) the purchase or use of milk or other products in connection with proscribed articles (Act, Section 1).

“Authorized person” is defined as (1) a medical practitioner; (2) a medical assistant registered or enrolled as such under the Medical Services Act of 1965; (3) a registered nurse; or (4) such other persons as may be prescribed. “Authorization” is defined as a written authorization to supply a proscribed article.

### Authorization for use of bottles and nipples

Authorization for use of proscribed articles may only be given by authorized persons to the mother or other person having care of the infant or baby to whom the authorization relates (Section 3). Authorization may only be given if (1) the person granting it is satisfied that it would be in the interest of the baby or infant, (2) the

prescribed instructions for use are also given and (3) the person granting the authorization is satisfied that the person receiving it understands the instructions (Section 3). The prescribed instructions are as follows:

#### INSTRUCTIONS

Baby's bottles, bottle teats and dummies.

Instructions for cleaning prior to each use -

1. Clean with bottle brush to remove any foreign matter that may be adhering to bottle, teat or dummy.
2. Place in clean water and boil for five minutes or soak in sterilizing solution. Sterilizing solution is manufactured especially for the purpose of sterilizing baby feed articles and is to be used at the strength and for the time specified in the manufacturer's instructions
3. The baby's feeding formula for use in a bottle shall be kept under refrigeration if not used, [The Baby Feed Supplies (Control) Regulation]

The written authorization form must include the following: (1) the signature of the authorizing person, (2) the name and address of the mother or other person having the care of the baby or infant to whom the authorization relates, (3) details of the proscribed article, (4) the name, address and qualifications of the authorizing person, and (5) such other information as may be prescribed (Section 1).

Pharmacists are required to keep a record of the issue of proscribed articles supplied in accordance with an authorization (The Baby Food Supplies (Control) Regulation).

#### Advertising and Promotion

It is prohibited to publish a proscribed advertisement, that is, one the intention of likely result of which is to encourage: (1) bottle feeding, (2) purchase of bottles, nipples and/or dummies, or (3) the purchase or used of milk and other products in connection with bottles, nipples and/or dummies. (Section 1). However, a person may, in the course of business display a proscribed advertisement to an authorized person and a pharmacist may display a proscribed advertisement to the extent necessary to enable persons with authorization to obtain proscribed articles to make their selection (Article 4).

#### Penal Provisions

It is an offence, punishable by fine, to (1) supply a proscribed article without authorization; (2) grant authorization without conforming to the prescribed conditions for doing so; and (3) to publish a proscribed advertisement (Sections 2-4). It is, however, not an offence for any person to use a proscribed article to sooth or feed an infant or baby if, in the opinion of that person, there exists at that time circumstances in which the infant or baby would suffer harm if such article was not used (Section 2).

## PERU

- Ministerial Resolution No. 0041-80-SA/DS of 1 April 1980.

### Purposes and Scope

The Resolution establishes requirements for all purchaser information on breastmilk substitutes; limitations on the promotion of breastmilk substitutes; and related obligations for undertakings which produce, sell or distribute breastmilk substitutes.

### Labeling

Labels must be clear and accurate and make specific reference to the content and hygienic use of the preparation (Chapter I. 7).

### Advertising and Promotion

Content of Informational Materials: Information must indicate the net contents, the composition of the product, details of the health registration, the rules of hygiene, and the need to use uncontaminated water (Chapter 1.4 and 1.5). It shall emphasize the principle that "Human milk is the ideal food for infants"; stress that constant vigilance and care is necessary when children are growing and developing; and make no indication that one product is superior to another (Chapter I.1, 1.6, and 1.7).

Supply of Informational Materials: Materials are to be supplied through the various communications media, in quantities sufficient to meet the demand, and with due regard to the economic, educational and social levels of the individuals towards whom it is directed (Chapter 11.11, II.8 and II. 10).

Informational Personnel: Informational material must be developed by qualified personnel, experienced in the importance of promoting breastfeeding and the hygienic use of formula (Chapter II. 9). Only specialists in health or nutrition may be employed in connection with dietary counselling services by undertakings which produce, sell and distribute infant formula (Chapter I. 3).

Demonstration and Free Distribution: The personnel of undertakings responsible for disseminating information on breastmilk substitutes at the community level may supply products only to health professionals and may receive no remuneration or gratuity other than from their own undertakings in respect of demonstrations on produce use carried out in health establishments (Chapter III. 4).

### Inspection and Control

The health authorities and executive agencies are responsible for ensuring that information is ethically disseminated: The Association of Physicians of Peru is to collaborate with the Ministry of Health to ensure due compliance (Chapter III. 12 and III. 13). Infringement is subject to penalties in accordance with legal provisions in force (Chapter III. 15).

## PORTUGAL

- Decree No. 315/70, 8 July 1970. Diario do Governo 1st series, 8 July 1970, No. 157 (on dietetic products)
- Decree-Law No. 314/72, 17 August 1972. Diarío do Governo 1st series, 17 August, 1972, No. 191 (on labeling generally)
- Order No. 471/72, 17 August 1972. Diarío do Governo 1st series, 17 August 1972, No. 191 (on labeling generally)

### Purposes and Scope

The basic purpose of the decree on dietetic products is consumer protection, made necessary because of the rapid expansion in the use of such products consequent upon scientific and technological progress and elevation in the standard of living (No. 315/70, Art. 1). The decree covers definitions, labeling, packaging, inspection, and control. Labeling requirements are also covered by the general enactments on labeling of pre-packaged foods (Nos. 414/72; 471/72) which aim towards both protection of consumers and harmonization with the Codex Alimentarius Commission Recommended International Standards for Labeling of Pre-Packaged Foods. (No. 314/72, Art. 6).

### Definitions

“Dietetic products” are defined as those (1) which are distinguished from normal food products of the same general category by certain characteristics of preparation or consumption and (2) which correspond to the needs of particular categories of persons. They may have quantitative or qualitative changes in composition which reinforce their nutritional value or give them particular characteristics, excluding therapeutic action (No. 315/70, Arts. 1-2). Dietetic products are divided into three classifications, including those which correspond to the particular physiological needs of persons in good conditions of health. Among such products are those designed for nursing babies and the nutrition of children (including foods based on cereal or carbohydrate, milk or milk products, horticultural products or fruit, meat or fish, or composites of these) (No. 315/70, Art. 2).

“Ingredient” includes all substances, including additives, utilized in the manufacture, composition, or preparation of a foodstuff and present in the finished product. “Constituent” is defined as any substance that is a component of an ingredient (No. 471/72, Art. 3(6)).

A “package” is any partial or complete commercial wrapping or container for a foodstuff, sold as a single item; while “pre-packaged” means that the foodstuff has been packaged before being offered for sale (No. 314/72, Art. 2). “Label” is defined as any form, shape, mark, brand, image, symbol or other written description that is printed, stencilled, marked, embossed or impressed on, or otherwise attached to the package of a foodstuff (No. 314/72, Art. 2).

### Packaging

Products must be offered for sale in sealed containers which satisfy the standards of hygiene and purity established by the Director General of Health. They may not be altered, nor may the label be removed, before they are opened by the final consumer (No. 315/70, Art. 4).

### Labeling

All labels must be in the Portuguese language and contain the following information: (1) the name and address of the manufacturer or commercial entity responsible or a conventional statement enabling the same to be identified (No. 315/70, Art. 5); (2) the name of the product (No. 315/70, Art. 5), using, where appropriate, the Portuguese legal standard [No. 471/72, Art. 1(2)]; (3) the purpose for which the product is intended (No. 315/70, Art. 5); (4) the characteristics which make the product appropriate for the intended purpose (No. 315/70, Art. 5); (5) the processes used in its preparation which confer upon it its particular dietary properties (No. 315/70, Art. 5); (6) the mass or liquid volume in metric units [No. 471/72, Art. 4(1)]; or, if appropriate the number of units per package [No. 471/72, Art. 4(1)]; (7) the ingredients in decreasing quantitative order of importance (No. 315/70, Art. 5); (8) all constituents of an ingredient [No. 471/72, Art. 3(2)]; (9) dietary composition per 100 grams of ready-to-sell product (No. 315/70, Art. 5); (10) directions for preservation of the product (No. 315/70, Art. 5); (11) normal conditions of product purchase and use in easily visible, clearly understood words (No. 471/72, Art. 12); (12) Necessary instructions for preparation (No. 314/72, Art. 5); (13) the statement, consume immediately after opening, if the opened product is subject to deterioration in a way prejudicial to health (No. 471/72, Art. 9); (14) the relevant Portuguese standards for the product, if appropriate (No. 471/72, Art. 2); and (15) the country of origin, or of the final processing which changes its nature, for imported products [No. 314/72, Art. 5; No. 471/72, Art. 6(1-2)].

No references to preventive or curative properties, or other statements confusing to the purchaser, on the composition, qualities, contents, ingredients, weight, or origin of the product may be made on the label (No. 315/70, Art. 6). Further, the label must not mention, describe or present the foodstuff in a false, mistaken, or illusory manner, or in a general way, susceptible of creating in whatever manner, on any aspect, an erroneous impression of the nature, composition, quality or quantity of the product, nor contradicting the required statements (No. 314/72, Art. 3). Foodstuffs must not be presented or described in a way which, through direct or indirect references to other products in any way have the capacity to induce the consumer to suppose that these products, are connected (No. 314/72, Art. 3).

### Advertising and Promotion

No commercial information or literature (other than that designed exclusively for the medical profession) may make any reference to curative or preventive properties, or other confusing statements on the composition, qualities, contents, ingredients, weight or origin of the product (No. 315/70, Art. 6).

Control and Inspection

Products can only be offered for sale after approval by the Office of the Director General of Health. Those requesting such authorization must follow the documentation provided by the official laboratory on composition, hygienic characteristics, mode of packaging, promotional literature, labeling, etc. Manufacturing, transporting, and selling establishments are subject to visits from the office of the Director General of Health (No. 315/70, Art. 7). Unfavorable judgements or decisions, not corrected in 30 days from receipt of the communication, require recourse to the Minister of Health and Welfare, who will render a decision following the advice of the Superior Counsel of Hygiene and Social Assistance (No. 315/70, Art. 8).

## SWEDEN

- Order No. 7 of the National Food Administration on the vitamin fortification of skim milk powder intended for export, 3 February 1978, Statens livsmedelsverks författningssamling, 21 February 1978.
- Instruction No. 30 of the National Board of Health and Welfare on the desirability of avoiding the use of human milk substitutes during the first week of life, 18 May 1978. Socialstyrelsens författningssamling, 3 July 1978.
- Order No. 17 of the National Food Administration on infant foods, 25 May 1978. Statens livsmedelsverks författningssamling, 31 May 1978.

### Purposes and Scope

Swedish legislation on foods for infants and small children is a rare and excellent example of regulations based upon sound nutritional policy as well as consumer protection principles. It includes measures to promote breastfeeding and to regulate the nutritional quality of exported infant foods, as well as the more frequently found provisions on ingredients, hygiene and purity, labeling, etc.

### Definitions

“Baby” is defined as a child up to one year of age. Three categories of foods are defined as follows: (1) “human milk substitute” means a liquid or powdered food intended to be used in place of human milk, whose composition covers the normal dietary requirements of babies up to six months of age; (2) “baby food” means an infant food that is offered for sale bearing a statement that it is especially suitable or intended for babies; and (3) “infant food” means a food that is offered for sale bearing a statement that it is especially suitable or intended for children up to three years of age. (Order No. 17, Section I).

### Packaging

Infant foods must be sold in packaged form unless otherwise authorized by the National Food Administration. Packaging must display all information required by the labeling provisions (Order No. 17, Section 9).

### Labeling

Infant foods are preferably to be labelled in Swedish; for human milk substitutes and baby cereals, directions for storage and packaging must be in Swedish. Directions may be given on a separate package insert (Order No. 17, Section 12).

The following information must be stated on the label: (1) details of the nutritional value of the food, including separate statements of the levels of proteins, fats, and carbohydrates and the total caloric value; (2) vitamin and mineral content (in the manner prescribed in the licence for fortification agents issued under Order No. 11 on food additives - 3 June 1975); (3) content of added monosaccharides and disaccharides, preferably in grams per 100 grams and, for human milk substitutes and baby cereals, the levels per litre of ready-to-consume product; (4) food additives indicated by their approved name; (5) food fortification agents; and (6) the minimum age child for which the product is suitable (Order No. 17, Articles 7, 11-14, Annexes 1 and 2). Special requirements for human milk substitutes are indicated in the Annexes.

### Control and Inspection

Special authorization must be obtained from the National Food Administration to offer for sale (1) any human milk substitute; (2) any baby food (intended for children up to one year old); (3) any infant food (intended for children up to 3 years old) with special feeding requirements. Other infant foods (except where specifically provided otherwise) are generally authorized for sale, provided the National Food Administration is first notified in writing of the following: (1) name of the food; (2) quantitative composition of the food; (3) name or trade name and address of the manufacturer or packer; (4) the importer, if appropriate; (5) the type and size of packaging; (6) the date on which sale is expected to commence; and (7) models of the proposed label and package marking. (Order No. 17, Section 3).

### Breast-feeding

Hospital maternity departments are to endeavour to ensure that all neonates, as far as possible, receive human milk. The requirement extends to the use of milkbanks, etc., for the neonates of mothers who, for any reason, are unable to breastfeed. It is recommended that large maternity departments have a nurse-midwife responsible for providing mothers and the personnel with instructions and information on breastfeeding and supervising the collection of human milk. It is particularly important to breastfeed children of families with a predisposition towards allergies; and all neonates should receive human milk during the first five to six days of life (Instruction No. 30).

The same Instruction states the reasons for this as follows: (1) the physical and chemical properties of human milk make it particularly suitable to meet the special needs of infants; (2) human milk contains a number of factors which reduce the risk of neonate infection; and (3) increasing evidence suggests that early administration of heterologous proteins to neonates may lead to subsequent allergies (Instruction No. 30).

### Export

Skim milk powder exported, or intended for export to the countries listed in the Annex to the Order, must, except where otherwise authorized by the National Food Administration, contain a quantity of vitamin A corresponding to 1.5 mg of retinol (5000 IU) in every 100 grams. The explanatory note in the order reads as follows:

General malnutrition and vitamin A deficiency regularly occur together. Serious vitamin A deficiency leads to blindness. The risk is particularly great if skim milk powder that has not been vitamin-fortified is used to compensate for a protein deficiency. When skim milk powder is used for purposes of food aid as part of an assistance project, it is therefore advisable that a proper intake of vitamin A be ensured at the same time.

## SRI LANKA

Directions under the Consumer Protection Act, No. 1 of 1979, Section 6(1) (c):

- Direction No. 3, 6 February 1979, The Gazette of the Democratic Socialist Republic of Sri Lanka, No. 22/7 - 7 February 1979.
- Direction No. 24, 7 November 1980, The Gazette of the Democratic Socialist Republic of Sri Lanka, No. 114/2, 10 November 1980.
- Direction No. 28, Sale of Milk Food (Powdered), The Gazette of the Democratic Socialist Republic of Sri Lanka, Extraordinary, No. 130/4, 3 March 1981.

### Purposes and Scope

The directions, issued pursuant to the Consumer Protection Act, establish labeling requirements for and prohibit the advertising of infant milk foods.

### Labeling

No manufacturer or trader may pack, sell or expose for sale any infant milk food unless the following statement appears, in three languages, on the wrapper or container, in capital letters, conspicuously and prominently displayed and distinct from all other text (Direction No. 3).

C.P.A.

### DOCTORS SAY BREAST FEEDING IS BEST

No manufacturer or trader shall sell, offer or expose for sale any powdered milk product unless one of the following formulae is conspicuously displayed on the label (Direction No. 28):

#### Formula I

The reconstituted product ready for consumption shall contain:

Milk fat - 3.00 to 3.80 gms/100 mls.

Protein - 1.20 to 3.20 gms/100 mls.

Carbohydrates - 6.70 to 7.40 gms/100 mls.

Recommended levels of vitamins and minerals in an available form.

Energy - 20 kilocalories (kals) fluid ounce (30 mls.), with between 35% and 55% originating from carbohydrates.

#### Formula II

Shall contain polyunsaturated fatty acids of the cis-cis form to the extent of not less than 12 of the total fatty acids present.

Shall not contain protein other than milk protein.

Shall not contain any ingredients of no nutritional value.

Formula III

Formula for infants over six months of age (who shall have other milk products in their diet) with a minimum fat content of 26%.

Formula IV

Therapeutic food to be sold only under prescription

Category 1; derived from vegetable protein

Category 2: with a fat content below 18%.

Advertising and Promotion

No manufacturer or trader shall advertise any infant milk food over the radio or in any visual advertisement in any way (Drection No. 24).

## THAILAND

- Notification of the Ministry of Public Health, Prescribing Modified Milk for Infants as Specially Controlled Food and Prescribing Quality or Standard and Manufacturing Process, No. 34 (1979), 13 September 1979, Government Gazette, Vol. 96, Part 163, Special Issue, 21 September 1979.
- Notification of the Ministry of Public Health, Prescribing Infant Food as Specially Controlled Food and Prescribing Quality or Standard and Manufacturing Process, No. 40 (1979), 13 September 1979, Government Gazette, Vol. 96, Part 163, Special Issue, 21 September 1979.
- Notification of the Ministry of Public Health, Prescribing Food for Young Children as Specially Controlled Food and Prescribing Quality or Standard, Mo. 41 (1979), 13 September 1979, Government Gazette, Vol. 96, Part 163, Special Issue, 21 September 1979.

### Purposes and Scope

The notifications establish precise standards for ingredients; hygiene and purity; and packaging of breastmilk substitutes, and other foods for young children.

### Definitions (No. 34, C1. 2/ No. 40, C1. 2-3; No. 41, C1. 2)

Infant is defined as a child between birth and twelve months of age. Modified Milk for Infants is defined as a product produced by modifying cow's milk constituents to meet infant nutritional requirements for the purpose of feeding as a replacement for mother's milk, Infant food includes all other breastmilk substitutes for infants. Food for Young Children is defined as one used together with mother's milk for feeding infants from the age of three months.

### Ingredients

#### A. Modified Milks and Infant Foods (No. 34, C1. 3; No. 40, C1. 4)

Modified milks must be composed of at least 60% milk constituents by dry weight and, if in dry or powdered form, contain not more than 5% moisture by weight. Carbohydrate must be at least 50% lactose. Substitutes for special diets are subject to approval by the Office of Food and Drug Administration. Infant foods must contain not more than 5% moisture by weight if instant, and not more than 7% moisture by weight if requiring pre-cooking. Other ingredient specifications are as follows:

- (1) Energy: Not less than 65 kilocalories (272 kilojoules) nor more than 70 kilocalories (293 kilojoules) per 100 ml of prepared food.
- (2) Protein: Reference protein not less than 1.8 g and not more than 3.0 g per 100 kilocalories, of a nutritional value not less than 70%, with an amino acid composition, per gram of protein, as follows: histidine - 26; isoleucine - 46; leucine - 93; lysine - 66; methionine and cystine - 42; phenylalanine and tyrosine - 72; threonine - 43; tryptophan - 17; valine - 55.

- (3) Fat: Not less than 3.0 g nor more than 6.0 g, including at least 300 mg of linoleic acid, per 100 kilocalories. Fatty acids composed of more than 20 carbon atoms must not exceed 1% per 100 kilocalories.
- (4) Vitamins: as in the table below:

Vitamin Requirements for Modified Milks and Infant Foods (per 100 kilocalories)

<u>Vitamin</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin A (computed as retinol)	75 mcg	150 mcg
Vitamin D	40 I.U.	80 I.U.
Vitamin K1	4 mcg	
Vitamin E (-tocopherol compounds calculated as di- - tocopherol-acetate)	0.7 I.U. (0.4 I.U./g linoleic acid for modified milk; 0.7 I.U./g linoleic acid for infant food)	
Vitamin B1 (Thiamine)	40 mcg	
Vitamin B2 (riboflavin)	60 mcg	
Nicotinamide	250 mcg	
Vitamin B6 (pyridoxin)	35 mcg (15 mcg/gm in food containing more than 1.8 gms protein/100 kcal)	
Folic acid	4 mcg	
Pantothenic acid	300 mcg	
Vitamin B12 (cyanocobalamin e)	0.15 mcg	
Biotin	1.5 mcg	
Choline	7 mcg	
Vitamin C (ascorbic acid)	8 mg	

(5) Minerals: as in the table below:

Mineral Requirements for Modified Milks and Infant Foods (per 100 kilocalories)

<u>Mineral</u>	<u>Minimum</u>	<u>Maximum</u>
Sodium	20 mg	60 mg
Potassium	80 mg	200 mg
Chloride	55 mg	150 mg
Calcium	50 mg	
Phosphorus	25 mg	
Calcium/Phosphorus ratio	1.2	2
Magnesium	6 mg	
Iron	0.15 mg	2.0 mg
Iodine	5 mcg	
Copper	60 mcg	
Zinc	0.5 mg	
Manganese	5 mcg	

Substitutions of proteins, fats, vitamins or minerals in infant foods for special diets are subject to approval of the Office of Food and Drug Administration.

---

B. Food for Young Children (No. 41, C1. 3)

(1) Protein: Reference protein not less than 2.5 g per 100 kilocalories, of a nutritional value of at least 70%, with an amino acid composition per gram of protein, as follows: isoleucine - 40; leucine - 70; lysine - 55; methionine and cystine - 50; phenylalanine and tyrosine - 60; threonine - 40; tryptophan - 10; valine - 50.

(2) Fat: Total fat at least 2.0 g/100 kilocalories; linoleic acid not less than 300 mg/100 kilocalories.

(3) Vitamins: as in the table below:

Vitamin Requirements for Food for Young Children (per 100 kilocalories)

<u>Vitamin</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin A (computed as retinol)	75 mcg	150 mcg
Vitamin D	40 I.U.	80 I.U.
Vitamin E (Alpha tocopherol compounds calculated as di - Alpha - tocopherol acetate)	0.7 I.U./g linoleic acid	
Vitamin C	8 mg	
Vitamin B1	40 mcg	
Vitamin B2	60 mcg	
Nicotinamide	250 mcg	
Vitamin B6	38 mcg or 15 mcg/g of available protein in food containing more than 2.5 g of protein/100 kcal.	
Folic acid	4 mcg	
Vitamin B12	0.15 mcg	

(4) Minerals as in the table below:

Mineral Requirements for Food for Young Children (per 100 kilcalories)

<u>Mineral</u>	<u>Minimum</u>	<u>Maximum</u>
Sodium	20 mg	100 mg
Potassium	80 mg	250 mg
Chloride	55 mg	200 mg
Calcium	60 mg	
Phosphorus	35 mg	
Calcium/Phosphorus ratio	1.2	2
Iron	1 mg	2 mg
Iodine	5 mcg	20 mcg

---

Hygiene and Purity (No. 34, C1.4; No. 40, C1. 4; No. 41, C1.3)

Food must have no lumps and be of the proper odour. Modified milks must not be coarse nor separate into layers, must be of proper consistency to pass through an ordinary rubber or plastic teat, and undergo no physical changes when stored for seven days at ordinary temperature.

Foods must contain no hormones, antibiotic substances, preservatives, pathogenic microorganisms, toxic substances in amount hazardous to health, or sweeteners other than sugar. No E. coli bacteria must be found in 1 gram of modified milk, 0.1 ml. of infant food, or 0.1 grams of foods for young children. The maximum permissible bacterial count for modified milks and infant foods is 10,000/g of dried or powdered food or 10/ml of ultra-high temperature processed modified milk. The maximum permissible bacterial count for foods for young children is 50,000/g of easily soluble ready-to-use food or 100,000/g of food requiring cooking.

In preparation, modified milk and infant food must be (a) sterilized at a temperature of at least 100 degrees Celsius, and then homogenized, or (b) ultra-high temperature processed at not less than 133 degrees Celsius for not less than 1 second and then homogenized. Alternative processes must be approved by the Office of Food and Drug Administration (No. 34, C1. 6; No. 40, C1.8).

Packaging (No. 34, C1. 6; No. 40, C1. 8; No. 41, C1. 6)

Ultra-high temperature processed modified milk and infant food must be packed in aseptic containers under aseptic conditions. Containers for all foods must be clean, tightly sealed, airtight, and release no toxic substances. Containers must be new or made of glass.

## UNITED STATES OF AMERICA

- Infant Formula Act of 1980, Public Law 96-359 (H.R. 6940), September 26, 1980.

### Purposes and Scope

Because, “more than any other food product, the public rightfully expects infant formula to be manufactured to exacting standards”, the Act amends the Food, Drug and Cosmetic Act by establish ingredient standards for infant formulas, means for modifying these standards consequent upon advances in nutritional knowledge, detailed measures for monitoring adherence to standards, and administrative review of labeling and export provisions.

### Definitions

“Infant formula” is defined as a food for infants which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk [Section 3(a)].

### INGREDIENTS

Infant formulas not in conformity with the nutrient requirements listed below are considered adulterated [Section 412 (a) (1) and subsection (g)].

NUTRIENTS

Nutrient	Minimum	Maximum
Protein (gm)	1.8b	4.5
Fat:		
gm	3.3	6.0
percent cal	30.0	54.0
Essential fatty acids (linoleate)		
percent cal	2.7	
mg	300.0	
Vitamins		
A(IU)	250.0. (75 ug)	750.0 (225 ug)
D (IU)	40.0	100.0
K (ug)	4.0	
E (IU)	0.7 (with 0.7IU/gm linoleic acid)	
C (ascorbic acid) (mg)	8.0	
B1 (thiamine) (ug)	40.0	
B2 (riboflavin) (ug)	60.0	
B6 (pyridoxine) (ug)	35.0 (with 15 ug/gm of protein in formula)	
B12 (ug)	0.15	
Niacin (ug)	250.0	
Folic acid (ug)	4.0	
Pantothenic acid (ug)	300.0	
Biotin (ug)	1.5 <sup>d</sup>	
Choline (mg)	7.0 <sup>d</sup>	
Inositol (mg)	4.0 <sup>d</sup>	
Minerals:		
Calcium (mg)	50.0	
Phosphorus (mg)	25.0	
Magnesium (mg)	6.0	
Iron (mg)	0.15	
Iodine (mg)	5.0	
Zinc (mg)	0.5	
Copper (ug)	60.0	
Manganese (ug)	5.0	
Sodium (mg)	20.0	60.0
Potassium (mg)	80.0	200.0
Chloride (mg)	55.0	150.0

The Secretary of health and Human Services may revise the list of nutrients, revise the required level for any nutrient, or establish requirements for quality factors for any nutrient, [Section 412(a) (1) (A) - (C)]. Formulas represented and labelled for use by an infant with an inborn error of metabolism, low birth weight, or other unusual or dietary problem, are exempted from these nutritional standards. [Section 412(f) (1) (A) - (B)].

#### Packaging and Labelling

The Secretary of Health and Human Services is required to conduct a review of labeling requirements; to determine the effect of labeling requirements on infant nutrition and formula use; and to make recommendations for legislative and administrative action on formula labeling [Section 7(b)].

#### Control and Inspection

The Secretary of Health and Human Services is required to establish quality control procedures for infant formula, including periodic testing [Section 412(a) (2) (D)]. Until such procedures come into effect, manufacturers are required to notify the Secretary every 90 days that infant formula is in conformity with standards [Section 412(b) (1) - (2)]. Manufacturers are required to notify the Secretary of any known nonconformity [Section 412(c)].

After a change in formulation or processing of any infant formula, the manufacturer must notify the Secretary that the product conforms to established standards, prior to the first processing for distribution for human consumption [Section 412(b) (3)].

Nonconforming products are subject to recall. The Secretary of Health and Human Services is to prescribe by regulation the scope and extent of such recall appropriate for the degree of risk to health [Section 412(b) (2)]. To facilitate such recall, manufacturers are to keep all records of formula distribution for two years [Section 412(2) (e) (1)] <sup>1/</sup>.

#### EXPORT

The Secretary of Health and Human Services shall conduct a review of issues concerning the export of infant formula which not be legally marketed in the united States, and make recommendations regarding legislative and administrative action to be taken to improve current export policies. [Section 7(c)].

---

<sup>1/</sup> The Food and Drug Administration has recently proposed quality control procedures for infant formula manufactures which would require manufacturers to test for proper ingredient and nutrient levels at various critical points during formula processing (Press Summary, Dept. of health and Human Services, HHS P80-65).

## VENEZUELA

- Resolution establishing the required characteristics of foods for special diets, 25 October 1976. Gaceta Oficial de la Republica de Venezuela No. 31.106, 9 November 1976

### Purposes and Scope

Issued pursuant to Article 10 of the National Health Law and with Article 1, Sections 2, 5 and 10, and Articles 37 and 38 of the General Food Law, the Resolution covers definitions for, and labeling of, foods for special diets in excellent, comprehensive fashion.

### Definitions

“Foods for special diets” are defined as those prepackaged foods which are (1) distinguished from common foods by special composition or by physical, chemical or biological modifications or other results of their manufacture, and (2) for this reason satisfy the nutritional needs of persons whose normal processes of assimilation and metabolism are altered, or those who desire to obtain a particular effect resulting from the controlled consumption of foods (Article 1). The definition is noteworthy because it refers to both the intrinsic characteristics of the foodstuffs and their fitness for the needs of particular categories of persons. Two such categories are listed; (1) persons who suffer from abnormal physiological states and (2) healthy persons under special physiological exigencies of nutrition. Infants (niños de pecho) and small children (niños de corta edad) are included in the second category (along with pregnant and lactating women and the elderly) (Article 2).

### Labelling

Labels must state the name of the food, in association with the prescribed name for they type of diet to which it belongs (except where specially provided otherwise). A brand name is also permitted provided it is (1) accompanied by the appropriate descriptive term and (2) does not lead to confusion or deceit (Article 3).

All ingredients must be stated in descreasing order of weight. For dehydrated products, the ingredients may be listed in decreasing proportions as occurring in the reconstituted product, provided that the list is headed by the statement “ingredients after reconstitution”. The percentage composition by weight of proteins, fats, carbohydrates, moisture, and all items established in special provisions; and the number of calories in a specified quantity of food must also be stated (Article 3). The date of manufacture must be marked or stamped indelibly, in code or plain language, on each container or package (Article 3).

The following complete information on proper storage and use must be stated on the label: (1) instructions for the preservation of the unopened package; (2) information necessary to guarantee the integrity of the product from the moment of opening until use; (3) instructions for the preservation of the opened product if necessary to insure its hygienic properties and nutritional value; (4) instructions for reconstitution of the product, if appropriate; (5) instructions on the appropriate mode of use; and (6) a warning if it is not possible to preserve the product after opening or to preserve it in the original container (Article 3).

### Advertising and Promotion

It is prohibited to make statements (1) relative to guaranteed results, (2) about curative or preventative properties, (3) relative to the product's desirability for a particular disease or disorder, or (4) from which it is possible to deduce that the advice of a physician is not necessary (Article 3).

## YUGOSLAVIA

- Regulations governing requirements for the sanitary wholesomeness of dietetic foodstuffs which may be brought into the trade, 29 October 1979. Sluzbeni List Sfrj No. 6, 8 February 1980, Text 97.

### Purposes and Scope

The Regulations cover standards for ingredients, hygiene and purity, packaging and labeling of dietetic foodstuffs which may be put into commerce.

### Definitions

“Dietetic foodstuffs” are defined as foodstuffs which are (1) intended for the nutrition of persons (with either normal or disordered metabolism) who must obtain certain effects by the controlled use of foodstuffs, and which are (2) essentially different from other foodstuffs of the same kind by virtue of particular composition or physical, chemical or biological changes resulting from the process of production (Article 2). Included in this category are foodstuffs intended for “infants” (defined as children up to 12 months of age and “small children” (defined as children more than 12 months and less than three years of age) (Article 3) produced; from (1) milk, dairy products or single milk components; (2) vegetable proteins; (3) cereals, cereal products and soya; (4) meat, fish, eggs and other protein-rich sources; (5) oil, hydrated oil, animal and vegetable fats; (6) fruits, vegetables and their products; (7) honey, sugar, other natural sweeteners, cocoabeans and their products; or (8) a combination of these, in liquid, pulpy, dehydrated or baked form (Article 9).

### Ingredients

Foodstuffs for infants and small children must conform to the physiological needs of the age groups for which they are intended and be produced in such a way as to permit satisfactory digestion and metabolism (Article 8). Liquid foods for infants must be manufactured so that they can be prepared for use quickly and easily and pass, without difficulty, through the opening of a nursing nipple (Article 10).

Foods put into commerce as breastmilk substitutes must contain: (1) at least 1.8 grams of protein, corresponding to at least 85% of the biological value of casein, per 100 kilocalories; and (2) at least 300 milligrams of linoleate in the form of triglycerides per 100 kilocalories; and (3) a minimum of 15% of the total calories

originating from fats (Article 15). Amino acids added to infant's foods must be exclusively in the natural L-form, except for methionine, which may be in the DL-form (Article 15). The vitamin content for breastmilk substitutes must be as follows:

VITAMIN REQUIREMENTS FOR BREASTMILK SUBSTITUTES

Calculated per 100 kilocalories

Vitamin A	from	250 to 500 I.U.
Vitamin D	from	60 to 100 I.U.
Vitamin E	at least	0.3 I.U.
Vitamin B1	at least	0.025 mg
Vitamin B2	at least	0.06 mg
Vitamin B6	at least	0.05 mg
Vitamin B12	at least	0.15 mg
Vitamin C	at least	10 mg
calcium pantheonate	at least	0.3 mg
biotin	at least	1.5 mg
folic acid	from	4 to 109 mcg
nicotinamid	at least	0.25 mg

Mineral content (in a form suitable for good absorption) for breastmilk substitutes must be as follows;

MINERAL REQUIREMENTS FOR BREASTMILK SUBSTITUTES

Calculated per 100 kilocalories		
Calcium	at least	50 mg
Phosphorus	at least	25 mg
Sodium	from	20 to 60 mg
Potassium	from	80 to 200 mg
Chlorine	from	60 to 160 mg
Magnesium	at least	6 mg
Iron	at least	1 mg

The ratio, by weight, of calcium to phosphorus shall not be less than 1.2:1 or greater than 2:1 (Article 14).

For foods for small children manufactured from cereals and cereal products (such as maize, wheat, barley, oats and rice): (1) the quantity of mineral substances insoluble in muriatic acid shall not exceed 0.10%; and (2) the quantity of water-soluble carbohydrates from the breakdown of starch by baking or through enzyme action shall not be less than 12%. The water content in children's foods shall not exceed: (1) 5% in biscuits and similar products; (2) 6% in milk powder; and (3) 7% in quickly prepared vegetables and dehydrated products (Article 10).

Hygiene and Purity

Except where otherwise prescribed, all raw materials and additives shall meet the requirements prescribed in the Yugoslav Pharmacopoeia and other provisions in force (Article 5). Except where otherwise prescribed, the following are prohibited: (1) artificial colouring, (2) chemical preservatives, (3) ionizing or ultraviolet radiation,

(4) artificial sweeteners, (5) stabilizers, (6) antioxidants, (7) artificial flavours, and (8) emulsifiers (Article 4). Limits per portion are as follows, for the following substances:

<u>Substance</u>	<u>Limit in breastmilk Substitute</u>	<u>Limit in vegetables, meat, cereals and <u>cereal</u> <u>products</u></u>
arsenic	0.08 ppm	0.08 ppm
cadmium	0.05 ppm	0.05 ppm
lead	0.08 ppm	0.08 ppm
mercury	0.005 ppm	0.08 ppm
manganese	1 ppm	6 ppm
copper	1.5 ppm	2.5 ppm
zinc	7 ppm	8 ppm (Article 11)

Foods for children from 12 weeks to three years of age must not contain nitrite and triptic inhibitors; nitrate content must not exceed 100 mg per kilogram of the ready-to-eat product (Article 6). Foods for infants and small children prepared from milk and milk products, cereals and cereal products with added fruits and vegetables, and meat shall be put into commerce only if the pesticide residue per portion does not exceed the following:

<u>Substance</u>	<u>Limit</u>
aldrin	0.001 ppm
DDT, etc.	0.003 ppm
dieldrin	0.001 ppm
forat	0.001 ppm
HCH (Alpha and Beta)	0.002 ppm
Heptachlor and Heptachlor epoxide	0.002 ppm

Other pesticides are permitted up to a quantity one tenth that allowed for the given pesticide in similar foodstuffs not specifically for infants and small children (Article 13). Additives permitted in foods for children are listed in the Table below:

LIST OF PERMITTED ADDITIVES FOR FOOD FOR CHILDREN

Name of additive	Permitted amount of additive (calculated for a ready-to-eat meal)	
1	2	
1. Antioxidants:		
1.1 L-ascorbic acid and equivalent amount of its Na and K salts (+)	max.	0.05 %
1.2 Alphas and other tocopherols (+) (calculated on fat)	max.	200 mg/kg of fat
1.3 L-ascorbic palmitate (+)	max.	0.02 %
2. Emulsifiers:		
2.1 Refined lecithin (+)	max.	0.02 %
2.2 Mono and diglycerides of fat acids of edible oils	max.	0.3 %
3. Thickening agents		
3.1 Agar-agar (+)	max.	65 mg
3.2 Tragacanth (of <i>Astrogalus</i> genus) (+)	max.	30 mg
3.3 Alginates (Na and K)	max.	30 mg
3.4 Pectin, not amidated (+)	max.	1% (only for products based on fruit)
3.5 Physically and enzymatically modified starch (+)	max.	6%
3.6 Flour	max.	0.2 %

4. Flavours:

4.1	Vanillin extract (7)	accordingly to the usual producer's practice
4.2	Natural flavours from the basic raw materials (+)	“ ”
4.3	Vanillin (+)	max. 0.007 %

5. pH value adjusters:

5.1	L-lactic acid and equivalent amount of its Na and K salts (+) *	max. 0.2 %
5.2	Citric acid and its Na and K salts (+)	max. 0.5 %
5.3	Potassium Carbonate (+)	as usual producer's practice
5.4	Hydrogen potassium carbonate (+)	“ ”
5.5	Sodium Carbonate (+)	“ ”
5.6	Hydrogen sodium carbonate (+)	“ ”
5.7	Calcium Carbonate (+)	“ ”

6. Enzymes

6.1	Diastase (+)	“ ”
-----	--------------	-----

7. Colours

7.1	Beta-carotene (C.I. 75.810) (+)	max. 0.08 %
7.2	Caramel (+)	max. 0.3 %

8. Other additives:

8.1	Potassium chloride (+)	max. 0.25 %
-----	------------------------	-------------

\* Calculate total amount of ions Na and K and their balance.

NOTE: Additives marked by (7) can be used in manufacturing of food for infants from 12 weeks up to 12 months of age. One dietary foodstuffs may contain maximum two additives from the same functional group.

Microbiological specifications for dehydrated products which must be cooked before use are as follows. The Salmonella count in 50 g (ml) must be negative. The count of the following must be negative in 0.01 g (ml): Salmonella, Staphylococcus (coagulase positive), sulfur-reducing Clostridium, Proteus bacteria, Coliform bacteria, and Beta-haemolytic Streptococcus. The total number of microorganisms must not be more than 50 000 per gram (ml) and the total number of sprouting mould spores not more than 200 per gram (ml).

For dehydrated foods which do not require cooking before use, the microbiological specifications are as follows. The Salmonella count in 50 g (ml) must be negative. The count of the following must be negative in 0.01 grams (ml); Staphylococcus (coagulase positive), sulfur-reducing Clostridium, Proteus bacteria, Beta-haemolytic Streptococcus, and Coliform bacteria. The total number of microorganisms per gram (ml) must not be more than 30 000 and the total number of sprouting mould spores not more than 100 in one gram (ml) (Article 12) .

In addition, milk powder used in children's foods must not show, upon direct microscopic examination, more than 10 000 000 sprouts per millilitre of reconstituted milk (Article 12). Ready-to-eat food for children, in hermetically sealed containers, must remain unaltered in its physical, chemical and organoleptic properties after an incubation period of 7 days at a temperature of 37 degrees Centigrade, and must not contain more than 100 bacteria per gram (ml) (Article 12).

#### Packaging

All products must be put into commerce in the producer's original packaging (Article 7).

#### Labelling

The following information must be contained on the label, packaging, or other suitable place: (1) the statement "Dietary product"; (2) the name and purpose of the product; (3) the name and address of the producer; (4) the final date of use of the product; (5) the producer's control number by which the product can be identified; (6) the net quantity by weight or volume; (7) the contents, amount and source of the components which give the product its dietary properties; (8) the chemical composition of the product per 100 grams; (9) the energy value per 100 grams of the product; (10) the number of meals contained and the quantity for each meal; (11) the type and amount of additives used; (12) instructions on the method of use; and (13) instructions on proper storage (Article 7).

If breastmilk substitutes do not contain all the ingredients required, and in the amount required, the statement on the original packaging must carry a warning, in a prominent place, that the food should not be used as a sole source of nutrients (Article 16).

## EUROPEAN ECONOMIC COMMUNITY

- Council Directive - on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (77/94/EEC) - 21 December 1976

### Summary

The purpose of the Directive, as is consonant with the overall purpose of the European Economic Community, is the facilitation of trade among the Member States. It is deemed necessary because differences between national laws impede the free movement of goods, and may create unusual competitive conditions, thus having a direct impact on the functioning of the common market. The Preamble to the Directive states that approximation presupposes the determination of protective measures against consumer fraud and the adoption of labeling rules. Thus, the Directive regulates, foods for infants and small children, on an international level, using consumer protection principles and the techniques of standardized definitions and proper labeling.

Foods for infants and young children in good health are classified as one type of “foodstuff for particular nutritional uses”, defined as food which, by virtue of its special composition is (1) clearly distinguishable from foodstuffs for normal consumption and (2) appropriate for its claimed nutritional purpose; and which, further, is marketed in such a way as to indicate its suitability.

Labels for foods for infants and small children must state: (1) either their particular nutritional characteristics or the purpose for which they are intended; (2) the particular elements of the qualitative and quantitative composition, or manufacturing process which give them their particular nutritional characteristics; (3) the available energy expressed in kilo joules and kilocalories; (4) the carbohydrate protein and fat content per 100 grams or 100 millilitres and, where appropriate, per specified quantity of the product as proposed for consumption; and (5) the net quantity. Except where designed for persons qualified in medicine, nutrition or pharmacy, labeling presentation and advertising may not attribute or imply that the product has properties for the prevention, treatment or cure of disease.

MAIN ELEMENTS AND PROVISIONS WHICH ARE RELEVANT FOR  
THE PREPARATION  
OF SPECIAL LEGISLATION ON FOODS FOR INFANTS AND SMALL  
CHILDREN

The following suggestions should prove useful for adapting the general principles and purposes of food law to the particular needs of infant and child nutrition.

PURPOSE

To maintain and improve the nutritional status of infants and small children, from birth through the fourth year of life.

SCOPE

The law should embrace the manufacture, processing, packaging, import, export, distribution, promotion and labelling of special dietary products for infants and small children, and the promotion and support of breastfeeding.

DEFINITIONS

Precise, appropriate definitions are essential in order to clearly establish the scope of the law. The definitions serve several purposes: (1) they are the basis for the promulgation of specific regulations regarding ingredients, labelling, distribution, etc.; (2) they serve as the basis for the attachment of liability to manufacturers, importers, vendors, health workers and other responsible actors when the product proves unfit for its designated purpose or is improperly used, and establish to whom and for what such actors may be liable; and (3) they inform purchasers of the ingredient and nutritional composition, storage and proper use and intended consumer of the product, and the limits of the product's suitability.

A sound definitional scheme should be based upon (1) an awareness of the actors upon whom responsibility and liability should appropriately be fixed; (2) a scientifically sound correspondence between the product itself and the nutritional needs of its intended consumer; (3) a correspondence between legal terminology and that used in nutrition and health policy and planning; and (4) approximation or harmonization of terminology with that which is generally used and accepted internationally.

Definitions of Infants and Small Children

Definitions of infants and small children should correspond to the developmental stages of early childhood, reflecting actual differences in nutritional requirements where these exist, and indicate age categories for which different types of regulation may be appropriate. One useful set of definitions is the following:

<u>Definition</u>	<u>Comment</u>
“Neonate” means an infant between birth and the end of the first week of life.	Although, where babies are artificially fed from birth and actual feeding practices for neonates and older infants may not differ significantly, special legal and policy

Definition

Comment

“Infant” means a person from birth through the end of the first year.

considerations govern the designation of neonates as a separate category, among them the need to develop specific measures to encourage breastfeeding during this critical period of the commencement of lactation, to provide breastmilk (through milkbanks and other means) where breastfeeding is not possible, and to aim statutes or regulations towards hospital personnel and other healthworkers whose responsibility or influence may extend only during this period.

This definition corresponds to that used in much national legislation and in the Codex Alimentarius Standards (i.e. CAC/RS 72-1976). In cases where foods are intended only for a portion of this age category it may be useful to provide for subcategories such as “younger infants”, meaning those in the nursing stage (through the fourth to sixth month), “older infants” meaning those who should be receiving supplementary foods, and “infants for whom breastfeeding is not indicated”, meaning those who are appropriately artificially fed.

“Small children” means persons from one year through three years of age.

The upper age limit of this category varies between two and three years in existing national legislation, as may be appropriate where weaning practices differ. The three year age limit should, in most regions, cover the time period during which the child is completely or substantially weaned and is being accommodated to the family diet but during which special foods may be appropriate for physical, physiological, or gustatory reasons.

Definitions of Foodstuffs

General Considerations: These definitions cover the basic categories of foodstuffs for infants and small children for which standards have been, or are being, developed. Some or all may be appropriate for particular national legislation. The definitions given are meant to indicate the following important distinctions.

When infants are artificially fed, different regulations may be appropriate for commercially prepared and home-prepared products, as well as for adequate and inadequate, complete and partial foods. In particular, it may be desirable to

stringently regulate the manufacture, promotion and distribution of commercial products while permitting somewhat greater leniency for home-prepared products. It is therefore necessary to distinguish among (1) commercially manufactured products formulated to adequately meet nutritional and physiological requirements; (2) nutritionally adequate home-prepared products, made through the modification of suitable foodstuffs; (3) products (such as liquid whole or powdered milk) which can be used as the basis of nutritionally adequate home preparations; and (4) products (such as condensed milk) which may be frequently used as, or represented as, suitable for infant feeding but which cannot be adequately modified. It is further necessary to distinguish these from foods designed to be used during and after weaning (both those which satisfy complete nutritional requirements and those which do not). One appropriate set of definitions is the following:

<u>Definition</u>	<u>Comment</u>
“breastmilk substitute” means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.	This definition is identical to that in the International Code for the Marketing of Breastmilk Substitutes (Art. e, WHA 34.22)
“commercial infant formula” means a breastmilk substitute formulated industrially in accordance with applicable Codex Alimentarius and/or national standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age and adapted to their physiological characteristics.	With the exception of “and/or national Standards” this definition is identical to that in the International Code for the Marketing of Breastmilk Substitutes (Art. 3, WHA 34.22). It is preferable to such terms as modified milk or maternalized milk because it encompasses non-milk based products, makes no misleading allusions to the product's similarity to breastmilk, and because it conforms to the definitional scheme of the Code.
“home-prepared infant formula” means a non-commercially prepared breastmilk substitute meeting normal nutritional and hygiene requirements of infants up to between four and six months of age and adapted to their physiological characteristics.	Because legal standards may reasonably be expected to differ in regards to the products themselves and the liability of those responsible, between industrial and home preparations this category should be included in national legislation where such preparations are common and serve a need.
“infant formula base” or “product suitable for modification into infant formula” means a product which may be suitably modified for use as an infant formula and which contains clear directions (conforming to the requirements on labelling, below) as to how this may be done.	This term is suggested in addition to the more inclusive term “breastmilk substitute” so that proper labelling requirements, etc., may be developed for inexpensive and local products, while the sale of unsuitable products for such purposes (and their home use) may be prohibited/discouraged.

<u>Definition</u>	<u>Comment</u>
“supplementary”, “complementary”, or “weaning” food means any product designed to be used in addition to breastmilk or infant formula for feeding infants from the fourth through sixth month onward, which is nutritionally, hygienically and physically suitable for such use.	Confusion exists in both the legal and nutritional literature regarding the best term for such foodstuffs. However, the category is generally considered to include foods which are positively indicated from a health and nutrition viewpoint but are not, by themselves, complete foods. Canned and cereal based products produced according to Codex Alimentarius Standards (CAC/RS 73-1976; CAC/RS 74-1976) may be included in this category.
“follow-up” food means a product specially designed for infants and children from the fourth to sixth month onward, intended to supply, and actually supplying, at least the minimum requirements of those nutrients likely to be deficient in the diets of children receiving insufficient breastmilk or formula, but not intended to serve as the sole source of nourishment.	The ingredients of such products may substantially differ regionally depending on local resources and dietary patterns. Essential composition and quality factors are in the process of development by the Codex Alimentarius Commission (see ALINORM 79/26, Appendix IV).
“food for small children” means any food product specially designed to meet the nutritional, physiological or gustatory needs of persons between one and three years of age.	

The above definition scheme, of course, should not supersede or conflict with any additional definitions based upon the generic names of raw foodstuffs (such as beef, corn, egg, etc.) the generic names of processed foods (such as dry cereal, strained food, etc.) or the non-misleading use of brand and trade names.

### INGREDIENTS

Mandatory and optional requirements for ingredients and nutrient contents should be established for manufactured infants' and children's foods of the above categories. In setting standards, the following issues should be considered:

III). 1. UNIVERSALITY. When possible and appropriate, national standards should conform to international standards, such as those of the FAO/WHO Codes Alimentarius Commission. Conformity with such standards helps both to ensure that products comply with sound principles of nutrition, and that imported and exported products can flow freely in the marketplace. Recommended International Standards have been established by the Codex Alimentarius Commission for infant formula (CAC/RS 72-1972), canned baby foods (CAC/RS 73-1976) and cereal based foods for infants and small children (CAC/RS 74-1976). These are included as Appendices II, III, and IV of this volume. In the process of development by the Codex Alimentarius Commission are standards for follow-up foods (See ALINORM 79/26, Appendix IV), and advisory lists of permissible vitamin compounds and mineral salts for use in infants' and children's foods (See ALINORM 79/26, Appendix III).

2. FLEXIBILITY. Mandatory standards should be designed to be modifiable, in whole or in part, upon developments in nutritional science and food technology, or the attainment of developmental goals, without recourse to legislative restructuring. One method of accomplishing this is to require conformity with standards established by an appropriate governmental, non-governmental or inter-governmental entity charged with developing and monitoring standards.

3. SPECIFICITY AND GOOD FAITH COMPLIANCE. Specific standards should be based primarily upon considerations of adequate or optimum nutrition and health. However, standards should be established with an awareness of the margin of deviation from the standard which will legally fall within a good faith compliance with it. The margin of deviation permissible for good faith compliance may be reasonably regarded as different, in appropriate cases, between products industrially produced and those produced on an artisanal scale; between those which are commercially marketed and those which are supplied through special nutritional programs; and among those which are offered for

sale or distributed under differing exigencies of nutritional need. In this way, standards can serve as targets for the achievement of nutritional goals and the development of new products, and for the regulation of industrially produced products, without prohibiting or limiting the flow of nonconforming foodstuffs which may be the best alternative available under conditions of real nutritional need.

#### HYGIENE AND PURITY

Hygiene and purity regulations should be designed with an eye to both local needs and internationally accepted standards and practices. Regulations and recommendations should embrace the following:

1. Food additives. Standards for thickening agents, emulsifiers, pH-adjusting agents, antioxidants and other preservatives, flavouring agents and other organoleptic components should be established in the form of positive lists, stating qualitatively and quantitatively the additives permissible in particular foodstuffs and food categories. Standards should include methods of analysis and assay.

2. Contaminants. Standards, including both maximum permissible limits and methods of laboratory analysis, should be established for pesticide residues, hormones, antibiotics and microbiological contamination.

The Codex Alimentarius Commission has established Recommended International Standards for infant formula (CAC/RS 72-1976), canned baby foods (CAC/RS 73-1976), and cereal-based foods for infants and children (CAC/RS 74-1976).

3. Hygienic Practice. Codes of hygienic practice should be developed for infants' and children's foods governing all stages of the process from the production of raw materials to the final feeding of the infant or small child. The Codex Alimentarius Commission has issued a Recommended International Code of Hygienic Practice for Food for Infants and Children (CAC/RCP 21-1979), and additional suggestions may be found in Guidelines for Developing an Effective National Food Control System (FAO Food Control Series No. 1, WHO Food Control No. 1, 1976). A suitable code of hygienic practice should include specifications on the entire system from production to consumption including (a) raw materials; (b) manufacturing and processing, including buildings and plants, personal hygiene of staff, and sources of water and means of waste disposal; (c) packaging; (d) transportation; (e) end product specifications; (f) retail sale and distribution; and (g) consumer/purchaser handling and child feeding.

The final stages of this system, from purchase to feeding (through not usually covered in codes of hygienic practice), are particularly important for infant foods because contamination through the use of impure water, spoiled milk or formula, or unsanitary feeding utensils is a major source of infantile malnutrition-infection syndromes. Codes should therefore include specific directives on the hygienic preparation, storage and feeding of such foods, and the care of feeding utensils; and healthworkers should be advised to limit recommendation of such products where adequate home sanitary facilities are unavailable. Legislators and policy makers should give serious consideration to adapting the idea of the Papua New Guinea Baby Feed Supplies Act and Regulation in limiting the distribution and purchase of highly perishable or easily contaminated infant foods to situations in which hygienic household facilities are available and purchasers understand hygienic practice. Code of hygienic household practice for infants' and children's foods may be distributed in conjunction with labelling, advertising or promotional materials.

### LABELLING

General Considerations. The primary goal of labelling is to communicate all essential information effectively. The difficulty in establishing labelling requirements for infants' and children's foods comes from the fact that labelling must include, within severe size and space limitations, information designed for two different purposes and types of readers. Thus, (1) labels must include the technical information required by national and international standards to ensure fair dealing in the food trade and the free flow of goods; (2) labels must include sufficient information to educate and inform the purchaser/consumer in everything necessary to use the product appropriately, effectively, and safely.

These two goals present somewhat conflicting types of problems. The information which serves trade purposes is often best expressed in a technical fashion which may be incomprehensible to the average purchaser/consumer, especially in an area where literacy rates and educational attainment levels are low. Fixing mandatory and optional labelling requirements for these purposes involves an accommodation or approximation of national standards to international ones.

Effective purchaser/consumer information requires that a large quantity of specific, technical information including quantitative statements of nutrient contents, proper preparation, storage, and use, and warnings against misuse be expressed in a form which is readily intelligible to the average purchaser/consumer. The decision as to how such information should be expressed must be made with reference to the informational levels, and cultural and linguistic patterns of the target group and may require the use of graphic, pictographic or symbolic representations.

The inclusion of nutrition information on the labels of foods for infants and small children is of particular importance for two reasons. First, because proper dietary intake is especially important for normal physical and mental development during the first three years. While the diets of children in this age period generally comprise a relatively small number of items selected for them by others, it is important that parents and other caretakers be informed of infants' and children's nutritional needs.

Second, because those products designed as complete and those designed as supplementary or follow-up foods may be easily confused, and therefore misused, it is essential that labelling inform the purchaser of the extent to which a product does or does not satisfy complete nutritional requirements, and how it may be necessary to supplement or modify the product.

Definitions<sup>1/</sup> For the purposes of this section, “label” means any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food; “labelling” includes the label and any written, printed, or graphic matter relating to and accompanying the food; principal display panel means the surface of a package which either through design or general use, is customarily displayed to the consumer.

Suggested labelling requirements. Labels and labelling should indicate the following:

1. The name of the product. The name should indicate the true nature of the product. A brand, trade, “coined” or “fanciful” name may also be used if it is not misleading, does not suggest that an artificial product resembles breastmilk, and does not suggest that the product may be used or enjoyed by a person of an age group for which it is not intended.

2. Information enabling the identification of the responsible person or entity. Usually the name and address of the manufacturer, packer, distributor, importer, exporter or vendor.

3. The intended consumer of the product. This statement should delimit with precision the minimum age group by which the product may be safely and appropriately used.

4. The purpose of the product. This statement should clearly explain whether the product is to be used as-is, reconstituted, or modified; and whether it is to be used as a complete or partial food. For a product to state such fitness for purpose it must conform to the legal definition of that product, and additional requirements as may be established. Where appropriate, the label should include the statement, “To be used only as ...” or “To be used only for the purpose of ...”.

5. The net contents - where appropriate in accordance with the provisions of the Codex Alimentarius Recommended International Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969).

6. The complete list of ingredients, given in descending order of proportion, except that vitamins and minerals may be listed in tabular form, and where appropriate, in accordance with the provisions of the Codex Alimentarius Recommended International Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969).

---

<sup>1/</sup> These definitions have been adopted from the Codex Alimentarius Recommended International Standard for the Labelling of Prepackaged Foods (Art. 1, CAC/RS 1-1969, and the Proposed Revision of the standard (CX/FL 80/7).

7. Nutrition labelling, including:

a. The energy and nutrient contents, including food energy (expressed in kilocalories and kilojoules per 100 ml or 100 g), protein, carbohydrate, fat and all nutrients considered essential for persons in the relevant age category. The information should be expressed both in numerical form and, if appropriate, in whatever other form will most effectively communicate to purchasers, including the use of standardized household measures, food group symbols, pictures or diagrams.

b. The energy and nutritional requirements of persons in the relevant age category expressed in the form which most effectively communicate to purchasers, including but not limited to RDA/RDIs, food group symbols, etc.

c. Where foods for infants are concerned, the percentage or proportion of daily nutritional and energy requirements supplied by the product, expressed in the form which will most effectively communicate to purchasers.

Additionally, the following information may be included where appropriate:

d. Information on how the product should be modified to be made into a complete or more nutritionally enriched food, and/or

e. Information on what additional foods or substances should be provided to comprise a balanced diet for persons in the relevant age group, expressed in such verbal, numerical, symbolic or graphic form as will most effectively communicate to purchasers.

8. Storage Instructions. Storage instructions for unopened packages should be included on the label if such information is of importance in keeping the qualities of the food. Storage instructions for opened food packages should be stated if necessary to ensure that the opened product maintains its wholesomeness and nutritive value. If the opened product should be stored in other than the original container, directions for the proper method of storage should be included. A clear warning should be stated if the product is not capable of being stored, after opening, in the original container or if it must be consumed immediately after opening.

The primary emphasis in designing storage instructions should be upon the effective communication to the target group, including, where appropriate, pictographic or graphic representations of local household conditions indicating how the product may be or must not be stored.

9. Directions for preparation. Labelling should contain clear, complete directions for the preparation of the product, including quantitative directions for reconstitution of the product or mixing of the product with other substances, where appropriate. Labelling should further include whatever additional measures (such as heating, boiling, mixing with clean water or keeping at cool temperature) may be necessary to maintain the hygienic and nutritive properties of the food. Such directions should be designed specifically to meet the needs of the target group, including pictographic or symbolic representations of how this may be effectively done under local household conditions.

10. Directions for use. Where appropriate, directions should be given for the following: (1) the recommended portion size per feeding; (2) the average number of recommended feedings per day; (3) the method of feeding (labels for supplementary and follow-up foods should indicate that they should be fed by spoon or similar local utensil; and (4) the proper method of cleaning feeding utensils.

11. Date Marking. (a) The “date of minimum durability” (preceded by the words “best before”) should be declared, where appropriate, in accordance with the provisions of the Codex Alimentarius Recommended International Standard for the Labelling of Prepacked Foods, and any special storage conditions upon which the date of minimum durability depends should also be stated; (b) Where the date of minimum durability alone is likely to mislead the consumer, and especially where products are likely to be frequently offered for sale or purchased beyond the date of minimum durability the expiration date should also be included.

12. Country of origin. The country of origin should be declared if its omission would mislead or deceive the consumer.

13. Additional Statements and Warnings. (i) Infant formula labelling should include a statement containing the following: (a) the words “Important Notice” or their equivalent; (b) a statement of the superiority of breastfeeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use; and (d) instructions for appropriate preparation, and a warning against the health hazards of misuse. Such labelling may also contain information on the social and financial implications of formula use; (ii) all products which may become hazardous to health when not stored, used, or prepared in accordance with directions on the label should contain statements to this effect; and (iii) where a product is likely to become confused with a similar product of different purpose, the label should contain the appropriate warning “Not to be used as ... “ or “Not to be used for ...”

Presentation of Information in Labelling. Labels and labelling should be designed so that all essential information is easily visible and clearly intelligible to the purchaser, and so that the purchaser can see the most important information prior to purchase. To ensure this, labels should conform to the following specifications:

1. Attachment of labels. Labels should be indelible and securely, permanently attached. They should not be superimposed on other labels or lithographed containers.

2. Visibility. Where the container is covered by a wrapper, the wrapper should carry the necessary information or the label on the container should be readily visible through the outer wrapper. Required statements should be (1) clear, prominent, and readily legible to the purchaser under normal conditions of purchase and use; (2) unobscured by designs or other written, printed or graphic matter and (3) be in contrasting colour to that of the background. The letters in the name of the food should be in a size similar to the most prominent printed matter on the label.

3. Placement of information. The name, net contents, purpose or intended consumer of the product, and other information as appropriate to national policy and the needs of the target group should appear in a prominent position on the principal display panel.

4. Language. All labels and labelling should be in a language understood by the intended purchasers. This is not meant to preclude the presentation of the same information in either the national language(s) or the language(s) of the country of origin of the product, where these are different.

5. Pictographic, graphic or symbolic statements. Wherever made appropriate by the percentage of non-literate purchasers, all possible information should also be in appropriate pictographic, graphic or symbolic form. All efforts should be made to develop simplified non-verbal means of providing information, including food group symbols, colour-coded packaging, etc.. The efficacy of pictographs and symbols should be pre-tested on a sample group of intended product purchasers.

6. Unattached labelling. Where directions for storage or use or other important information is provided through enclosed materials, the label on the container should so indicate. Where products are sold in bulk, rather than pre-packaged, the relevant items in 1-5 above should be provided with the product.

7. Additional information. Wherever made appropriate by the percentage of non-literate purchasers, labelling should not be deemed sufficient by itself, but should be accompanied by standardized oral instructions given by the vendor, health workers, and health educators (as appropriate to the country concerned) and in radio and television advertising and educational broadcasting.

#### ADVERTISING AND PROMOTION

Advertising and promotion of foods for infants and small children should (a) comply with the requirements of honesty and fair dealing; (b) comport with national nutrition and health policy; and (c) be utilized, wherever appropriate, as a means of consumer education in sound infant and child feeding practices.

1. Infant Formula. Because of the serious health hazard presented by infant formula misuse, national regulations should be designed to adapt the demarketing and depromotional provisions of the International Code of Marketing of Breastmilk Substitutes (WHA 34.22, included as Appendix I to this volume) in whatever manner is most suitable to local conditions. Among the most important concerns are:

a. Elimination of advertising, promotion, sample distribution, feeding utensil distribution, and demonstrations by sales personnel to the general public;

b. Elimination of devices and schemes designed to induce sales directly to the consumer at the retail level, including point-of-sale advertising, special displays, discount coupons, premiums, special sales, loss leaders, and tie-in sales;

c. Regulation of word of mouth advertising and promotion by regulating contact between marketing personnel (in their professional capacities) and potential product purchasers;

d. The elimination of promotion, sales, advertising and display of infant formula and associated products from facilities of the health care system, and the limitation of formula use demonstrations, by appropriate health or community workers, to persons who require these.

2. Other infants' and children's foods Advertising for other infants' and children's foods should promote, to whatever extent applicable under national law, national nutritional policies. Among the most important concerns are:

a. Advertising should clearly state the intended purpose and intended consumer of the product and any special necessary conditions for safe product use, so as not to mislead into inappropriate purchase and/or use of the product.

b. Advertising should make no nutritional claims for a product which do not comport with national nutritional policy, or lack the approval of the appropriate nutritional or health authorities, or fail to conform to such requirements as may be established by national regulation.

c. Advertising should make no statements, suggestions or implications, verbally, pictographically or in any other way which would lead the average purchaser to believe that the product should be used for a purpose or person for which it is not intended, or that the product is nutritionally superior to similar products, where such is not the case. In particular, fallacious implications that the product is modern, fashionable or a major factor in promoting healthy babyhood should be avoided.

d. Where appropriate to national needs or those of the target group the content, extent and media used for advertising may be further regulated.

#### IMPORT AND EXPORT

Import and export legislation should be designed so as to foster adequate nutrition as well as facilitate international trade. In view of these goals, the following considerations should be kept in mind:

1. Ingredient, hygiene, and purity standards for imported products and products destined for export should harmonize, insofar as appropriate, with those established by the Codex Alimentarius Commission and other relevant international and regional bodies.

2. Standards for imported products should conform to those required for domestically produced products.

3. Standards for export products should conform to the nutritional needs of the country of destination, even if these standards are stricter than those for domestic products. At a minimum, products destined for export should not be exempted from compliance with domestic standards.

4. Inspection and control regulations and infrastructures should be adequate to prevent non-conforming products from being exported, imported or distributed.

#### PROMOTION AND SUPPORT OF BREASTFEEDING

Promotion and support of breastfeeding entails a close integration of planning in the legislative, health, education and employment sectors. Among the measures to be given primary consideration are:

1. Development of informational and educational materials, in accordance with Article 4.2 of the International Code of Marketing of Breastmilk Substitutes (included as Appendix I in this volume). Such materials should be designed to meet the needs of, and use the media channels appropriate to reach, the target group and include information on (a) the superiority of breastfeeding; (b) preparation for breastfeeding; (c) the difficulty of reversing the decision not to breastfeed, and (d) the social and financial implications of formula use. Strategies for education on breastfeeding should be designed for school and community education programs.

2. Preparation for breastfeeding during the pre-natal period, through the health care system and other community channels. Such preparation may include education, psychological counselling, breast strengthening exercises and periodic medical examination of the breast.

3. Support of breastfeeding during the puerperal period, may include specific in-hospital measures including rooming-in, on-demand feeding, demonstration and education by specially trained personnel, and the development of milkbanks.

4. Support of breastfeeding during the post-natal period, through the continued supervision, support, and counselling of medical personnel, community health workers and other community groups.

5. Support of breastfeeding in working mothers, through adoption or adaptation of the provisions in the ILO Conventions guaranteeing paid maternity leave, job security, nursing breaks, and creches near the workplace for working mothers.

