




**FOOD SAFETY  
AUTHORITY**  
OF IRELAND



**Recommendations  
for a national  
infant feeding policy**



Nutrition



Recommendations  
for a national  
infant feeding policy



Published by:  
Food Safety Authority of Ireland  
Abbey Court  
Lower Abbey Street  
Dublin 1

Tel: 8171 300, Fax: 8171 301  
Email: [info@fsai.ie](mailto:info@fsai.ie) Website: [www.fsai.ie](http://www.fsai.ie)  
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ISBN 0-9533624-6-9

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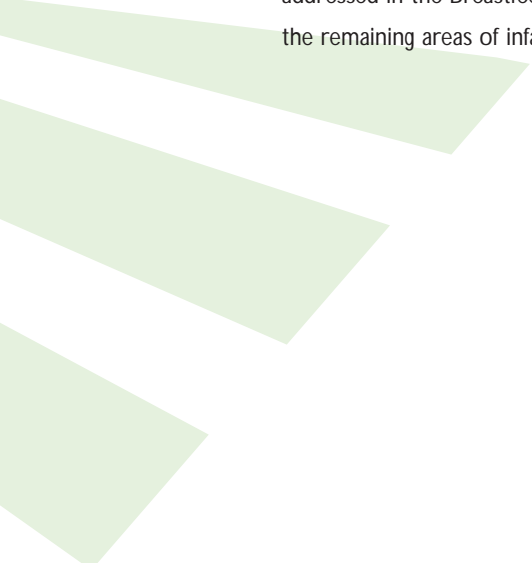


## FOREWORD

During the first year of life, infants triple their birth-weight and double their surface area, making this a period of very rapid growth which is never repeated during the life cycle. In addition to sustaining the growth of the infant, infant nutrition significantly influences health during childhood and probably into adult life. Nutrient requirements during infancy are unique, are dependent on the adequacy of maternal nutrition during pregnancy, the level of nutrient stores with which the infant is endowed at birth and the individual rate of growth and development of each infant.

This report on infant feeding provides information on nutrition and nutrition-related topics for children during the first year of life. It has been developed in response to increasing awareness of the importance of infant nutrition and in the knowledge that no comprehensive source of information on infant feeding was available in Ireland.

The recommendations within this report are designed to complement *A National Breastfeeding Policy for Ireland*, which was published by the Department of Health in 1994. The Breastfeeding Policy specifically aimed to increase the initiation and duration of breastfeeding in Ireland. It is agreed that breastfeeding is the optimal feeding method. It is also accepted that infant formula and complementary foods have important roles to play in infant nutrition. Only breastfeeding was addressed in the Breastfeeding Policy, so a comprehensive infant feeding policy is necessary to cover the remaining areas of infant nutrition.



*Dr Mary Flynn*  
*Chairperson*  
*Infant Feeding Sub-committee*



## EXECUTIVE SUMMARY

### Background

Recent research has highlighted a number of areas in which feeding practices in Ireland remain less than optimal (Freeman, 1996). A low level of breastfeeding, early introduction of cows' milk and complementary foods and inappropriate use of drinks, such as tea, are of concern. It is well recognised that such sub-optimal feeding practices impact on both immediate and longer term health. The low level of breastfeeding results in Irish infants being at increased risk of a range of infections; cows' milk feeding during the first year predisposes infants to the development of iron deficiency anaemia; early introduction of complementary foods is linked with increased percentage body fat and body weight in children and tea is known to inhibit iron absorption. The provision of an official reliable source of information on infant feeding, on which education programmes on infant feeding could be based, was considered an essential step towards eliminating these undesirable feeding practices and improving the health of infants in Ireland.

In 1997, a Sub-committee was established under the auspices of the Food Safety Advisory Board to draft recommendations for a national infant feeding policy for infants from birth to age one year. In the course of researching the document it became apparent that, as a result of medical or social circumstances, sub-groups of infants had special needs. The Sub-committee acknowledged that the needs of these infants might not be met by recommendations which are appropriate for the majority. Short sections outlining some of the additional requirements of infants with special needs are included in Chapter 10.

It also became apparent that issues not directly related to infant nutrition had the potential to influence significantly how Irish infants were fed. For this reason, in addition to addressing areas which are specifically nutritional in nature, administrative, legislative, fiscal and environmental issues related to feeding infants were examined (Chapter 13).

### Objectives

The objectives of the Infant Feeding Sub-committee were:

- To provide clear, unambiguous information on all areas related to infant feeding
- To complement and supplement the information and objectives outlined in the National Breastfeeding Policy for Ireland
- To encourage infant feeding practices consistent with health promotion and disease prevention

- To provide consistent, reliable information which would form the basis of advice disseminated by all health professionals
- To enable parents to make informed choices as to how they wish to feed their infants
- To create a framework for education programmes by the Health Promotion Unit of the Department of Health and Children, the Department of Education and Science and other interested groups
- To make recommendations on the dissemination of the information contained in the report
- To suggest a system by which the infant feeding policy will be reviewed and updated
- To highlight specific areas where further research is necessary.

### Issues addressed


In pursuance of its objectives, the Sub-committee decided that the following issues would be addressed:

- The nutrient requirements and food recommendations for infants up to the age of one year, including infants with specific requirements due to
  - cultural diversity
  - social disadvantage
  - prematurity or low birth-weight
  - physical or mental disability
  - specific medical disorders
- Current practices of infant feeding in Ireland
- Short and long term health problems which may result from inappropriate feeding
- The role of parents, community workers, teachers and health professionals
- The role and responsibility of the food industry and commercial interests
- The role and responsibility of the media and the community
- Relevant policies and practices of statutory agencies, including legislation and health, educational, environmental and fiscal policies

### Nutrition and infant health

Growth and development of the infant begin *in utero* and are influenced by genetic, environmental and nutritional factors which affect the health of the mother. Strategies designed to promote infant health must consider maternal and paternal health pre-conception and the intra-uterine environment in

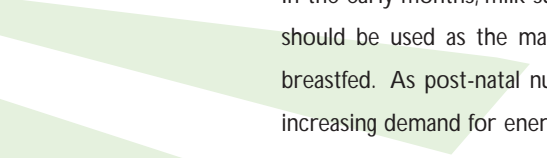




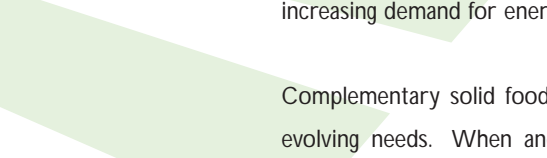
which the infant grows. Nutritional guidelines for pre-conception and pregnancy are included in Appendix A in recognition of the major role that ante-natal nutrition of the foetus plays in health promotion and disease prevention post-natally.

There are indications of some improvement during the last decade in the number of Irish mothers who initially breastfeed their babies, although up-to-date national figures are not available. Informal reports from some maternity units report an increase in the numbers who are discharged from hospital breastfeeding and, in its annual report, the Eastern Health Board reported a breastfeeding initiation rate of 38% (Eastern Health Board, 1998). Whether or not mothers are continuing to breastfeed for longer is not known.


However, the majority of Irish infants still receive no breast milk and are deprived of the major nutritional, immunological and psychological benefits which breastfeeding confers. Efforts to encourage breastfeeding are continuing at national, regional and local level, but a co-ordinated strategy will be necessary in order to monitor progress and increase breastfeeding initiation and duration in Ireland to acceptable levels.



In the early months, milk supplies all the nourishment an infant needs. An appropriate formula milk should be used as the main milk drink throughout the first year of life for infants who are not breastfed. As post-natal nutrient stores are utilised and the rapid growth of the infant creates an increasing demand for energy and nutrients, milk alone becomes inadequate.



Complementary solid foods provide additional energy and a diversity of nutrients to meet these evolving needs. When and how complementary feeding begins, and which foods are used, are important considerations in infant nutrition, having the potential to affect growth, development, nutritional status, disease expression and dental health.



Appropriate, efficient, timely and consistent procedures for monitoring infant feeding practices, growth and health are essential if targeted interventions to improve services are to be provided in an effective and structured manner. Current systems of data collection on feeding methods are inadequate and require updating. Infant growth is a valuable indicator of nutritional status and health, but only weight, a crude measure of growth, is measured routinely in Ireland. Additional measurements would provide more comprehensive information about the health of Irish infants

including early indications of the development of obesity or of growth faltering associated with underlying disease or malnutrition.

Health is defined by the World Health Organization as "*a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity*". The Convention on the Rights of the Child ensures the right of all children to "*the highest standards of health*". Consistent with this objective and with those of the Health Strategy for Ireland, *Shaping a Healthier Future* (Department of Health, 1994), this report outlines the various nutritional issues which have the potential to influence the health and well-being of Irish infants and makes recommendations by which optimal infant health can be achieved.

### Key issues and recommendations

- The nutritional needs of each infant are unique. Feeding of infants should be individualised, rather than dictated by schedules.
- Levels of breastfeeding in Ireland remain unacceptably low. The promotion of breastfeeding and education and support of the breastfeeding mother should continue to be the primary focus of health promotion for infants.
- For the infant who is not breastfed, a suitable milk-based infant formula should be used (in compliance with S.I. No. 243 of 1998) during the first year of life. Specialised products, such as soya-based or hypoallergenic formulae, should be used only under medical supervision.
- The early (usually not before 15 weeks) introduction of complementary foods (solids) should be discouraged, unless medically recommended.
- Audit and further research, as detailed in Chapter 13 of this policy, should be undertaken to clarify the specific nutritional needs and feeding practices of infants in Ireland. Resources should be provided by the Minister, and the Department of Health and Children should take a lead role in commissioning and supporting this research.

The Food and Nutrition Policy (Nutrition Advisory Group, 1995) states that "*a proactive approach should be taken to the dissemination of nutrition information to the public*". It is our hope that the information contained in this policy will be transmitted to the public through relevant government organisations and health-care professionals and that it will make a contribution to improved health for all infants in Ireland.

## SUMMARY OF RECOMMENDATIONS

The recommendations outlined in this report are based on the most recent available scientific knowledge and are designed to provide guidelines for optimal infant feeding practices for Irish infants.

### Chapter 2 Breastfeeding

- All babies should be breastfed, except in very rare cases when breastfeeding is medically contraindicated; exclusive breastfeeding should be practised during the first four to six months of life. At least 15 weeks of exclusive breastfeeding provides optimal benefit in terms of disease prevention (Wilson *et al*, 1998).
- Evaluation of the achievement of the objectives of the National Breastfeeding Policy should be undertaken in a structured manner and this evaluation should be supported by the Health Promotion Unit of the Department of Health and Children.
- A committee to undertake this task should be established; the committee should include health professionals, scientists and legislators with responsibility for, and have expertise in, infant nutrition and representatives from voluntary breastfeeding support groups. A National Breastfeeding Co-ordinator should be appointed.

### Chapter 3 Formula feeding

- Infants should always be supervised while feeding.
- Information on all aspects of infant feeding should be provided to all mothers ante-natally; infants who are not breastfed should be fed infant formula during the first year of life; follow-on formula may be used from the age of six months; cows' milk should not be used as the main milk drink until age 12 months.
- In addition to ante-natal education, mothers who are not breastfeeding and those who may wish to cease breastfeeding during the first year should be individually educated post-natally in how to prepare, store and feed infant formula to ensure that no ambiguity or lack of understanding exists.
- Because of the complex nutritional requirements of infants with specific medical/nutritional needs, all specialised formulae should be used only under medical supervision.

### Chapter 4 Other drinks

- Milk (breast milk or formula) and cooled boiled water should be the only drinks given up to about the age of four months and should constitute the great majority of the drinks given during infancy.


- Fruit drinks should not be given (1) in lieu of milk, (2) from a bottle or (3) at bedtime; small amounts may be given from a cup at mealtimes or with snacks. Tea (ordinary or herbal) is an unsuitable drink for infants. Aerated drinks, because of their unpredictable composition, are not suitable for infants. Mineral waters may have a high solute content, may contain inadequate fluoride and should not be used either to reconstitute formula or as an infant drink.
- Sugar, honey, rusks or other cereals should not be added to milk drinks; over-concentration of feeds results and the infant is deprived of the opportunity to learn to take food from a spoon.
- Use of a cup should be encouraged from the age of six months and feeding from a bottle should be discouraged after the age of one year. Drinks in bottles should not be taken to bed.

#### **Chapter 5 Introduction of complementary foods**

- Complementary foods should usually be introduced between the ages of four and six months.
- First foods should be puréed and of a soft, runny consistency, without lumps, and should be introduced one at a time, leaving a few days between the addition of each new food. In this way any adverse reaction to a new food can be easily pinpointed.
- Either cereals (gluten-free to age six months), fruits or vegetables are suitable as first foods. Expressed breast milk, infant formula or cooled boiled water should be used to mix foods.
- Food allergy or hypersensitivity is uncommon and should always be medically diagnosed.
- In families where there is a confirmed diagnosis of allergy, breastfeeding should be encouraged and, under medical supervision, the introduction of complementary foods, especially potentially allergenic foods, delayed.
- The adequacy of diets should always be assessed by a nutritionist if weaning is delayed or foods excluded.
- The role of peanuts in the aetiology of allergic disease in infants in Ireland should be investigated and guidelines for prevention of peanut allergy should be issued.

#### **Chapter 6 The weaning diet and dental health**

- Guidelines for the appropriate use of foods and drinks (Chapters 4 & 5) should be followed to prevent dental decay. Neither fruit drinks nor milk drinks should be left with infants at night or during daytime sleep periods. Fruit drinks, if given after the age of four to six months, should be restricted to mealtimes.
- Soothers, if used, should not be dipped in sugar, honey or any other sugary solution.

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- Teeth should be cleaned gently from the time of their appearance, but toothpaste should be used sparingly and only after age 18 months. Because the infant is unable to spit out and may swallow the excess, the fluoride in toothpaste may lead to opacities in the teeth.

### Chapter 7 Food energy and nutrients

- Breast milk or milk-based infant formula (or follow-on formula from the age of six months) should be fed throughout the first year of life as the main milk drink in order to ensure an adequate vitamin and mineral intake; unmodified cows' milk should not be used as the main milk drink before the age of one year. Low-fat milk, whether or not it is fortified with vitamins and minerals, is generally unsuitable for infants.
- Foods which contain heme iron (meat, chicken or fish), and fruits and vegetables, which supply a range of minerals and vitamins, should be chosen to complement the nutrients supplied by milk. Meat, as well as providing heme iron, is a good source of zinc and B-group vitamins. The needs of vegetarian infants are discussed in Chapter 10.
- Breastfed babies do not require iron supplementation if a good variety of complementary foods are consumed. Nutrients from breast milk are usually very well absorbed but if, after the age of four months, complementary foods or drinks are given with breast milk nutrient absorption may be diminished. Ideally, some time should elapse between breastfeeding and feeding other foods.
- Adult dietary guidelines should not be applied to infants.

### Chapter 8 Growth monitoring

- Growth reference curves based on data collected from Irish infants should be developed for use in Ireland.
- Equipment used to measure growth should be accurate and scientifically approved.
- Weight at birth, length and head circumference on day two or three post-natally, and weight, length and head circumference throughout infancy should be measured routinely by appropriately trained health professionals and recorded on a recognised growth chart; for a given infant, as few charts as possible should be used. Particular care should be taken when the growth of a breastfed infant is compared to current reference curves.
- If an infant fails to thrive or obesity or feeding difficulties develop, appropriate professional advice should be sought; food should not be used either as a reward or a punishment.

## Chapter 9 Pre-term and low birth-weight babies

- Each special care baby unit should have a nutrition policy for the care of low birth-weight infants and should be cognisant of the importance of providing these infants with optimal nutrition; units should have access to the expertise of a neonatologist and a nutritionist.
- Parents of premature or low birth-weight infants should be educated in the special contribution that breast milk can make to the improved nutrition of their infants. Until such infants can feed from the breast, mothers should be supported to express breast milk which can be stored and given to their infants, even if the infant is being ventilated.
- For the infant who is not breastfed, low birth-weight formula rather than standard formula should be used initially.

## Chapter 10 Special groups

- Appropriate health care, including nutritional care, should be available to all infants and clear and full information should be given to parents, in particular those whose infants have special needs.
- HIV-positive mothers and mothers in groups at risk of being infected with HIV should not breastfeed, even if the infant is known to be already infected; such mothers should be counselled to encourage best practice in relation to formula and food selection and preparation, with the objective of minimising the risk of exposure to infection and maximising the nutritional status of the infant.
- Breastfeeding is not usually contra-indicated if a mother is exposed to infections other than HIV.
- Information and assistance should be provided to disadvantaged families in ways appropriate to their situation.

## Chapter 11 Nutritional management of conditions which commonly arise during infancy

- Conditions which commonly arise during infancy do not usually necessitate changing the infant's feed.
- Medical advice should always be sought if symptoms persist.

## Chapter 13 Policy issues influencing infant feeding

### Access to information

- The information in this report should be disseminated to relevant organisations, interest groups and the national media.
- The information contained in this report should be reviewed and updated on a regular basis. The Sub-committee suggests that reviews should occur two yearly and updates at intervals of not more than five years.

### Education

- Plans to incorporate health and nutrition education into the primary and post-primary curricula should continue.
- Information on health and nutrition, and specifically infant nutrition, should be incorporated into teacher training courses.
- All mothers should be encouraged ante-natally to breastfeed their babies:  
The compositional differences between breast milk and formula and between infant formula and follow-on formula and the outcome of feeding each should be explained as part of all ante-natal education programmes in Ireland.
- Health-care professionals who are responsible for the provision of ante-natal education should have access to in-service training to regularly update their knowledge.
- Public health nurses should make a visit to all mothers within 24 hours of the infant's discharge from hospital. At a later date, a visit should be made to support the continuation of breastfeeding, provide information on other feeding, in particular the timely introduction of complementary foods, and record weight, length and head circumference.
- The public health nurse and general practitioner should be informed by the maternity unit on the day of discharge of the infant from hospital and the public health nurse should ensure that the family is visited on the day of discharge or the following day; special attention should be given to ensure an early visit to premature or low birth-weight babies or infants with special needs (Chapters 9 & 10).
- Those who provide education on infant feeding should be made aware of the high level of adult illiteracy.
- As far as possible, classes should include practical demonstrations and written information should be supported by illustrations, diagrams and pictures. This is especially important in relation to preparation of powdered milks, gluten-free products and infant medicines.

## **Fiscal**

- Resources should be allocated by the Minister for Health and Children to support the implementation of the recommendations detailed in this report.
- The cost of formula-feeding an infant in Ireland should be calculated so that, in compliance with current legislation, this important information can be made available to prospective parents.
- If mothers on low incomes are given financial support, it should be especially designed to encourage and support breastfeeding.
- The cost of not breastfeeding should be calculated for Ireland and taken into account when consideration is given to the allocation of resources for promotion of good infant nutrition.

## **Legislation and codes of practice**

- Immediate elaboration is required of a revised Code of Practice for the Marketing of Infant Formulae and Follow-on Formulae in the Republic of Ireland. This is provided for in Article 13 of S.I. No. 243 of 1998. The Food Safety Authority of Ireland (FSAI) should establish a group representative of interested parties in order to develop the code.
- Verification of compositional compliance should be carried out by the health boards following the provisions detailed in the European Communities (Official Control of Foodstuffs) Regulations, 1998 (S.I. No. 85 of 1998).
- The introduction by the industry of a voluntary compliance system with defined sampling and inspection frequencies which could be independently verified should be considered.

## **Environmental**


- Each community care area should have at least one community paediatric nutritionist to provide nutrition education and care for the nutritional needs of infants.
- Consideration should be given to the routine inclusion of length/height and head circumference measurement in the public health care programme.

## **Chapter 14 Recommended audit and research**

### **Collection of data on infant feeding**

- The current method of providing statistics on infant feeding should be revised and updated by the Department of Health and Children; data collection methods should be standardised, accurate and timely.



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- Consideration should be given to the implementation of a survey method of collecting accurate, relevant statistical data on infant feeding, which would allow for follow-up of the cohort at the age of four months.
  - Feeding information on newborn screening cards should be collated, analysed and used as a more immediate source of information on breastfeeding between days three and five post-natally.
  - Methods by which public health nurses collect data on infant feeding and growth should be standardised.

#### **Complementary foods**

- Research into existing and optimal weaning practice and introduction of complementary foods should be encouraged and supported financially by the Department of Health and Children.
- Feeding practices which are associated with the development of specific diseases – for example, obesity, hypertension, allergy, coeliac disease and iron deficiency – require detailed examination; in particular the role of peanuts in the aetiology of allergy and anaphylaxis should be investigated urgently and appropriate guidelines should be issued for Irish mothers and their infants.

#### **Nutritional status**

- The nutritional status, dietary intakes and additive exposure of Irish infants should be assessed.
- The vitamin and mineral status of Irish infants should be assessed.
- This research should be supported by the Department of Health and Children.

#### **Cows' milk**

- Further research, or a review of available data, is required to address the contradictions relating to the use of cows' milk-based products in infant foods and produce recommendations which are more consistent.

#### **Toddlers and pre-school children**

- The Department of Health and Children should develop a policy to address the nutritional needs of toddlers and pre-school children.



## CHAPTER 1: CURRENT INFANT FEEDING PRACTICES IN IRELAND

### Breastfeeding

Limited information is currently available about the feeding of Irish infants. Since the early 1970s a number of studies have assessed the rates of breastfeeding in various groups of infants in the community. Two nationally representative samples conducted in the 1980s (McSweeney & Kevany, 1982; McSweeney, 1986) noted breastfeeding rates of 32% and 34%. Since then higher levels of breastfeeding have been recorded, but samples were either volunteers or biased towards mothers of higher socio-economic status. In one sample recruited in a disadvantaged community, only 1.6% of infants had been breastfed (Lee, 1988). The most recently published perinatal statistics from the Department of Health and Children confirm that, in 1993, 34% of mothers were breastfeeding on discharge from hospital (Department of Health and Children, 1993).

In the Euro-Growth Study, a longitudinal, prospective study carried out in 22 European centres from 1992 to 1996 on a mixed socio-economic group of infants from birth and throughout the first year of life, the lowest level of breastfeeding was recorded in Ireland (Freeman, 1996). This research also showed that, as had been seen in other groups, a significant fall-off in the numbers who were breastfeeding occurred in the early weeks post-discharge. Although 44% of mothers

wished to breastfeed, at age one month only 26% were continuing to do so. Throughout the first year of life, breastfed infants fed more frequently than those who were fed either formula or cows' milk.

In an effort to improve breastfeeding rates the Department of Health published a *National Breastfeeding Policy for Ireland* in 1994. In 1997, a breastfeeding training pack for health professionals which was commissioned by the Health Promotion Unit of the Department of Health and Children was compiled (Becker & Kelleher, 1997).

### Formula feeding

The majority of Irish infants have been formula fed since national data collection began in the early 1980s. Earlier figures from smaller studies have recorded significantly higher breastfeeding rates than those recorded nationally (Becker & Kelleher, 1997). In 1992, 74% of infants were being fed only formula at age one month and of the 26% who were breastfed, 8% were being given some formula milk (Freeman, 1996). Soya-based or hydrolysate formula was being fed to more than 5% of infants between the ages of three and nine months.

The effects of formula feeding on infant health have not been investigated in Ireland. It is known from international findings that

variations in formula composition are reflected in different outcomes for infants (Dewey *et al*, 1995a). Usually formula feeding is compared with feeding human milk and, in general, human milk has acted as the "gold standard" for formula composition.

Common problems associated with bottle feeding include:

- inappropriate choice of product
- inappropriate under- or over-concentration of feeds
- addition of solid food to bottles
- inappropriate use of drinks other than formula, for example tea or juices
- inadequate hygiene in feed preparation
- prolonged bottle feeding and a failure to encourage consumption of a wide variety of foods.

Bottle feeding is also associated with increased levels of gastroenteritis, respiratory infections, coughing and other illnesses (Heinig & Dewey, 1996; Wilson *et al*, 1998).

### Introduction of complementary solid foods

Little information is available on weaning practices in Ireland. None of the available data distinguish between the introduction of solids to breastfed in contrast to formula-fed infants. Public health nurses document information on the age of introduction of complementary foods, but currently these data are not collected using a standardised methodology and are neither collated nor analysed.

Some information about early feeding can be gleaned from the thesis *Nutrition Intervention in Pre-School Children* (Lee, 1988) but the mean age of those enrolled was  $10.4 \pm 3.9$  months. From the data recorded retrospectively it can be seen that solid foods were introduced at an early age with 47% of infants having solids before the age of three months. Infants in this study and in the research sponsored by the Combat Poverty Agency (Lee & Gibney, 1989) were recruited from socio-economically

disadvantaged areas, so results could not be assumed to be applicable to the wider infant population.

In the Irish component of the Euro-Growth Study solids were introduced as early as age one month, with 31% having solids by age two months and over two-thirds of infants being given some solid food by age three months (Table 1) (Freeman, 1996). It appears that for the majority of Irish infants complementary foods are currently introduced at a very early age.

### Iron deficiency anaemia

Iron deficiency anaemia in infants has attracted a great deal of attention in recent years because infants who became anaemic during infancy were found to suffer long-term psycho-motor disadvantage (Lozoff *et al*, 1991). Although only 2.6% of one-year-old Irish infants were found to be anaemic, by age two years the number had increased to 9% (Freeman, 1996). The most important nutritional risk factor for the development of anaemia is the feeding of unmodified cows' milk as the main milk drink during the first year of life.

**Table 1.**  
**Age of introduction of solids (percentage of children)**

Age (months)	1	2	3	4	5	6	9	12
n =	114	112	113	111	111	109	110	108
Solids	12	31	68	92	97	99	100	100
No solids	88	69	32	8	3	1	0	0

## CHAPTER 2: BREASTFEEDING

The *National Breastfeeding Policy for Ireland* was published by the Department of Health in 1994 (Health Promotion Unit, Department of Health, 1994). The policy aimed to increase the uptake and duration of breastfeeding in Ireland and set out targets for the attainment of these objectives. A summary of its recommendations are included in Appendix B. The policy highlighted the unique nutritional, immunological and psychological advantages of breastfeeding for infants. Since 1994, this body of knowledge has continued to expand and new findings provide additional support for breastfeeding as the optimal feeding method (Wright *et al*, 1995; Dewey *et al*, 1995a, 1995b; Desci *et al*, 1995; Bishop *et al*, 1996; Hasselbalch *et al*, 1996; Riva *et al*, 1996; Fall *et al*, 1997; Golding *et al*, 1997; Wilson *et al*, 1998; Newberg *et al*, 1998; Wright *et al*, 1998).


Breast milk is uniquely adapted to be digested, absorbed and metabolised by the immature gastrointestinal, renal and metabolic systems of the infant and provides a wide range of health benefits. These benefits are known to persist during infancy, throughout childhood and possibly even into late adult life (Wright *et al*, 1995; Bishop *et al*, 1996; Fall *et al*, 1997). Important compositional differences between human milk and formula based on cows' milk are continually being discovered. The significance of these differences for health is still not completely understood and much

research continues to be undertaken. Known compositional differences between breast milk and formula are outlined in Appendix C.

Because of the reported risk of anaphylaxis associated with allergic reactions to peanuts, in the UK breastfeeding mothers with a family history of atopic disease are advised not to consume peanuts while breastfeeding. Currently no policy on peanut use exists in Ireland. The Sub-committee believes that this issue should be examined urgently by the Food Safety Authority of Ireland and that clear recommendations for Irish mothers should be published (Department of Health and Social Security, 1998).

Booklets entitled *Food and Babies* and *Breast Fed is Best Fed*, which are available from the Health Promotion Unit of the Department of Health and Children, give practical guidance on good breastfeeding practice, provide answers to the questions often asked by mothers and discuss difficulties which may be encountered and ways to solve them. These publications should be made available to prospective parents. Information materials are also available from voluntary breastfeeding support groups.

New-borns should be fed whenever they show signs of hunger such as increased alertness, mouthing or rooting, feeding eight to twelve



times in 24 hours. Crying is a late stage in the development of hunger. Non-demanding young babies should be woken to feed if three hours have elapsed.

The Sub-committee fully supports and endorses the aims and objectives of the *National Breastfeeding Policy for Ireland*, reiterates the substantial health benefits of feeding human milk and believes that the promotion of breastfeeding as the optimal feeding method should continue to be a primary focus of health promotion and disease prevention in Ireland.

**The Sub-committee recommends that:**

- All babies should be breastfed except in very rare cases when breastfeeding is medically contraindicated; exclusive breastfeeding should be practised during the first four to six months of life. At

least 15 weeks exclusive breastfeeding provides optimal benefit in term of disease prevention (Wilson *et al*, 1998).

- Evaluation of the achievement of the objectives of the National Breastfeeding Policy should be undertaken in a structured manner and this evaluation should be supported by the Health Promotion Unit of the Department of Health and Children.
- A committee to undertake this task should be established; the committee should include health professionals, scientists and legislators with responsibility for, and expertise in, infant nutrition and representatives from voluntary breastfeeding support groups. A National Breastfeeding Co-ordinator should be appointed.

## CHAPTER 3: FORMULA FEEDING

For the infant who is not breastfed a suitable infant formula is required (Nutrition Advisory Group, 1995). The various formulae marketed in Ireland comply with EU compositional guidelines and are suitable for feeding infants who are not breastfed. All are fortified with a range of vitamins and minerals and some trace elements. These milks may be divided into two major categories, infant formulae and follow-on formulae.

### Milk-based infant formulae


Infant formulae made from cows' milk which are currently marketed in Ireland may be whey- or casein-predominant. The cows' milk protein in whey-predominant infant formula is altered in an effort to reflect the composition of breast milk, while the protein in casein-predominant formula maintains its similarity to cows' milk. However, as the casein and whey proteins of human milk differ significantly from those of cows' milk, important differences between breast milk and either type of formula remain (Janas *et al*, 1985, 1987; Emmett & Rogers, 1997). It is generally recommended that the infant who is not breastfed should be given a whey-predominant formula, although both whey- and casein-based formulae fulfil the EU compositional guidelines for infant formula. It is known that casein inhibits iron absorption more than whey (Hurrell *et al*, 1989). However, scientific research comparing the effect of feeding casein-predominant with whey-predominant formula is lacking.

### Follow-on formulae

Follow-on formulae have been marketed to discourage mothers from feeding infants unmodified cows' milk. It is known that the use of unmodified cows' milk as the main milk drink during infancy predisposes infants to the development of iron deficiency anaemia (Chapter 7). In comparison to feeding cows' milk, follow-on formula has been shown to be effective in diminishing the risk of iron deficiency anaemia in deprived inner-city toddlers in the UK (Daly *et al*, 1996). The difference between using follow-on formula and iron-fortified infant formula has not been studied. Studies comparing the difference in iron status which results from using an iron-fortified follow-on formula or a non-iron-fortified, but otherwise identical, formula (not commercially available in Ireland) have failed to show an advantage for the iron-fortified follow-on formula in terms of anaemia prevention (Stevens & Nelson, 1995; Gill *et al*, 1997; Walter *et al*, 1998). International experts on iron deficiency now agree that the iron content of "follow-on formula" is unnecessarily high (Walter *et al*, 1998).

The World Health Assembly adopted a resolution in 1986 stating that follow-on formulae are "*not necessary*" (World Health Assembly, 1986). However, the EU has published regulations permitting their use






after the age of four months (European Commission Directive 91/321/EEC). Those companies which currently market follow-on formulae in Ireland have agreed voluntarily to market them only for infants from the age of six months. Marketing of infant formula is prohibited under Irish law but marketing of follow-on formula is permitted (S.I. No. 243 of 1998; Appendix F).

#### Specialised formulae

The formulae previously described are those that are suitable for normal, healthy infants. An additional range of products is available for infants with special needs who are not breastfed.

#### Soya-based and "hypoallergenic" formulae



Formulae based on soya protein and hydrolysed formulae have been designed for infants who develop an allergy to cows' milk. Soya formulae are made from soya protein, rather than cows' milk protein. (These are not the same as soya "milks", which may be bought in a carton in the supermarket but which are unsuitable for infants). Hydrolysed formulae are those in which the protein (casein or whey from cows' milk or soya or collagen proteins) has been treated, either by heat or enzymes, to diminish the size of the peptide fraction. Hydrolysis may be either partial or extensive.

Hydrolysed formulae may be beneficial in reducing the symptoms of eczema and infantile colic in infants diagnosed with cows' milk protein intolerance (Halcken *et al*, 1995; Verwimp *et al*, 1995). A well-controlled Swedish study supports an allergy-preventive effect of extensively hydrolysed formula in infants from atopic families, but partially hydrolysed formula and regular cows' milk formula were found to be similar in allergic outcome (Oldaeus *et al*, 1997). It is not possible to ascertain from current labelling which hydrolysates are extensively or which partially hydrolysed.

Soya-based formulae are cows' milk and lactose free and should be used only under medical supervision for term infants. They have been shown to be beneficial in the treatment of transient lactose intolerance, galactosaemia and IgE mediated cows' milk allergy. However, infants who are allergic (IgE mediated) to cows' milk protein may also develop a sensitivity to soya protein (American Academy of Pediatrics, 1998). They may provide an alternative to breast milk or cows' milk-based formula for term infants whose parents wish to feed a vegan diet, but in these cases medical supervision is necessary to avoid the development of nutrient deficiencies.

Soya-based formula should not be used routinely for term infants as mineral

absorption is less predictable, and the precise physiological effect of high concentrations of aluminium (4–65 ng/ml in human milk vs 600–1300 ng/ml in soya formula) is unknown (American Academy of Pediatrics, 1998). Soya also contains high levels of phytoestrogens, the long-term effects of which are unknown (Essex, 1996; Sheehan, 1998). In cases of cows' milk protein induced enterocolitis or enteropathy, soya-based formulae should not be used. Neither have they been shown to be beneficial in the treatment of colic or as a preventive measure in atopic disease.

Soya-based formulae are not suitable for pre-term infants, as pre-term infants fed soya formula demonstrate less weight gain, less length gain, lower serum albumin and serum phosphorous levels and increased osteopaenia of prematurity (American Academy of Pediatrics, 1998).

In Ireland, in 1992, 5% of infants between the ages of three and nine months were being fed either a soya-based or hydrolysate formula (Freeman, 1996). In the Euro-Growth Study group, a maximum of 7.3% of infants were being fed soya-based or hydrolysed formula at the age of three months (van't Hof *et al*, 1999a). It is likely that the true incidence of food allergy (all foods) is only 3% (Kilgallen & Gibney, 1996). This suggests that in some cases these special formulae are being used

inappropriately. Diagnosis and treatment of allergy is complex, so specialised formulae should be used only under medical supervision.

#### **Breast milk or hydrolysed formula?**

A longitudinal Finnish study has confirmed that breastfeeding is prophylactic against atopic disease, including atopic eczema, food allergy and respiratory allergy, throughout childhood and adolescence (Saarinen & Kajosaari, 1995). While hydrolysed formulae have been shown to reduce symptoms in formula-fed babies, when compared with breastfeeding "*the various protein-hydrolysed formulae are not equivalent in terms of nutritional safety for new-born infants*" (Rigo *et al*, 1994). Hydrolysates are less allergenic than cows' milk formulae but children with cows' milk allergy can also react to hydrolysed formulae (Hide & Wharton, 1995). Hydrolysates should be used only under medical supervision.

#### **Medical disorders**

Specialised formulae are also used in the treatment of certain medical disorders. These include products with altered nutrient profiles suitable for feeding infants with specific medical conditions. All such products are available, and must be used, only on prescription and under close medical supervision, as careful monitoring of these conditions and of nutrient intake is required.

### Low birth-weight formulae

Formulae for low birth-weight infants are discussed in Chapter 9.

### Issues currently under review in relation to formula composition

Ongoing efforts are made by manufacturers of infant formulae to improve the quality of their products so that they provide as reliable an alternative as possible to breast milk. This effort is justified based on the large numbers of infants who currently rely, wholly or in part, on formula for their early nutrition. However, a number of issues remain unresolved in relation to optimal formula composition. These include protein : energy ratio, long chain polyunsaturated fatty acid (LCPUFA) composition, the addition of nucleotides, selenium and sialic acid and the optimal level of iron fortification.

Until the scientific debate surrounding these issues is resolved, formula manufacturers may differ in their interpretation of the optimal composition of formula in relation to specific nutrients. Formulae marketed in Ireland vary somewhat as a result of these differences of interpretation. It is important to reiterate that all products comply with EU regulations for infant formulae. As the results of scientific research provide new information in relation to optimal composition, these are included as amendments to the European Commission

Directive 91/321/EEC on infant formulae and follow-on formulae and incorporated into national legislation.

### Formula use

Formula milks are produced either in dried powdered or ready-to-feed form. In either case the manufacturer's instructions for use should be followed precisely. For the normal, healthy infant no other food should be added to the bottle of milk. An increased risk of developing obesity has been reported in infants fed on formula reconstituted from dried powder, probably due to errors in the mixing process (Lucas *et al*, 1992c). Formula-fed babies should be fed on demand; frequent feeding in the early weeks is the normal physiological requirement for all infants (ESPGAN Committee on Nutrition, 1982).

Regulations governing the provision of information to parents are detailed in S.I. No. 243 of 1998, No. 11 (Appendix F). All information given to parents should be in compliance with this regulation.

Practical advice on formula preparation, feeding and sterilisation of equipment is detailed in *Food and Babies: pregnancy and the first year of life* (Health Promotion Unit, Department of Health). All mothers should be provided with an up-to-date copy of this booklet during the ante-natal period and those

who are not breastfeeding and breastfeeding mothers who wish to feed formula at a later date should be given individual instruction, preferably post-natally, in formula preparation and care and sterilisation of equipment.

**The Sub-committee recommends that:**

- Infants should always be supervised while feeding.
- Information on all aspects of infant feeding should be provided to all mothers ante-natally; infants who are not breastfed should be fed infant formula during the first year of life; follow-on formula may be used from the age of six months; cows' milk should not

be used as the main milk drink until age 12 months.

- In addition to ante-natal education, mothers who are not breastfeeding and those who may wish to cease breastfeeding during the first year should be individually educated post-natally in how to prepare, store and feed infant formula to ensure that no ambiguity or lack of understanding exists.
- Because of the complex nutritional requirements of infants with specific medical/nutritional needs, all specialised formulae should be used only under medical supervision.

## CHAPTER 4: OTHER DRINKS

### Cows' milk

All mammalian milks are species specific and unmodified cows' milk does not meet the nutrient requirements of human infants. It is currently recommended that cows' milk should not be used as the main milk drink in the first year of life (American Academy of Pediatrics, Committee on Nutrition, 1992; DHSS, 1994). In summary, all of the macronutrients are found in significantly different forms and in different quantities in cows' milk than they are in human breast milk (Emmett & Rogers, 1997). Cows' milk is also a poor source of iron and, because of its high casein, calcium and phosphate levels, little of the iron is bioavailable (Harbottle & Duggan, 1992; DHSS, 1994). Infants fed whole, unmodified cows' milk have low intakes of iron and copper, together with excessively high intakes of protein, sodium, potassium, magnesium and chloride. The overall mineral content of cows' milk is significantly greater than that of human milk, resulting in an increased renal solute load. Levels of vitamin D in cows' milk are low.

### Cows' milk and gastrointestinal bleeding

Cows' milk which has not been heat treated may cause gastrointestinal bleeding (Ziegler *et al*, 1990; Fuchs *et al*, 1993). The processing of cows' milk, which is used in formula manufacture, may denature the protein and make it less of an irritant to the gastrointestinal tract of the infant. It has

recently been shown that infants fed cows' milk are at greater risk of developing iron deficiency anaemia than those fed an infant formula which is not fortified with iron (Daly *et al*, 1996; Gill *et al*, 1997). It is possible that, during the first six months of life, the feeding of unmodified cows' milk is a risk factor for increased gastrointestinal blood loss but that later in infancy the difference between using cows' milk and infant formula or pasteurised cows' milk may not be significant (Fuchs *et al*, 1993). However, this issue is still not clearly resolved. While the possibility remains that cows' milk may be a gastrointestinal irritant, it seems wise to exclude it completely from the diet of infants, at least to age six months. It may be used to mix foods or as an ingredient in foods after the age of six months.

### Goats' or sheeps' milk

Neither goats' nor sheeps' milk are suitable drinks for infants. They are nutritionally inadequate in terms of iron, sodium, vitamin D and folic acid when compared with human milk. Levels of vitamin A also differ from those in human milk. Although there is the perception that these milks may be less allergenic than cows' milk, there is no scientific evidence to support this hypothesis (DHSS, 1994).

Only infant formulae in which the protein source is either cows' milk or soya protein are

currently governed by EU or Irish legislation. Products in which the protein source is goats' or sheeps' milk are not covered. No statutory regulations are in place to ensure that such products satisfy the nutritional requirements of infants and this is an additional reason why their use is not recommended.

#### **Drinks other than milk**

In 1995 in Great Britain, 7% of mothers of six- to ten-week-old infants reported giving their babies drinks of water with sugar or honey added (Foster *et al*, 1997). By the age of four to five months, 63% of mothers were giving unsweetened baby drinks, while 41% gave drinks of water. The use of water at about four months had increased from 31% in 1990 to 41% in 1995. Between 1990 and 1995 there was a significant fall in the use of commercial herbal drinks at both six and ten weeks and at four months.

In Ireland, little is known about the use during infancy of drinks other than milk, but in a sample of Irish children 43% and 28% were drinking juice from a bottle at ages 18 and 24 months respectively (Freeman, 1996). Failure to thrive, diarrhoea and poor appetite have been reported in children as a result of excessive consumption of fruit juices and squashes (Smith & Lifshitz, 1994; Hoekstra *et*

*al*, 1995; Hourihane & Rolles, 1995). Fruit juices are seen to be "healthy" but this perception increases the risk that they will be used inappropriately and could displace the essential nutrients which are provided to the infant by milk.

#### **Bottle or cup**

In the UK, babies who were breastfed were more likely than those who were bottle fed to have ever taken drinks from a cup at age nine months, although the use of a cup is encouraged from the age six months (Foster *et al*, 1997). Infants who continue to drink only from a bottle tend to drink excessively large quantities of milk, can fail to develop the habit of eating a variety of foods and may develop dental problems. In an Irish study, whether infants were drinking from a bottle or cup was not recorded during the first 12 months of life, but, at age 18 months, 82% were still drinking milk or formula, 43% were drinking juice and 12% drank tea from a bottle (Freeman, 1996). Bottle use at bedtime was common and the majority were still using a bottle at the age of 24 months. Details are shown in Table 2.

#### **The Sub-committee recommends that:**

- Milk (breast milk or formula) and cooled boiled water should be the only drinks given up to about the age of

four months and should constitute the great majority of the drinks given during infancy.

- Fruit drinks should not be given (1) in lieu of milk, (2) from a bottle or (3) at bedtime; small amounts may be given from a cup at mealtimes or with snacks. Tea (ordinary or herbal) is an unsuitable drink for infants. Aerated drinks, because of their unpredictable composition, are not suitable for infants. Mineral waters may have a high solute content, may contain inadequate fluoride and should

not be used either to reconstitute formula or as an infant drink.

- Sugar, honey, rusks or other cereals should not be added to milk drinks; over-concentration of feeds results and the infant is deprived of the opportunity to learn to take food from a spoon.
- Use of a cup should be encouraged from the age of six months and feeding from a bottle should be discouraged after the age of one year. Drinks in bottles should not be taken to bed.

**Table 2.**  
**Percentage of children drinking from a bottle, and drinks consumed (Freeman, 1996)**

Age (months)	18 (n = 106)	24 (n = 109)
<b>Bottle</b>		
Milk/formula	82	62
Tea	12	10
Juice	43	28
Other	6	6
<b>Bottle at bedtime</b>		
Milk/formula	46	45
Tea	40	41
Tea + sugar	1	0
Juice	1	1
Juice	4	3
<b>No bottle</b>		
	13	28

## CHAPTER 5: INTRODUCTION OF COMPLEMENTARY FOODS

As the various systems of the infant mature, the introduction of complementary food serves to meet the increased demand for energy and nutrients which is imposed by rapid growth. This gradually reduces the reliance on milk as the primary energy and nutrient source, encourages the development of neuromuscular co-ordination and introduces the infant to an increasing variety of tastes and textures. New legislation (S.I. No. 241 of 1998; Appendix G) lays down regulations for the composition, labelling and marketing of processed cereal-based foods and baby foods for infants and young children.

### Age of introduction of complementary foods

There may be wide physiological variation in the needs of individual infants and recommendations for breastfed babies differ somewhat from those for babies who are formula fed. For all infants, the introduction of solid foods becomes necessary at some point, usually not earlier than between four and six months.

Data available for Ireland suggest that 92% of infants were being fed solid foods by the age of four months (Freeman, 1996). The 1995 data from the UK show that, by the age of three and four months, 55% and 91% of infants respectively were being fed some complementary food, while 13% were taking


solids at age eight weeks. In general, at each age point, there was a decrease in the percentage of infants fed foods other than milk compared with 1990 figures (Foster *et al*, 1997). As has been shown previously (Whitehead *et al*, 1986), breastfed infants were introduced to solid foods at a later age than infants who were formula fed (Foster *et al*, 1997).

### Not too early

Early solid feeding is not recommended because:


- breast milk is adequate as the sole food up to the age of four to six months (Hervada & Newman, 1992; Pisacane *et al*, 1995; American Academy of Pediatrics, 1997)
- cows' milk-based infant formula can be used as a substitute for the infant who is not breastfed
- other fluids or foods displace the essential nutrients supplied by breast milk (Heinig *et al*, 1993; Michaelsen *et al*, 1994; Børresen, 1995)
- solid foods increase the renal solute load on the infant's immature kidneys (ESPGAN, 1982)
- antigens may be introduced to the infant's immature gastrointestinal tract (ESPGAN, 1982)
- breastfeeding enhances the maturation of the gastrointestinal tract and the





immune system (Sheard & Walker, 1988; Cattasi *et al*, 1995; Pickering *et al*, 1998)

- it has been shown that the introduction of complementary foods to either breastfed or formula-fed infants before the age of 15 weeks results in significantly greater risk of wheezing, and increased body weight and percentage body fat at age 7.3 years (Wilson *et al*, 1998)
- the onset of certain diseases may be precipitated (e.g. coeliac disease, allergy).



In the early months, breast milk provides the stimulus for the development of the digestive, renal and metabolic systems and aspects of the intestinal defence mechanism which are initially passive or incompletely developed (Hendricks & Badruddin, 1992). Exclusively breastfed babies tend to grow faster than formula-fed babies in these initial months (Persson, 1985; Rowland, 1985; Dewey *et al*, 1995b), but there is currently no evidence to suggest that the formula-fed baby requires complementary foods at an earlier age. During the first four months, as infants grow they require increased energy and nutrient intakes. Initially, this should be met by feeding breast milk or formula more frequently. The extra suckling will stimulate an increased production of breast milk. The volume of formula feeds should also be increased gradually. However, there will still be individual variation in the

precise age at which complementary foods become necessary. Some babies, probably due to their greater initial birth-weight or faster growth velocity, may require complementary foods earlier than others. The needs of individual infants should be discussed with a health professional.

#### **Not too late**

Complementary foods should usually be introduced by about the age of six months to meet the infant's increasing demand for energy and nutrients (ESPGAN, 1982). By then post-natal levels of nutrient stores are becoming depleted and the infant's gastrointestinal and renal systems have developed sufficiently to allow digestion and absorption of a more complex range of foods (Hendricks & Badruddin, 1992). The mucosal barrier to foreign antigens has developed and the production of enzymes, such as pancreatic amylase, which is necessary for the digestion of complex carbohydrates, is more fully developed. The ability to suck and swallow are already developed *in utero* but during the first few months of life the infant does not know how to chew. Post-natally, the extrusion reflex is very strong to protect infants from choking on chunks of food but this reflex weakens during the first half of infancy. By the age of six months, neuromuscular co-ordination has matured, allowing the infant to maintain an upright head position and begin to take food

from a spoon. The timely introduction of complementary foods encourages the development of gross and fine motor control, exploratory behaviour and manual dexterity (Hendricks & Badruddin, 1992).

### Which Foods?

The range of foods used as first foods will vary widely from one culture to another. Preliminary results from the Euro-Growth Study show that in the Mediterranean countries (Italy, Greece, Spain) fruits were the first foods offered. At more northerly latitudes (Ireland, Sweden) cereal-based foods were used more commonly. *Weaning and the Weaning Diet* (DHSS, 1994) suggests a range of foods which may be used as first foods. These include gluten-free cereals, mashed potato, puréed meat, pulses and fruit. A similar range of foods should be suitable for Irish infants. However, no longitudinal studies published to date have examined the effects of initially using different foods in normal healthy infants. The great majority of commercially prepared infant foods are now marketed as being suitable from the age of four months.


### Gluten-free foods and coeliac disease

The recommendation to delay the introduction of gluten until the age of six months is designed to prevent or postpone the onset of coeliac disease, although the precise relationship between disease onset and diet is yet to be clarified.

The prevention of coeliac disease is particularly important because histological changes in the intestine result in malabsorption of essential nutrients and, if the condition remains untreated, long-term damage to the intestine can result. However, the condition resolves completely if gluten-containing foods are excluded from the diet. Data from epidemiological studies have shown that prolonged breastfeeding and later introduction of gluten-containing foods are protective (Greco *et al*, 1988; Ascher *et al*, 1993).

A marked decrease has been recorded in the incidence of the disease in west of Ireland children between 1971–1980 and 1981–1990 (Gumaa *et al*, 1997). Although no feeding data were recorded, it is hypothesised that the change may have resulted from improved infant feeding practices; specifically, delayed introduction of gluten-containing foods. However, a study from Sweden (Ascher *et al*, 1997) suggests that as yet unidentified additional genetic markers may be the crucial factor, with feeding practices only influencing disease expression. Whatever the reason, it appears that "*coeliac disease is moving from the realm of the paediatrician to the adult physician*" (Gumaa *et al*, 1997).

While the aetiology of coeliac disease remains unclear and epidemiological evidence points to



a protective role for breastfeeding and later introduction of gluten, both of these preventive measures should be encouraged.

#### **Which foods are gluten-free?**

The recommendation to delay the introduction of gluten-containing foods until the age of six months has posed some problems in terms of the marketing of commercially prepared infant foods. Some foods which contain gluten have been marketed as being suitable for use from the age of four months. This anomaly increases the importance of effectively educating health professionals and parents in relation to appropriate gluten-free food choices for their young infants. Under new legislation (European Communities [Processed Cereal-Based Foods and Baby Foods for Infants and Young Children] Regulations, 1998 – S.I. No. 241 of 1998; Appendix G), cereal-based foods marketed for infants of less than six months of age must state clearly whether or not they contain gluten.

Gluten is found in wheat, rye and barley. Although pure oats do not contain gluten (Srinivasan *et al*, 1996), there is a risk that oats used in manufactured products may be contaminated with gluten from other cereals.

#### **Weaning in the family with atopy**

While it is difficult to find definitive data on

which to base recommendations for the normal infant, many researchers have examined the effectiveness in infants at high risk of atopy of delayed, considered weaning (Halken *et al*, 1995; Marini *et al*, 1996).

The 12.5% prevalence of food allergy, as perceived by parents, in Irish children (birth to four years), although lower than that reported from other countries, is still significantly higher than the figure for true food allergy, which is thought to be about 3% (Kilgallen & Gibney, 1996). It is important, therefore, that allergy/atopy should always be medically diagnosed.

Prolonged breastfeeding (with or without maternal avoidance of potential allergens) protects against the development of allergy (Saarinen & Kajosaari, 1995; Marini *et al*, 1996). Saarinen & Kajosaari prospectively followed a sample of healthy infants during infancy and throughout childhood to age 17 years. The highest prevalence of atopy was in the group which had little or no breastfeeding. Prevalence of eczema at one and three years was lowest in the prolonged (> 6 months) breastfeeding group. Breastfeeding also resulted in less food and respiratory allergy. The use of hypoallergenic formula milks, which may have a role to play in allergy treatment, is discussed in the section relating to formula feeding above (Chapter 3).

In atopic families (families in which one or more first-degree relative suffers from confirmed atopic disease such as asthma, rhinitis, eczema, urticaria or hay fever), breastfeeding should be encouraged and the introduction of complementary foods, in particular potentially allergenic foods (e.g. eggs, cows' milk), delayed. Any modified feeding plan should be supervised by a nutritionist to ensure that the diet remains nutritionally adequate. This is of particular importance if a major food group (e.g. dairy produce) is excluded from the diet.

#### **Peanut allergy**

In recent years allergy to peanuts has received increasing attention because "*allergy to peanuts is the most common cause of fatal and almost fatal food related anaphylaxis*" (Hourihane *et al*, 1996). The increase in the use of peanuts in vegetarian meals and as a food ingredient means that, even at an early age, infants can be exposed to peanuts (Hourihane *et al*, 1998). In response to the increasing realisation that peanut allergy may have very serious consequences, the DHSS in the UK has published a leaflet detailing the preventive measures which should be taken by pregnant and breastfeeding women and mothers of young children. Currently no guidelines are available for Ireland, so this issue needs to be addressed urgently.

#### **The Sub-committee recommends that:**

- Complementary foods should usually be introduced between the ages four and six months.
- First foods should be puréed and of a soft, runny consistency, without lumps, and should be introduced one at a time, leaving a few days between the addition of each new food. In this way any adverse reaction to a new food can be pinpointed more easily.
- Either cereals (gluten-free to age six months), fruits or vegetables are suitable as first foods. Use expressed breast milk, infant formula or cooled boiled water to mix foods.
- Food allergy or hypersensitivity is uncommon and should always be medically diagnosed.
- In families where there is a confirmed diagnosis of allergy, breastfeeding should be encouraged and, under medical supervision, the introduction of complementary foods, especially potentially allergenic foods, delayed.
- The adequacy of diets should always be assessed by a nutritionist if weaning is delayed or foods excluded.
- The role of peanuts in the aetiology of allergic disease in infants in Ireland should be investigated and guidelines for prevention of peanut allergy should be issued.

## CHAPTER 6: THE WEANING DIET AND DENTAL HEALTH

The introduction of complementary foods to the infant's diet coincides with the time when the first teeth are beginning to appear. Few teeth erupt during infancy (0–12 months), but feeding patterns established then have the potential to predispose young children to the development of caries. Incisors and the first baby molars, which erupt during this period, are the teeth which are most vulnerable to the development of rampant caries.

### Dental caries

Dental caries develops when bacteria produce acid, a by-product of carbohydrate metabolism, which causes demineralisation of the tooth enamel. Caries, once established, can progress rapidly and cause extensive damage to teeth. *Strep. mutans*, the primary bacteria involved in the development of caries in children, may be present during the latter half of infancy (6–12 months). Colonisation is more common in infants who consume sweetened drinks in a bottle (Mohan *et al*, 1998) and, as a result, exposure to foods or drinks containing sugars facilitates caries development. Both the quantity and frequency of exposure are important factors (Holt & Moynihan, 1996).

### Nursing bottle caries

Nursing bottle caries is the term given to the dental caries which results from the constant exposure of the teeth to drinks from a bottle.

It is a rapidly progressing form of caries and tends to follow the pattern of tooth eruption. All surfaces can be affected, including those not normally affected by caries, as the defence mechanisms of the infant against caries are overwhelmed. Incisors tend to be immune because they are afforded better protection by the tongue and salivary flow. Exposure of the teeth is significantly increased if the infant sucks the bottle for prolonged periods (Department of Health and Children, 1999). For this reason bottles should not be left with infants while they are sleeping. Usually sugary drinks are implicated, but infant formulae have also been shown to be cariogenic (Sheikh & Erickson, 1996; Bowen *et al*, 1997). If soya-based formula is used, particular attention should be given to oral hygiene, as these products contain sugars which are potentially more cariogenic than the lactose in cows' milk-based formulae (Holt & Moynihan, 1996).

### Other risk factors

Additional situations associated with increased risk for the development of caries include maternal complications during pregnancy, low socio-economic status, pre-term birth, the use of soothers (pacifiers), prolonged bottle feeding, failing to use fluoride toothpaste and the use of sugary drinks during the night as well as the day (Torney, 1992; Holt *et al*, 1996; Moynihan & Holt, 1996; van Everdingen *et al*, 1996; Febres *et al*, 1997; Seow, 1997).

### **Breastfeeding and caries**

Prolonged demand breastfeeding has been investigated as a cause of caries, but it appears that other factors, such as maternal complications during pregnancy (Torney, 1992) and failure to use fluoride toothpaste, contribute to the dental decay seen in some breastfed infants. Antibodies to *Strep. mutans* are found in breast milk and may offer protection against caries (Eggert & Gurner, 1984). However, breastfed infants who sleep with the mother at night and continue to feed very frequently during the second year of life have been shown to have an increased risk of caries (Weerheijm *et al*, 1998).

### **Protection against caries**

The presence of fluoride in water and the use of fluoride toothpaste provide protection against caries (World Health Organization, 1994; Department of Health and Children, 1999). Water fluoridation began in Dublin in 1964 (O'Mullane *et al*, 1996). The programme of fluoridation is continuing in Ireland, 67% of the population being covered in 1996.

Gentle cleaning of the teeth may begin, using gauze or a soft cloth, as soon as the teeth begin to appear. No toothpaste should be used before the age of 18 months, as the child is unable to spit out efficiently. After the age of 18 months a small amount (pea-

sized) of toothpaste may be used and the child should be encouraged to spit after cleaning.

### **Sugar in foods and drinks**

There is no one accepted method of categorising sugars in food. Many sweet foods, and some savoury manufactured processed foods, contain sugars. All fruit juice preparations contain some fruit sugars, as the sugar is released from the cell structure during the processing. Complementary foods with a high sugar content should be used with care and home prepared foods should not usually have large amounts of added sugar.

Sugar may be listed on labels as sugar, glucose syrup, dried glucose syrup, dextrose, dextrose monohydrate or anhydrous dextrose; sugars in fruit juices may also be labelled as fructose or sugars derived from fruits. It is important to note that "low sugar" or "free from added sugar" does not mean "safe for teeth", but may well carry this implication (Holt & Moynihan, 1996).

Infant fruit drinks are not necessary, and milk or water should be the primary drinks consumed during the first year of life. Whole fresh fruits are a more reliable and less cariogenic source of vitamin C.



**The Sub-committee recommends that:**

- Guidelines for the appropriate use of foods and drinks (Chapters 4 & 5) should be followed to prevent dental decay. Neither fruit drinks nor milk drinks should be left with infants at night or during daytime sleep periods. Fruit drinks, if given after the age four to six months, should be restricted to mealtimes.
- Soothers, if used, should not be dipped in sugar, honey or any other sugary solution.
- Teeth should be cleaned gently from the time of their appearance, but toothpaste should be used sparingly and only after the age of 18 months. Because the infant is unable to spit out and may swallow the excess, the fluoride in toothpaste may lead to opacities in the teeth.

## CHAPTER 7: FOOD ENERGY AND NUTRIENTS

### Energy

Providing an adequate intake of energy to sustain normal growth and development is a primary consideration for children whose rate of growth, particularly during infancy, is very rapid. During the first year of life, infants triple their birth-weight and double their surface area, an achievement which is not repeated during the life cycle. Growth patterns vary considerably during this time and differences in growth velocity will be reflected in varying energy requirements. For this reason, feeding should be adapted to the needs of the individual infant.

### Protein

Proteins in the diet supply the amino acids, including essential amino acids, required for the growth and maintenance of tissues of infants. Infants, as a result of their accelerated rates of growth, require more protein per unit body weight than adults. The requirement for protein correlates with the rate of growth, which is greatest in early infancy. In addition to providing the amino acids necessary for growth, breast-milk proteins fulfil a range of important functions, such as the provision of immunologically active cells, which enhance the infant's resistance to infection (Appendix C).

In late infancy, those who are consuming a variety of foods including meat, chicken, fish or

eggs are unlikely to become protein deficient. However, if the diet excludes animal foods and is based solely on vegetables and grains, care will be needed to ensure that all of the essential amino acids are included in sufficient quantities. Most plant foods are low in protein in comparison to animal foods and do not contain all the essential amino acids. A combination of plant foods will be necessary to ensure an adequate protein intake (DHSS, 1994).


### Fat

Fat is the primary energy provider during about the first six months of life and throughout infancy continues to be an important source of energy, fat-soluble vitamins A, D, E and K and essential fatty acids. About 50% of the energy in breast milk comes from fat. The high energy density of fat allows infants to consume adequate energy in a manageable quantity of food. Low-fat products are unsuitable for use in infancy and dietary guidelines for adult population groups should not be applied to young children. The importance of long chain polyunsaturated fatty acids for brain and nerve growth is discussed in detail in Appendix C.

### Carbohydrate


Carbohydrate in the diet complements the energy provided by fat and is used preferentially as a source of energy for the





brain. As the proportion of energy derived from fat decreases, that from carbohydrate increases. The primary carbohydrate in milk is lactose, which is metabolised to glucose. Lactose provides about 37% of the energy of breast milk. A continuous supply of glucose is of particular importance to the young infant after birth. During the third trimester of pregnancy, large amounts of glycogen are accumulated in the liver and skeletal muscle. Liver glycogen levels fall rapidly in the immediate post-natal period and the infant then becomes reliant on a dietary source of carbohydrate.

### Vitamins



No data exist on the vitamin status of infants in Ireland. During the time when cows' milk feeding of infants was deemed acceptable, the addition of multivitamin drops to the cows' milk was advocated. However, vitamin supplementation is not now routinely practised. In the UK, a vitamin supplement containing vitamins A, D and C is recommended for pregnant and lactating women and for infants. The provision of an adequate maternal intake serves to ensure that the infant will lay down good vitamin stores *in utero*. Requirements for mothers during pre-conception and pregnancy are outlined in Appendix A. The DHSS (1994) recommends that, until the age of six months, breastfed babies of well-nourished mothers do

not require vitamin supplementation. Infants being fed at least 500 mls/day of formula which is fortified with vitamins will also have adequate intakes. Whether or not additional vitamins are necessary for Irish infants is not known. The RDAs for vitamins for infants are included in Appendix D.

### Vitamin A

Vitamin A, which is essential for growth, is supplied primarily by breast or formula milk. It should be noted that unmodified cows' milks supplemented with vitamins A and D are low-fat milks and are *not* suitable for infants. Vitamin A can also be formed from carotenoids, such as beta-carotene, found in plant foods (e.g. carrots). Vitamin A deficiency has been reported in developing countries and is associated with growth deficits, increased morbidity and mortality and iron deficiency (Semba *et al*, 1992; Fawzui *et al*, 1994). Vitamin A toxicity may result from ingestion of large doses or use of supplements over a prolonged period.

### Vitamin D

Infants have a high requirement for vitamin D as a result of the rapid rate at which calcium is being laid down in bone. However, hypercalcaemia can result from excessive intakes. Vitamin D status can be enhanced by gentle exposure to sunlight, but extreme care must be taken, especially in infancy, to avoid

sunburn. In certain areas, exposure to sunlight may be very limited. For example, it is known that the risk of deficiency in Scotland is greater than in the south of England, which is probably due to the difference in sunlight exposure. In this case the infant will have to rely on dietary vitamin D. Foods containing vitamin D, such as oily fish, are usually found in limited quantities in the infant's diet.

### **Vitamin C**

Vitamin C is an antioxidant and, when taken at the same meal, enhances the absorption of non-heme iron from foods. The inclusion of foods containing vitamin C, such as fruits and vegetables, in the infant's diet should be encouraged.

### **Vitamin K**

The newborn infant is deficient in vitamin K and breast milk does not supply sufficient vitamin K to meet the infant's needs. This means that the infant is at risk of haemorrhagic disease of the new born, which results from vitamin K deficiency. Those known to be particularly at risk are pre-term babies, those with liver disease and those whose mothers have received certain medications, for example, anticonvulsants. It is recommended that all newborn babies receive prophylactic vitamin K after birth. There has been some controversy about the method of administration of vitamin K

(McKinney *et al*, 1998; Parker *et al*, 1998; Passmore *et al*, 1998a; Passmore *et al*, 1998b). All high-risk infants should continue to be given vitamin K intramuscularly. Parents may be given the option of an oral vitamin K preparation for infants who are at low risk, but three doses of the oral preparation are necessary. In view of the ongoing uncertainty, the Department of Health and Children and maternity units should continue to review their policies as new information emerges.

### **Minerals**

#### **Iron**

Iron deficiency is the most common nutrient deficiency worldwide and is prevalent in infants, particularly those who are socio-economically disadvantaged and members of ethnic minority groups. Infants grow rapidly and, therefore, have a high requirement for iron. Iron deficiency anaemia has been associated with impaired psycho-motor development and it is not yet clear if these adverse effects are fully reversible (Lozoff *et al*, 1991). A prospective longitudinal study has shown that 2.6% of one-year-olds and 9.2% of two-year-olds in Ireland had iron deficiency anaemia (Freeman *et al*, 1998). The disorder may remain undiagnosed because the symptoms of anaemia are non-specific, so dietary recommendations should aim to prevent its development.

### **Iron requirements**

If the mother is iron sufficient during pregnancy, post-natal stores should provide enough iron to meet the infant's needs during the first four to six months of life. Little dietary iron is usually required during these early months (Hemminki *et al*, 1995). However, infants of mothers who are anaemic during pregnancy have reduced levels of iron stores and are at increased risk of developing iron deficiency anaemia (Poulakka *et al*, 1980; Milman *et al*, 1987; Bhargava *et al*, 1991; Singla *et al*, 1996). Maternal smoking may also increase the risk of developing deficiency (Freeman, 1996). Women who smoke have lower intakes of iron than non-smoking women (Thompson *et al*, 1992) and smoking during pregnancy may impair the trans-placental supply of iron to the foetus.

The iron requirements of breastfed babies during the second half of infancy remain controversial. In a population of hospitalised Korean infants aged 6–24 months, who had been admitted with acute infections or inflammatory disease, anaemia was more prevalent in children who had been breastfed exclusively beyond the age of six months (Kim *et al*, 1996). The presence of infection or inflammation complicates the interpretation of markers of iron status such as haemoglobin or serum ferritin. In a small sample of infants from Naples, no infant who was exclusively

breastfed for longer than seven months was anaemic (Pisacane *et al*, 1995).

### **Dietary risk factors for iron deficiency anaemia**

The use of unmodified cows' milk and the lack of heme iron in the diet (Mira *et al*, 1996; Freeman *et al*, 1998 ) have been identified as the most important dietary factors which predispose to the development of iron deficiency anaemia in infancy. Exclusive breastfeeding (Pisacane *et al*, 1995) or feeding an iron fortified infant formula , with the gradual addition of appropriate iron-rich complementary foods, will ensure an adequate iron intake. Heme iron, which is well absorbed, is contained in meat, fish and chicken. The absorption of iron from cereals and vegetables (non-heme iron) is less predictable and is influenced by the overall composition of the meal. For example, the phytate in infant cereals inhibits non-heme iron absorption, while vitamin C enhances it (Cook *et al*, 1997). It has been suggested that the addition of complementary foods may interfere with the absorption of iron from breast milk (Oski & Landaw, 1980; Pisacane *et al*, 1995). For this reason, breast feeds should be given at a different time than solids.

### **Iron toxicity**

It should also be noted that iron is potentially toxic, so iron medication should be stored in a

safe place and used only under medical supervision (Gutteridge, 1989). Large doses of iron given to iron-replete children have been shown to inhibit growth (Idjradinata *et al*, 1994).

#### **Other minerals**

Deficiencies of zinc, copper and selenium (Kumpulainen *et al*, 1987; Lönnnerdal & Hernell, 1994; Darlow *et al*, 1995; Persson *et al*, 1998) have also been investigated in infant populations but have generally attracted less attention than iron deficiency. Zinc, for example, is thought to play an essential role in maintaining immunocompetence (Hanson, 1997) but no information on the zinc status of infants in Ireland is available. In the pre-term infant, disturbed bone mineralisation and growth are common and are thought to be

related to inadequate calcium and phosphorus intake. It has been shown that, in a sample of pre-term babies, bone mineral content at the age of five years increased with increasing volume of human milk (Bishop *et al*, 1996).

#### **Recommended Dietary Allowances**

Recommended Dietary Allowances (RDAs), which outline nutrient requirements for the Irish population, have recently been reviewed and updated. In general, the new recommendations are in accordance with the Population Reference Intakes of the European Union but, for infants, the UK Dietary Reference Values have been adopted. These cover a more comprehensive range of nutrients than the European recommendations and are shown in Appendix D.



**The Sub-committee recommends that:**

- Breast milk or milk-based infant formula (or follow-on formula from the age of six months) should be fed throughout the first year of life as the main milk drink in order to ensure an adequate vitamin and mineral intake; unmodified cows' milk should not be used as the main milk drink before the age of one year. Low-fat milk, whether or not it is fortified with vitamins and minerals, is generally unsuitable for infants.
- Foods which contain heme iron (meat, chicken or fish), and fruits and vegetables, which supply a range of minerals and vitamins, should be chosen to complement the nutrients supplied

by milk. Meat, as well as providing heme iron, is a good source of zinc and B-group vitamins. The needs of vegetarian infants are discussed in Chapter 10.

- Breastfed babies do not require iron supplementation if a good variety of complementary foods are consumed. Nutrients from breast milk are usually very well absorbed, but if, after the age of four months, complementary foods or drinks are given with breast milk nutrient absorption may be diminished. Ideally, some time should elapse between breastfeeding and feeding other foods.
- Adult dietary guidelines should not be applied to infants.

## CHAPTER 8: GROWTH MONITORING

The monitoring of growth is an important tool in the assessment of infant health and nutritional status. Growth adequacy is assessed by plotting anthropometric measurements on curves which represent normal somatic growth. During the past decade it has become increasingly apparent that reference curves used to monitor infant growth require updating because:

- growth patterns of breastfed infants differ from those of infants who are not breastfed
- current reference curves are based on data derived from measurements made primarily of formula-fed infants
- growth of breastfed babies is generally more rapid in the initial months, and subsequently less rapid, than that of formula-fed babies
- improved nutrition and decreased morbidity have resulted in enhanced growth potential
- it is important to detect growth faltering or the early development of obesity.


Currently no growth data are available for Irish infants, so the provision of appropriate growth reference curves presents a number of difficulties. Standards for the Irish population are based on measurements of subjects aged 5 to 19 years inclusive (Hoey *et al*, 1987). Data used to extend the Irish curves to cover infancy were taken from Tanner *et al* (1966a, 1966b), but these

UK data are now considered outdated. More modern UK curves were recently produced (Freeman *et al*, 1995). These are based on measurements taken between 1978 and 1990 from seven sources in the UK. Only white subjects were included. In comparison with the Tanner–Whitehouse charts, the 3rd, 50th and 97th percentiles for stature and weight are greater and a change in the shape of the curve is evident. Results from the Euro-Growth Study, in which a sample of Irish infants was included, confirm some significant differences between the growth of European infants and existing standards (van't Hof *et al*, 1999b, 1999c). Currently, it is not possible to recommend any one set of reference curves for use in Ireland during infancy.

### Practicalities of growth monitoring

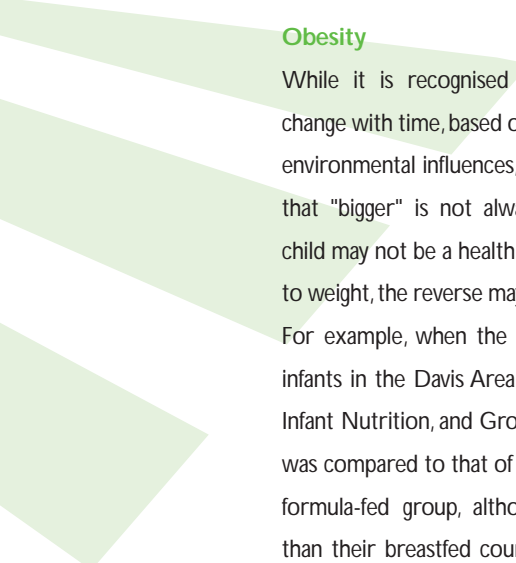
A standardised methodology is essential for the accurate measurement of growth. Ongoing education in measurement techniques should be made available to medical and nursing staff who are responsible for growth monitoring.

Equipment used must be reliable and measurements should be recorded on charts with which the anthropometrist is familiar. The most accurate results can be achieved by using a single chart on which weight, length and head circumference can be recorded throughout infancy and early childhood.



In Ireland only weight is measured routinely. Infants are weighed at birth and during the first two years of life. If length/height were measured, weight relative to length/height, which would give some information about body composition, could be calculated. The Euro-Growth Study confirms that, during infancy, body mass index (BMI) provides a more accurate indicator of growth (van't Hof *et al*, 1999b). Monitoring of BMI would provide an opportunity to pre-empt the development of obesity or failure to thrive and detect growth abnormalities. Measurement of head circumference, an indicator of brain growth, should also be included. Head circumference is altered by the birth process, so initial measurement of head circumference should be delayed a few days.

### Obesity



While it is recognised that growth patterns change with time, based on nutritional, social and environmental influences, it must be emphasised that "bigger" is not always "better". "A larger child may not be a healthier child and, in relation to weight, the reverse may be true" (Cole, 1993). For example, when the morbidity of breastfed infants in the Davis Area Research in Lactation, Infant Nutrition, and Growth (DARLING) study was compared to that of formula-fed infants, the formula-fed group, although they grew faster than their breastfed counterparts, had a higher incidence of diarrhoea and longer duration of respiratory illness (Dewey *et al*, 1991).

Milk is the major energy provider during the first year of life. In order to avoid the development of obesity the infant's diet should comprise a wide variety of nutrient-dense foods which will complement the nutrients provided by milk. Adequate energy intake should be guaranteed but foods such as high-fat, high-sugar fromage frais, chocolate, sweets, ice-creams and crisps are best avoided or used only very occasionally in later infancy as the range of foods expands.

If infants become obese, careful management is required to minimise the impact of the problem. Both nutritional and psychological factors need to be considered. Drastic interventions are inappropriate and the advice of a paediatric nutritionist is essential so that advice can be tailored to individual needs.

### Failure to thrive

Failure to thrive is a phrase used to describe the faltering of growth of an infant in comparison with an appropriate growth reference, having taken into account gestational age at birth and the genetic factors which exert a major influence on growth. Growth faltering may be an early sign that a problem exists, so growth monitoring is a useful tool in the early detection of disease or under-nutrition (Shaw & Lawson, 1994).

Failure to thrive should be suspected in all infants who:

- as newborns are below the 10th percentile, according to gestational age
- fall below the 3rd percentile at any age
- show a downward deviation in weight across two or more major percentiles.

Because length is not affected as quickly as weight, a weight which persistently falls below the length percentile may also be considered failure to thrive. In suspected cases, weight, length and head circumference measurements should be monitored longitudinally.

The causes of failure to thrive are multifactorial; they may relate to underlying genetic, gastrointestinal, metabolic, neurological or cardiac disease, functional feeding difficulties or behavioural or social conditions which result in a diminished nutrient intake. Excessive consumption of apple juice or high-fibre foods have also been reported as causes (Smith & Lifshitz, 1994; Morgan *et al*, 1995). A very small number of breastfed babies do not show signs of hunger but fail to thrive and hypernatraemia has been reported (Cooper *et al*, 1995). Assistance with establishing good breastfeeding practices and accurate weight monitoring are the key preventive measures.

Management of the infant who presents with failure to thrive is best undertaken by a multi-disciplinary team. This approach facilitates comprehensive assessment of the underlying

factors, treatment of the cause and restoration of a dietary intake which is nutritionally adequate. Nutritional management may involve the provision of additional energy, protein or micronutrients to promote "catch-up" growth together with the initiation of a regular feeding regime. Supplementation may be necessary. Interventions should always be supervised and their effectiveness monitored by the appropriate health professional.

**The Sub-committee recommends that:**

- Growth reference curves based on data collected from Irish infants should be developed for use in Ireland.
- Equipment used to measure growth should be accurate and scientifically approved.
- Weight at birth, length and head circumference on day two or three post-natally, and weight, length and head circumference throughout infancy should be measured routinely by appropriately trained health professionals and recorded on a recognised growth chart; for a given infant, as few charts as possible should be used. Particular care should be taken when the growth of a breastfed infant is compared to current reference curves.
- If an infant fails to thrive or obesity or feeding difficulties develop, appropriate professional advice should be sought; food should not be used either as a reward or a punishment.



## CHAPTER 9: PRE-TERM AND LOW BIRTH-WEIGHT BABIES

Nutritional management of pre-term or low birth-weight infants will vary depending on the age, size and health of the infant, each infant requiring individual assessment. The objective of nutritional management is to minimise the risk of morbidity and mortality and to support appropriate growth (Gorman *et al*, 1996), which is more rapid in the premature or low birth-weight baby than in those born at term. A team approach based on a clear nutrition policy is particularly necessary for these infants.

Regimens used in neonatal units in Ireland vary from one unit to another. Not all have the services of a neonatologist and few have access to the expertise of a nutritionist. The majority, but not all, encourage breastfeeding or feeding of mother's pre-term breast milk. It appears that breast milk fortifiers are used in some units but not in others.

### **Breast milk and the pre-term baby**

During the last ten years much research has focused on the nutritional needs of the pre-term infant and has resulted in notable changes in our understanding of what constitutes optimal nutrition. Studies in the late 1980s concluded that, at the age of nine months, pre-term infants fed donor breast milk did not grow as well as those who were formula fed (Lucas *et al*, 1989). These conclusions gave rise to a number of publications in which low

birth-weight infant formula was considered to be preferable to pooled donor breast milk. However, a follow-up of the 502 infants included in the original Lucas trial showed that, at the age of 18 months, no differences in outcome were detected between the two diet groups (mature donor breast milk or pre-term formula), in spite of the low nutrient content of donor milk in relation to the estimated needs of pre-term infants (Lucas *et al*, 1994). Results from the same group showed that pre-term babies who were fed mother's milk had significantly higher intelligence quotient, at age seven-and-a-half to eight years, than those who received no maternal milk (Lucas *et al*, 1992a).

It is important to understand that milk produced by the mother of an infant who is born prematurely differs from that of a mother whose infant is born at term and that donor breast milk differs significantly from mother's own milk. It is now well accepted that feeding mother's own pre-term breast milk offers significant nutritional and emotional advantages to the pre-term infant. Expression of breast milk is sometimes necessary. To effectively express breast milk, at least five expressions, lasting in total a minimum of 100 minutes daily is optimal (Hopkinson *et al*, 1988).

Breast milk provides the essential long chain polyunsaturated fatty acids, arachidonic and

docosahexanoic acid, which play an important role in influencing cell membrane structure and brain development in the pre-term infant (Farquharson *et al*, 1992, 1993, 1995). Better bone mineralisation at age five years has been reported in pre-term breastfed infants than in those fed pre-term formula (Bishop *et al*, 1996). The selenium status of premature and low birth-weight infants is known to be lower than that of term infants. The antioxidant activity of selenium is particularly important to the premature infant, who is exposed to a range of oxidative stresses (Darlow *et al*, 1995). Breast milk selenium concentration varies depending on the selenium status of the mother, but the selenium appears to be very well absorbed and breastfeeding results in higher selenium status than formula feeding (Kumpulainen *et al*, 1987). Selenium supplementation of formula milks is not yet routine. The new regulations (S.I. No. 243 of 1998) have set maximum levels for selenium in infant formulae but no minimum is specified. Pre-term infants, due to their diminished body size, are known to have lower levels of storage iron at birth than term infants. For these infants, iron medication may be medically prescribed. When complementary foods are introduced, care should be taken to include iron-rich foods to avoid the development of iron deficiency. Mothers who are cytomegalovirus (CMV) seropositive should be screened for the presence of the virus if their


infants are of very low birth-weight (Vochem *et al*, 1998). This issue is discussed in greater detail in section 8 of Chapter 10.

#### **Low birth-weight formulae**

Since the 1970s, formulae designed specifically to meet the calculated increased requirements of the low birth-weight baby have been available. In the absence of mother's breast milk, low birth-weight formula should be used. These formulae contain greater amounts of energy, fat, protein, sodium, calcium, phosphorus, copper, zinc, etc. than standard formula, and are based on recommendations from the European Society for Paediatric Gastroenterology and Nutrition (ESPGAN). Low birth-weight formulae continue to evolve in line with latest scientific knowledge, including more recently published consensus recommendations of international experts on low birth-weight and very low birth-weight feeding. For example, the long chain polyunsaturated fatty acids discussed above, which were not traditionally added to low birth-weight formula, are now included. Infants who are discharged from hospital on a low birth-weight formula should be medically supervised.

#### **Post discharge special formulae**

Post discharge formulae are formulae which are modified to meet the needs of the premature infant following their discharge



from hospital. It has been shown that infants fed on these formulae have better weight and length gain and better bone mineral density than infants fed standard infant formula (Lucas *et al*, 1992b; Bishop *et al*, 1993).

### **Breast-milk fortification**

Commercial breast-milk fortifiers have been developed to provide additional energy and nutrients for the low birth-weight infant who is breastfed. However, their use remains controversial and it is not yet clear if the addition of fortifiers to breast milk is necessary or for whom. The results from one well-controlled study found "areas of benefit, areas of possible concern, unexplained outcomes and important unresolved questions" (Lucas *et al*, 1996). Further work is required before definitive recommendations can be made with regard to breast-milk fortification. It is likely that more selective use of fortifiers based on assessment of individual infants may provide the best option. A clearer understanding of the risks and benefits and the consequences of fortification for the biological functioning of breast milk may result in fortification techniques which will "*minimise risk and optimise benefit*". At present, their use cannot be recommended unconditionally.

Hind breast milk has a greater energy and fat content than fore milk and increasing the proportion of hind milk fed to low birth-

weight infants has been shown to be beneficial in promoting weight gain in low birth-weight infants. However, the impact of the accompanying decrease in the proportions of protein, copper and zinc being fed requires further study (Valentine *et al*, 1994).

### **Necrotising enterocolitis**

Necrotising enterocolitis is more common in low birth-weight babies and is related to the introduction of enteral feeding as well as other factors. It has been shown that, in exclusively formula-fed pre-term babies, confirmed necrotising enterocolitis was six to ten times more common than in those fed breast milk, and three times more common than in those fed formula plus breast milk. In infants born at more than thirty weeks gestation the disease was twenty times more common in those fed only formula. Banked breast milk was as effective in preventing necrotising enterocolitis as was maternal milk. The authors suggest that the fall in the use of breast milk in British neonatal units and a reliance on exclusive formula feeding could result in an estimated 500 extra cases of necrotising enterocolitis each year. The disease carries a high risk of mortality (Lucas & Cole, 1990).

### **Community support**

On discharge from hospital it is imperative that community services are mobilised to offer support to mothers of all infants but in

particular to those with special needs due to prematurity. The ability of the family to continue to provide adequate nourishment at home will be crucial to the satisfactory growth and development of the infant.

**The Sub-committee recommends that:**

- Each special care baby unit should have a nutrition policy for the care of low birth-weight infants and should be cognisant of the importance of providing these infants with optimal nutrition; units should have access to the expertise of a neonatologist and a nutritionist.
- Parents of premature or low birth-weight infants should be educated in the special contribution that breast milk can make to the improved nutrition of their infants. Until the infant can feed from the breast, mothers should be supported to express breast milk which can be stored and given to their infants, even if the infant is being ventilated.
- For the infant who is not breastfed low birth-weight formula, rather than standard formula, should be used initially.

## CHAPTER 10: SPECIAL GROUPS

The recommendations outlined in this report are intended to address the needs of the normal healthy infant from birth. It is recognised that a number of infants have nutritional needs which differ considerably from these basic guidelines. In these cases specialist nutritional management under the direction of health care professionals will be required. The following sections are included to support the need for such specialist care and to highlight areas in which changes in policy might contribute to improved nutritional management.

### Neurodevelopmental disorders (e.g. cerebral palsy)

Infants with neurodevelopmental difficulties are at risk of receiving inadequate nutrition due to their compromised ability to swallow and chew (Reilly *et al*, 1996). This can result in failure to thrive and a reduced immune response and leads to nutritional deficiencies and an increased risk of recurrent respiratory infection.

Feeding, which should be a pleasurable experience, may take the parent or carer of an infant with a neurodevelopmental disorder four to six hours daily. Excessive loss of food, drooling, spitting, coughing, choking and vomiting make mealtimes a stressful time for both the infant and his parents.

Successful management necessitates the involvement of a team of professionals to assess

the problem and advise on the best treatment strategy. The team may include parents, carers, paediatrician, radiologist, speech and language therapist, nutritionist, occupational therapist, psychologist and surgeon. Referral to a specialist paediatric centre, where appropriate expertise is available, may be necessary.

### Cleft lip / cleft palate

A cleft lip results from the failure of the upper lip to fuse in the fifth week of embryonic development. Cleft palate results from the failure of the palatal shelves to meet and fuse in the mid-line during the seventh to eighth week of intra-uterine development (Styer & Freeh, 1981). Cleft lip and cleft palate may occur individually or together. The incidence of these disorders in Ireland is about 1 in 800 live births.

A number of management problems are associated with the presence of a cleft. These include feeding difficulties, dental and orthodontic problems, speech impairments, otitis media and psychological and emotional issues (Shah & Wong, 1980). Reported feeding problems include poor oral suction, lengthy feeding times, nasal regurgitation, choking and gagging, excessive air intake and poor food intake, which may result in malnutrition. However, a significant number of infants do not have major feeding problems.

### **Management**

The management of the cleft lip and palate requires a multi-disciplinary team approach including paediatrician, surgeon, speech and language therapist, nutritionist, orthodontist, dentist, public health nurse and psychologist. The Cleft Lip and Palate Association provides support for parents and patients. The address is given in Appendix I.

### **Nutritional support**

Breast milk is the food of choice for infants with cleft lip/palate. It has been shown to offer protection against otitis media, which is more common in infants in this group (Paradise *et al*, 1994). Breastfeeding may be possible and, if successful, should be encouraged. If breastfeeding is unsuccessful, expressed breast milk may be fed from a bottle or a cup.

A regular infant formula should be used if breast milk is not available. Many babies feed well from a bottle using a normal soft teat with an extra hole or an enlarged hole. Occasionally, special teats are recommended if the baby is having difficulty feeding. Special squeezable bottles are designed to allow the mother to control the flow of milk into the baby's mouth.

### **Down's syndrome**

Some children with Down's syndrome experience difficulties with feeding (Frazier &


Friedman, 1996; Spender *et al*, 1996). For some, problems may be relatively minor. For example, an infant might be slow to suck or might experience some difficulty in moving onto a varied mixed diet. Others experience more severe feeding difficulties which can compromise growth and development and these infants may present with failure to thrive. The development of obesity, constipation and diarrhoea are common.

Feeding problems are a consequence of the multiple cranial skeletal defects, which can result in a short and narrow palate or a small oral cavity. Generalised facial/oral hypotonia may contribute to poor lip seal, poor suck and poor tongue control. Some infants may have congenital heart abnormalities, which can exacerbate the feeding difficulties.

Involvement of a multi-disciplinary team is the key to good management. This will help to minimise the stress for parents, ensure adequate growth and prevent the development of more serious feeding difficulties or malnutrition.

### **Coeliac disease**

Coeliac disease is a disorder in which the lining of the small intestine is damaged by exposure to gluten. The damage results in a flattening of the mucosal villi resulting in malabsorption of nutrients. Blood loss from the intestine may exacerbate the condition and iron deficiency is



common. The most recent figures suggest that presentation in infancy is on the decline, but traditionally Ireland has had a high incidence of coeliac disease (Gumaa *et al*, 1997). Current recommendations to prevent the early onset of coeliac disease are discussed in Chapter 5.

In infants, the condition may become apparent some time after the introduction of gluten-containing complementary foods but presentation is very variable. Classically, the infant who has been thriving on a milk-based diet may begin to refuse feeds or stop gaining weight and develop a "pot-bellied" appearance. Positive diagnosis will involve examination of a biopsy from the small intestine.

Treatment, which results in a complete resolution of the condition, involves the removal of all gluten-containing foods from the diet. Care of the infant will require input from a paediatrician and nutritionist. A regularly updated list of gluten-free manufactured foods is available from the Coeliac Society of Ireland (Appendix I). New legislation (S.I. No. 241 of 1998; Appendix G) requires that foods marketed for infants under the age of six months should state clearly whether or not they contain gluten.

### **Cystic fibrosis**

Nutritional management is central to the treatment of the infant with cystic fibrosis. Nutritional requirements will vary depending

on the extent and severity of the disease and on the condition of the individual patient. The efforts of a multi-disciplinary team, including a clinical nutritionist, ideally in a dedicated cystic fibrosis centre, are necessary to ensure optimal nutritional status and offer appropriate education and support (Dodge, 1992; Mahadeva *et al*, 1998).

Chronic malnutrition, which results in inadequate weight gain, growth retardation, increased susceptibility to infection and diminished muscle strength, is a major complication of the disease and improved nutritional status results in improved prognosis for the infant.

The focus of management is to achieve normal growth and development and to maintain optimal nutritional status. To achieve these objectives a vigorous approach is often needed, as the patient's energy requirements are increased while appetite is decreased. Recurrent infections and fevers contribute to the increased energy requirements and energy may be lost through vomiting.

### **Vegetarian/vegan infants**

All infants whose diets are restricted, but in particular those which omit foods from a major food group, are at risk of developing nutritional deficiencies. Vegetarian or vegan infants, who consume no meat, chicken or fish,

are particularly vulnerable to the development of iron deficiency. In addition, vegan infants, who do not consume any product of animal origin, require a supplementary source of calcium, vitamin B12 and vitamin D and are at risk of having an inadequate energy intake. Due to the tendency for vegan diets to be high in fibre, absorption of nutrients such as zinc and iron may be compromised.

In the preparation of a nutritionally adequate vegetarian or vegan diet for infants, medical supervision is essential. Breastfeeding should be encouraged. If infants are not breastfed, an acceptable cows' milk or soya-based infant formula should be fed until at least the age of 12 months. Complementary foods which supply a range of nutrients will be required.

#### **Cows' milk protein allergy/ intolerance**

Cows' milk protein allergy/intolerance may present with a variety of non-specific symptoms such as food refusal, vomiting, diarrhoea, rectal bleeding or failure to thrive and may involve the gut, skin and respiratory tract. The diagnosis is made by confirming that the cows' milk protein induces the specific immunological reaction. Once the condition is diagnosed, milk and all foods containing milk, need to be excluded from the infant's diet. During infancy milk is the primary energy and nutrient provider and, in addition, the majority of commercial infant foods

contain milk protein. When milk is excluded very careful restructuring of the diet is necessary. Frequently, infants who are allergic to cows' milk protein are also allergic to other foods. The condition should always be medically diagnosed and dietary interventions planned and supervised by a nutritionist.


#### **Maternal infectious diseases and infant feeding**

In certain circumstances, infections to which a mother has been exposed during the pregnancy or has experienced post-natally may influence the choice of feeding method for her infant.

#### **The human immunodeficiency virus (HIV)**

The human immunodeficiency virus (HIV) may be passed from mother to infant during pregnancy or delivery or post-natally via colostrum or breast milk (Van de Perre *et al*, 1991; Committee on Pediatric AIDS, 1995). Exact modes of transmission are not yet clearly understood, nor is it known why the majority of infants born to seropositive mothers are uninfected (Pizzo & Butler, 1991). The risk of transmission to the infant varies with the stage of HIV infection of the mother. It increases during the viraemia of primary HIV infection and with the progression to acquired immunodeficiency syndrome (AIDS).





In Ireland, HIV-positive mothers are advised against breastfeeding their infants. Even if the infant is already infected at birth, breastfeeding should be avoided.

Where the HIV status of the mother is unknown but it is recognised that she is at particular risk of being seropositive (injecting drug users and sexual partners of known HIV-positive persons or active drug users), parents should be counselled not to breastfeed their babies.

### **Cytomegalovirus**

Breastfeeding is not usually contraindicated in the infant whose mother is infected with CMV (Oxtoby, 1988). Maternal antibodies against CMV, which afford protection to the infant, are transmitted trans-placentally to the foetus after about 28 weeks of intra-uterine life. However, in premature, very low birth-weight infants (<1500g) of CMV seropositive mothers, CMV infection can be transmitted to infants via breast milk (Vochem *et al*, 1998). Milk from mothers of these infants should be screened for CMV.

### **Hepatitis B**

It appears that transmission of hepatitis B via breast milk is only theoretical and breastfeeding in hepatitis B infected mothers is not contraindicated.

### **Hepatitis C**

Hepatitis C virus (HCV) RNA and antibody have been detected in breast milk (Croxson *et al*, 1997). To date, published information pertaining to the risk of transmission of infection through breastfeeding is limited. If transmission through this route occurs, it is likely that it is a rare event. Nevertheless, women should be advised that, while the evidence is not strong enough to discourage breastfeeding, transmission of HCV via breast milk is theoretically possible. HCV is thus not an absolute contraindication to breastfeeding.

### **Social or economic disadvantage**

For some families, the ability to provide good nutrition for their infant may be compromised due to social or economic factors. A young single mother may be well supported and provided for by the father of her child or by her family of origin but this will not be true for all. Difficulties may be created by a parent's inability to read or by a particular lifestyle. Members of the travelling community may experience difficulties with food storage and preparation. This report aims to highlight the needs of all members of Irish society, including sub-groups who require special social or economic support.

### **Equity of access**

All families should have access to appropriate water, hygiene, sanitation and laundry facilities.

Food storage and cooking should be possible in all households to enable parents to provide adequate meals for their infants.

To maintain a good standard of basic nutrition, it is essential that information on infant feeding and nutritional requirements, budgeting, shopping and cooking skills be made available to parents in an appropriate and comprehensible manner.

Changing social and demographic patterns have resulted in a lack of role modelling and often young parents are not motivated to use traditional food preparation methods. The use of convenience foods may be appropriate in certain situations but as a rule these products are expensive and are not suitable as staple foods.

To ensure equity of access to printed information, the problem of low literacy may need to be addressed. A recent international investigation revealed that 25% of adults in Ireland have limited literacy skills (Morgan *et al*, 1997). Where possible, information on infant feeding should be produced and made available in a form which does not necessitate reading, as it is known that low literacy levels have a direct bearing on nutritional status.


#### **Advice and support for all parents**

Video presentations in health centres could cover a range of topics and serve as an

education resource within the community. Cookery demonstrations in community centres would help to increase interest in food preparation and presentation. Community mothers and volunteers interested in promoting good nutrition should be supported financially and encouraged in their efforts to increase awareness within local communities about the importance of good infant nutrition. Other voluntary groups within communities may also be in a position to organise education sessions on infant feeding under the guidance of health professionals. The Health Promotion Unit of the Department of Health and Children, which is already designated a breastfeeding resource centre, should support these community initiatives by making available appropriate information and expertise on all areas of infant feeding.

#### **Sudden Infant Death Syndrome (SIDS)**

Factors now known to be implicated in the sudden unexplained death of infants are not primarily nutritional. However, it is clear that there is a need to continue to educate parents to try to prevent SIDS. About 80% of cases occur between the ages of one and six months, with a peak between two and three months (Chantler, 1996). General preventive measures are discussed in more detail in the section on pre-conception and pregnancy (Appendix A).



Earlier studies examined the effect of different feeding regimens on SIDS and, although breastfeeding was seen as potentially protective, other factors are now known to be more important (Health Promotion Unit, 1994). However, a recent study has again concluded that bottle feeding is a risk factor (l'Hoir *et al*, 1998). Breastfeeding should be actively encouraged because, as well as making a positive contribution to the health of the infant, it confers protection against gastrointestinal and respiratory infections, which increase the risk of SIDS.

**The Sub-committee recommends that:**

- Appropriate health care, including nutritional care, should be available to all infants and clear and full information should be given to parents, in particular those whose infants have special needs.

- HIV positive mothers and mothers in groups at risk of being infected with HIV should not breastfeed, even if the infant is known to be already infected; such mothers should be counselled to encourage best practice in relation to formula and food selection and preparation, with the objective of minimising the risk of exposure to infection and maximising the nutritional status of the infant.
- Breastfeeding is not usually contraindicated if a mother is exposed to infections other than HIV.
- Information and assistance should be provided to disadvantaged families in ways appropriate to their situation.

## CHAPTER 11: NUTRITIONAL MANAGEMENT OF CONDITIONS WHICH COMMONLY ARISE DURING INFANCY

### Colic

Colic, or unexplained excessive crying, is commonly reported in infancy. Usually it is most problematic during the first six weeks of life and will resolve spontaneously (Hill *et al*, 1995). It is of uncertain cause and no one satisfactory solution is known. Causes which have been considered include the lack of expertise of parents in responding appropriately to their infants, parental stress, infant temperament and cows' milk allergy. It has also been shown that, at birth, motilin levels were raised in the cord blood of infants who went on to develop colic (Lothe *et al*, 1990). One study has shown an improvement in symptoms after a range of allergens were excluded from the diets of the mothers of breastfeeding infants or from the diets of those who were bottle fed (Hill *et al*, 1995). Parent counselling has also been shown to be effective in reducing symptoms (Wolke *et al*, 1994). Transient lactose intolerance may be a contributory factor (Kearney *et al*, 1998). Cows' milk allergy has not been proven to be a common cause.

Anecdotal evidence suggests that mothers frequently change the type of formula milk used in an effort to lessen symptoms of colic and that this usually proves ineffective. Some periods of fussiness are to be expected with all young infants but in all cases of severe distress medical advice should be sought. On no


account should specialised formulae be given unless medically prescribed. Any dietary manipulations should be carried out under medical supervision or with the assistance of a nutritionist.

### Constipation

Constipation is defined as the passing of hard, rather than infrequent, stools. It is unusual in breastfed babies but is sometimes associated with formula feeding (Morley *et al*, 1997). It may result initially from over-concentration of feeds or, as a more varied diet is introduced, from inadequate intakes of fluid or fibre. A mixed infant diet should include fruits and vegetables, together with milk, meats and cereals. Coarser wheat- or oat-based cereals may be used from about the age of eight months. Caution is necessary to avoid "muesli-belt malnutrition" which can result from infant diets which contain too much fibre and inadequate energy (Morgan *et al*, 1995). An adequate fluid intake should always be assured. If symptoms persist, medical advice should be sought.

### Gastroenteritis

Gastroenteritis is an acute inflammatory condition of the intestine which results in diarrhoea and/or vomiting; the infection is usually caused by viruses and, as such, requires no medication. If diarrhoea is not accompanied by irritability, pyrexia or vomiting and the



infant is in the older age group (> 9 months), treatment can be initiated by parents. If symptoms persist, medical advice should be sought. In the neonate, or if the diarrhoea is accompanied by any of the symptoms listed above, medical help should be enlisted at an earlier stage.

Fluids are lost from the body as a result of both vomiting and diarrhoea. The cornerstone of treatment is to maintain an adequate fluid intake in order to prevent dehydration. A further concern is the loss of electrolytes (salts) during more severe episodes of diarrhoea. It is now well established that starving the patient is not necessary and that early feeding helps to decrease the intestinal permeability induced by infection and results in a more rapid recovery of the gut mucosa (Duggan & Nurko, 1997; Walker-Smith *et al*, 1997).

#### **Infant feeding and gastroenteritis**

In the very young infant, vomiting and diarrhoea can be serious clinical conditions requiring prompt medical intervention. When possible, the infant's normal feeding regimen should be continued. Continued feeding is usually possible if diarrhoea is the primary symptom. For the breastfed infant, the frequency of breastfeeding should be increased. For infants who are formula fed, there is no evidence to suggest that lactose-

free products are of benefit in the vast majority of cases. Feeding of the infant's usual formula, at full strength, should continue.

If the infant is vomiting, the use of oral rehydration solution (ORS), commercially prepared, hypo-osmolar, glucose-based, sodium solution, may be necessary for a short period (three to four hours). Unflavoured solutions should be chosen for infants. The use of decarbonated soft drinks, as an alternative to ORS, is controversial. Caffeine-free, soft drinks which have been boiled to sterilise them and remove the carbonated gases diluted 50/50 with cooled boiled water are sometimes used, as the high salt content of ORS appears to induce further vomiting in some children. However, these drinks can be hyperosmolar, require dilution and should not be used for prolonged periods (Bucens & Catto-Smith, 1991). They may also have an inappropriate electrolyte content.

The key to successful management is to ignore the stool consistency and to concentrate on oral intake. ORS should be used for acute rehydration and not for the maintenance of hydration. If feeding is stopped, normal feeding of full-strength milk feeds should be resumed as quickly as possible. If vomiting or diarrhoea are prolonged, medical advice should always be sought in case additional hydration or electrolyte replacement is required.

### **Gastro-oesophageal reflux**

Gastro-oesophageal reflux can be defined as the retrograde flow of gastric contents into the oesophagus. A child with uncomplicated reflux typically vomits effortlessly. Children with reflux frequently continue to thrive and parents can be reassured that the infant is well nourished and that no intervention is necessary. This condition generally improves with age.

If gastro-oesophageal reflux is complicated by oesophagitis the infant typically will be irritable at the time of feeding and will sometimes

refuse feeds. If complicated gastro-oesophageal reflux is suspected, the infant will require medical and nutritional intervention to confirm the diagnosis, initiate a treatment programme and monitor the nutritional status of the infant.

### **The Sub-committee recommends that:**

- Conditions which commonly arise during infancy do not usually necessitate changing the infant's feed.
- Medical advice should always be sought if symptoms persist.

## CHAPTER 12: EARLY NUTRITION AND LATER DISEASE

### Early "programming" of chronic disease

During the last decade interest in the field of early nutrition has been stimulated by the possibility that the influences of foetal nutrition and nutrition in the neonatal period may impact on health during childhood and adult life. The "programming" hypothesis put forward by Barker and his colleagues has prompted numerous studies seeking to confirm or refute links between intra-uterine growth, growth during the first year and the development of coronary heart disease (CHD) or CHD risk factors in later life (Barker *et al*, 1990; Fall *et al*, 1992; Fall *et al*, 1995; Godfrey *et al*, 1996). The hypothesis is based on the fact that undernutrition of the foetus results in adaptive mechanisms, including metabolic, circulatory and endocrine changes, which are designed to maximise the benefit to the foetus of the limited nutrients available. For example, brain growth may be protected at the expense of the growth and development of other organs. Relationships between early nutrition and hypertension, hyperlipidaemia, obesity and glucose intolerance have been explored. A recent review summarised the issues involved, clarified what is currently known and outlined how future research needs to develop in order to further our understanding of these complex relationships and enable the knowledge to be used in the prevention of disease (Barker, 1998).

### Hypertension

Correlations between low birth-weight and childhood and adult hypertension have been extensively documented. In adults there are no exceptions to this association while in adolescents the relationship is less consistent. The association relates to babies who were small for dates as a result of reduced foetal growth, not to babies born pre-term, and is independent of socio-economic environment, body mass index and alcohol consumption. The highest blood pressure is found in those who were small for dates at birth but became obese as adults. For example, intra-uterine growth retardation resulting from the siege of Leningrad resulted in increased endothelial damage and a stronger relationship between obesity and adult hypertension (Stanner *et al*, 1997).

### Type II diabetes mellitus

Type II diabetes mellitus has a U-shaped association with birth-weight; infants of both high and low birth-weight are at greater risk. In high birth-weight babies, the development of the disease is associated with maternal diabetes during pregnancy. Birth-weight is a rather crude measure of foetal growth and ponderal index ( $\text{weight}/\text{length}^3$ ), which includes the length of the infant, gives a more accurate indication of risk. A combination of metabolic disturbances is involved in the development of Type II diabetes. These include

insulin resistance and insulin deficiency. Insulin resistance is related to low ponderal index at birth together with the later development of obesity. This effect is seen in those who were *in utero* during the Dutch famine. Men and women exposed to famine *in utero* had higher two-hour plasma glucose concentrations than those born before, or conceived after, the famine. Fasting pro-insulin and two-hour plasma insulin concentrations were also higher in the "famine" group (Barker, 1998).

### **Cholesterol**

Infants born with a short body, a low birth-weight and a disproportionately large head have disturbances of cholesterol metabolism. In order to protect the brain, the foetus may redirect blood away from the liver, resulting in permanent disruption of cholesterol regulation and blood clotting.


Raised low-density lipoproteins and plasma fibrinogen are also known to be associated with specific measurements at birth. Dietary factors in the neonatal period may also impact on cholesterol status. It is known that, as a result of the higher concentrations of cholesterol in breast milk, serum cholesterol levels are higher during infancy in infants fed human breast milk than in those fed formula (Kallio *et al*, 1992; Wong *et al*, 1993). The long-term significance of these differences are not known. Total serum cholesterol levels show a tracking pattern from infancy through to later

life (Vobecky *et al*, 1993). However, variations in serum lipid profiles in relation to different infant feeding regimens have been reported in a cohort of Swedish adolescents (Bergström *et al*, 1995) but in eight-year-old American children no relationship between serum cholesterol and infant-feeding method was apparent (Fomon *et al*, 1984).

### **Summary**

In spite of a wealth of research, the exact nature of the relationship between maternal nutrition and foetal growth and development is still incompletely understood. The complex interactions which exist between genetic, nutritional and environmental factors and the potential for confounding by such important and potentially influential variables as socio-economic status, leaves some doubt as to the exact nature of the reported associations between early growth and development and the onset of chronic diseases in later life. Barker (1998) suggests that *"we need to progress beyond epidemiological associations to greater understanding of the cellular and molecular processes that underlie them. We need to know what factors limit the delivery of nutrients and oxygen to the human fetus; how the fetus adapts to a limited supply; how these adaptations programme the body; and by what molecular mechanisms nutrients and hormones alter gene expression."* Additional prospective clinical, animal and epidemiological studies will be





required to further investigate the role of nutrition in general and to examine the possibility that specific nutrient deficiencies experienced during vulnerable periods of intra-uterine or early infant growth may "programme" for major diseases of adulthood.

#### Early feeding practices and children's health

Results from a recently reported longitudinal prospective study provide information on the relationship between nutrition in infancy and body mass index and blood pressure at a mean age of 7.3 years (Wilson *et al*, 1998). Earlier findings from this cohort of 617 term infants in Dundee, Scotland, initially followed to the age of two years, showed that breastfeeding during the first 13 weeks of life conferred protection against gastrointestinal illness (episodes of > 48 hours) and, to a somewhat lesser degree, respiratory illness. Infants who were breastfed had a 7% to 17% reduction in gastrointestinal illness compared with those who were formula fed after controlling for social class, maternal age and parental smoking. The effect persisted whether or not supplements were introduced but infants who were breastfed for < 13 weeks had disease occurrence similar to formula feeders (Howie *et al*, 1990).

The latest findings are the results of a study on the same cohort of infants, 81% of whom were available for follow-up at a mean age of 7.3

years. At this age the protective effect of breastfeeding on respiratory illness persisted, exclusive breastfeeding to at least age 15 weeks providing the best protection. Having controlled for influencing variables, the risk of these children ever having respiratory illness was 17%, in contrast to 32% for those who were formula fed. Similarly, exclusive breastfeeding for 15 weeks significantly reduced the risk of cough from 24% in children who were exclusively formula fed to 11% in breastfeeders. The introduction of solid foods before the age of 15 weeks was associated with an increased risk of wheezing during childhood.

Blood pressure, body mass index and percentage body fat were examined in sub-groups of the population. Blood pressure was influenced by body mass index, gender (higher in boys) and maternal blood pressure, but not by birth-weight. After controlling for these variables, systolic blood pressure was significantly raised in children who were exclusively formula fed compared with those who received breast milk. The effect was found to be continuous; the longer the duration of breastfeeding the lower the systolic blood pressure. The introduction of solids before the age of 15 weeks resulted in an increase in body weight and in percentage body fat, an effect which was also found to be continuous (Wilson *et al*, 1998).

Another very recent study investigated the effect of exclusive breastfeeding on the development of obesity in 9,357 five- and six-year-old German children (von Kries *et al*, 1999). Exclusive breastfeeding was found to reduce significantly the risk of both overweight (BMI > 90th centile) and obesity (BMI > 97th centile) in a dose-dependent manner.

#### **Conclusion**

These findings confirm that infant nutrition does have the potential to influence CHD risk

factors in childhood and lend weight to the argument that strategies for the prevention of cardio-vascular and related diseases should begin by focusing on intra-uterine and early-infant nutrition. Women should be supported and encouraged to prepare for pregnancy and to eat well while they are pregnant. Breastfeeding for at least 15 weeks is beneficial in reducing the risk of hypertension and the introduction of complementary foods should be delayed until this age to avoid the possibility of developing obesity and increased body fat.

## CHAPTER 13: POLICY ISSUES INFLUENCING INFANT FEEDING

In the course of researching this document it became apparent that infant feeding is influenced by a range of factors which, although crucial, are not specifically nutritional in nature. These include access to information, education, codes of practice and legislation under which the marketing of infant foods is controlled and the implementation of such legislation, hospital and community health-care policies and economic considerations. On the understanding that such issues can be powerful barriers to the successful implementation of the recommendations laid down in this document, a brief examination of each issue was undertaken.

### Access to information

Parents are ultimately responsible for the nutritional welfare of their infants. Health-care professionals play an important and influential role by providing parents with the information which is necessary to enable them to make informed choices about food and feeding. However, many health-care professionals themselves have difficulty accessing good scientific information. The appropriate library and information services may not always be available or accessible and access for both professionals and parents to more modern, sophisticated information systems is still limited (MacDougall, 1995, 1998). As a result, there has been no consistent independent source of information on infant feeding and this lack of

consistency has frequently been highlighted as a reason why efforts to initiate change have been unsuccessful. Information on a range of health topics, including infant nutrition, is readily accessible by the public through the Internet. Care needs to be taken that such information is reliable and is used appropriately.

This report, together with the *National Breastfeeding Policy for Ireland*, should be the basis for education programmes by the Health Promotion Unit of the Department of Health and Children, the Food Safety Authority of Ireland, the Department of Education and Science and other interested groups and should help to provide reliable information to health professionals concerned with infant feeding. It should be made readily available to all those concerned with the nutritional management of infants and should be regularly reviewed and updated in a structured manner so that it will continue to be reliable and based on the most recent scientific knowledge. Responsibility for dissemination and review should rest with the Food Safety Authority of Ireland. The Health Promotion Unit of the Department of Health and Children should ensure that education programmes on infant nutrition are based on this report and the Department of Health and Children and other relevant government departments should ensure that the recommendations outlined are implemented.

### **Role of the media**

The *National Breastfeeding Policy for Ireland* recommended that "*the media should support and promote a positive image of breastfeeding and portray it as the norm*". Although neither the broadcast nor print media currently appear to have any official policy on infant feeding, they have important roles to play in helping to disseminate the information contained in this report.

### **The Sub-committee recommends that:**

- The information in this report should be disseminated to relevant organisations including all maternity and paediatric hospitals and units both public and private, the Health Promoting Hospitals' Network, the health boards, An Bord Altranais, the Irish Nurses Organisation, the Institute of Community Health Nursing, the Medical Faculties of Universities and the Royal College of Surgeons, the Irish College of General Practitioners, the Institute of Obstetrics and Gynaecology, the Faculties of Paediatrics, Public Health Medicine and Occupational Medicine of the Royal College of Physicians, the Irish Medical Organisation, the Irish Society of Medical Officers of Health, the Irish Paediatric Association, the Irish Perinatal Society, the Irish Practice Nurses Organisation, the Irish Nutrition and


Dietetic Institute, the Irish Cancer Society, the Association of Lactation Consultants of Ireland, the Irish Baby Friendly Hospitals Initiative, the Pharmaceutical Society of Ireland, the Library Association of Ireland, Public Libraries, the Department of Education and Science, the Department of Justice, Equality and Law Reform, the Department of Enterprise, Trade and Employment, the Employment Equality Agency, the Irish Congress of Trade Unions, the national media, the Irish Business and Employers Confederation, voluntary groups with an interest in infant nutrition including La Leche League, Cuidiú – The Irish Childbirth Trust, the Irish National Committee for UNICEF, the National Council for Curriculum and Assessment and the Council for the Status of Women.

- The information contained in this policy should be reviewed and updated on a regular basis. The Sub-committee suggests that reviews should occur two yearly and updates at intervals of not more than five years.

### **Education**

#### **Schools**

The education of parents about maternal and infant nutrition usually begins in ante-natal classes, after a woman becomes pregnant.



Recently, it was decided to incorporate some health education, including infant nutrition, into the primary and post-primary curricula. At primary level nutrition education focuses on general topics but includes some discussion of pregnancy and the care of babies. Provision is made at secondary level for those who wish to study nutrition and health. For example, in the Applied Leaving Certificate, a core course, Social and Health Education 1, includes a health and nutrition module, and an optional course on Care of Babies and Young Children is offered. The introduction of such courses should help to improve knowledge about nutrition and health among young people at an early age.

In order to enable teachers to teach a food, nutrition and health programme, such information will need to continue to be included and updated regularly in teacher training courses.

**The Sub-committee recommends that:**

- Plans to incorporate health and nutrition education into the primary and post-primary curricula should continue.
- Information on health and nutrition, and specifically infant nutrition, should be incorporated into teacher training courses.

**Ante-natal classes**

Ante-natal education is still the main source of information for parents and is provided during a time when parents are likely to be most interested in learning about health-related issues which will affect their infants. Attendance at ante-natal classes is low among women who are geographically or socio-economically disadvantaged. Individual educational opportunities should be sought by health workers providing care for these women; for example, public health nurses could initiate ante-natal contact and education. Efforts should continue to make classes available and accessible to all parents and information on nutrition should be disseminated based on the recommendations of the *National Breastfeeding Policy for Ireland* and on this Report.

**The Sub-committee recommends that:**

- All mothers should be encouraged ante-natally to breastfeed their babies.
- The compositional differences between breast milk and formula and between infant formula and follow-on formula and the outcome of feeding each should be explained as part of all ante-natal education programmes in Ireland.

- Health-care professionals who are responsible for the provision of ante-natal education should have access to in-service training to regularly update their knowledge.

### **Community-based education**

In Ireland, public health nurses have formed the major education and support network for parents. They are now assisted in certain areas by community mothers, volunteer breastfeeding support groups, parenting and other groups. The success of the community mothers' scheme has recently been confirmed. Infants in the travelling community and home-based infants whose mothers were supported by a community mother were found to have better diets than those of controls and were less likely to be drinking cows' milk before the age of 26 weeks (Fitzpatrick *et al*, 1997). Nutritionists based in the community are now available in a few health board areas but more are needed. Mothers should be encouraged to use these services and to attend the local health clinic for help with management of feeding, regular weight/length checks, developmental checks and parenting skills.

### **The Sub-committee recommends that:**

- Public health nurses should make a visit to all mothers within 24 hours of the infant's discharge from hospital. At a later date, a visit should be made to support

the continuation of breastfeeding, provide information on other feeding, in particular the timely introduction of complementary foods, and record weight, length and head circumference.

- The public health nurse and general practitioner should be informed by the maternity unit on the day of discharge of the infant from hospital and the public health nurse should ensure that the family is visited on the day of discharge or the following day; special attention should be given to ensure an early visit to premature or low birth-weight babies or infants with special needs (Chapters 9 & 10).

### **Literacy**

A recent survey conducted by the Department of Education and Science revealed that 25% of adults have very limited reading ability. As discussed in the section on socio-economic disadvantage, the great majority of educational material is provided in written form. Parents who cannot read are at a very considerable disadvantage and their infants at risk as a result of their inability to interpret information on foods, drinks and medicines.

### **The Sub-committee recommends that:**

- Those who provide education on infant feeding should be made aware of the high level of adult illiteracy.

- As far as possible, classes should include practical demonstrations and written information should be supported by illustrations, diagrams and pictures. This is especially important in relation to preparation of powdered milks, gluten-free products and infant medicines.

#### **Fiscal considerations**

Currently, mothers who do not breastfeed are provided with infant formula milk during their post-natal stay in hospital. The cost of providing this formula for the three major maternity hospitals in Dublin was calculated by the Sub-committee to be in excess of £150,000 annually. In a sample of rural maternity units, cost of providing formula varied between £6,500 and £16,000 annually per unit. Asking mothers to supply formula while in hospital might create administrative difficulties but formula milks from the hospital supply should not normally be given to mothers on discharge from hospital.

On discharge, in certain health board areas, mothers on low incomes can apply to the Community Welfare Officer for formula for which they do not pay. In one major health board area the cost of providing this service in 1996 was almost £90,000. While it is imperative that all mothers have access to appropriate food for their infants, the practice of giving out formula milk for which mothers do not pay

discriminates against the breastfeeding mother and could discourage low-income mothers from choosing to breastfeed. Furthermore, the quantity of formula milk allocated may not meet the infant's requirements, leading to the possibility that feeds will be overdiluted or that other milk, for example unmodified cows' milk, will be given inappropriately to infants. Breast milk should be promoted as both the best and the most economical infant food.

In 1993, \$885 was estimated to be the cost of formula feeding an infant in the US for the first year of life. The cost of formula feeding an infant in Ireland is not known. Under current legislation (S.I. No. 243 of 1998, Article 11.3a) it is required that "*information provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition*" shall include the "*social and financial implications*" of the use of infant formula.

Significant costs are incurred in the treatment of illnesses which result directly from not breastfeeding (Ball & Wright, 1999). These relate to both infant and maternal disease and to infancy, childhood and adult life. Based on results from a Scottish study the cost of treating hospitalised cases of gastroenteritis which were the result of not breastfeeding was calculated for England and Wales. If there was an increase of 5% (30% to 35%) in the number of mothers who breastfed for more than 13

weeks, it was calculated that an annual saving of £2,642,584 would result (Broadfoot, 1995; National Breastfeeding Working Group, 1995). The saving which would result from a greater increase in the numbers breastfeeding or from the reduction in both community and hospital-based treatments for all illnesses which would be prevented in mothers and babies would obviously be of a much greater magnitude. Together with the direct financial saving, a reduction in days lost at work and a reduction in the emotional stress suffered by families in which an infant is ill should be of significant benefit.

The Sub-committee recognises that many of the recommendations contained in this document have significant resource implications for the Department of Health and Children, the health boards and other agencies. We would, therefore, recommend that if these recommendations for an Infant Feeding Policy are accepted by the Minister for Health and Children, that dedicated resources are earmarked for the implementation of the report.

#### **The Sub-committee recommends that:**

- Resources should be allocated by the Minister for Health and Children to support the implementation of the recommendations detailed in this report.
- The cost of formula feeding an infant in Ireland should be calculated so that, in

compliance with current legislation, this important information can be made available to prospective parents.


- If mothers on low incomes are given financial support, it should be especially designed to encourage and support breastfeeding.
- The cost of not breastfeeding should be calculated for Ireland and taken into account when consideration is given to the allocation of resources for promotion of good infant nutrition.

#### **Legislation and codes of practice**

The purpose of legislation and codes of practice is to provide protection for the health of infants, through mandatory and voluntary provisions. These provisions provide control on the composition, labelling and advertising of infant formula and follow-on formulae.

Previous and complex relationships between Irish and European Law, the International Code of Marketing of Breast Milk substitutes and the Irish Code of Practice for the Marketing of Infant Formulae in the Republic of Ireland have largely been resolved by the recent transposition of European Directives 91/321/EEC, 92/52/EEC and 96/4/EC into Irish law by the European Communities (Infant Formulae and Follow-on Formulae) Regulations, 1998 (S.I. No. 243 of 1998).





Having examined the current situation the following key points emerge:

- The *Code of Practice for the Marketing of Infant Formulae in the Republic of Ireland*, issued in January 1991, is restricted to infant formulae only. It can now be considered as superseded by the legislation.
- There is a lack of knowledge and detailed prescription of the legislative requirement for infant formulae and follow-on formulae, especially in regard to marketing aspects. Determining legal compliance in marketing aspects is therefore both difficult for the industry and enforcement authorities, unlike in compositional aspects where detailed quantitative prescriptive limits are available.
- S.I. No. 243 of 1998 necessarily transposes the detail of Directives 91/321/EEC and 96/4/EC and does not reference the International Code of Marketing of Breast-Milk Substitutes noted in the recitals in the Directives. However, this could be addressed in a proposed revised code of practice.

A reissue of the code of practice as an interpretative guide as provided by Article 13 of the S.I. is under active consideration by both the Food, Drink and Tobacco Federation (part of the Irish Business and Employers

Federation) and Food Safety Authority of Ireland (FSAI). Such a code would require the approval of the Minister for Health and Children. A revised code of practice is necessary to enable consistent interpretation of the S.I., in particular, its marketing provisions. Labelling and advertising issues could also be addressed through a self-regulatory system which would maintain and strengthen the existing Code Monitoring Committee.

Whilst primary responsibility for the implementation of the measures contained in the S.I. resides with the regulatory authorities, principally the health boards and the FSAI, a revised code would assist those authorities and others involved in the industry, together with the public at large.

**The Sub-committee recommends that:**

- Immediate elaboration of a revised Code of Practice for the Marketing of Infant Formulae and Follow-on Formulae in the Republic of Ireland. This is provided for in Article 13 of S.I. No. 243 of 1998. The FSAI should establish a group representative of interested parties in order to develop the code.
- Verification of compositional compliance should be carried out by the health boards following the provisions detailed in the European Communities (Official

Control of Foodstuffs) Regulations, 1998 (S.I. No. 85 of 1998).

- The introduction by the industry of a voluntary compliance system with defined sampling and inspection frequencies which could be independently verified should be considered.

#### **Environmental considerations**

In spite of an increased awareness of the central role of nutrition in health promotion and disease prevention, not all community-care areas have access to the services of a paediatric nutritionist. In order to enhance the service which is already available, the public

health-care programme should make available information on nutritional issues and provide the expertise necessary to offer nutrition advice in all community-care areas.

#### **The Sub-committee recommends that:**

- Each community-care area should have at least one community paediatric nutritionist to provide nutrition education and care for the nutritional needs of infants.
- Consideration should be given to the routine inclusion of length/height and head circumference measurement in the public health-care programme.

## CHAPTER 14: RECOMMENDED AUDIT AND RESEARCH

### Collection of data on infant feeding

Statistical information on infant feeding is collected in the immediate post-natal period in each maternity unit and collated and published by the Department of Health and Children. These data are usually published a number of years in arrears. As part of the neonatal screening programme, feeding method is recorded on the newborn screening (Guthrie) card collated at the Children's Hospital, Temple Street, Dublin. However, currently this information is not utilised to provide statistical information on feeding. Public health nurses collect feeding data regularly throughout infancy, but these data are generally neither collated nor analysed. Consistent definitions for terms used in data collection, for example exclusive breastfeeding and complementary foods, should be used.

In order to improve practice and provide a baseline from which to monitor progress,

### The Sub-Committee recommends that:

- The current method of providing statistics on infant feeding should be revised and updated by the Department of Health and Children; data collection methods should be standardised, accurate and timely.
- Consideration should be given to the implementation of a survey method of collecting accurate, relevant, statistical

data on infant feeding, which would allow for follow-up of the cohort at the age of four months.

- Feeding information on newborn screening cards should be collated, analysed and used as a more immediate source of information on breastfeeding between days three and five post-natally.
- Methods by which public health nurses collect data on infant feeding and growth should be standardised.

### Complementary foods

More Irish research into the introduction of complementary foods is required. Available data are limited, data collection methods are not standardised, little information relates to breastfeeding infants and some data focus only on socio-economically disadvantaged communities.

### The Sub-committee recommends that:

- Research into existing and optimal weaning practice and introduction of complementary foods should be encouraged and supported financially by the Department of Health and Children.
- Feeding practices which are associated with the development of specific diseases, for example obesity, hypertension, allergy, coeliac disease and iron deficiency, require detailed examination; the role of peanuts in the

aetiology of allergy and anaphylaxis should be investigated urgently and appropriate guidelines should be issued for Irish mothers and their infants.

### **Nutritional status/dietary intakes of Irish infants**

There is an urgent need to assess the nutritional and vitamin and mineral status of Irish infants. Only when more data are available will it be possible to make accurate dietary recommendations. Infants differ from adults and health professionals need to understand the specific nutrient and vitamin and mineral requirements of infants and how these can be met.

The Irish National Nutrition Survey (Irish Nutrition and Dietetic Institute, 1990) did not include children under the age of eight years, so currently very little information is available on nutrient intakes of Irish infants. Efforts should be made to address this issue.

Recent EU legislation (European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs; European Parliament and Council Directive 94/36/EC on colours for use in foodstuffs; European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners) places a legal obligation on all Member States to provide information on the


intake of food additives. For a number of additives, young children may be considered an 'at risk' group because they have a higher consumption of food, particularly of fluids, per kilogram of body weight than adults. Food consumption data for infants, which are necessary in order to calculate their exposure to additives, are currently not available in Ireland.

### **The Sub-committee recommends that:**

- The nutritional status, dietary intakes and additive exposure of Irish infants should be assessed.
- The vitamin and mineral status of Irish infants should be assessed.
- This research should be supported by the Department of Health and Children.

### **Cows' milk**

Some contradictions surround the recommendation to avoid the use of cows' milk before the age six months (DHSS, 1994, p. 58). One reason for this recommendation is that it is known that the proteins in cows' milk are more allergenic to the human infant than those in human milk (DHSS, 1994). However, infant formula is manufactured from dried cows' milk and casein-predominant formula is based on unmodified cows' milk protein. In whey-predominant formula (modified formula) the extra whey is bovine in origin and differs significantly from human-milk whey. Human-

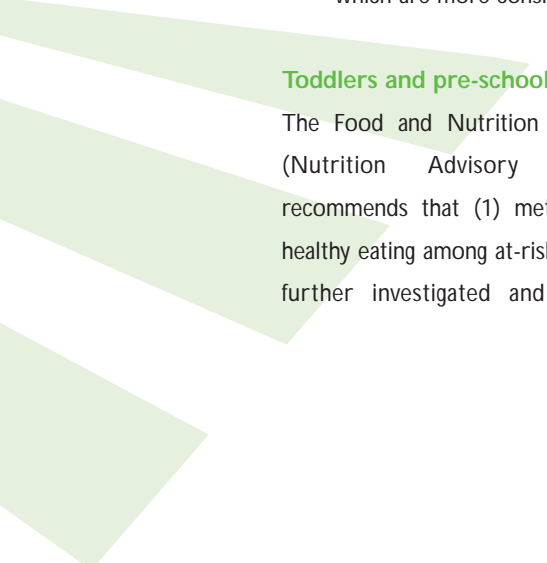


milk whey contains primarily alpha lactalbumin while bovine contains beta lactoglobulin, the bovine protein with the highest antigenic activity (ESPGAN Committee on Nutrition, 1982). Dried skimmed milk powder is also a basic ingredient in a range of infant cereal products which are marketed for use from age four months. The DHSS (1994) suggests that plain yoghurt is a suitable first food. This also contains whole cows' milk.

**The Sub-committee recommends that:**

- Further research, or a review of available data, is required to address the contradictions relating to the use of cows' milk-based products in infant foods and produce recommendations which are more consistent.

**Toddlers and pre-school children**



The Food and Nutrition Policy for Ireland (Nutrition Advisory Group, 1995) recommends that (1) methods to promote healthy eating among at-risk groups should be further investigated and (2) a proactive

approach should be taken to the dissemination of nutrition information to the public.

This policy outlines recommendations for feeding infants up to the age of 12 months. The dietary habits and nutritional needs of toddlers and pre-school children (1–5 years) differ significantly from those of infants. The Department of Health and Children should now undertake the drafting of a policy to provide nutritional guidelines for toddlers and pre-school children, for whom little nutrition information is currently available. Such a policy, together with the *National Breastfeeding Policy for Ireland* and this Report would provide the basis for a proactive approach in the dissemination of information to the public on the nutritional needs of children up to school-going age.

**The Sub-committee recommends that:**

- The Department of Health and Children develops a policy to address the nutritional needs of toddlers and pre-school children.

## APPENDIX A: NUTRITION FOR PRE-CONCEPTION AND PREGNANCY

### Maternal nutrition

The health of a woman before she becomes pregnant and during pregnancy influences the growth and development potential of the foetus, perinatal morbidity and mortality and the ability of the woman to successfully breastfeed her baby. In order to guarantee an optimal intra-uterine environment for the foetus, dietary or lifestyle changes which may be necessary should be made well before conception.

### Weight

In general, the nutritional adequacy of the diet can be ensured by eating a wide variety of foods including cereals, breads and potatoes, fruits and vegetables, milk, cheese and yoghurt, and meat, fish or poultry. If a woman needs to lose weight she should be encouraged to do this gradually, before becoming pregnant. Weight loss during pregnancy is not desirable and restrictive diets should be avoided. Similarly, if an increase in body-weight is indicated, this should precede conception.

### Calcium


Calcium requirements increase during pregnancy. Absorption of calcium improves physiologically, but dietary intakes also need to increase. In the Irish diet, calcium is usually supplied by dairy produce and, apart from teenage girls, vegans or those on milk-free diets, intakes are usually adequate. In these

sub-groups, a dietary assessment of calcium intake should be undertaken and advice given based on individual needs. Milk, cheese and yoghurt are excellent sources, as are fish with bones, such as sardines and tinned salmon. Calcium absorption and utilisation is enhanced by vitamin D.

### Iron

Iron deficiency anaemia is common in women of child-bearing age. Increased menstrual blood losses (McKenna *et al*, 1989), multiple pregnancies and inadequate dietary intakes of iron are factors which contribute to the development of anaemia. Maternal anaemia is associated with increased perinatal mortality and morbidity. Irish research has demonstrated that mothers who have low iron stores in early pregnancy are at increased risk of delivering low birth-weight babies (Cahill, 1995), a factor known to correlate with low total body iron content of the infant at birth (Dallman, 1992). Iron stores of the normal healthy make a significant contribution to iron requirements in the first four to six months of life (Chapter 7).

Oral iron supplementation during pregnancy has traditionally been used as a measure to prevent iron deficiency. It is known, however, that compliance is sometimes poor as a result of the side-effects (nausea, constipation) which can accompany iron supplementation. Furthermore, failing to achieve the normal



haemodilution (*reduction* in haemoglobin concentration) which takes place during pregnancy has been associated with a less favourable birth outcome for the infant (Steer *et al*, 1995). As a result, routine iron supplementation is becoming less common and advice is based on an assessment of the iron status of the individual mother. Iron supplementation is known to be of particular benefit to those mothers who have low levels of storage iron in early pregnancy (Cahill, 1995). A diet which contains adequate iron should prevent the development of deficiency in the mother who is initially iron sufficient.

Meat, fish and chicken contain heme iron, which is well absorbed. Non-heme iron (cereals, vegetables, pulses, breads, eggs) absorption is less efficient and is promoted by the inclusion of enhancers, such as vitamin C or meat, eaten at the same meal. Inhibitors of iron absorption include tannins from tea or coffee and phytates in cereals. Excess tea and coffee drinking with meals should be discouraged.

#### **Vitamin A**

Vitamin A is essential for growth and is found in dairy products, eggs, liver and fatty fish. A pre-cursor of vitamin A,  $\beta$ -carotene, from which vitamin A can be synthesised in the intestinal mucosa, is found in green leafy vegetables, and carrots are a very rich source.

However, vitamin A in excess is potentially teratogenic and supplements which contain vitamin A or large amounts of liver should not be taken during pregnancy.

#### **Folate**

Folate is one of the B group of vitamins. Good folate status at the time of conception and during early pregnancy significantly reduces the risk of neural tube defects (MRC Vitamin Study Research Group, 1991). Foliates are found in dark-green leafy vegetables, oranges, melon, avocado pear, banana, wholegrain cereals, breakfast cereals, almonds, walnuts and dairy produce. They are destroyed by heat and 30–90% may be lost during cooking. An important Irish study has shown that folate supplements and foods which are supplemented with folate, but not folate-rich foods, are effective in increasing red cell folate concentrations (Cuskelly *et al*, 1996). However, of women attending the three major Dublin maternity hospitals in 1996, only 5.8% had taken a folate supplement before becoming pregnant (Sayers *et al*, 1997).

It is recommended that, in addition to eating a folate-rich diet, a tablet which provides 400  $\mu$ g folate be taken daily by all women for at least three months prior to conception and during the first 12 weeks of pregnancy (Health Promotion Unit, Department of Health and Children). In families with a previous history

of neural tube defect, higher levels of supplementation are required and medical advice should be sought.

### **Vitamin C**

The best sources of vitamin C are fruits, in particular citrus fruits and kiwi, and vegetables and potatoes. Vitamin C, as well as enhancing iron absorption, is an important antioxidant, therefore adequate intakes (about five portions per day) of these foods during pregnancy should be encouraged.

### **Vitamin D**

Vitamin D, a fat-soluble vitamin, is produced endogenously through the action of ultra-violet light on skin and is found in the diet in oily fish, fish oils, fortified margarines and milks. Adequate intakes during pregnancy are essential to facilitate calcium absorption and metabolism. During the summer months, when the skin is exposed to sunlight, serum levels are usually high, while in winter dietary sources become more important. Supplementation during pregnancy will improve the vitamin status of the infant and should be considered where there is limited exposure to sunlight. Like vitamin A, vitamin D is potentially toxic and supplementation, for example with cod liver oil, during pregnancy should be discouraged.


### **Foods to avoid during pregnancy**

Certain foods, which may be a source of infection, should not be consumed during pregnancy. *Listeria monocytogenes* can multiply, even in the refrigerator. An increased risk of listeriosis is associated with foods which have been stored for prolonged periods or foods which are not thoroughly cooked before consumption. These include pâtés, cold meats or fish, pre-prepared salads or coleslaw and soft or blue-veined cheeses made with unpasteurised milk. In order to protect the foetus from exposure to potentially harmful infections, care should be taken to ensure that all food is clean, hygienically prepared and stored appropriately. Meat, fish, poultry and eggs should be well cooked. Leftover foods should be reheated thoroughly before eating. When eating out, choose hot, well cooked, rather than cold dishes. Products such as home-made mayonnaise or mousses containing raw egg may contain salmonella and should be avoided. The ingredients used in commercially produced mayonnaise are pasteurised and so do not constitute a risk.

### **Pregnant vegetarians/vegans**

During pregnancy the requirement for certain nutrients increases and vegetarians who become pregnant need to be particularly aware of these additional needs. Vegans may





require calcium and vitamin B<sub>12</sub> supplementation and non-meat eaters additional iron. Ideally, as for non-vegetarians, recommendations should be based on a comprehensive assessment of the nutritional status of the individual and in consultation with a nutritionist.

### Smoking

The adverse effects of maternal smoking during pregnancy on foetal growth and development are undisputed. It is known that infants born to mothers who smoke are lighter and shorter at birth and have smaller head circumferences and an increased risk of morbidity and mortality. Increased risk of sudden infant death (Taylor & Sanderson, 1995; Alm *et al*, 1998), intracranial haemorrhage (Spinillo *et al*, 1995) and hypertension (Morley *et al*, 1995) and increased blood lead levels (Rhains *et al*, 1997) are among the effects which have been reported. Irish research also suggests that long-term nutrient deficiencies may result from maternal smoking during pregnancy (Freeman *et al*, 1998); infants whose mothers smoked were found to be at greater risk of developing iron deficiency and iron deficiency anaemia.

Passive smoking post-natally is also known to adversely influence the health of infants. Smokers who stop smoking during pregnancy

frequently resume smoking post-natally and mothers who smoke are less likely to continue to breastfeed, possibly due to a nicotine-induced lack of prolactin (Schulte-Hobein *et al*, 1992). Infants who are exposed to smoke have an increased risk of developing asthma (Weitzman *et al*, 1990), lower respiratory tract infections, bronchitis, pneumonia (Schulte-Hobein *et al*, 1992), cancer (Hackshaw *et al*, 1997; Sorahan *et al*, 1997) and ischaemic heart disease (Law *et al*, 1997) in later life. Irrespective of the smoking habits of the mother, the smoking habits of the father may also have important implications for the health of the infant (Sorahan *et al*, 1997).

The majority of Irish women appear to be aware of the harmful effects of smoking during pregnancy (Daly *et al*, 1992) but, in spite of this, few smokers stop smoking when they become pregnant (Freeman, 1996). Increased efforts to discourage all young women from smoking are necessary to reduce the exposure of the foetus and young infant to tobacco smoke. The negative effects of smoking should continue to be emphasised to pregnant women and mothers of young children. However, it must be recognised that smoking is closely related to socio-economic disadvantage and efforts to discourage smoking must take account of the general circumstances influencing the smoking habits of mothers.

## Alcohol

There is no doubt that alcohol is a teratogen and that excessive alcohol consumption during pregnancy causes serious birth defects such as mental retardation and microcephaly, which are associated with foetal alcohol syndrome (Beattie, 1992). Effects of more moderate alcohol consumption are controversial although a range of adverse effects has been reported (Verkerk *et al*, 1993; Bolumar, 1994; Shu *et al*, 1995). A reduction in head circumference measurement at birth is of particular concern and suggests that brain growth may be impaired as a result of even moderate maternal alcohol consumption (Davis *et al*, 1982; Sulaiman *et al*, 1988; Freeman, 1996). Reductions in birth-weight and birth length have also been reported. Alcohol consumption during pregnancy may also increase the risk of SIDS, particularly in smokers.

A recent case-control study has shown that, compared to women who did not drink alcohol during pregnancy, the relative risk of cleft lip, with or without cleft palate, rose with increasing levels of maternal drinking. Taking one to three drinks per month increased the risk by 50%, with corresponding increases for greater intakes of alcohol. Adjustment for maternal smoking, vitamin use, education and household income did not substantially alter the results (Munger *et al*, 1996). Although

further research is required to validate these particular findings the balance of evidence now suggests that drinking alcohol during pregnancy should be avoided.


Irish doctors may be less aware of the adverse effects of alcohol consumption than of smoking and are less likely to advise against drinking during pregnancy (Daly *et al*, 1992). Avoidance of alcohol during the full pregnancy (i.e. from before conception) should be advised. If a mother chooses to drink, "binge" drinking should be definitely discouraged.

## Caffeine

Excess consumption (> 300 mg/day) of caffeine during pregnancy should be discouraged. It has been associated with poor intra-uterine growth and spontaneous abortion (Hinds *et al*, 1996) and with intakes of > 400 mg/day (4 cups of coffee) there may be an increased risk of sudden infant death syndrome (SIDS) (Ford *et al*, 1998). Further research is necessary to clarify the effects of caffeine on pregnancy outcome. Caffeine is contained in coffee, tea, carbonated cola-type soft drinks and, to a lesser degree, chocolate.

## Sudden infant death syndrome (SIDS)

Good maternal nutrition during pregnancy to ensure adequate intra-uterine growth and diminish the risk of prematurity and low birth-weight is an important factor in the prevention



of SIDS. The risk of SIDS is increased in socio-economically disadvantaged families.

Avoidance of cigarette smoking both during pregnancy and post-natally is a most important preventive measure; 30% of SIDS deaths could be avoided if mothers did not smoke (Taylor *et al*, 1995; Blair *et al*, 1996). The ISIDA's National Sudden Infant Death Register, which is supported by the Department of Health and Children, registers all sudden infant deaths in Ireland. They have shown that smoking during pregnancy or post-natally increases the odds ratio for SIDS very significantly; the greater the number of cigarettes smoked, the greater the risk. Drinking during pregnancy also increases the risk in a dose-dependent manner. The effect of alcohol is greater in smokers. The occurrence of "illness", mostly respiratory or gastrointestinal, since birth also leads to an increased risk.

Sleep position is extremely important and mothers should be reminded that infants should be placed on their backs to sleep.

Prone and side sleeping and co-sleeping with parents increase the risk of SIDS. The risk associated with co-sleeping is increased in smokers. Taking the baby into bed to breastfeed does not constitute a risk, but breastfed babies should be returned to their own cots after feeding. The safest sleeping arrangement is if the baby has a cot beside the parents' bed.


Another risk factor is overheating of the infant. This should be avoided by not overwrapping the infant or putting on excessive clothing (e.g. hats) and by ensuring that rooms are not overheated. Duvets or quilts (Ponsonby *et al*, 1998) are more dangerous than blankets, as the infant has more freedom of movement, which can result in covering of the face and asphyxia. The use of pillows should be avoided.

A number of studies have shown that the use of soothers is protective against SIDS (Mitchell *et al*, 1993; Fleming *et al*, 1996). The mechanism by which soothers protect is not known.

## APPENDIX B: THE NATIONAL BREASTFEEDING POLICY FOR IRELAND: SUMMARY OF RECOMMENDATIONS

### Chapter 3 Promoting breastfeeding in maternity hospitals and units

- Every maternity hospital and unit should have a clear written policy promoting and supporting breastfeeding and incorporating all of the recommendations made later in this chapter. This policy should be communicated routinely to all health-care staff and to women and their partners.
- Hospital personnel, particularly midwives, should have the skills to give accurate up-to-date advice to mothers. Ideally information should be provided, not just in a neutral way, but in the context of positive supportive attitudes from staff.
- Uninterrupted contact between the mother and baby should be encouraged for the first hour after birth and the baby should be put to the breast during this time, with the support of trained staff.
- For successful breastfeeding rooming-in is advisable and should be the norm in all maternity hospitals and units.
- Time schedules relating to the frequency and time on the breast should be avoided. Baby-led feeding should be encouraged.
- Mothers should be educated to recognise the cues from the baby that feeding is required. Most babies will feed from both breasts at each feed and therefore the baby should be offered both breasts while not necessarily requiring the second breast.
- Night feeding should be encouraged to ensure that prolactin levels are maintained, as there is a greater release of prolactin during night-time feeding.
- Maternity hospitals and units should avoid giving supplementary feeds unless they are medically indicated. Water or glucose/dextrose should have no place in the nutrition of breastfed babies at this time.
- The use of artificial teats and pacifiers (sometimes called dummies or soothers) should be discouraged in maternity hospitals and units while breastfeeding is being established.
- Correct positioning from the first feed is the most effective way of preventing sore/cracked nipples. Correcting the baby's position at the breast is usually effective in resolving the problem of sore nipples and therefore the use of nipple shields should be the exception.
- Before leaving hospital, mothers should be shown how to express breast milk. All maternity hospitals and units should maintain a supply of breast pumps which would be loaned to those mothers for whom the cost of purchasing such a



pump might constitute a disincentive to breastfeeding.

- Mothers who have had instrumental deliveries and caesarean sections should be given extra support with breastfeeding.
- There is sufficient evidence of the value of breast milk for pre-term babies to encourage and support all mothers who wish to breastfeed such babies.

However, it is essential to ensure that an adequate volume is fed to the infant to ensure optimum growth and to reduce mineral deficiency. This may necessitate supplementation by previously expressed own mother's milk or by an appropriate formula.

- Where babies require admission to special baby units either in a maternity hospital or in a children's hospital, mothers should be advised that this does not preclude breastfeeding and staff should be trained to provide extra support with breastfeeding in such circumstances.
- Mothers should be advised that the use of sprays and creams is unnecessary and may hinder effective breastfeeding.
- Free samples, other gifts or literature promoting infant formulae directly or indirectly should not be provided to the general public, pregnant women, mothers or members of their families


through the health-care services. Gift items promoting such products, such as pens, diaries, calendars, should not be in use in public health-care facilities.

- Hospitals should distribute the literature on breastfeeding produced/approved by the Health Promotion Unit of the Department of Health and Children or by the breastfeeding support groups.
- Mothers should be encouraged to practice exclusive breastfeeding for at least four months and thereafter with appropriate weaning foods.
- Mothers should be advised that there are very few medical reasons for discontinuing breastfeeding.
- Staff should afford due recognition to the fact that some mothers will choose not to breastfeed or may have great difficulty in doing so and these mothers should be given every support in their chosen feeding methods.
- Those who have chosen to breastfeed should be encouraged to continue breastfeeding and to avail of specialised help to overcome problems which may occur such as mastitis, apparent poor milk supply, crying baby, etc.
- Mothers should be informed while in hospital of the various breastfeeding support groups in the community such as La Leche League and Cuidiú – The Irish Childbirth Trust.

- Hospitals should be as prompt as possible in notifying discharges to the appropriate health board medical officer in each community care area.
- Strict implementation of the stated policy is essential. Ward management should be centred round the mother–infant dyad to facilitate breastfeeding. The Sub-committee further recommends the establishment of a breastfeeding team, including representatives of voluntary support groups, to oversee the implementation of the policy.

#### Chapter 4 Promoting breastfeeding at community care level including the role of voluntary support group

- Each Health Board Area should have a written breastfeeding policy. This should be consistent with that recommended for hospitals as well as incorporating elements specific to community care at local level. This policy should be routinely communicated to all public health nurses, public health doctors, general practitioners, practice nurses, relevant voluntary groups and breastfeeding mothers themselves.
- Health-care professionals and others, e.g. general practitioners and public health nurses organising ante-natal classes, should ensure that during the ante-natal period all women have information on the advantages and management of breastfeeding and are assured that, pre- and post-natally, support will be available from health-care professionals and voluntary groups. Mothers should also be alerted to the fact that, should their baby require special care, this will not necessarily exclude breastfeeding and should be advised that special support with breastfeeding will be available to them.
- Health centres should distribute the literature on breastfeeding produced/approved by the Health Promotion Unit of the Department of Health and Children or by the breastfeeding support groups.
- Each community care area should identify a public health nurse as a resource person with expertise in breastfeeding who would provide ongoing support to colleagues and conduct in-service training.
- A breastfeeding clinic to which mothers can come with their babies should be held weekly in each health centre. The existence of such a clinic should be made known to women both ante-natally and post-natally.
- There should be regular meetings and ongoing liaison between health professionals and voluntary



breastfeeding support groups such as La Leche League and Cuidiú – The Irish Childbirth Trust – at local level. Each health centre should maintain lists of these voluntary groups in their area with names and phone numbers which would be given to mothers at the public health nurse's first visit if a mother had not already received them. Adequate resources should be made available to the voluntary support groups to enable them to participate effectively in these programmes.

- Since community mothers' groups have been found to be a very effective channel for health promotion, where such groups exist they should be availed of, in conjunction with established breastfeeding support groups, to help breastfeeding mothers.
- Data on the prevalence of breastfeeding at discharge and at four months should be collected and published by each community care area for the purpose of monitoring and evaluation at local level.

## Chapter 5

### Training of health professionals

- The concept of the 10 Steps to Successful Breastfeeding (Department of Health, 1994) should form the basis of an education programme for all nursing and medical personnel at undergraduate level. Due attention should be paid in the curriculum to the physiology of, and rationale for, breastfeeding, based on current knowledge of effective management of lactation. The education programme should also include awareness of the codes for the marketing of infant formulae.
- All existing nursing, midwifery and medical personnel caring for pregnant women, mothers and infants in maternity hospitals and units and in the community should receive training in the skills necessary to promote and facilitate successful breastfeeding. The Sub-committee considers communication and counselling skills to be particularly important in this context.
- In-service training of new, and updating of existing, staff needs to take place on a regular basis, at least annually. Seminars and workshops with invited representatives of breastfeeding support groups such as La Leche League and Cuidiú – The Irish Childbirth Trust – could form part of this training. Staff should be facilitated in attending these training sessions.
- In maternity hospitals and units, the lactation team should organise and coordinate the training and supervision of personnel, while a breastfeeding

resource person should be identified to perform these functions in each community care area.

- Provision should be made for the inclusion of education on breastfeeding for GPs through the GP Vocational Training Scheme and through the Continuing Medical Education (CME) Scheme at local level.
- To help ensure consistency in training and in practice, the Sub-committee recommends the adoption of a manual of best practice for use in all education and training courses. This should also be available in all maternity hospitals and units, in health centres and ideally in GP surgeries. The Sub-committee recommends the Royal College of Midwives' publication *Successful Breastfeeding* (2nd Edition, 1991) as the manual of best practice, with *The Breastfeeding Answer Book* (La Leche League International, 2nd Edition, 1992) as an additional resource.

### Chapter 6 Promoting breastfeeding in the wider community

- There should be no discrimination against breastfeeding over bottle feeding babies in public places.
- Since breastfeeding is recognised as the optimum health care for the normal

term baby, the media should support and promote a positive image of breastfeeding and portray it as the norm.

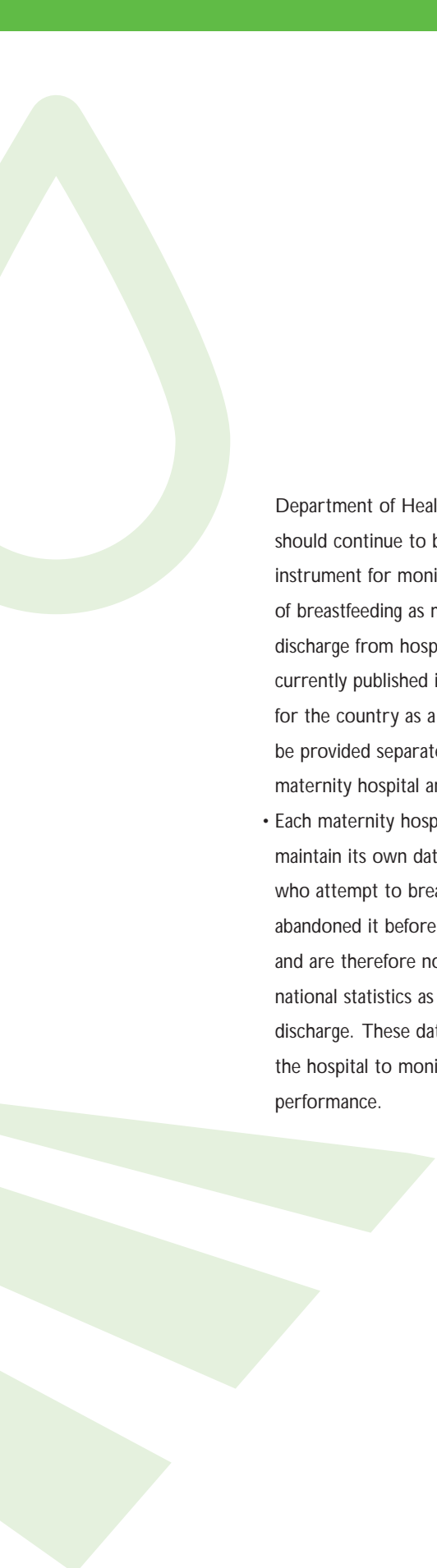
- Basic physiology relating to the breast should be a component of a social and health education programme in primary and secondary schools with a view to promoting from an early age the value of breastfeeding. The curricula should foster a positive body image, with the aim of enabling young people, both male and female, to be comfortable with the idea of breastfeeding.
- There should be greater legislative flexibility in relation to post-natal maternity leave. Initially this might involve more extended optional unpaid leave with a gradual extension in the longer term of the length of paid leave.
- Employers should provide facilities where breastfeeding mothers who are working can express milk.
- Workplace crèche facilities should be extended along the lines recommended in the *Second Report of the Commission for the Status of Women*. The public sector, and in particular the health sector, should give a lead in providing crèche facilities and lactation breaks.



## Chapter 7 Targets, implementation and monitoring

- The following targets are being set:
  - An overall breastfeeding initiation rate of 35% by 1996 and 50% by the year 2000.
  - A breastfeeding initiation rate of 20% among lower socio-economic groups by 1996 and 30% by the year 2000.
  - A breastfeeding rate of 30% at four months by the year 2000.
- In order to achieve the above medium- and long-term targets, the following also need to be achieved:
  - All maternity hospitals and units to have a breastfeeding policy and a lactation team in place by early 1995.
  - By early 1995, the national structures necessary for Ireland's participation in the Baby Friendly Hospital Initiative should be in place.
  - All community care areas to have identified a breastfeeding resource person by early 1995.
  - The Health Promotion Unit Budget Plan for 1995 should include provision for the designation of the Unit as a National Breastfeeding Resource Centre.
  - From 1995, all courses for health professionals should incorporate the recommendations on professional training contained in this report.
- At the 1996 review of the EC Directive on Maternity Leave, Ireland should support the extension of such leave to 16 weeks.
- By the year 1997, the social and health education programme in primary and secondary schools should contain a component on breastfeeding along the lines recommended in this report.
- By 1998, the public sector, and in particular the health sector, should be giving a lead in the provision of workplace crèche facilities and lactation breaks.
- Given that the recommendations of this Sub-committee on promoting breastfeeding at hospital level are in line with the Ten Steps to Successful Breastfeeding advocated by the Baby Friendly Hospital Initiative, the Sub-committee is recommending Ireland's participation in this initiative. However, the Sub-committee wishes to emphasise that this designation should not be taken to insinuate that hospitals not so designated are not friendly to babies.
- The Department of Health and Children should take responsibility for ensuring that the structure necessary for Ireland's participation in the Baby Friendly Hospital Initiative, such as a National Designation Authority and a Board of Assessors, are put in place.

- The lead role in co-ordinating the implementation of the report's recommendations should be undertaken by the Health Promotion Unit of the Department of Health and Children in conjunction with other relevant divisions within the Department such as the Secondary Care Division and the Community Health Division. This role will include (a) the dissemination of the recommendations of this report to relevant organisations, (b) acting as a national resource centre for breastfeeding materials, (c) ensuring that necessary research data, additional to that currently available in the *Perinatal Statistics Report*, are collected and published and (d) ensuring that a review of progress on the achievement of the targets set in this report takes place at two-yearly intervals starting in 1996.
- The Health Promotion Unit should disseminate the recommendations of this report to relevant organisations including all maternity hospitals and units both public and private, the Health Boards, An Bord Altranais, the Irish Nurses Organisation, the Institute of Community Health Nursing, the Medical Faculties of the Universities and the Royal College of Surgeons, the Irish College of General Practitioners, the Institute of Obstetrics and Gynaecology, the Faculties of Paediatrics, Public Health Medicine, and Occupational Medicine of the Royal College of Physicians, the Irish Medical Organisation, the Irish Society of Medical Officers of Health, the Irish Paediatric Association, the Irish Perinatal Society, the Irish Practice Nurses Organisation, the Department of Education and Science, the Department of Justice, Equality and Law Reform, the Department of Enterprise, Trade and Employment, the Irish Congress of Trade Unions, the Irish Business and Employers Confederation, La Leche League, Cuidiú – The Irish Childbirth Trust, the Association of Lactation Consultants of Ireland, the Irish National Committee for UNICEF, the National Council for Curriculum and Assessment and the Council for the Status of Women.
- The Health Promotion Unit should be designated a Resource Centre for breastfeeding materials which have national application.
- The Department of Health and Children should ensure standardisation of the way the data are collected – for instance, definitions of breastfeeding (whether it is exclusive or partial).
- The *Perinatal Statistics Report* published each year by the Planning Unit of the



Department of Health and Children should continue to be the main instrument for monitoring the incidence of breastfeeding as measured at discharge from hospital. These statistics, currently published in aggregated form for the country as a whole, should also be provided separately for each maternity hospital and unit.

- Each maternity hospital and unit should maintain its own data on any mothers who attempt to breastfeed but have abandoned it before they leave hospital and are therefore not recorded in national statistics as breastfeeding at discharge. These data can be used by the hospital to monitor its own performance.

- The appropriate health board medical officer should submit an annual return to the Department of Health and Children on the total number of births in his/her area and the percentage of mothers breastfeeding at hospital discharge and at four months. The Department will have responsibility for collation and publication of the data at national level.
- The Health Promotion Unit should keep under constant review the need, which may arise periodically, for more in-depth research on the factors influencing the initiation and duration of breastfeeding.

## APPENDIX C: COMPOSITIONAL DIFFERENCES BETWEEN BREAST MILK AND FORMULA MILKS

### Introduction


Human breast milk does not have a constant composition and major differences exist between it and cows' milk or formula manufactured from dried cows' milk (Goedhart & Bindels, 1994; Heinig & Dewey, 1996). Each of the major macronutrients is represented in human milk, together with a complex mixture of micronutrients and non-nutritive factors. These combine to provide optimal nutrition and support a range of functions which enhance the growth and development of the baby. Many constituents of human milk play multiple roles in health promotion, disease prevention and growth and development. The known range and extent of the advantages continue to expand as knowledge of breast-milk composition unfolds. Some of the most important known differences between breast milk and formula are outlined below.

### Lipid


Lipid (fat) is the main energy-supplying nutrient for the newborn and during infancy particular fatty acids are known to be important for brain and nerve development. Many differences exist between the fat supplied by human breast milk and formula derived from cows' milk. During early lactation, the fat content of human milk increases from about 2.6 g/dl in colostrum to 3.5 g/dl in mature human milk. Lipid also increases during the course of a feed

and during the day. Increases in lipid concentration are offset by decreases in carbohydrate, while obviously no such physiological variation can occur in formulae.

In spite of the constant compositional changes which take place in human milk, the fatty acid concentration of the milk remains constant. Arachidonic (AA) and docosahexanoic acid (DHA) are long chain polyunsaturated fatty acids (LCPUFAs) which are found in significant concentrations in human milk but have not traditionally been added to formula. These fatty acids constitute a large proportion of the total lipid in the brain and retina and are accreted particularly during the last trimester of pregnancy and the first year of life. Adults can synthesise AA and DHA from their precursors, linoleic and linolenic acid. Whether these fatty acids can be synthesised by infants is still controversial. In the pre-term infant, enzyme systems may be incompletely developed and, as a result, the ability to synthesise AA and DHA is compromised, so these fatty acids are now added to all pre-term formulae marketed in Ireland. The situation for term infants remains unclear and AA and DHA are not added routinely to term formulae. It appears to be the case that, in early infancy, term infants who are fed breast milk have higher levels of these LCPUFAs in the phospholipid of the cerebral cortex, subcutaneous adipose tissue and red blood cell



membrane (Farquharson *et al*, 1993, 1995; Jørgensen *et al*, 1995). One recent investigation has shown that even in infants who are taking a mixed diet, the typical differences between the serum cholesterol ester fatty acid profiles persist; breastfed infants had significantly higher concentrations of both AA and DHA at age seven months (Salo *et al*, 1997). Whether altering the linoleic to alpha linolenic acid ratio in formula can enhance AA and DHA production in term infants is also under investigation (Jensen *et al*, 1997).



Triacylglycerols (triglycerides) comprise about 98% of the fat in human milk and differ from the triglycerides of formula, which are derived from animal or vegetable fats. Notably, palmitic acid, a fatty acid which in human milk is found in the middle position on the triglyceride molecule, in formula is more commonly in the first or third positions. This positional variation influences the ability of the infant to absorb fat and minerals such as calcium and phosphate (Goedhart & Bindels, 1994). It has been shown that, when the triacylglycerol configuration of formula is similar to that found in breast milk, there is an increase of more than 20 mg/kg/day in calcium retention (Carnielli *et al*, 1995). This may be one of the factors which contributes to the enhanced bone mineralisation seen in pre-term children fed human milk in infancy (Bishop *et al*, 1996).

Cholesterol levels in breast milk are significantly higher than in formulae and result in higher serum cholesterol concentrations in babies who are breastfed. The long-term physiological significance of this difference is not fully understood. It has been hypothesised that high cholesterol concentrations are necessary for the synthesis of myelin in the rapidly developing brain of the neonate, but it appears that cholesterol needed for myelinisation is synthesised within the brain (Goedhart & Bindels, 1994). It has also been suggested that early high concentrations seen in serum of breastfed infants may down-regulate endogenous cholesterol production in later life or act as a stimulant for the production of cholesterol degrading enzymes which will allow for enhanced cholesterol degradation in adulthood (Wong *et al*, 1993; Worthington-Roberts, 1993)

Breast milk lipids are more readily digested by infants than those in formula. Initially, the infant's pancreatic function is immature and pancreatic lipase activity diminished. Fat digestion in the breastfed infant is enhanced by the presence of a bile salt dependent lipase in human milk. This lipase promotes rapid hydrolysis of the milk fat, providing a ready supply of energy to the breastfed term or pre-term infant. Duodenal lipases also manifest higher activity levels in pre-term infants fed breast milk or formula supplemented with


LCPUFAs than in those fed regular formula. Because lipid intake influences lipid structure in tissues such as brain, the relationship between intelligence quotient (IQ) and feeding method has been examined. A group of 300 infants who had received mother's milk in early infancy were found to have significantly higher developmental scores at ages 18 months and seven-and-a-half to eight years, after adjusting for maternal level of education and social class. Infants of mothers who opted to provide breast milk but failed to do so showed no advantage, confirming that the effect was due to a constituent in the milk rather than to confounders (Lucas *et al*, 1992a). The effect is thought to be due, at least in part, to the presence of specific fatty acids in breast milk.

### Carbohydrate

Lactose is the primary carbohydrate in breast milk. The lactose to oligosaccharide ratio changes during early lactation and, in tandem with the increase in fat, there is a decrease in breast milk carbohydrate. Variations in milk composition may be a factor in signalling satiety. The formula-fed infant is denied exposure to this diverse range of milk consistencies, as clearly the composition of formula remains constant (Goedhart & Bindels, 1994). Lactose content is considered to be one of the factors which contributes to the variation in faecal flora seen between breastfed and formula-fed infants.


Many of the oligosaccharides which are synthesised by the mammary gland and found in human milk have been characterised, but their functions are still incompletely understood. They represent about 27% of the carbohydrate in colostrum, a proportion which decreases as lactation progresses. In general, oligosaccharides in human milk differ from those in cows' milk-based formula and it has been suggested that in the future it may be appropriate to add oligosaccharides to formula, if those that would be of benefit to infants can be determined (Goedhart & Bindels, 1994). It is accepted that specific oligosaccharides influence the gut flora of the infant, favouring the growth of *Bifidobacteria*, a process which is enhanced by the presence of bifidus factor in breast milk. The proliferation of *Bifidobacteria* ensures the suppression of potentially pathogenic bacteria such as *E. coli*. Human milk oligosaccharides may also have the potential to inhibit adhesion of pathogens to the mucosal linings of the gut, the respiratory tract and the urinary tract.

It is known that breast milk is a rich source of sialylated oligosaccharides, which are found in only very small amounts in formulae. Brain gangliosides in the cerebral cortex contain high concentrations of sialic acid and, in the rat, administration of sialic acid results in increased concentration of sialic acid in



the brain. Human infants may not have a fully developed capacity to synthesise sialic acid from its precursors. When levels of salivary sialic acid were measured in neonates, infants fed human milk had double the amount of free sialic acid and 50% more total sialic acid compared with those who were formula fed. The additional sialic acid could critically influence developmental and intellectual scores of human infants during the early months of life (Tram *et al*, 1997). Further research will be required to validate these findings, but it looks likely that another functionally significant constituent of human milk is emerging.

### Protein



Human-milk proteins are synthesised in the mammary gland from free amino acids taken up from the mother's bloodstream. Relative to the milk of other mammals, the protein concentration of human milk is low, is related to the slower growth rate of infants, and necessitates frequent feeding in the early months. In cows' milk, about 20% of the energy is supplied by protein, in contrast to human milk in which protein supplies only 7%. The ratio between the protein fractions, casein and whey, also differs, as do the amino acid distributions within these fractions. During the course of lactation there is a reduction in the whey protein in human milk and a corresponding increase in casein.

Early formulae were relatively unmodified but, as the composition of breast milk and the nutritional requirements of infants are more clearly understood, the trend has been towards a gradual reduction of protein in formula milks (Fomon *et al*, 1995). The ratio between casein and whey can also be changed so that it resembles the casein:whey ratio of human milk. Whey-predominant formulae have a casein:whey ratio which is similar to breast milk. However, formula milks are derived from cows' milk and, even with the altered casein:whey ratio, their amino acid profiles differ significantly from breast milk (Harzer *et al*, 1984; Janas *et al*, 1985, 1987; Lönnerdal & Chen, 1990).

Human-milk whey, which contributes about 80% of the protein component, is made up of predominantly alpha-lactalbumin, lactoferrin and secretory IgA. Bovine whey, which is added to dried cows' milk to increase the ratio of whey to casein, is predominantly beta-lactoglobulin, the cows' milk protein with the highest antigenic activity (ESPGAN, 1982).  $\beta$ -casein is the predominant casein in human milk, whereas cows' milk contains a large proportion of  $\alpha$ -casein (Goedhart & Bindels, 1994). Differences between the caseins influence milk curd formation, gastric emptying and intestinal transit time. The differing amino acid contents of breast milk and formula result in variations in serum

amino acid profiles relative to feeding method (Janas *et al*, 1985, 1987; Fomon *et al*, 1995).

Lactoferrin is the second most predominant whey protein in human milk. Concentrations range from 1–2 to 5–7 g/l in mature milk and colostrum respectively. Cows' milk contains about 0.1 g/l. Human lactoferrin is acid resistant and passes through the hydrochloric acid of the stomach and the proteolytic enzymes of the digestive tract un-degraded (Iyer & Lönnerdal, 1993). Its functions include controlling the absorption of iron, binding iron in the gut, thereby making it unavailable to pathogenic organisms, and stimulating mucosal proliferation. Lactoferrin may also have bactericidal properties.

Secretory IgA contributes about 90% of human-milk immunoglobulin while, in cows' milk, IgG and IgM predominate. IgA acts along the mucosal linings of the gastrointestinal, urinary and respiratory tracts to inhibit the adhesion of pathogenic micro-organisms. Significant amounts of IgA, like lactoferrin, pass unchanged through the digestive system into the infant's gut, where, as well as adhering to the intestinal mucosa, it binds antigenic material which can then be cleared by peristalsis (Wright & Walker, 1987). The high concentration of IgA in human milk is one of the important factors which enhances the


immune response of the breastfed baby. Early milk is also rich in T and B lymphocytes, granulocytes and macrophages.

Lysozyme in human milk is found in concentrations 300 times greater than that of cows' milk. It acts as a bactericidal agent by attacking the cell wall of bacteria and enhancing the effect of immunoglobulins (ESPGAN, 1982).

Unlike formula, human milk contains small amounts of free amino acids and peptides which may have important functional significance. For example, a portion of urea nitrogen, which accounts for 30-50% of the non-protein nitrogen fraction, is reabsorbed in the intestine and recycled. This capacity to salvage nitrogen has two metabolic advantages for the breastfed neonate. Firstly, it reduces the need for excessive excretion of urea by the immature renal system, and secondly, it provides an intermediate regulatory system between the body's demand for amino acids and the dietary intake of protein. Other non-protein nitrogen compounds are known to influence the maturation of the gastrointestinal tract and cell proliferation and differentiation (Goedhart & Bindels, 1994).

Breast milk also contains nucleotides but their functional significance is not fully understood and, although their role has been investigated, results are inconclusive and they are not






currently added to all formulae (Janas & Picciano, 1982; Carver *et al*, 1991; Cosgrove *et al*, 1996). A recent publication suggests that breast milk and, to some degree, formula with added nucleotides stimulate the immune response to immunisation in a manner which is not apparent in infants fed infant formula which is not fortified with nucleotides (Pickering *et al*, 1998). Additional research is necessary to confirm or refute these findings.

### Minerals and trace elements

#### Calcium and phosphorus



Calcium and phosphorus levels of human milk are significantly lower than those of cows' milk and cows' milk-based infant formulae. However, as is discussed above, the absorption of these minerals is affected by compositional differences between human and formula milks, and bone mineralisation has been shown to be comparable in infants fed either type of milk. A recent paper has revealed that, in pre-term infants, who are deemed to be at greater risk of poor bone mineralisation, those fed maternal milk had the better bone density at age five years (Bishop *et al*, 1996). The low phosphorus level in human milk is thought to be advantageous to the infant because it contributes to the promotion of a non-pathogenic gut flora and helps to maintain low serum phosphorus levels, thereby minimising the risk of hypocalcaemia or metabolic acidosis.

#### Iron

Neither cows' milk nor human breast milk are good sources of iron, but absorption of iron from breast milk is efficient (Abrams *et al*, 1996); the high level of supplementary iron which is included in formula compensates for its significantly lower level of absorption. Currently, all formulae marketed in Ireland are iron fortified, with fortification levels ranging from about 7–12 mg/100 ml. However, the optimal level of fortification of formula remains controversial (Bradley *et al*, 1993; Schulz-Lell *et al*, 1987; Gill *et al*, 1997; Walter *et al*, 1998). Absorption of iron is inhibited by calcium and casein, both major constituents of cows' milk, and enhanced by reducing agents such as ascorbic acid, which is added to formulae. A recent study has shown that as the level of ascorbic acid fortification of formula was increased there was a corresponding increase in the level of hydroxyl-radical production. Addition of ascorbic acid to breast milk resulted in significantly less radical production than equivalent addition to low iron formula. A variety of hypotheses are put forward by the authors as to why this difference exists. They conclude that the issue requires further investigation but should be borne in mind when determining the optimal level of iron fortification for formulae (Almaas *et al*, 1997).

It has been shown that post-natal iron stores usually supply enough iron for term infants

until about four months of age and that, during this period, no additional dietary iron is needed (Hemminki *et al*, 1995). Arguments against the unnecessary fortification of formula include the concern that unabsorbed iron passes into the infant's gastrointestinal tract and provides a ready nutrient source for pathogenic bacteria. The lower level of iron in breast milk results in less free iron remaining in the gut. Lactoferrin from breast milk further deprives pathogens of access to unabsorbed iron. Lower intakes also result in lower iron stores which, in turn, enhances iron absorption in breastfed babies. As iron stores decrease, absorption increases.

### **Zinc**

The zinc content of human breast milk falls during the course of lactation; colostrum contains  $176 \pm 72 \mu\text{mol/l}$ , while levels at one and seven months have been recorded as  $44.3 \pm 10.7 \mu\text{mol/l}$  and  $7.6 \pm 4.7 \mu\text{mol/l}$  respectively (Aggett, 1994). Zinc absorption from human milk is more efficient than from soya or cows' milk-based formula in which phytate acts as an inhibitor (Casey *et al*, 1981). Zinc intake from human milk appears to be adequate to maintain zinc status in infants exclusively breastfed to age five months (Krebs *et al*, 1994).


### **Selenium**

Selenium is an important antioxidant,


influences growth, is essential for the synthesis and activity of glutathione peroxidase and is well absorbed from breast milk. Maternal dietary factors also influence selenium concentrations in breast milk. How much selenium should be added to formula is still not clear, but the addition of selenium has been shown to be beneficial for the pre-term infant (Daniels *et al*, 1996). Selenium levels of mature human milk range from  $12\text{--}20 \mu\text{g/l}$ , while formulae which are not selenium-fortified contain  $3\text{--}9 \mu\text{g/l}$ . Higher intakes and enhanced selenium absorption from breast milk result in higher serum selenium concentrations and higher retention in infants fed human milk (Kumpulainen *et al*, 1987; Goedhart & Bindels, 1994).

### **Breast milk and gastrointestinal maturation**

In the early post-natal weeks, significant development of the gastrointestinal tract takes place. Human milk contains hormones, peptides, amino acids and glycoproteins which have the potential to promote the maturational process, involving changes in villous membrane composition, cell differentiation and nutrient transport processes. Variations in intestinal permeability can potentially influence antigen and bacterial diffusion across the intestinal mucosa. In a group of healthy term neonates, intestinal permeability was shown to diminish more by



day seven in infants who were exclusively breastfed than in those fed a cows' milk-based formula or a partially hydrolysed hypoallergenic formula (Catassi *et al*, 1995). This effect may explain the protective effect of breastfeeding against atopy (Saarinen & Kajosaari, 1995). Gastric emptying is also known to be faster following the feeding of human milk (Schanler, 1995).



## APPENDIX D: RECOMMENDED DIETARY ALLOWANCES FOR INFANTS

Recommended dietary allowances are levels of intake of a nutrient which are estimated to satisfy the requirements of 97.5% of the

population. They are designed for use in population groups, not in individuals.

**Table of recommended dietary allowances for infants  
(Department of Health [UK], 1991).**

Age (months)	0–3	4–6	7–9	10–12
Weight* (Kg)	5.9	7.7	8.8	9.7
Energy (Mj/d)				
males	2.28	2.89	3.44	3.85
females	2.16	2.69	3.20	3.61
Protein g/d	12.5	12.7	13.7	14.9
Vitamin A# µg/d	350	350	350	350
Thiamin mg/d	0.2	0.2	0.2	0.3
Riboflavin mg/d	0.4	0.4	0.4	0.4
Niacin† mg/d	3	3	4	5
Vitamin B <sub>6</sub> mg/d	0.2	0.2	0.3	0.4
Vitamin B <sub>12</sub> µg/d	0.3	0.3	0.4	0.4
Folate µg/d	50	50	50	50
Vitamin C mg/d	25	25	25	25
Vitamin D µg/d	8.5	8.5	7	7
Calcium mg/d	525	525	525	525
Magnesium mg/d	55	60	75	80
Sodium mg/d	210	280	320	350
Potassium mg/d	800	850	700	700
Chloride <sup>f</sup> mg/d	320	400	500	500
Iron mg/d	1.7	4.3	7.8	7.8
Zinc mg/d	4.0	4.0	5.0	5.0
Copper mg/d	0.3	0.3	0.3	0.3
Selenium µg/d	10	13	10	10
Iodine µg/d	50 <sup>‡</sup>	60	60	60


\* Where applicable

# µg retinol equivalent/d

† mg niacin equivalent/1000 kcal

‡ formula fed

<sup>f</sup> Corresponds to sodium 1 mmol = 35.5 mg



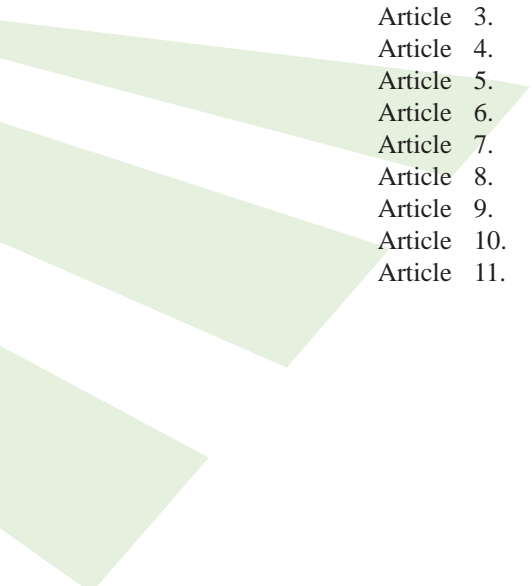
**APPENDIX E**  
**INTERNATIONAL CODE OF MARKETING**  
**OF BREAST-MILK SUBSTITUTES, 1981**

*International Code of Marketing  
of Breast-Milk Substitutes*

World Health Organization

Geneva  
1981

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The Member States of the World Health Organization:

Affirming the right of every child and every pregnant and lactating woman to be adequately nourished as a means of attaining and maintaining health;

Recognizing that infant malnutrition is part of the wider problems of lack of education, poverty, and social injustice;

Recognizing that the health of infants and young children cannot be isolated from the health and nutrition of women, their socio-economic status and their roles as mothers;

Conscious that breast-feeding is an unequalled way of providing ideal food for the healthy growth and development of infants; that it forms a unique biological and emotional basis for the health of both mother and child; that the anti-infective properties of breast milk help to protect infants against disease; and that there is an important relationship between breast-feeding and child-spacing;


Recognizing that the encouragement and protection of breast-feeding is an important part of the health, nutrition and other social measures required to promote healthy growth and development of infants and young children; and that breast-feeding is an important aspect of primary health care;

Considering that when mothers do not breast-feed, or only do so partially, there is a legitimate market for infant formula and for suitable ingredients from which to prepare it; that all these products should accordingly be made accessible to those who need them through commercial or non-commercial distribution systems; and that they should not be marketed or distributed in ways that may interfere with the protection and promotion of breast-feeding;

Recognizing further that inappropriate feeding practices lead to infant malnutrition, morbidity and mortality in all countries, and that improper practices in the marketing of breast-milk substitutes and related products can contribute to these major public health problems;

Convinced that it is important for infants to receive appropriate complementary foods, usually when the infant reaches four to six months of age, and that every effort should be made to use locally available foods; and convinced, nevertheless, that such complementary foods should not be used as breast-milk substitutes;

Appreciating that there are a number of social and economic factors affecting breast-feeding, and that, accordingly, governments should develop social support systems to protect, facilitate and encourage it, and that they should create an environment that fosters



breast-feeding, provides appropriate family and community support, and protects mothers from factors that inhibit breastfeeding;

Affirming that health care systems, and the health professionals and other health workers serving in them, have an essential role to play in guiding infant feeding practices, encouraging and facilitating breast-feeding, and providing objective and consistent advice to mothers and families about the superior value of breast-feeding, or, where needed, on the proper use of infant formula, whether manufactured industrially or home-prepared;

Affirming further that educational systems and other social services should be involved in the protection and promotion of breastfeeding, and in the appropriate use of complementary foods;

Aware that families, communities, women's organizations and other nongovernmental organizations have a special role to play in the protection and promotion of breast-feeding and in ensuring the support needed by pregnant women and mothers of infants and young children, whether breast-feeding or not;

Affirming the need for governments, organizations of the United Nations system, nongovernmental organizations, experts in various related disciplines, consumer groups and industry to cooperate in activities aimed at the improvement of maternal, infant and young child health and nutrition;

Recognizing that governments should undertake a variety of health, nutrition and other social measures to promote healthy growth and development of infants and young children, and that this Code concerns only one aspect of these measures;

Considering that manufacturers and distributors of breast-milk substitutes have an important and constructive role to play in relation to infant feeding, and in the promotion of the aim of this Code and its proper implementation;

Affirming that Governments are called upon to take action appropriate to their social and legislative framework and their overall development objectives to give effect to the principles and aim of this Code, including the enactment of legislation, regulations or other suitable measures;

Believing that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products;

THEREFORE:

The Member States hereby agree the following articles which are recommended as a basis for action.

***Article 1. Aim of the Code***

The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

***Article 2. Scope of the Code***

The Code applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.

***Article 3. Definitions***

For the purposes of this Code:

"Breast-milk substitute"	means any food being marketed or otherwise represented as a partial or total replacement for breast-milk, whether or not suitable for that purpose.
"Complementary food"	means any food, whether manufactured or locally prepared, suitable as a complement to breast-milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called "weaning food" or "breast-milk supplement".
"Container"	means any form of packaging of products for sale as a normal retail unit, including wrappers.





"Distributor"

means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.

"Health care system"

means governmental, nongovernmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets.

"Health worker"

means a person working in a component of such a health care system, whether professional or non-professional, including voluntary, unpaid workers.

"Infant formula"

means a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics. Infant formula may also be prepared at home, in which case it is described as "home-prepared".

"Label"


means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container (see above) of any products within the scope of this Code.

"Manufacturer"	means a corporation or other entity in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code.
"Marketing"	means product promotion, distribution, selling, advertising, product public relations, and information services.
"Marketing personnel"	means any persons whose functions involve the marketing of a product or products coming within the scope of this Code.
"Samples"	means single or small quantities of a product provided without cost.
"Supplies"	means quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.

#### ***Article 4. Information and education***

4.1. Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover either the planning, provision, design and dissemination of information, or their control.

4.2. Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include clear information on all the following points: (a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; (d) the difficulty of reversing the decision not to breast-feed; and (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breast-milk



substitutes. Such materials should not use any pictures or text which may idealize the use of breast-milk substitutes.

4.3. Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval of the appropriate Government authority or within Guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.

#### ***Article 5. The general public and mothers***

5.1. There should be no advertising or other form of promotion to the general public of products within the scope of this Code.

5.2. Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.

5.3. In conformity with paragraphs 1 and 2 of this Article, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.

5.4. Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.

5.5. Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

#### ***Article 6. Health care systems***

6.1. The health authorities in Member States should take appropriate measures to encourage and protect breast-feeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2.

6.2. No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Article 7.2.

6.3. Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in Article 4.3.

6.4. The use by the health care system of "professional service representatives", "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.

6.5. Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary, and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.

6.6. Donations or low-price sales to institutions or organizations of supplies of infant formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organizations concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement.

6.7. Where donated supplies of infant formula or other products within the scope of this Code are distributed outside an institution, the institution or organization should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.

6.8. Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.

#### ***Article 7. Health workers***

7.1. Health workers should encourage and protect breast-feeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.

7.2. Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. It should also include the information specified in Article 4.2.

7.3. No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.

7.4. Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.

7.5. Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

#### ***Article 8. Persons employed by manufacturers and distributors***

8.1. In systems of sales incentives for marketing personnel, the volume of sales of products within the scope of this Code should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.

8.2. Personnel employed in marketing products within the scope of this Code should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children. This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with the written approval of the appropriate authority of the government concerned.

#### ***Article 9. Labelling***

9.1. Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.

9.2. Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points: (a) the words "Important Notice" or their equivalent; (b) a statement of the superiority of breast-feeding; (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; (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. Neither the

container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation. The terms "humanized", "maternalized" or similar terms should not be used. Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.

9.3. Food products within the scope of this Code, marketed for infant feeding, which do not meet *all* the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of infant formula, its label should not contain purported instructions on how to modify it for that purpose.

9.4. The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used; (b) the composition/analysis of the product; (c) the storage conditions required; and (d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.


#### ***Article 10. Quality***

10.1. The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognized standard.

10.2. Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.

#### ***Article 11. Implementation and monitoring***

11.1. Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures. For this purpose, governments should seek, when necessary, the cooperation of WHO, UNICEF and other agencies of the United Nations system. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of products within the scope of this Code.



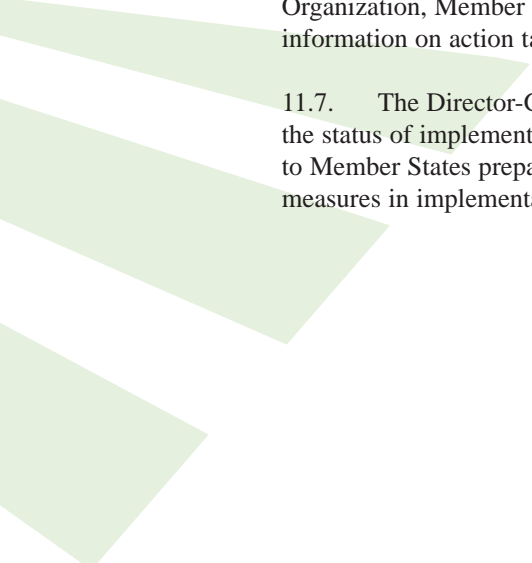
11.2. Monitoring the application of this Code lies with governments acting individually and collectively through the World Health Organization as provided in paragraphs 6 and 7 of this Article. The manufacturers and distributors of products within the scope of this Code, and appropriate nongovernmental organizations, professional groups, and consumer organizations should collaborate with governments to this end.

11.3. Independently of any other measures taken for implementation of this Code, manufacturers and distributors of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.

11.4. Nongovernmental organizations, professional groups, institutions, and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed.

11.5. Manufacturers and primary distributors of products within the scope of this Code should apprise each member of their marketing personnel of the Code and of their responsibilities under it.

11.6. In accordance with Article 62 of the Constitution of the World Health Organization, Member States shall communicate annually to the Director-General information on action taken to give effect to the principles and aim of this Code.



11.7. The Director-General shall report in even years to the World Health Assembly on the status of implementation of the Code; and shall, on request, provide technical support to Member States preparing national legislation or regulations, or taking other appropriate measures in implementation and furtherance of the principles and aim of this Code.

**APPENDIX F**

**STATUTORY INSTRUMENTS**

**S.I. No. 243 of 1998**

**EUROPEAN COMMUNITIES (INFANT FORMULAE  
AND FOLLOW-ON FORMULAE) REGULATIONS, 1998**

Dublin

Published by the Stationery Office





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## S.I. No. 243 of 1998

### EUROPEAN COMMUNITIES (INFANT FORMULAE AND FOLLOW-ON FORMULAE) REGULATIONS, 1998

I, BRIAN COWEN, Minister for Health and Children in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No. 27 of 1972), having regard to Council Directive 89/398/EEC<sup>1</sup> of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses as amended by Directive 96/84/EC<sup>2</sup> of the European Parliament and of the Council of 19 December 1996 and for the purposes of giving effect to Commission Directive 91/321/EEC<sup>3</sup> of the 14th of May, 1991 and Council Directive 92/52/EEC<sup>4</sup> of the 18th June, 1992 and Commission Directive 96/4/EC<sup>5</sup> of the 16th February 1996, hereby make the following Regulations:

#### **Title, Commencement and Interpretation**

1. These Regulations may be cited as the European Communities (Infant Formulae and Follow-on Formulae) Regulations, 1998.
2.
  - (1) These Regulations shall come into operation on the 17th day of July, 1998.
  - (2) Trade in products which do not comply with these Regulations is prohibited with effect from 31 March 1999.
3.
  - (1) In these Regulations:  

"advertising" means the making of any pronouncement in the course of a trade, business or profession for the purpose of promoting the supply of goods or services;

"authorised officer" means

    - (a) an officer of the Minister for Health and Children who is authorised in writing by the Minister for Health and Children to be an authorised officer for the purposes of these Regulations; or
    - (b) an officer of a health board who is authorised in writing by the Chief Executive Officer of the health board to be an authorised officer for the purposes of these Regulations.

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<sup>1</sup> OJ No. L 186, 30.6.1989, p.27

<sup>2</sup> OJ No. L 48, 19.2.1997, p.20

<sup>3</sup> OJ No. L 175, 4.7.1991, p.35

<sup>4</sup> OJ No. L179, 1.7.1992, p.129

<sup>5</sup> OJ No. L 49/12, 28.2.1996, p.12

"export" means to market a product in a country outside the European Union;

"follow-on formulae" means foodstuffs intended for particular nutritional use by infants in good health aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons;

"health board" means a health board established under Section 4(1) of the Health Act, 1970 (No.1 of 1970);

"health care system" means institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child-care institutions and health workers in private practice;

"infant formulae" means foodstuffs intended for particular nutritional use by infants in good health during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;

"infant milk" and "follow-on milk" means products within the meaning of these Regulations manufactured entirely from cows' milk proteins;

"infants" means children under the age of twelve months;

"labelling" means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a product and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such product;

"to market" includes to supply, whether or not for profit, offer, expose for sale and/or have in possession for sale and cognate words shall be construed accordingly;

"Minister" means the Minister for Health and Children;

"presentation" in relation to an infant formula or a follow-on formula, includes the shape, form, aspect, appearance or packaging of the product concerned, the packaging materials used, the way in which the product is arranged when it is exposed for sale and/or the setting in which the product is displayed with a view to sale, but does not include any form of labelling or advertising;

"product" means infant formulae and/or follow-on formulae as appropriate;

"young children" means children aged between one and three years.

(2) In these Regulations any reference to an article or Schedule shall be construed as a reference to an article contained in these Regulations or, as

the case may be, to a Schedule thereto and any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article unless otherwise stated.


- (3) A word or expression that is used in these Regulations and is also used in Council Directive 89/398/EEC, Directive 96/84/EC of the European Parliament and of the Council, Commission Directive 91/321/EEC, Council Directive 92/52/EEC and Commission Directive 96/4/EC has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council, Commission and Parliament Directives.

#### **Conditions for the Marketing of Infant Formula and Follow-on Formula**

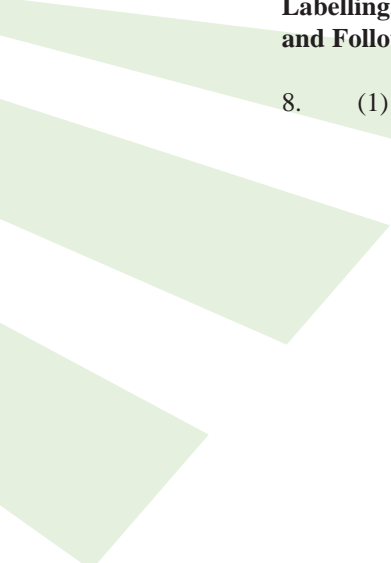
4. (1) The name under which the products defined in Article 3(1) are marketed shall be, respectively, "infant formula" and "follow-on formula" and in the case of products manufactured entirely from cows' milk proteins, "infant milk" and "follow-on milk".
- (2) No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.
- (3) No foodstuff other than infant formula may be marketed as suitable for infants aged under four months.
- (4) It shall be an offence to market the products defined in Article 3(1) which do not comply with these Regulations.

#### **Composition of Infant Formula and Follow-on Formula**

5. (1) Infant formulae shall be manufactured from protein sources defined in the Schedules to these Regulations and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has, in the opinion of the Minister, been established by generally accepted scientific data.
- (2) Follow-on formulae shall be manufactured from protein sources defined in the Schedules to these Regulations and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over four months has, in the opinion of the Minister, been established by generally accepted scientific data.
- (3) The use of food ingredients is subject to the prohibitions and limitations specified in Schedules I and II to these Regulations.
- (4) The Minister may, when forming an opinion in accordance with sub-articles (1) and (2) of this Article, have regard to the views of such persons or authorities as he considers appropriate.

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6.
    - (1) Infant formulae shall comply with the compositional criteria specified in Schedule I.
    - (2) Follow-on formulae shall comply with the compositional criteria specified in Schedule II.
    - (3) For the purpose of making infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.
    - (4) No substance other than a substance specified in Schedule III may be used in the manufacture of infant formulae and follow-on formulae for the purposes of satisfying the requirements on:
      - mineral substances,
      - vitamins,
      - amino acids and other nitrogen compounds,
      - other substances having a particular nutritional purpose.
    - (5) Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.
  7.
    - (1) The Minister may, by order, stipulate the maximum levels of any substance included in infant formulae or follow-on formulae.
    - (2) The Minister may by order establish such microbiological criteria as he considers appropriate.

#### **Labelling, Advertising and Presentation of Infant Formula and Follow-on Formula**

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8.
    - (1) The labelling of infant formulae shall bear the following particulars in addition to general EU and national labelling requirements:
      - (a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast-fed;
      - (b) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;
      - (c) the available energy value, expressed in kJ and kcal expressed in numerical form, per 100 ml of the product ready for use;
      - (d) the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;
      - (e) the average quantity of each mineral substance and of each vitamin mentioned in Schedule I, expressed in numerical form, per 100 ml of the product ready for use;
      - (f) where applicable, the average quantity of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use;

- (g) instructions for appropriate preparation of the product;
  - (h) a warning against the health hazards of inappropriate preparation.
  - (2) The labelling of infant formulae may bear the average quantity of nutrients mentioned in Schedule III when such declaration is not covered by the provisions of paragraphs (e) and (f) of sub-article (1) of this Article, expressed in numerical form, per 100 ml of the product ready for use.
  - (3) Without prejudice to sub-article (1) the labelling of infant formulae shall also fulfil the following requirements:
    - (a) it shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding;
    - (b) the use of the terms "humanised", "maternalised" or similar terms shall be prohibited;
    - (c) the term "adapted" may only be used in conformity with sub-article (4) paragraph (b) of this Article and Schedule IV, point 1;
    - (d) the label shall include the following particulars, preceded by the words "Important Notice" or their equivalent:
      - (i) a statement concerning the superiority of breast-feeding,
      - (ii) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, midwives, public health nurses, general practitioners or other professionals responsible for maternal and child care;
    - (e) the label shall not include:
      - (i) pictures of infants,
      - (ii) other pictures or text which may idealise the use of the product.
  - (4) The labelling of infant formulae may:
    - (a) have graphic representations for easy identification of the product and for illustrating methods of preparation;
    - (b) bear claims concerning the special composition of an infant formula only in the cases listed in Schedule IV and in accordance with the conditions laid down therein.
  - (5) The requirements, prohibitions and restrictions referred to in sub-articles (3) and (4) shall also apply in respect of the products concerned in relation to:
    - (i) advertising
    - (ii) presentation.
9. (1) The labelling of follow-on formulae shall bear the following particulars in addition to general EU and national labelling requirements:
- (a) a statement which specifies the minimum age of the infant for whom the product is suitable and such minimum age so specified shall be not less than four months;
  - (b) that it should form only part of a diversified diet;
  - (c) that it is not to be used as a substitute for breast milk during the first four months of life;

- (d) the available energy value, expressed in kJ and kcal, expressed in numerical form, per 100 ml of the product ready for use;
  - (e) the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;
  - (f) the average quantity of each mineral substance and of each vitamin mentioned in Schedule II, expressed in numerical form, per 100 ml of the product ready for use;
  - (g) where applicable, the average quantity of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use;
  - (h) instructions for appropriate preparation of the product;
  - (i) a warning against the health hazards of inappropriate preparation;
  - (j) in addition to numerical information, information on vitamins and minerals included in Schedule VIII expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference values.
- (2) The labelling of follow-on formulae may bear the average quantity of nutrients mentioned in Schedule III when such declaration is not covered by the provisions of paragraphs (f) and (g) of sub-article (1) of this Article, expressed in numerical form, per 100 ml of the product ready for use.
- (3) Without prejudice to sub-article (1) the labelling of follow-on formulae shall also fulfil the following requirements:
- (a) It shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding;
  - (b) the use of the terms "humanised", "maternalised" or similar terms shall be prohibited;
  - (c) the packaging at the point of sale shall, to the satisfaction of the Minister, ensure a clear distinction is made between infant formulae and follow-on formulae.
- (4) The requirements, prohibitions and restrictions referred to in sub-article (3) shall also apply in respect of the products concerned in relation to:
- (i) advertising
  - (ii) presentation.
10. (1) Advertising of infant formulae shall be subject to the conditions laid down in Article 8(3) and 8(4).
- (2) Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications.
- (3) The Minister may from time to time by order restrict or prohibit such forms of advertising or promotion, either directly or indirectly, of infant formulae as he considers necessary.

- (4) Advertisements for infant formulae shall contain only information which is, in the opinion of the Minister, of a scientific and factual nature, such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.
- (5)
  - (a) There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formulae directly to the consumer at the retail level;
  - (b) Without prejudice to the generality of paragraph (a) of this sub-article the following are prohibited: special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.
- (6) The provision of free or low-priced products, samples or any other promotional gifts to the general public, including, *inter alia*, pregnant women, mothers or members of their families, either directly or indirectly, via the health care system or health workers by manufacturers and distributors of infant formulae or their associates, is prohibited.

#### **Provision of Information and Education Regarding Infant and Young Child Feeding**

- 11.
  - (1) Information provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition shall be objective and consistent in its planning, provision, design and dissemination.
  - (2) Informational and educational materials including, *inter alia*, written and audiovisual materials, in relation to the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all of the following:
    - (a) the benefits and superiority of breast-feeding;
    - (b) the importance of maternal nutrition and the preparation for and maintenance of breast-feeding;
    - (c) the possible negative effect on breast-feeding of introducing partial bottle-feeding;
    - (d) the difficulty of reversing the decision not to breast-feed;
    - (e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.
  - (3) Any material referred to in sub-article (1) shall not use any pictures which may idealise the use of infant formulae. Any such material containing information about the use of infant formulae shall include:
    - (a) the social and financial implications of its use;
    - (b) the health hazards of inappropriate foods or feeding methods;
    - (c) the health hazards of improper use of infant formulae.



### **Donations of Low-Price Sales of Supplies of Infant Formula and Informational and Educational Equipment to Institutions**

12. (1) Donations or low-price sales of supplies of infant formulae to institutions or organisations, whether for use in the institutions or for distribution outside them, shall ensure that those products may only be used by, or distributed for, infants who have to be fed on infant formulae and only for as long as required by such infants and may be made only in accordance with guidelines, if any, approved by the Minister.
- (2) (a) Donations of informational or educational equipment or materials by manufacturers or distributors or by persons or individuals associated with manufacturers or distributors shall be made only on request of the intended recipient and within guidelines, if any approved by the Minister.
- (b) Such equipment or materials:
  - (i) may bear the donating company's name or logo;
  - (ii) shall not refer to a proprietary brand of infant formulae;
  - (iii) shall be distributed only through the health care system.

### **Codes of Practice**

13. (1) The Minister may by order approve of such codes of practice, including guidelines at Article 12(1) and (2) which he may consider will assist industry and other affected organisations to comply with the provisions of these Regulations and codes so ordered shall form part of these Regulations.
- (2) The Minister may withdraw any approval referred to in sub-article (1) as he sees fit.

### **Export of Infant Formula and Follow-on Formula**

14. (1) Infant formulae and follow-on formulae intended for export shall comply with:
  - (a) (i) the requirements of Articles 5, 6 and 7 of these Regulations or
  - (ii) a relevant applicable world standard established by Codex Alimentarius;
  - (b) the provisions of Articles 8(1) to 8(4) and 9(1) to 9(3) of these Regulations;
  - (c) the provisions of Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which the product belongs; unless otherwise requested or stipulated by provisions established by the importing country.


- (2) The labelling of infant formulae and follow-on formulae intended for export shall be in an appropriate language and ensure that a clear distinction is made between infant formulae and follow-on formulae.
- (3) The stipulations, prohibitions and restrictions laid down in Articles 8(1) to 8(4) and 9(1) to 9(3) of these Regulations shall also apply to the presentation of the products concerned intended for export and in particular their form, aspect or packaging and the packaging materials used.
- (4) No product other than infant formula may be represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

#### **Enforcement**


15. These Regulations shall be enforced and executed by each health board in respect of its functional area through its authorised officers and/or the officers of the Minister for Health and Children who are authorised officers for the purposes of these Regulations.
16. For the purposes of ensuring compliance with these Regulations, the provisions of the European Communities (Official Control of Food) Regulations, 1998 (S.I. No. 85 of 1998) shall apply.

#### **Offences**

17. (1) A person shall not manufacture, prepare, import, export, distribute, market, advertise and/or label any product or promotional material which does not comply with these Regulations.
- (2) Any person who contravenes any article or sub-article of these Regulations shall be guilty of an offence.
- (3) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,000 or at the discretion of the Court, to imprisonment for a term not exceeding six months or to both.
- (4) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of a director, secretary or other officer of the body corporate, the director, secretary or other officer or any person purporting to act in such capacity shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against and punished accordingly.
- (5) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted within twelve months from the date of the offence or any time within twelve months from the date on which knowledge of the commission of the offence came to the attention of an authorised officer.

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18. (1) An offence under these Regulations shall be prosecuted by the Minister for Health and Children or, subject to the provisions of sub-article (2), by a health board in whose functional area the offence was committed.  
(2) Legal proceedings arising from contraventions of any or all of Articles 8, 9, 10, 11 and 12 shall be initiated by the health board only with the consent of the Minister for Health and Children.
  19. (1) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and when exercising any power conferred on an authorised officer by these Regulations shall, if so requested by a person affected, produce the certificate for the inspection of the person.  
(2) It shall be offence for a person falsely to represent himself to be an authorised officer.
  20. A health board shall
    - (a) forward to the Minister such information as he may request in respect of the exercise of the functions conferred on it by or under these Regulations;
    - (b) comply with any directions given by the Minister from time to time as to the exercise of its powers or the performance of its functions and duties under these Regulations.

#### **Revocation**

21. (1) The European Communities (Infant Formulae) Regulations, 1994 (S.I. No. 459 of 1994) are hereby revoked.  
(2) References in another instrument to any of the Regulations revoked under sub-article (1) shall be construed as references to these Regulations, as appropriate.
- 

## SCHEDULE I

### ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB: the values refer to the product ready for use

#### 1. ENERGY

Minimum	Maximum
250 kJ	315 kJ
(60 kcal/100 ml)	(75 kcal/100 ml)

#### 2. PROTEIN

(protein content = nitrogen content x 6.38) for cows' milk proteins.

(protein content = nitrogen content x 6.25) for soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

##### 2.1. Formulae manufactured from cows' milk proteins

Minimum	Maximum
0.45 g/100 kJ	0.7 g/100 kJ
(1.8 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

##### 2.2. Formulae manufactured from protein partial hydrolysates

Minimum	Maximum
0.56 g/100 kJ	0.7 g/100 kJ
(2.25 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

The protein efficiency ratio (PER) and the net protein utilisation (NPU) must be at least equal to those of casein.

The taurine content shall be equal to at least 10 mmol/100 kJ (42 mmol/100 kcal) and the L-carnitine content shall be equal to at least 1.8 mmol/100 kJ (7.5 mmol/100 kcal).

**2.3. Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins**

<b>Minimum</b>	<b>Maximum</b>
0.56 g/100 kJ (2.56 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

Only soya protein isolates must be used in manufacturing these formulae.

The Chemical Index shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Schedule VI).

For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Schedule V).

The L-carnitine content shall be at least equal to 1.8  $\mu$ mol/100 kJ (7.5  $\mu$ mol/100 kcal).

**2.4.** In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

**3. LIPIDS**

<b>Minimum</b>	<b>Maximum</b>
1.05 g/100 kJ (4.4 g/100 kcal)	1.5 g/100 kJ (6.5 g/100 kcal)

**3.1. The use of the following substances is prohibited:**

- sesame seed oil,
- cotton seed oil.

### 3.2. Lauric Acid

Minimum	Maximum
-	15% of the total fat content

### 3.3. Myristic Acid

Minimum	Maximum
-	15% of the total fat content

### 3.4. Linoleic Acid (in the form of glycerides = linoleates)

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal)	285 mg/100 kJ (1,200 mg/100 kcal)

3.5. The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal). The linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

3.6. The trans fatty acid content shall not exceed 4% of the total fat content.

3.7. The erucic acid content shall not exceed 1% of the total fat content.

3.8. Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

- 1% of the total fat content for n-3 LCP and
- 2% of the total fat content for n-6 LCP (1% of the total fat content for arachidonic acid)
- The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

## 4. CARBOHYDRATES

Minimum	Maximum
1.7 g/100 kJ (7 g/100 kcal)	3.4g/100 kJ (14 g/100 kcal)

4.1. Only the following carbohydrates may be used:

- lactose
- maltose
- sucrose
- malto-dextrins

- glucose syrup or dried glucose syrup
- pre-cooked starch naturally free of gluten
- gelatinised starch naturally free of gluten

#### 4.2. Lactose

Minimum	Maximum
0.85 g/100 kJ	-
(3.5 g/100 kcal)	-

This provision does not apply to formulae in which soya proteins represent more than 50% of the total protein content.

#### 4.3. Sucrose

Minimum	Maximum
-	20% of the total carbohydrate content

#### 4.4. Pre-cooked starch and/or gelatinised starch

Minimum	Maximum
-	2 g/100 ml, and 30% of the total carbohydrate content

### 5. MINERAL SUBSTANCES

#### 5.1. Formulae manufactured from cows' milk proteins

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
sodium (mg)	5	14	20	60
Potassium (mg)	15	35	60	145
chloride (mg)	12	29	50	125
calcium (mg)	12	-	50	-
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
iron (mg) <sup>(1)</sup>	0.12	0.36	0.5	1.5
zinc (mg)	0.12	0.36	0.5	1.5
copper (µg)	4.8	19	20	80
iodine (µg)	1.2	-	5	-
Selenium (µg) <sup>(2)</sup>	-	0.7	-	3

<sup>(1)</sup> limit applicable to formulae with added iron.

<sup>(2)</sup> limit applicable to formulae with added selenium.

The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.

## 5.2. Formulae manufactured from soya proteins alone or in a mixture with cows' milk proteins

All requirements of paragraph 5.1 are applicable except those concerning iron and zinc, which are as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.25	0.5	1	2
Zinc (mg)	0.18	0.6	0.75	2.4

## 6. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A ( $\mu\text{g-E}$ ) <sup>(1)</sup>	14	43	60	180
Vitamin D ( $\mu\text{g}$ ) <sup>(2)</sup>	0.25	0.65	1	2.5
Thiamin ( $\mu\text{g}$ )	10	-	40	-
Riboflavin ( $\mu\text{g}$ )	14	-	60	-
Niacin ( $\mu\text{g-NE}$ ) <sup>(3)</sup>	0.2	-	0.8	-
Pantothenic acid ( $\mu\text{g}$ )	70	-	300	-
Vitamin B <sub>6</sub> ( $\mu\text{g}$ )	9	-	35	-
Biotin ( $\mu\text{g}$ )	0.4	-	1.5	-
Folic acid ( $\mu\text{g}$ )	1	-	4	-
Vitamin B <sub>12</sub> ( $\mu\text{g}$ )	0.025	-	0.1	-
Vitamin C ( $\mu\text{g}$ )	1.9	-	8	-
Vitamin K ( $\mu\text{g}$ )	1	-	4	-
Vitamin E (mg $\alpha\text{-TE}$ ) <sup>(4)</sup>	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ	-	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal	-

<sup>(1)</sup> RE = all trans retinol equivalent.

<sup>(2)</sup> in the form of cholecalciferol, of which 10  $\mu\text{g}$  = 400 i.u. of vitamin D.

<sup>(3)</sup> NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60.

<sup>(4)</sup>  $\alpha\text{-TE}$  = d- $\alpha$ -tocopherol equivalent.



**7. THE FOLLOWING NUCLEOTIDES MAY BE ADDED:**

	Maximum <sup>(1)</sup>	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0.60	2.50
uridine 5'-monophosphate	0.42	1.75
adenosine 5'-monophosphate	0.36	1.50
guanosine 5'-monophosphate	0.12	0.50
inosine 5'-monophosphate	0.24	1.00

<sup>(1)</sup> The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/100 kcal)

## SCHEDULE II

### ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB: the values refer to the product ready for use

#### 1. ENERGY

Minimum	Maximum
250 kJ/100 ml (6 kcal/100 ml)	335 kJ/100 ml (80 kcal/100 ml)

#### 2. PROTEINS

(protein content = nitrogen content x 6.38) for cows' milk proteins.  
(protein content = nitrogen content x 6.25) for soya protein isolates.

Minimum	Maximum
0.5 g/100 kJ (225 g/100 kcal)	1 g/100 kJ (4.5 g/100 kcal)

The Chemical Index of the proteins present shall be at least equal to 80% of that of the reference protein (casein or breast milk as defined in Schedule VI).

The Chemical Index shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used.

Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.

For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Schedule V.

#### 3. LIPIDS

Minimum	Maximum
0.8 g/100 kJ (3.3 g/100 kcal)	1.5 g/100 kJ (6.5 g/100 kcal)

**3.1. The use of the following substances is prohibited:**

- sesame seed,
- cotton seed oil.

**3.2. Lauric Acid**

Minimum	Maximum
-	15% of the total fat content

**3.3. Myristic Acid**

Minimum	Maximum
-	15% of the total fat content

**3.4. Linoleic Acid (in the form of glycerides = linoleates)**

Minimum	Maximum
70 mg/100 kJ (300 mg/100 kcal) this limit applies only to follow-on formulae containing vegetable oils	-

**3.5.** The trans fatty acid content shall not exceed 4% of the total fat content.

**3.6.** The erucic acid content shall not exceed 1% of the total fat content.

**4. CARBOHYDRATES**

Minimum	Maximum
1.7 g/100 kJ (7 g/100 kcal)	3.4 g/100 kJ (14 g/100 kcal)

**4.1. Gluten**

The use of ingredients containing gluten is prohibited.

**4.2. Lactose**

Minimum	Maximum
0.45 g/100 kJ (1.8 g/100 kcal)	-
	-

This provision does not apply to follow-on formulae in which soya protein isolates represent more than 50% of the total protein content.

#### 4.3. Sucrose, Fructose, Honey

Minimum	Maximum
-	separately or as a whole: 20% of the total carbohydrate content

### 5. MINERAL SUBSTANCES

#### 5.1.

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.25	0.5	1	2
Iodine (µg)	1.2	-	5	-

#### 5.2. Zinc

##### 5.2.1. Follow-on formulae manufactured entirely from cows' milk

Minimum	Maximum
0.12 mg/100 kJ	-
(0.5 mg/100 kcal)	-

##### 5.2.2. Follow-on formulae containing soya protein isolates, or mixed with cows' milk

Minimum	Maximum
0.18 mg/100 kJ	-
(0.5 mg/100 kcal)	-

#### 5.3. Other Mineral Substances

The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Schedule VII.

#### 5.4. Calcium/Phosphorus Ratio

The calcium/phosphorus ratio shall not exceed 2.0.

## 6. VITAMINS

	per 100 KJ		per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A ( $\mu\text{g-E}$ ) <sup>(1)</sup>	14	43	60	180
Vitamin D ( $\mu\text{g}$ ) <sup>(2)</sup>	0.25	0.75	1	3
Vitamin C ( $\mu\text{g}$ )	1.9	-	8	-
Vitamin E (mg $\alpha\text{-TE}$ ) <sup>(3)</sup>	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ	-	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal	-

<sup>(1)</sup> RE = all trans retinol equivalent.

<sup>(2)</sup> in the form of cholecalciferol, of which 10  $\mu\text{g}$  = 400 i.u. of vitamin D.

<sup>(3)</sup>  $\alpha\text{-TE}$  = d- $\alpha$ -tocopherol equivalent.

## 7. THE FOLLOWING NUCLEOTIDES MAY BE ADDED:

	Maximum <sup>(1)</sup>	
	(mg / 100 kJ)	(mg / 100 kcal)
Cytidine 5'-monophosphate	0.60	2.50
Uridine 5'-monophosphate	0.42	1.75
Adenosine 5'-monophosphate	0.36	1.50
Guanosine 5'-monophosphate	0.12	0.50
Inosine 5'-monophosphate	0.24	1.00

<sup>(1)</sup> The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/100 kcal).

**SCHEDULE III**  
**NUTRITIONAL SUBSTANCES**

**1. VITAMINS**

<b>VITAMIN</b>	<b>VITAMIN FORMULATION</b>
Vitamin A	Retinyl acetate Retinyl palmitate Beta-carotene Retinol
Vitamin D	Vitamin D <sub>2</sub> (ergocalciferol) Vitamin D <sub>3</sub> (cholecalciferol)
Vitamin B <sub>1</sub>	Thiamin hydrochloride Thiamin mononitrate
Vitamin B <sub>2</sub>	Riboflavin Riboflavin-5'-phosphate, sodium
Niacin	Nicotinamide Nicotinic acid
Vitamin B <sub>6</sub>	Pyridoxine hydrochloride Pyridoxine-5'-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
Vitamin B <sub>12</sub>	Cyanocobalamin Hydroxocobalamin
Biotin	D-biotin
Vitamin C	L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate
Vitamin E	D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate DL-alpha tocopherol acetate
Vitamin K	Phylloquinone (Phytomenadione)

## MINERAL SUBSTANCES

MINERAL SUBSTANCES	PERMITTED SALTS
Calcium (Ca)	Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide
Magnesium (Mg)	Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium salts of orthophosphoric acid Magnesium sulphate Magnesium gluconate Magnesium hydroxide Magnesium salts of citric acid
Iron (Fe)	Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferric ammonium citrate Ferrous fumarate Ferric diphosphate (Ferric pyrophosphate)
Copper (Cu)	Cupric citrate Cupric gluconate Cupric sulphate Copper-lysine complex Cupric carbonate
Iodine (I)	Potassium iodide Sodium iodide Potassium iodate
Zinc (Zn)	Zinc acetate Zinc chloride Zinc lactate Zinc sulphate Zinc citrate Zinc gluconate Zinc oxide
Manganese (Mn)	Manganese carbonate Manganese chloride Manganese citrate Manganese sulphate Manganese gluconate

<b>MINERAL SUBSTANCES</b>	<b>PERMITTED SALTS</b>
Sodium (Na)	Sodium bicarbonate Sodium chloride Sodium citrate Sodium gluconate Sodium carbonate Sodium lactate Sodium salts of orthophosphoric acid Sodium hydroxide
Potassium (K)	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium salts of citric acid Potassium gluconate Potassium lactate Potassium salts of orthophosphoric acid Potassium hydroxide
Selenium	Sodium selenate Sodium selenite

### **3. AMINO ACIDS AND OTHER NITROGEN COMPOUNDS**

L-arginine and its hydrochloride  
 L-cystine and its hydrochloride  
 L-histidine and its hydrochloride  
 L-isoleucine and its hydrochloride  
 L-leucine and its hydrochloride  
 L-lysine and its hydrochloride  
 L-cysteine and its hydrochloride  
 L-methionine  
 L-phenylalanine  
 L-threonine  
 L-tryptophan  
 L-tyrosine  
 L-valine  
 L-carnitine and its hydrochloride  
 Taurine  
 Cytidine 5'-monophosphate and its sodium salt  
 Uridine 5'-monophosphate and its sodium salt  
 Adenosine 5'-monophosphate and its sodium salt  
 Guanosine 5'-monophosphate and its sodium salt  
 Inosine 5'-monophosphate and its sodium salt

### **4. OTHERS**

Choline  
 Choline chloride  
 Choline citrate  
 Choline bitartrate  
 Inositol



## SCHEDULE IV

### COMPOSITIONAL CRITERIA FOR INFANT FORMULAE WARRANTING A CORRESPONDING CLAIM

Claim Related To	Conditions Warranting the Claim
1. Adapted protein	The protein content is lower than 0.6 g/100 kJ (2.5 g/100 kcal) and the whey protein/casein ratio is not less than 1.0.
2. Low sodium	The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal).
3. Sucrose free	No sucrose is present.
4. Lactose only	Lactose is the only carbohydrate present.
5. Lactose free	No lactose is present. <sup>(1)</sup>
6. Iron enriched	Iron is added.
7. Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced allergen of reduced antigen properties.	<p>The formulae shall satisfy the provisions laid down in Section 2.2 of Schedule I and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1% of nitrogen containing substances in the formulae;</p> <p>(b) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90% of infants (confidence interval 95%) hypersensitive to proteins from which the hydrolysate is made;</p> <p>(c) The formulae administered orally should not induce sensitisation, in animals, to the intact proteins from which the formulae are derived;</p> <p>(d) Objective and scientifically verified data as proof to the claimed properties must be available.</p>

<sup>(1)</sup> when determined by a method the detection limits of which will be established at a later stage.

**SCHEDULE V**  
**ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS**  
**IN BREAST MILK**

For the purpose of this report, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal are the following:

	per 100 kJ <sup>(1)</sup>	per 100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

<sup>(1)</sup> 1 kJ = 0.239 kcal.

**SCHEDULE VI**  
**Amino Acid Composition of Casein and Breast Milk Protein**

The amino acid composition of casein and breast milk protein:

	CASEIN <sup>(1)</sup> g/100 g of protein	BREAST MILK <sup>(1)</sup> g/100 g of protein
Arginine	3.7	3.8
Cystine	0.3	1.3
Histidine	2.9	2.5
Isoleucine	5.4	4.0
Leucine	9.5	8.5
Lysine	8.1	6.7
Methionine	2.8	1.6
Phenylalanine	5.2	3.4
Threonine	4.7	4.4
Tryptophan	1.6	1.7
Tyrosine	5.8	3.2
Valine	6.7	4.5

<sup>(1)</sup> amino acid content of foods and biological data on protein.  
 FAO Nutritional Studies, no 24, Rome 1970, items 375 and 383.



## SCHEDULE VII

### THE MINERAL ELEMENTS IN COWS' MILK

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-no-fats and per g of proteins are the following:

	per 100 g SNF <sup>(1)</sup>	per g of proteins
Sodium (mg)	550	15
Potassium (mg)	1,680	43
Chloride (mg)	1,050	28
Calcium (mg)	1,350	35
Phosphorus (mg)	1,070	28
Magnesium (mg)	135	3.5
Copper (mg)	225	6
Iodine	ns <sup>(2)</sup>	ns <sup>(2)</sup>

<sup>(1)</sup> SNF : 'solids-no-fats'

<sup>(2)</sup> ns: non-specific, varies widely according to season and stock farming conditions

## SCHEDULE VIII

### REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient	Labelling reference value
Vitamin A	( $\mu\text{g}$ ) 400
Vitamin D	( $\mu\text{g}$ ) 10
Vitamin C	(mg) 25
Thiamin	(mg) 0.5
Riboflavin	(mg) 0.8
Niacin equivalents	(mg) 9
Vitamin B <sub>6</sub>	(mg) 0.7
Folate	( $\mu\text{g}$ ) 100
Vitamin B <sub>12</sub>	( $\mu\text{g}$ ) 0.7
Calcium	(mg) 400
Iron	(mg) 6
Zinc	(mg) 4
Iodine	( $\mu\text{g}$ ) 70
Selenium	( $\mu\text{g}$ ) 10
Copper	(mg) 0.4

GIVEN under the Official Seal of the Minister for  
Health and Children this 16th day of July 1998.

BRIAN COWEN T.D.  
Minister for Health and Children

### Explanatory Note

*(This note is not part of the Instrument and does not purport to be a legal interpretation).*

These Regulations give effect to Commission Directive 91/321/EEC of 14 May 1991, Council Directive 92/52/EEC of 18 June 1992 and Commission Directive 96/4/EEC of the 16th February 1996 on compositional, labelling and marketing requirements for infant formulae and follow-on formulae intended for infants in good health.

These Regulations come into effect on the 17th of July, 1998.



**APPENDIX G**

**STATUTORY INSTRUMENTS**

**S.I. No. 241 of 1998**

**EUROPEAN COMMUNITIES (PROCESSED CEREAL-  
BASED FOODS AND BABY FOODS FOR INFANTS AND  
YOUNG CHILDREN) REGULATIONS, 1998**

Dublin

Published by the Stationery Office

## ARRANGEMENT OF SECTIONS

### Articles

- 1–3 Title, Commencement and Interpretation
- 4–6 Conditions for the Marketing of Processed Cereal-Based Foods and Baby Foods
- 7–10 Composition of Processed Cereal-Based Foods and Baby Foods
- 11–12 Labelling of Processed Cereal-Based Foods and Baby Foods
- 13–14 Enforcement
- 15–19 Offences

SCHEDULE I – Essential Composition of Processed Cereal-Based Foods for Infants and Young Children

SCHEDULE II – Essential Composition of Baby Foods for Infants and Young Children

SCHEDULE III – Amino Acid Composition of Casein

SCHEDULE IV – Nutritional Substances

SCHEDULE V – Reference Values for Nutrition Labelling for Foods Intended for Infants and Young Children

## S.I. No. 241 of 1998

### EUROPEAN COMMUNITIES (PROCESSED CEREAL-BASED FOODS AND BABY FOODS FOR INFANTS AND YOUNG CHILDREN) REGULATIONS, 1998

I, Brian Cowen, Minister for Health and Children in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No. 27 of 1972) having regard to Council Directive 891/398/EEC<sup>1</sup> of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses as amended by Directive 96/84/EC<sup>2</sup> of the European Parliament and of the Council of 19 December 1996 and for the purposes of giving effect to Commission Directive 96/5/EC<sup>3</sup> of the 16th of February 1996, hereby make the following Regulations:

#### **Title, Commencement and Interpretation**

1. These Regulations may be cited as the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations, 1998.
2. (1) These Regulations shall come into operation on the 17th day of July, 1998.  
(2) Trade in products which do not comply with these Regulations is prohibited with effect from 31 March 1999.
3. (1) In these Regulations:

"authorised officer" means:

- (a) an officer of the Minister for Health and Children who is authorised in writing by the Minister for Health and Children to be an authorised officer for the purposes of these Regulations; or
- (b) an officer of a health board who is authorised in writing by the Chief Executive Officer of the health board to be an authorised officer for the purposes of these Regulations.

"export" means to market a product in a country outside the European Union;

"functional area", in relation to a health board, means the functional area of the board as defined in the Health Board Regulations, 1970 (S.I. No. 170 of 1970);

"health board" means a health board established under Section 4(1) of the Health Act, 1970 (No. 1 of 1970);

<sup>1</sup> OJ No. L1 86, 30.6.1989, p. 27

<sup>2</sup> OJ No. L48, 19.2.1997, p. 20

<sup>3</sup> OJ No. L49, 28.2.96, pp. 17 – 28

"infants" means children under the age of twelve months;

"to market" includes to supply, whether or not for profit, offer, expose for sale, and/or have in possession for sale and cognate words shall be construed accordingly;

"Minister" means the Minister for Health and Children;


"young children" means children aged between one and three years.

- (2) In these Regulations, any reference to an article or Schedule shall be construed as a reference to an article contained in these Regulations, or, as the case may be, to a Schedule thereto and any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article, unless otherwise stated.
- (3) A word or expression that is used in these Regulations and is also used in Council Directive 89/398/EEC and/or Commission Directive No. 96/5/EC and/or Directive 96/84/EC of the European Parliament and of the Council has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council and Commission Directives.

#### **Conditions for the Marketing of Processed Cereal-Based Foods and Baby Foods**

4. These Regulations relate to foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health and are intended for use by infants while they are being weaned, and by young children as a supplement to their diet and/or for their progressive adaptation to ordinary food. They comprise of:
  - (1) "Processed cereal-based foods" which are divided into the following four categories:
    - (a) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;
    - (b) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;
    - (c) pastas which are to be used after cooking in boiling water or other appropriate liquids;
    - (d) rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.
  - (2) "Baby foods" other than processed cereal-based foods.
5. These Regulations do not apply to milks intended for young children.



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6. The products referred to in Article 4 may be marketed only if they conform to the provisions laid down in these Regulations.

#### **Composition of Processed Cereal-Based Foods and Baby Foods**

7. Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has, in the opinion of the Minister, been established by generally accepted scientific data.
8.
  - (1) Processed cereal-based foods must comply with the compositional criteria specified in Schedule I.
  - (2) Baby foods which are described in Schedule II must comply with the compositional criteria specified therein.
  - (3) Only the nutritional substances listed in Schedule IV may be added in the manufacture of processed cereal-based foods and baby foods.
9. Processed cereal-based foods and baby foods shall not contain any substance in such quantity which, in the opinion of the Minister, endangers the health of infants and young children.
10.
  - (1) The Minister may, by order, stipulate the maximum levels of any substance included in infant or follow-on formulae.
  - (2) The Minister may, by order, establish such microbiological criteria as he considers appropriate.

#### **Labelling of Processed Cereal-Based Foods and Baby Foods**

11. The labelling of foodstuffs as set out in Article 4 shall bear the following particulars in addition to EU and general food labelling requirements:
  - (1) A statement as to the appropriate age from which the product may be used, with regard to its composition, texture or other particular properties. The stated age may not be less than four months for any product.
  - (2) Products recommended for use from the age of four months may indicate that they are suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, advise otherwise.
  - (3) If the indicated age from which the product may be used is below six months, the label must contain information as to the presence or absence of gluten.
  - (4) The available energy value expressed in kJ and kcal, and the protein, carbohydrate and lipid content, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption.


- (5) The average quantity of each mineral substance and of each vitamin governed by a specific level in Schedule I and Schedule II respectively, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption.
  - (6) Instructions for appropriate preparation when necessary, and a statement as to the importance of following those instructions.
12. The labelling may bear:
  - (1) The average quantity of the nutrients set out in Schedule IV when such declaration is not covered by the provisions of Article 11(5), expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption.
  - (2) In addition to numerical information, information on vitamins and minerals shown in Schedule V, expressed as a percentage of the reference values given therein, per 100 g or 100 ml of the product as sold, and where appropriate, per specified quantity of the product as proposed for consumption, provided that the quantities present are at least equal to 15% of the reference values.

### **Enforcement**

13. These Regulations shall be enforced and executed by each health board in respect of its functional area through its authorised officers and/or the officers of the Minister for Health and Children who are authorised officers for the purposes of these Regulations.
14. For the purposes of ensuring compliance with these Regulations, the provisions of the European Communities (Official Control of Foodstuffs) Regulations, 1998 (S.I. No. 85 of 1998) shall apply.


### **Offences**

15.
  - (1) A person shall not manufacture, prepare, import, distribute, market and/or label any product which does not comply with these Regulations.
  - (2) Any person who contravenes any article or sub-article of these Regulations shall be guilty of an offence.
  - (3) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,000 or at the discretion of the Court, to imprisonment for a term not exceeding six months or to both.
  - (4) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of a director, secretary or



other officer of the body corporate, the director, secretary or other officer or any person purporting to act in such capacity shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against and punished accordingly.

- (5) Notwithstanding Section 10(4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted within twelve months from the date of the offence or any time within twelve months from the date on which knowledge of the commission of the offence came to the attention of an authorised officer.

16. An offence under these Regulations may be prosecuted by –
- (a) the Minister, or
  - (b) a health board within whose functional area the offence was committed.
17. (1) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and when exercising any power conferred on an authorised officer by these Regulations shall, if so requested by a person affected, produce the certificate for the inspection of the person.
- (2) It shall be offence for a person falsely to represent himself to be an authorised officer.
18. A health board shall
- (a) forward to the Minister such information as he may request in respect of the exercise of the functions conferred on it by or under these Regulations;
  - (b) comply with any directions given by the Minister from time to time as the exercise of its powers or the performance of its functions and duties under these Regulations.
- 

## SCHEDULE I

### ESSENTIAL COMPOSITION OF PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

The requirements concerning nutrients refer to the products ready for use marketed as such or reconstituted as instructed by the manufacturer.

#### 1. CEREAL CONTENT

Processed cereal-based foods are prepared primarily from one or more milled cereals and/or starchy root products.

The amount of cereal and/or starchy root shall not be less than 25% of the final mixture on a dry weight for weight basis.

#### 2. PROTEIN

2.1. For products mentioned in Article 4(1) (b) and (d), the protein content shall not exceed 1.3 g/100 kJ (5.5 g/100 kcal).

2.2. For products mentioned in Article 4(1) (b), the added protein shall not be less than 0.48 g/100 kJ (2 g/100 kcal).

2.3. For biscuits mentioned in Article 4(1) (d), made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36 g/100 kJ (1.5/100 kcal).

2.4. The chemical index of the added protein shall be equal to at least 80% of that of the reference protein (casein as defined in Schedule III), or the protein energy ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.

#### 3. CARBOHYDRATES

3.1. If sucrose, fructose, glucose, glucose syrups or honey are added to products mentioned in Article 4(1) (a) and (d):

- the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/ 100 kcal).
- the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal).

- 3.2.** If sucrose, fructose, glucose syrups or honey are added to products mentioned in Article 4 (1)(b),
- the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kJ (5 g/100 kcal).
  - the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).

#### **4. LIPIDS**

- 4.1.** For products mentioned in Article 4(1) (a) and (d), the lipid content shall not exceed 0.8 g/100 kJ (3.3 g/100 kcal).
- 4.2.** For products mentioned in Article 4(1) (b), the lipid content shall not exceed 1.1 g/100 kJ (4.5 g/100 kcal). If the lipid content exceeds 0.8 g/100 kJ (3.3 g/100 kcal):
- (a) the amount of lauric acid shall not exceed 15% of the total lipid content;
  - (b) the amount of myristic acid shall not exceed 15% of the total lipid content;
  - (c) the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1,200 mg/100 kcal).

#### **5. MINERALS**

##### **5.1. Sodium**

- Sodium salts may only be added to processed cereal-based foods for technological purposes,
- the sodium content of processed cereal-based foods shall not exceed 25 mg / 100 kJ (100 mg / 100 kcal).

##### **5.2. Calcium**

- 5.2.1.** For products mentioned in Article 4(1) (b), the amount of calcium shall not be less than 20 mg/100 kJ (80 mg/100 kcal).
- 5.2.2.** For products mentioned in Article 4(1) (d), manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

#### **6. VITAMINS**

- 6.1.** For processed cereal-based foods the amount of thiamin shall not be less than 2.5 µg / 100 kJ (100 µg / 100 kcal).
- 6.2.** For products mentioned in Article 4(1) (b)

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A ( $\mu\text{g RE}$ ) <sup>(1)</sup>	14	43	60	180
Vitamin D ( $\mu\text{g}$ ) <sup>(2)</sup>	0.25	0.75	1	3

<sup>(1)</sup> RE = all trans retinol equivalents

<sup>(2)</sup> In the form of cholecalciferol, of which 10  $\mu\text{g}$  = 400 i.u. of vitamin D.

These limits are also applicable if vitamins A and D are added to other processed cereal-based foods.

## SCHEDULE II

### ESSENTIAL COMPOSITION OF BABY FOODS FOR INFANTS AND YOUNG CHILDREN

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

#### 1. PROTEIN

1.1. If meat, poultry, fish, offal or other traditional source of protein are the only ingredients mentioned in the name of the product, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40% by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,
- the total protein from the named sources shall not be less than 1.7 g/100 kJ (7g/100 kcal).

1.2. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination, are mentioned first in the name of the product, whether or not the product is presented as a meal, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10% by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,
- the protein from the named sources shall not be less than 1 g/100 kJ (4g/100 kcal).

- 1.3.** If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal, then:
- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8% by weight of the total product,
  - each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,
  - the protein from the named sources shall not be less than 0.5 g/100 kJ (2.2 g/100 kcal),
  - the total protein in the product from all sources shall not be less than 0.7g/100 kJ (3g/100 kcal).
- 1.4.** If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, then:
- the total protein in the product from all sources shall not be less than 0.7 g/100 kJ (3 g/100 kcal).
- 1.5.** The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

## **2. CARBOHYDRATES**

The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed:

- 10 g/100 ml for vegetable juices and drinks based on them,
- 15 g/100 ml for fruit juices and nectars and drinks based on them,
- 20 g/100 g for fruit-only dishes,
- 25 g/100 g for desserts and puddings,
- 5 g/100 g for other non-milk-based drinks.

## **3. FAT**

### **3.1.** For products referred to in point 1.1 of this Schedule:

If meat or cheese are the only ingredients or are mentioned first in the name of a product, then:

- the total fat in the product from all sources should not exceed 1.4 g/100 kJ (6 g/100 kcal).

**3.2.** For all other products:

- the total fat in the product from all sources should not exceed 1.1 g/100 kJ (4.5 g/100 kcal).

**4. SODIUM**

- 4.1.** The final sodium content in the product should be either not more than 48 mg/100 kJ (200 mg/100 kcal) or not more than 200 mg per 100g. However, if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product should not be fore than 70 mg/100 kJ (300 mg/100 kcal).
- 4.2.** Sodium salts may not be added to products based on fruit, nor to desserts, puddings except for technological purposes.

**5. VITAMINS**

**Vitamin C**

In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product should be either not less than 6 mg/100 kJ (25 mg/100 kcal) or not less than 25 mg per 100 g.

**Vitamin A**

In vegetable juices, the final content of vitamin A in the product should be not less than 25 µg RE/100 kJ (100 µg RE/100 kcal).<sup>1</sup>  
Vitamin A shall not be added to other baby foods.

**Vitamin D**

Vitamin D shall not be added to baby foods.

<sup>1</sup> RE = all trans retinol equivalents



### SCHEDULE III

#### AMINO ACID COMPOSITION OF CASEIN

(g per 100 g of protein)

Arginine	3.7
Cystine	0.3
Histidine	2.9
Isoleucine	5.4
Leucine	9.5
Lysine	8.1
Methionine	2.8
Phenylalanine	5.2
Threonine	4.7
Tryptophan	1.6
Tyrosine	5.8
Valine	6.7

### SCHEDULE IV

#### NUTRITIONAL SUBSTANCES

##### 1. VITAMINS

###### *Vitamin A*

Retinol

Retinyl acetate

Retinyl palmitate

beta carotene

###### *Vitamin D*

Vitamin D2 (= ergocalciferol)

Vitamin D3 (= cholecalciferol)

###### *Vitamin B1*

###### **THIAMIN HYDROCHLORIDE**

Thiamin mononitrate

###### *Vitamin B2*

Riboflavin

Riboflavin-5'-phosphate, sodium

**Niacin**

Nicotinamide  
Nicotinic acid

**Vitamin B6**

Pyridoxine hydrochloride  
Pyridoxine-5-phosphate  
Pyridoxine dipalmitate

**Pantothenic Acid**

D-pantothenate, calcium  
D-pantothenate, sodium  
Dexpanthenol

**Folate**

Folic acid

**Vitamin B12**

Cyanocobalamin  
Hydroxocobalamin

**Biotin**

D-biotin

**Vitamin C**

L-ascorbic acid  
Sodium L-ascorbate  
Calcium L-ascorbate  
6-Palmityl-L-ascorbic acid  
(ascorbyl palmitate)  
potassium ascorbate

**Vitamin K**

Phylloquinone (Phytomenadione)

**Vitamin E**

D-alpha tocopherol  
DL-alpha tocopherol  
D-alpha tocopherol acetate  
DL-alpha tocopherol acetate

**2. AMINO ACIDS**

L-arginine <sup>1</sup>  
L-cystine <sup>1</sup>  
L-histidine <sup>1</sup>  
L-isoleucine <sup>1</sup>  
L-leucine <sup>1</sup>  
L-lysine <sup>1</sup>  
L-cysteine <sup>1</sup>  
L-methionine  
L-phenylalanine  
L-threonine  
L-tryptophan  
L-tyrosine  
L-valine

<sup>1</sup> and their hydrochlorides

**3. OTHERS**

Choline  
Choline chloride  
Choline citrate  
Choline bitartrate  
Inositol  
L-Carnitine  
L-carnitine hydrochloride

**4. SALTS OF MINERALS AND TRACE ELEMENTS****Calcium**

Calcium carbonate  
Calcium chloride  
Calcium salts of citric acid  
Calcium gluconate  
Calcium glycerophosphate  
Calcium lactate  
Calcium oxide  
Calcium hydroxide  
Calcium salts of orthophosphoric acid



***Magnesium***

Magnesium carbonate  
Magnesium chloride  
Magnesium salts of citric acid  
Magnesium gluconate  
Magnesium oxide  
Magnesium hydroxide  
Magnesium salts of orthophosphoric acid  
Magnesium sulphate  
Magnesium lactate  
Magnesium glycerophosphate

***Potassium***

Potassium chloride  
Potassium salts of citric acid  
Potassium gluconate  
Potassium lactate  
Potassium glycerophosphate

***Iron***

Ferrous citrate  
Ferric ammonium citrate  
Ferrous gluconate  
Ferrous lactate  
Ferrous sulphate  
Ferrous fumarate  
Ferric diphosphate (Ferric pyrophosphate)  
Elemental iron (carbonyl + electrolytic + hydrogen-reduced)  
Ferric saccharate

Sodium ferric diphosphate  
Ferrous carbonate

***Copper***

Copper-lysine complex  
Cupric carbonate  
Cupric citrate  
Cupric gluconate  
Cupric sulphate

***Zinc***

Zinc acetate  
Zinc citrate  
Zinc lactate  
Zinc sulphate  
Zinc oxide  
Zinc gluconate

***Manganese***

Manganese carbonate  
Manganese chloride  
Manganese citrate  
Manganese gluconate  
Manganese sulphate  
Manganese glycerophosphate

***Iodine***

Sodium iodide  
Potassium iodide  
Potassium iodate  
Sodium iodate

## SCHEDULE V

### REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient	Labelling Reference Value
Vitamin A	(mg) 400
Vitamin D	(mg) 10
Vitamin C	(mg) 25
Thiamin	(mg) 0.5
Riboflavin	(mg) 0.8
Niacin equivalents	(mg) 9
Vitamin B6	(mg) 0.7
Folate	(mg) 100
Vitamin B12	(mg) 0.7
Calcium	(mg) 400
Iron	(mg) 6
Zinc	(mg) 4
Iodine	(mg) 70
Selenium	(mg) 10
Copper	(mg) 0.4

GIVEN under the Official Seal of the Minister for  
Health and Children this 16th day of July 1998.

BRIAN COWEN  
Minister for Health and Children

### Explanatory Note

*(This note is not part of the Instrument and does not purport to be a legal interpretation).*

These Regulations give effect to Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children.

These Regulations come into effect on the 17th of July, 1998

## APPENDIX H: STATE SUPPORT SERVICES FOR PREGNANT WOMEN AND PARENTS OF INFANTS

### All women

Maternity cash grant – a once-off payment of a small sum of money to cover an initial visit to the GP.

Children's allowance – payment based on the number of children.

### Women working, paying PRSI and fulfilling the necessary conditions

Maternity allowance – 14 weeks total, at least four and not more than 10 of which must be taken before the baby is due. May be extended by four weeks unpaid leave. Further information from the Employment Equality Agency (Appendix I).

Parental leave – According to the Parental Leave Act, 1998, each parent may take 14 weeks unpaid leave up to the time the child is five years old. In the case of multiple births the leave is applicable for each child. Force majeure leave entitles a parent to take 3 days leave in 12 months (5 days in 36 months) to look after a sick child (or other family member) without providing a Medical Certificate.

Further information from the Department of Justice, Equality and Law Reform.

### Women who hold medical cards or are on Social Welfare Benefit

Some financial support may be available on application to the Community Welfare Officer.

Special diet allowance – available by special

arrangement and on application to the community welfare officer, to assist with additional costs incurred if a therapeutic diet is prescribed.

### One-parent family payment

Unmarried, widowed, separated or divorced mothers or prisoner's spouse are entitled to a special allowance.

### Health and safety benefit

Payable when the employer cannot remove a risk to the employee's health or safety or her pregnancy or breastfeeding or cannot assign her to alternative risk-free duties. Available to working women who are pregnant or breastfeeding (for 26 weeks after the birth). Not payable as well as maternity benefit. For further information contact the Health and Safety Authority and the Employment Equality Agency (Appendix I).

### Adoptive benefit

Payable to eligible adoptive parents for 10 weeks from the date of placement of the child.

### Special groups

Mothers of mentally or physically handicapped infants may be entitled to extra support.

For further information contact your local health board.

Home help may be available to certain mothers, for example those who have had difficult births.

## APPENDIX I: USEFUL ADDRESSES

### **Association of Lactation Consultants in Ireland**

Ardkilly  
Ballinderry  
Mullingar  
Co. Westmeath  
Tel: 044 44792

### **Caesarean Support Group**

14 Clonard Lawns  
Sandyford  
Dublin 16  
Tel: 01 2954953

### **Cerebral Palsy Ireland**

Head Office  
Sandymount Avenue  
Dublin 4  
Tel: 01 2695355

### **Cleft Lip and Palate Association of Ireland**

152 Ard na Mara  
Malahide  
Co. Dublin  
Tel: 01 8450234

### **Coeliac Society of Ireland**

Carmichael House  
4 North Brunswick Street  
Dublin 7  
Tel: 01 8721471

### **Cuidiú – Irish Childbirth Trust**

Carmichael House  
4 North Brunswick Street  
Dublin 7  
Tel: 01 8724501  
Details of local branches available  
from above number

### **Down Syndrome Ireland**

Dominick Court  
41 Lower Dominick Street  
Dublin 1  
Tel: 01 8733199

### **Employment Equality Agency**

Maternity Information Officer  
36 Upper Mount Street  
Dublin 2  
Tel: 01 6624577

### **Gingerbread**

Association for One Parent Families  
29-30 Dame Street  
Dublin 2  
Tel: 01 6710291

### **Health and Safety Authority**

10 Hogan Place  
Dublin 2  
Tel: 01 6147000

### **Health Promotion Unit**

Department of Health and Children  
Hawkins House  
Dublin 2  
Tel: 01 6354000

### **Incu-babes**

105a Old County Road  
Dublin 12  
Tel: 01 4532181

### **Irish Multiple Births Association**

P.O. Box 5053  
Swords  
Co. Dublin  
Tel: 01 8451087



**Irish Sudden Infant Death Association**

Carmichael House  
4 North Brunswick Street  
Dublin 7  
Helpline: 1800 391391  
General: 01 8732711

**La Leche League**

(Breastfeeding help and information)  
30 Idrone Close  
Knocklyon  
Dublin 16  
Tel: 01 4941279  
Listed in all area directories

**National Association for the Mentally  
Handicapped of Ireland**

5 Fitzwilliam Place  
Dublin 2  
Tel: 01 6766035

**National Sudden Infant Death Register**

George's Hall  
The Children's Hospital  
Temple Street  
Dublin 1  
Tel: 01 8788455

**Parentline**

(Organisation for Parents under Stress)  
Carmichael Centre for Voluntary Groups  
4 North Brunswick Street  
Dublin 7  
Helpline: 01 8733500  
General: 01 8787230

**Postnatal Distress Support Group**

Carmichael House  
4 North Brunswick Street  
Dublin 7  
Tel: 01 8727172

## GLOSSARY

*Atopy:*

The term used to describe disorders characterised by the development of IgE antibodies.

*Atopic family:*

Family in which one or more first-degree relatives are diagnosed with atopic disease.

*Breastfeeding:*

*Full breastfeeding* - may be exclusive or almost exclusive.

*Almost exclusive* - baby may receive small, trivial amounts of culturally valued supplements (e.g. vitamins) as well as breast milk.

*Partial breastfeeding* - additional drinks of breast-milk substitute or other fluids or weaning foods as well as breast milk.

*Token breastfeeding* - minimal, occasional or irregular breastfeeding.

*Complementary food:*

Any food, whether manufactured or home prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant.

*Complementary feeding:*

The addition of complementary foods to the infant's diet.

*ESPGAN:*

European Society for Paediatric Gastroenterology and Nutrition.

*Formula milks:*

Definitions based on EC (Infant Formulae and Follow-on Formulae) Regulations, 1998 (Appendix F).

*Infant formulae* - foodstuffs intended for particular nutritional use by infants in good health during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons.

*Follow-on formulae* - foodstuffs intended for particular nutritional use by infants in good health aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons.

*Infant milk and follow-on milk* - products within the meaning of these regulations manufactured entirely from cows' milk proteins.

*Infant:*

A child who has not attained the age of one year.

*Introducing solids:*

Introducing complementary foods to the infant's diet.

*Nutritionist:*

In this document the term "nutritionist" is used to describe a person holding a recognised degree in Human Nutrition/Dietetics, or a post-graduate Diploma in Human Nutrition/ Dietetics, or, prior to 1987, a Diploma in Human Nutrition and Dietetics. The term is used to cover both clinical and community nutritionists/dietitians.

*Weaning:*

The process of ceasing to feed from the breast by the addition of any other foods or drinks to breastfeeding.



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## INFANT FEEDING SUB-COMMITTEE


The Sub-committee on Infant Feeding was appointed by the Nutrition Committee of the Food Safety Advisory Board. All activities of the Nutrition Committee were subject to the direction of the Board, which was established by the Minister for Health on 22 June 1995 under the Food Safety Board (Establishment) Order, 1995 (S.I. No. 155 of 1995), published by the Department of Health in 1994. In January 1998 the activities of the Food Safety Advisory Board were transferred to the Food Safety Authority of Ireland under the Food Safety Authority of Ireland (Establishment) Order, 1997 (S.I. No. 524 of 1997). Membership of the Sub-committee was determined by its requirements to fulfil its functions. In addition, some experts and representatives of interested groups were consulted in relation to specific topics.

### Number of meetings

The Sub-committee met on 19 occasions between October 1996 and 14 January 1999.

### Commissioned research

Dr Valerie Freeman, paediatric research nutritionist, was appointed by the Sub-committee to research relevant areas of infant nutrition, to provide information to the Sub-committee from which decisions on policy matters could be taken and to draft the document.



## Members of the Infant Feeding Sub-committee

### Chair

*Dr Mary Flynn* Lecturer in Nutrition and Dietetics  
Dublin Institute of Technology and Trinity College Dublin

### Members

*Ms Genevieve Becker* Maternal and Child Research Nutritionist  
National University of Ireland, Galway

*Ms Breda Cleary* Institute of Community Health Nursing  
Co. Kildare

*Ms Cathy Donnelly* Community Mother

*Dr Valerie Freeman* Paediatric Research Nutritionist

*Ms Pauline Gibney* Dietitian  
National Maternity Hospital

*Prof Hilary Hoey* Department of Paediatrics  
Adelaide and Meath Hospital, inc NCH

*Dr Mary Hurley* National Committee for the Promotion of Breastfeeding  
Eastern Health Board

*Mr Pat Ivory* Irish Dairy Industries Association  
IBEC

*Ms Ann Martin* An Bord Altranais (Nursing Board)

*Dr Niall O'Cleirigh* Irish College of General Practitioners

*Ms Miriam O'Donoghue\** Department of Education Representative

*Ms Ita Saul* Paediatric Interest Group  
Irish Nutrition and Dietetic Institute

### Secretariat

*Ms Sonya Byrne* Food Safety Authority of Ireland

*Mr Michael Mul Kerrin* Food Safety Authority of Ireland  
(until June 1998)

\*Note: Ms O'Donoghue resigned from the Sub-committee in September 1997 due to a change of employment.



## ACKNOWLEDGEMENTS

In the course of researching this document a number of experts were consulted on a variety of topics. We are grateful to them for their interest in and dedication to the completion of this report and their willing co-operation in response to our requests for information and advice. These included Dr Billy Bourke, Dr Karina Butler, Dr Gerard Canny, Dr Kevin Connolly, Mr Ray Ellard, Dr Patrick Fleming, Ms Philomena Flood, Ms Ailish Forde, Ms Paula Gahan-Mullen, Dr Freda Gorman, Dr Siobhán Gormley, Dr Owen Hensey, Ms Noreen Kavanagh, Professor Peter Kearney, Ms Joyce Lambe, Dr Shiela Macken, Dr Brian McDonagh, Mr Hugh Magee, Professor Tom Matthews, Ms Michelle Moran, Dr Philip Mayne, Dr Eileen Naughten, Professor Denis O'Mullane, Dr Lelia Thornton, Dr Martin White and the members of the Paediatric Interest Group of the Irish Nutrition and Dietetic Institute.

## NOTES



## NOTES



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ISBN 0-9533624-6-9



9 780953 362462

£5.00    ₣6.35