



A National Breastfeeding Policy for Ireland



DEPARTMENT
OF HEALTH
AN ROINN
SLÁINTE

A National Breastfeeding Policy for Ireland

A Report to the Minister for Health
by the National Committee to Promote Breastfeeding

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Introduction

Terms of Reference

The terms of reference given to the Committee by the Minister for Health in 1992 – to develop a national policy to promote breastfeeding – were broad, allowing the Committee itself on an examination of the issue, to decide what were the most important aspects on which to focus. At its first meeting the Committee agreed on the objectives of the policy. These objectives were to be pursued having due regard to the right of the mother to make an informed choice about how she wished to feed her infant and with care that no woman should be made to feel inadequate if she chose not to breastfeed. The objectives of the policy are:

- (a) to increase the percentage of mothers in all socio-economic groups who breastfeed.
- (b) to increase the number of mothers who practise exclusive breastfeeding for at least four months and thereafter with appropriate weaning foods.

Given the context of maternity and infant care in Ireland, it was agreed that the policy should focus on the following issues:

- breastfeeding policy in hospitals,
- breastfeeding policy at community level including the role of voluntary support groups,
- the training of health professionals,
- the promotion of support for breastfeeding in the wider community,
- targets, implementation and monitoring of the policy.

Introduction

Membership

The following were appointed Members of the National Committee to Promote Breastfeeding:

Dr Mary Hurley, M.B., D.P.H., F.F.P.H.M.I.,
(Chairperson)
Senior Area Medical Officer,
Eastern Health Board.

Ms Mary Bird,
La Leche League.

Dr Patricia Crowley,
Consultant Obstetrician,
Coombe Women's Hospital.

***Dr Geraldine Dennis,**
General Practitioner.

Ms Paula Gahan-Mullen,
Irish Childbirth Trust.

Dr Elizabeth Griffin,
Consultant Neonatologist/Paediatrician,
Coombe Women's Hospital and
Our Lady's Hospital for Sick Children,
Crumlin.

Ms Rita Maunsell,
Institute of Community Health Nursing.

Ms Maria McInerney,
Principal Nurse Tutor,
Regional Maternity Hospital,
Limerick.

Ms Berna O'Hanrahan,
Council for the Status of Women.

***Ms Dora Hennessy,**
Assistant Principal,
Health Promotion Unit,
Department of Health.

Ms Anna May Harkin
(Secretary),
Health Promotion Unit.

Ms Fiona Keane
(Assistant to the Secretary),
Health Promotion Unit.

*Note: Dr Geraldine Dennis resigned from the Committee in November 1992, because of a change in work schedule. The Irish College of General Practitioners nominated Dr Austin O'Carroll to replace her.

Ms Dora Hennessy also resigned in November 1992 on her transfer to other duties in the Department of Health.

Number of Meetings

The National Committee to Promote Breastfeeding met on 11 occasions in total – 8 plenary sessions and 3 meetings of sub-groups.

Commissioned Research

The National Committee commissioned a Registrar in Higher Specialist Training in Public Health Medicine, Dr Gerardine Sayers, Eastern Health Board, to do a research review on relevant aspects of breastfeeding as background information for the Committee's deliberations. Dr Sayers attended a number of meetings at the Committee's request.



Summary of recommendations

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, 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 breastmilk. 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 on the value of breastmilk for preterm 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 or by the breastfeeding support groups.

Mothers should be encouraged to practise exclusive breastfeeding for at least 4 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 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 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 groups

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 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 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 4 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 (see Appendix G) 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 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 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 co-ordinate 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 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 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 creche 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 creche 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 4 months by the year 2000.**

In order to achieve the above medium and longterm 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 in 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 creche facilities and lactation breaks.**

Given that the recommendations of this 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 Committee is recommending Ireland’s participation in this initiative. However the 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 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 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, the Department of Equality and Law Reform, the Department of Enterprise and Employment, the Irish Congress of Trade Unions, the Irish Business and Employers Confederation, La Leche League, 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 a national application.

The Department of Health 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 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 on the total number of births in his/her area and the percentage of mothers breastfeeding at hospital discharge and at 4 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 indepth research on the factors influencing the initiation and duration of breastfeeding.



Chapter 1:

Breastfeeding policy in Ireland –
the current situation

Chapter 1

Breastfeeding policy in Ireland – the current situation

The Department of Health has always promoted breastfeeding as the infant feeding method of choice. In the early days this was done through health education leaflets and through circulars to health boards and maternity hospitals recommending that all mothers should be encouraged to breastfeed their infants.

In the late 1970s and early 1980s a number of developments took place both at international and national level which raised the profile of breastfeeding as an issue on the agenda of the Department of Health and its agencies.

At international level, following a recommendation of a joint WHO/UNICEF meeting on the Feeding of Infants and Young Children in 1979, the World Health Assembly in 1981 adopted an International Code of Marketing of Breast-Milk Substitutes (see Appendix A), on the grounds that while there was a legitimate market for these where mothers do not breastfeed or only do so partially “they should not be marketed or distributed in ways that may interfere with the protection and promotion of breast-feeding”.^{1,2} The Code states that “Governments should take action to give effect to the principles and aims of this Code, as appropriate to their social and legislative framework including the adoption of national legislation, regulations or other suitable measures”.

Ireland took on board the aims and principles of the International Code as appropriate to this country, by means of a Voluntary Code of Practice on the Marketing of Infant Formulae in the Republic of Ireland drawn up by the industry. This Voluntary Code is subject to monitoring and examination by a special Code Monitoring Committee, representative of the infant formulae manufacturing industry, Department of Health, Physicians of Ireland, Institute of Obstetrics and Gynaecology of the Royal College of Physicians of Ireland, Irish Congress of Trade Unions, Irish Medical Organisation and the Irish Nutrition and Dietetic Institute.

The Code Monitoring Committee, which published a revised version of the Code in 1991 (see Appendix B), continues to meet to review the operation of the Code.*

The following extract from the preface to the Code sets out concisely the Department of Health’s policy in relation to infant feeding.

“It is recognised that breastfeeding is the most satisfactory method of infant feeding for the normal infant from birth. It is the Department of Health’s policy to promote and encourage breastfeeding.”

“It is recognised and agreed by all that when a mother can produce enough milk and wants to breastfeed her infant she should be encouraged to do so but it is also emphasised that for those mothers who choose not to breastfeed and those who do not have enough breastmilk, artificial feeding would be necessary and alternatives to human breastmilk must be available. Mothers who are unable to breastfeed must not be made to feel inadequate.

It is the right of the mother to make an informed choice about how she wishes to feed her infant”.

***Note:** Regulations are in the course of preparation to give effect to EC Directive 91/321/EEC on infant formulae and follow-on formulae (see Appendix C). The continued commitment of industry to voluntary codes of practice is welcomed but such codes cannot displace or dilute the Directive as transposed. Regulations are also in preparation to give effect to EC Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries (see Appendix D).

Another development at national level with implications for the promotion of breastfeeding (by educational means) was the establishment, in the late 1970s, of the Health Education Bureau (HEB). As a specialised agency within the health sector, the HEB, in consultation with the Department, took on board the education and research aspects of promoting breastfeeding. HEB publications “The Book of the Child” and “Food and Babies”, distributed to mothers through maternity hospitals, promoted breastfeeding as the infant feeding method of choice. Some materials were developed to assist health professionals in encouraging mothers to breastfeed and some financial support was provided for mother-to-mother support groups. These aspects of the promotion of breastfeeding have been continued by the Health Promotion Unit of the Department of Health since its establishment in 1988.

In the early to mid 1980s a series of surveys^{3,4,5} were commissioned by the HEB to monitor the national incidence of breastfeeding. The 1986 survey also included a follow-up study of breastfeeding mothers at 3 months post-partum. In 1981 the national incidence of breastfeeding on leaving hospital was 32%; in 1983 it was 34.6% and in 1986, 33.9%. In 1984, the Department of Health began to publish, in its Perinatal Statistics Report, annual national statistics on breastfeeding at discharge collected through the birth notification form. National figures from 1984 to 1990 reveal that the incidence of breastfeeding at discharge remains more or less static in the region of 30%⁶ (31.8% in 1984, 33.9% in 1986, 31.7% in 1990). In 1986 the percentage of mothers breastfeeding at 3 months was 15%. The experience of health professionals suggests that since then that percentage has decreased.

The recognition by the Department of Health that the percentage of mothers breastfeeding was low* by international standards and was not increasing, together with representations from interested parties such as

the Irish Nurses Organisation, La Leche League and WHO/UNICEF's Baby Friendly Hospital Initiative,⁷ led to a decision by the Department that a more comprehensive and pro-active policy to promote breastfeeding should be put in place. In 1992, the Minister for Health announced the establishment of a National Committee to Promote Breastfeeding with a brief to develop such a policy.

***Note:** In comparing incidence figures for the initiative of breastfeeding, caution is required to ensure that like is being compared with like. In Ireland the national incidence figures relate to the percentage of mothers breastfeeding at discharge from maternity hospitals or units. In many other European countries national incidence figures mean if the baby has been put to the breast at all. Therefore more accurate comparisons with these countries can be made by examining the prevalence of breastfeeding at later stages e.g. 1 week or 3 or 4 months where these data are available. Such comparisons, detailed later in this Report, still show Ireland in an unfavourable position.



Chapter 2:

Why promote breastfeeding?

Chapter 2

Why promote breastfeeding?

In developing a more comprehensive and pro-active breastfeeding policy, and particularly in the context of seeking to mobilise support for its implementation, it is useful to outline the rationale for such an undertaking. In other words why promote breastfeeding?

The major reasons include the following:

- Benefits to the health of the infant.
- Benefits to the health of the mother.
- Benefits to the mother-infant relationship.
- Economic benefits.
- The right of the mother to make an informed choice about how she wishes to feed her infant.
- Ireland's comparatively low level of breastfeeding.
- Initiatives by international organisations.

Each of these factors will now be discussed.

Benefits to the health of the infant

Human milk is a living fluid which contains active hormones, enzymes and cells and is considered to be the optimal food for the human infant.^{1,2,3} The main health benefits are outlined below.

Protection against Acute Infectious Diseases: There is evidence that both in the developing and developed world, breastfeeding protects against gastroenteritis. A recent well-designed study in Scotland,⁴ concluded that breastfeeding during the first 13 weeks of life confers protection against gastrointestinal illness for up to one year of age. There is also some, though less evidence, that breastfeeding has a protective effect against respiratory tract disease; that it reduces the duration of secretory otitis media; that it protects against H. influenzae disease; that it enhances cell-mediated immunity to BCG vaccine and to conjugate Haemophilus influenzae type b (Hib) vaccine at 7 and 12 months of age; and that it may have a protective role against paralytic poliomyelitis during the first 6 months of life. Some further discussion on the protective effect of breastfeeding against acute infectious disease is contained in Appendix E.

Protection Against Chronic Diseases: In a recent review of the aetiology of ulcerative colitis, it was suggested that a period of breastfeeding for as short as 2 weeks, may reduce the risk of developing ulcerative colitis in later life and that early exposure to cow's milk protein may play a part in its aetiology.⁵ In addition artificial feeding is considered to be a risk factor for the development of Crohn's disease.⁶ Artificial feeding is also considered to accelerate the development of coeliac disease.⁷ Insulin-dependant diabetes was attributed to lack of breastfeeding in 2-26% of cases in one case-control study.⁸ Recent work in Finland also found an association between bottle-feeding and type 1 diabetes mellitus.⁹ Davis et al. showed that the relative risk of developing lymphoma for those who were bottlefed or breastfed for less than 6 months was 5 to 8 times as great as that of those who were breastfed for longer than six months.¹⁰ The role of breastfeeding in the prevention of asthma, eczema, allergic rhinitis and mixed allergic disorders seems to be inconclusive according to Kramer (1988).¹¹ However a recent study suggests that the development of eczema may be related to the early introduction of solids.¹²

Protection Against Sudden Infant Death Syndrome: In some case control studies,^{13,14} but not in others,^{15,16} babies who were breastfed were found to be significantly less likely to succumb to sudden infant death syndrome. The national case-control study in New Zealand¹⁷ and another study in the US¹⁸ found breastfeeding to have a protective effect against sudden infant death syndrome. However while breastfeeding protects against several diseases in infancy, recent work has identified other risk factors which are more specific for sudden infant death syndrome.¹⁹

Premature Infants: Premature infants are a special group in that they stand to benefit most from their own mother's breastmilk but yet are the most difficult to feed.²⁰ A study published in 1983 found that mature human milk* did not constitute an optimal diet for pre-term infants since its use was associated with slower growth rates than in infants fed with premature human milk.²¹ Because of the risk of transmission of infection e.g. HIV, it is now advised that only a baby's own mother's milk should be given to infants, whether term or preterm. Premature infants tolerate their own mother's milk more quickly than formula.²² There is also some evidence to suggest that premature babies fed their own mother's milk are less prone to necrotising enterocolitis – a potentially lethal condition.²³

***Note:** In this context mature human milk is milk expressed from another mother who has delivered a term baby and whose baby is aged over two weeks.

Research in the UK has also found that the mother's choice to provide breastmilk was associated with higher mean development scores at 18 months of age post-term even with adjustment for potential confounders.²⁴ Further follow up of these children found that those who had consumed premature human milk had a significantly higher IQ at 7 - 8 years than those who had not received human milk.²⁵ There is sufficient evidence on

the value of breastmilk to encourage and support all mothers who wish to breastfeed their preterm babies.²⁶ However it is essential to ensure that an adequate volume is fed to the infant to ensure optimum growth and to reduce the risk of mineral deficiency. This may necessitate supplementation either by previously expressed own mother's milk or by an appropriate formula.

Other Health Issues: An objective assessment of the benefits of breastfeeding must pay due regard to some concerns relating to breastfeeding. These concerns relate to the iron status of babies breastfed after 6 months (the bioavailability of iron is reduced by solid foods), cholesterol levels of breastfed babies, growth rates of breastfed babies, transmission of HIV by breastmilk and breastmilk jaundice. Some discussion on each of these issues is presented in Appendix. F.

Benefits to Maternal Health

A number of studies have shown evidence of a protective effect of breastfeeding on the risk of breast cancer in pre-menopausal women.^{27,28} The most recent one was a population based case-control study in the UK which found that the risk of breast cancer decreased with increasing duration of breastfeeding, with breastfeeding each baby for 3 months or more giving the greatest protection.²⁹ The contraceptive benefit of breastfeeding was recognised by the Bellagio Consensus Conference in 1988,³⁰ but should not be relied on as an exclusive method. Breastfeeding may also decrease the risk of ovarian cancer.³¹

Benefits for the Mother/Infant Relationship

Breastfeeding brings the mother and infant physically close and when successful is very satisfying to both.³² The mother-infant relationship is facilitated by the ongoing somatosensory contact involved in breastfeeding.³³ The mother's level of endorphins increase significantly during suckling, which promotes a sense of well-being and a feeling of relaxation.³⁴

Economic Benefits

Breastfeeding provides a financially free source of nutrition for infants in the first months of life. It is ironic therefore that those in the lowest socio-economic groups are least likely to breastfeed. In 1989, for example, 68% of mothers whose partners were in the higher professional category were breastfeeding on leaving hospital compared to 14% of those with partners in the unskilled manual category and 10% of those whose partners were unemployed.³⁵ Breastfeeding frees financial resources for other uses – a

benefit likely to make most impact on lower socio-economic group households. However it is recognised that breastfeeding mothers will require improved quality of nutrition during the breastfeeding period.³⁶

The right of the mother to make an informed choice about how she chooses to feed her infant

The right of the mother to make an informed choice about how she chooses to feed her infant is a principle already enunciated by the Department of Health in its promotion of breastfeeding. This implies, not just that mothers have access to written information on the issue but that accurate up-to-date and consistent information is available on a one-to-one basis from health care professionals particularly to support the decision of those who choose to breastfeed. There is some evidence that there is room for improvement in the level of knowledge of health professionals in relation to breastfeeding and also that there is an over-reliance on infant formulae companies in providing continuing education to such professionals.³⁷ The Committee is also aware that gifts such as pens, diaries, calendars and charts, indirectly promoting breastfeeding alternatives, are to be found in maternity hospitals and units.

Ireland's relatively low level of breastfeeding

There is evidence that Ireland compares unfavourably with many other countries both in terms of initiation and duration of breastfeeding. In 1990 (the latest year for which national statistics are available) 31.7% of Irish mothers were breastfeeding at discharge from hospital.³⁸ As already mentioned the incidence of breastfeeding is particularly low in the lowest socio-economic groups. A more recent study undertaken in 1992 in an urban community showed that this difference in uptake between socio-economic groups still persists.³⁹ The most recent national figures for duration of breastfeeding refer to 1986 when only 15% of mothers were breastfeeding at 3 months.⁴⁰ Anecdotal feedback from health professionals suggests that this percentage has decreased since then.

In England and Wales the incidence of breastfeeding is considerably higher. It rose from 51% in 1975 to 67% in 1980.⁴¹ However since 1980 the incidence has levelled off but was still at 65% in 1985 and 64% in 1990.⁴² Fifty four per cent (54%) were breastfeeding at 1 week in 1990 and 25% at 4 months.⁴³ The corresponding figures for 1985 were 65% and 26%, showing little or no change.

In the US there was an upsurge in breastfeeding from the early 1970s, when about one quarter of mothers commenced breastfeeding, to the early 1980s when approximately 60% of mothers breastfed.⁴⁴ However since 1982 the trend has been downwards and by 1989 only 52.2% of women in the US commenced breastfeeding⁴⁵ – a level still considerably higher than in

Ireland. Of the 52% of American women who initiated breastfeeding, in the late 1980s, as many as one in three stopped within the first few weeks postpartum.^{46,47}

Norway is the European country with the highest incidence and duration of breastfeeding at present.⁴⁸ Traditionally, approximately 90% of women breastfeed for at least one week.⁴⁹ The prevalence of women breastfeeding at 3 months dropped steadily from a rate of 90% at the time of the Second World War to an all-time low in 1967 when just over 30% of women breastfed for 3 months.⁵⁰ From 1968 onwards, the rates of breastfeeding started to rise again, so that by 1982 the mean frequency of breastfeeding at 3 months had increased to 70%.⁵¹ The rate had remained at this level for the past 10 years.⁵²

The experience of Norway, in particular, suggests that it is possible to increase significantly the duration of breastfeeding. Some of the factors which are regarded as having contributed to Norway's success in this area are mentioned in later Chapters of this Report.

Initiatives by International Organisations

A number of relatively recent initiatives by international organisations give impetus to the need for a more comprehensive national policy on breastfeeding in Ireland i.e. the WHO/UNICEF Innocenti Declaration 1990,⁵³ the UN Convention on the Rights of the Child 1989⁵⁴ and the Joint WHO/UNICEF Baby Friendly Hospital Initiative launched in 1991.⁵⁵

The Innocenti Declaration: This Declaration on the promotion, protection and support of breastfeeding was produced and adopted by participants at the WHO/UNICEF policymakers' meeting on "Breastfeeding in the 1990's: A Global Initiative" held in 1990 in Florence, Italy.

The Declaration recognised that breastfeeding:-

- is a unique process which provides ideal nutrition for infants, contributes to their healthy growth and development and reduces the incidence and severity of infectious disease;
- contributes to women's health by reducing the risk of breast and ovarian cancer and by increasing the spacing between pregnancies;
- provides social and economic benefits to the family and the nation;
- provides most women with a sense of satisfaction when successfully carried out.

The Innocenti Declaration recommends that:-

- all women should be enabled to practise exclusive breastfeeding and all infants should be fed exclusively on breastmilk for 4-6 months from birth. Thereafter children should continue to be breastfed along with supplementary food up to the age of two years. (Attainment of this goal requires in many countries, the reinforcement of a “breastfeeding culture” and its vigorous defence against incursions of a “bottlefeeding culture”. In this respect, efforts should be made to improve the woman’s confidence in her ability to breastfeed. This involves the removal of constraints and influences that affect breastfeeding directly and indirectly. This requires a comprehensive communications campaign which involves all media and is addressed to all levels of media. Furthermore, obstacles to breastfeeding within the health system, workplace and community should be removed);
- measures should be taken to ensure that women have adequate nutrition, and access to family planning information and services to help them sustain breastfeeding;
- all Governments should develop national breastfeeding policies and set appropriate targets for the 1990s. A system to monitor achievement of their targets should be set up and indicators such as the prevalence of exclusive breastfeeding leaving hospital and exclusive breastfeeding at 4 months should be developed; and
- breastfeeding programmes should be integrated nationally into overall health and development programmes. All healthcare staff should be trained in the skills necessary to implement these breastfeeding policies.

The UK Convention on the Rights of the Child: The Irish Government ratified this important UN Convention in September 1992. The relevant sections of the Convention relating to breastfeeding are:

- (a) Article 24 Section 1 which states:
“State Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment and rehabilitation of health. State Parties shall strive to ensure that no child is deprived of his/her right of access to such health care services”.
- (b) Article 24 Section 2(e) which states:
“State Parties shall pursue full implementation of this right, and, in particular, shall take appropriate measures: to ensure that all segments of society, in particular parents and children, are informed, *have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding,* hygiene and environmental sanitation and the prevention of accidents” (our italics).

The Baby Friendly Hospital Initiative: This initiative, described in more detail in Chapter 7, provides for the designation of maternity hospitals as “Baby Friendly” when they have been assessed as carrying out the Ten Steps to Successful Breastfeeding promulgated in a Joint WHO/UNICEF Statement in 1989 (see Appendix G). The Committee is aware that the Department of Health has received representations from both organisations on the desirability of Ireland’s involvement in this initiative.

All of these factors suggest that it is an opportune time for Ireland to develop and implement a comprehensive breastfeeding policy.



Chapter 3:

Promoting breastfeeding in
maternity hospitals and units

Chapter 3

Promoting breastfeeding in maternity hospitals and units

Research indicates that a range of factors influence mothers to start and continue breastfeeding. Reference is made to these in relevant later sections of the Report. Though hospital policy and practice may not be the first influence chronologically on a mother's decision to breastfeed, since over 99% of Irish mothers give birth in hospital¹ and breastfeeding commences there, it seems an obvious entry point for a policy of promoting breastfeeding. From the starting point it is possible to work forward to community care policies which can support a woman's decision to breastfeed and help her to continue one she leaves hospital, to work backwards to ante-natal factors which may influence her decision, and then examine the crucial issues of training of health professionals and the promotion of support for breastfeeding in the wider community.

Research indicates that most mothers have already decided on their method of feeding before delivery,² so hospital activity should be primarily oriented to supporting the mother's chosen feeding practice. It should also be mentioned however that there may be an opportunity too at this stage to influence the feeding decisions of some mothers. A study of Irish mothers in the early 1980s, for example, found that, while only 5% of breastfeeding mothers made their decision on feeding method after the baby was born, 33% of bottlefeeders said they made their decision at that stage and a high proportion of those were from a lower socio-economic background.³

Accepting that the main thrust of hospital activity to promote breastfeeding should be supporting those mothers who have chosen this method, the question arises as to how this can best be done. In this context it is useful to consider the hospital factors which influence breastfeeding under two main headings – hospital staff and hospital routines.

Hospital Staff

Knowledge Level of Staff: Breastfeeding, though partly instinctive, is a learned experience.⁴ Successful breastfeeding depends on what mothers learn and on the skilled teaching and support they receive while they are learning.⁵ The knowledge of health care staff, particularly about those practices which have been shown to be effective, influence both the information and the quality of support the mother receives. A recurring theme in the research literature and in comments made personally to many members of this Committee is the importance of consistency in the advice given. **The Committee recommends therefore that hospital personnel, particularly midwives, should have the skills to give accurate up-to-date advice to mothers.** (The training implications of this are discussed in Chapter 5).

Attitudes of Hospital Staff: The attitudes of hospital staff, particularly midwives, are also important. The duration of breastfeeding has been found to be significantly longer in mothers who perceived that their medical advisors favoured breastfeeding than among mothers who felt that their medical advisors were neutral or did not favour breastfeeding.⁶ Non-verbal behaviour can sometimes be at variance with verbal behaviour, as for example, where staff were providing accurate knowledge to mothers but doing so in a way that conveys that providing the information is a nuisance or taking up time that staff would have preferred to spend on other tasks. **Ideally information should be provided, not just in a neutral way, but in the context of positive supportive attitudes from staff.**

Hospital Routine

Initiation of Feeding: While no research has demonstrated a “critical period” for the first feed in terms of breastfeeding success,⁷ a number of studies suggest that putting the baby to the breast earlier rather than later is preferable.

A randomised study in Dundee, found that immediate postpartum suckling resulted in mothers feeding for longer periods than mothers whose infants were not put to the breast until a few hours after delivery.⁸ Non-random studies have also found that those who commence breastfeeding early rather than late have a longer duration of breastfeeding.^{9,10,11} The rate of early cessation among women who were low in confidence has been found to be significantly higher if the first breastfeeding experience occurred late rather than early.¹²

Research indicates that babies have a wide range of behaviour following delivery and are ready to feed from 15 to 50 minutes after delivery.¹³ Similarly it was found in a Swedish study, that babies who were in uninterrupted contact with their mother for 1 hour after birth were sucking at the breast within an average of 50 minutes.¹⁴

The Committee recommends that 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.

Rooming-In: Rooming-in has been found to facilitate the early initiation of breastfeeding and increase the proportion of women who attempt to breastfeed.¹⁵ In a Japanese study, it was found that rooming-in infants had significantly higher breastfeeding frequencies than non-rooming-in infants during the first week of life.¹⁶ One study found that rooming-in did not have an effect on exclusive breastfeeding.¹⁷ Rooming-in was found to be significantly associated with the initiation and continuation of breastfeeding in a heterogenous group in a health maintenance organisation.¹⁸

The Committee recommends that for successful breastfeeding rooming-in is advisable and should be the norm in all maternity hospitals and units.

Frequency and duration of feeds: There is evidence that babies who regulate the frequency of their feeds themselves gain weight more quickly and remain breastfeeding for longer than those who have external limitations placed on them.¹⁹ An Irish study found that breastfeeding on demand rather than scheduled feeding was associated with breastfeeding for longer than twelve weeks.²⁰ Another study found that the overall duration of breastfeeding was significantly shorter among a group of mothers who were on a timed regime versus those who fed as long as they wished.²¹ Correct positioning of the baby at the breast together with frequent breastfeeding helps prevent sore or cracked nipples and breast engorgement.^{22,23} The frequency of feeding required will vary from baby to baby. Feeding 12 - 13 times per day may be required on the third or fourth day.

The Committee recommends that 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.

Supplementation of Breastfeeding: The supplementation of breastmilk with either water, glucose or formula in hospitals is common.^{24,25} The need for supplementary fluids while breastfeeding is being established has not been supported by evidence.²⁶ Furthermore Houston et al^{27,28} claim that a healthy baby has no need for large volumes of fluid any earlier than these become available from the breast. A controlled randomised trial found that there was no statistically significant reduction in the development of breastmilk jaundice or in mean bilirubin levels among the babies receiving supplementary fluids.²⁹ A study involving a control group of infants who were weighed each morning as well as before and after each breastfeed and supplementary feed, and a test group, who were weighed only in the morning and had unsupplemented breastfeeding, found that there was no difference in weight gain among the babies but that the mothers in the control group were 5 times more likely than those in the test group to give up breastfeeding in the first week and twice as likely in the second week.³⁰ The balance of evidence from aggregated trials suggests that infant problems with breastfeeding or lack of maternal motivation to breastfeed may induce a relationship between early supplementation and early weaning for some mothers.³¹

The Committee is of the view that there should be minimal need for supplementary and complementary feeds in the healthy term breastfed baby.

The Committee recommends that maternity hospitals and units should avoid giving supplementary feeds unless they are medically indicated and that water, glucose/dextrose should have no place in the nutrition of breastfed babies at this time.

The Committee recommends that 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.

The Committee recommends that correct positioning from the first feed is the most effective way of preventing cracked nipples. Correcting the baby's position at the breast is usually effective in resolving the problems of sore nipples and therefore, the use of nipple-shields should be the exception.

Expressing Milk: In the months after discharge from hospital, there may be times when mother and baby are separated either for short periods or more extended ones, for example if the baby is hospitalised. The baby can still benefit from its mother's milk during those separations if the mother can express the milk. Knowing that she can do this can increase a mother's sense of freedom and may make it easier for her to breastfeed in the first place.

The Committee recommends therefore that before leaving hospital, mothers should be shown how to express breast milk. The Committee further recommends that all maternity hospitals and units 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.

Instrumental Deliveries and Caesarian Sections:

The Committee recommends that mothers who have had instrumental deliveries and caesarian sections should be given extra support with breastfeeding.

Premature Babies:

The Committee considers that there is sufficient evidence on the value of breastmilk for preterm babies to recommend that all mothers who wish to breastfeed their preterm babies be encouraged and supported to do so. However it is essential to ensure that an adequate volume is fed to the infant to ensure optimum growth and to reduce the risk of mineral deficiency. This may necessitate supplementation either by previously expressed own mother's milk or by an appropriate formula.

Babies requiring admission to Special Baby Units:

The Committee recommends that 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.

Sprays and Creams:

The Committee recommends that mothers should be advised that the use of sprays and creams is unnecessary and may hinder effective breastfeeding.

Promotion of Infant Formula: The distribution of hospital gift packs containing infant formula has been shown to affect the duration of breastfeeding in a number of randomised evaluations. One study found that hospital gift packs significantly shortened the duration of breastfeeding in three subgroups: primiparae, mothers who had less than 14 years of schooling and mothers who were ill postpartum.³² In a randomised controlled trial in a multi-ethnic population, it was concluded that in high risk population commercial discharge packs may pose an independent and significant risk factor to the duration of breastfeeding.³³

In a randomised trial of women who received either a discharge sample of infant formula or a breast pump it was found that those who received the infant formula carried on exclusive breastfeeding for a significant shorter time and overall had a shorter duration of breastfeeding.³⁴ Though one study in Chicago failed to demonstrate the effect of discharge samples on the duration of breastfeeding, the weight of evidence clearly demonstrates that the provision of such samples increases the risk of cessation. For this reason, since 1990, under the Voluntary Code of Practice on the Marketing of Infant Formulae in the Republic of Ireland, the formulae companies have agreed not to provide free samples to hospitals. However the Committee is aware that gift items such as pens, diaries, charts, indirectly promoting infant formulae, are to be found in maternity hospitals and units.

The Committee recommends that 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 and that gift items 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 or breastfeeding support groups.

Support for the maintenance of breastfeeding. While hospital staff may view their role as primarily concerned with assisting mothers in the successful establishment of breastfeeding, it is also important that mothers go home with a sense of confidence in their ability to maintain breastfeeding.

Research suggests that a considerable proportion of Irish mothers who are breastfeeding at discharge, discontinue the practice in the early weeks and months. One study which followed up, after three months, mothers who had been breastfeeding at discharge from Irish maternity hospitals and units in 1986, found 15% had ceased breastfeeding by the end of the third week and 33% by the end of 6 weeks, with only 41% of the original breastfeeders still breastfeeding at 12 weeks.³⁵

Many of the reasons put forward for discontinuing breastfeeding are based on misconceptions.

The Committee recommends that mothers be encouraged to breastfeed for at least 4 months. Mothers should be advised that there are very few medical reasons for discontinuing breastfeeding. However staff should afford due recognition to the fact that some mothers will choose not to breastfeed or 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, e.g. La Leche League and the Irish Childbirth Trust.

In order to ensure that help is available to mothers from the health service when they leave hospital,

the Committee recommends that all hospitals be as prompt as possible in notifying discharges to the appropriate health board medical officer in each Community Care Area.

Application of a Hospital Policy: The importance of consistency in the information about breastfeeding given to women is a constant theme in the literature and indeed among health workers and mothers themselves. One of the factors which could increase such consistency is a written hospital policy which is routinely communicated to all health care staff and to mothers and their partners. The Committee is aware that a number of maternity hospitals and units have, or are in the process of developing, such a policy and welcomes this fact. The Committee is also aware that practice in relation to policy even where such exists can be quite variable. A recent study of three rural maternity units in Ireland found that one unit had a written and displayed policy but was not totally supportive of breastfeeding, a second had a supportive policy which was filed away and very few healthcare staff knew it existed and a third had no written policy but did have regular ward discussions regarding breastfeeding practices.³⁶

Research from the UK also suggests that even where policies exist there is considerable room for improving their implementation. One study on midwifery practices and policy found that though midwives indicated that

babies were put to the breast soon after delivery, in practice many labour-ward routines made it difficult for mother and baby to commence feeding.³⁷ Another recent UK study found that, though the professionals said that rooming-in occurs frequently or very frequently, 66% of the mothers and babies were separated on the first night and a third of babies received formula even though professionals stated that glucose, dextrose or formula were infrequently given.³⁸

The Committee recommends that every maternity hospital and unit should have a clear written policy promoting and supporting breastfeeding and incorporating all of the recommendations made earlier in this Chapter. This policy should be communicated routinely to all health care staff and to women and their partners. The Committee emphasises that strict implementation of the stated policy is essential and that ward management should be centred round the mother-infant dyad to facilitate breastfeeding. The Committee further recommends the establishment of a lactation 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 groups

Chapter 4

Promoting breastfeeding at community care level including the role of voluntary support groups

Support for breastfeeding at community care level can be said to fall into two main time periods – ante-natally during a pregnant woman’s contacts with the health care services and post-natally when she and her baby are discharged from hospital. Ideally during this time mothers have available to them the support of appropriately trained health professionals and of mother-to-mother support groups.

Ante-Natal Period

Many women decide on their method of feeding during their pregnancy. An Irish study in the early 1980s found that while the largest percentage (54% of breastfeeders and 43% of bottlefeeders) said they always knew which they would do, 41% of breastfeeders and 24% of bottlefeeders made the decision during their pregnancy.¹ Research conducted in other countries supports the fact that many women made the decision during this time, often early on in the pregnancy.^{2,3,4} Mothers’ contacts with health professionals during this time provide windows of opportunity for staff to raise the issue of infant feeding.

There is evidence to suggest that in a number of cases feeding methods are not discussed with mothers ante-natally. According to the 1990 national survey in the UK, some 12% of women had not been asked about their plans for feeding.⁵ In the Irish national survey in 1982, 13% of mothers said that they had not been asked about their proposed method of feeding at ante-natal care.⁶

While it is recognised that the decision on feeding method rests with the mother herself and that no woman should be made to feel guilty or inadequate if she chooses to bottlefeed, one might suggest that during the pregnancy period health professionals raise the issue of feeding in a way which suggests that breastfeeding is the assumption and the expectation – a natural stage in the reproductive process. Health professionals who are themselves knowledgeable about, and positive towards breastfeeding, will be in the best position to convey a supportive message to mothers. The comments made in Chapter 3 in relation to the distribution of materials promoting infant formulae either directly or indirectly are also applicable to health centres.

The Committee recommends that, at a minimum, health professionals should ensure that during the ante-natal period all women have information on the advantages and management of breastfeeding and are assured that post-natally, support will be available from health care

professionals and voluntary groups. Mothers should also be alerted to the fact that in the event of their baby requiring special care this should not necessarily preclude breastfeeding and that special support with breastfeeding will be available to them. Health centres should distribute the materials on breastfeeding produced/approved by the Health Promotion Unit or the breastfeeding support groups.

Post-Natal Period

Support for breastfeeding mothers is often crucial in the first few days after discharge from hospital. For this reason it has already been recommended in Chapter 3, that hospitals be prompt in notifying the appropriate health board medical officer in each Community Care Area of discharges. Since public health nurses routinely visit new mothers, they have a pivotal role in providing information and support to those who are breastfeeding. Mothers may also seek the advice of their GPs during this period and may also be in contact with mother-to-mother support groups. As has already been stressed in Chapter 3, the need for consistency in the advice given to mothers cannot be overstated. While training of health professionals has an important role to play in trying to achieve consistency and is considered in Chapter 5, formal co-ordination of approach at local level would also be critical.

The Committee recommends therefore that each Community Care Area have a written breastfeeding policy. This should be consistent with that recommended for hospitals as well as incorporating elements relevant 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.

In relation to a number of health issues where it is considered that special expertise is required and that updating of knowledge is important, a resource person has been identified in Community Care Areas. This has happened for example in the area of incontinence.

The Committee recommends that 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.

It is recognised that due to pressure of workload public health nurses are not always in a position to visit breastfeeding mothers who need help, as often as may be desirable.

For that reason the Committee recommends that a Breastfeeding Clinic to which mothers can come with their babies be held weekly in each health centre and that the existence of such a clinic be made known to women both ante-natally and post-natally.

Mother-to-Mother Support Groups

Voluntary support groups are an important community resource available to assist health professionals in their task of supporting breastfeeding mothers. In Ireland a number of these is well-established since the 1960s. The existence of a strong network of mother-to-mother support groups is one of the factors identified as having helped to increase the incidence of breastfeeding in Norway. In 1968 (the same time that the rise in breastfeeding started to occur) a voluntary group of women, “Ammehjelpen” was set up to support breastfeeding mothers and assist those who cannot, or have chosen not to, breastfeed. This support is available by telephone around the clock.⁷

When good collaboration is established, lay groups and professionals mutually reinforce each other’s assistance to mothers. A joint WHO/ UNICEF statement “Ten Steps to Successful Breastfeeding”⁸ (see Appendix G) urges that every facility providing maternity services and care for newborn infants should “foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic”. This Report has already recommended that mothers should be informed during their pregnancy and before discharge from hospital of the various breastfeeding support groups in the community.

The Community further recommends that there be regular meetings and liaison at local level between health professionals and voluntary breastfeeding support groups such as La Leche League and the Irish Childbirth Trust and that each health centre 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 been introduced to them. Adequate resources should be made available to the voluntary support groups to enable them to participate effectively in these programmes.

Community Mothers’ groups have been found to be a very effective channel for health promotion.⁹

The Committee recommends that where such groups exist, they should be availed of, in conjunction with established breastfeeding support groups, to help breastfeeding mothers.

While national statistics on breastfeeding at discharge are routinely gathered and published by the Department of Health in its annual Perinatal Statistics Report, there is no breakdown available by Community Care Area nor is there routine data available on the duration of breastfeeding. Such data would be valuable in providing feedback to health professionals and for monitoring and evaluation purposes.

The Committee recommends that data on the prevalence of breastfeeding at discharge and at 4 months 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

Chapter 5

Training of health professionals

A recurring theme through this Report so far has been the need for accurate, up-to-date, consistent information, in the context of positive attitudes, to be provided to mothers regarding breastfeeding. During the ante-natal and post-natal periods women have contact with a range of health professionals – general practitioners, midwives, public health nurses, public health doctors, obstetricians and paediatricians. If each of these contacts is to be fully utilised, for the promotion of breastfeeding, there is a presupposition that health professionals are receiving the necessary education and training. Both research and anecdotal reports from those in the field suggest that there is need for improvement in training.

A recent study of three rural maternity units presented to staff a very basic knowledge test of nine questions, the content of which was based on WHO/UNICEF guidelines for optimal management of breastfeeding in hospital.¹ This study showed that there was considerable variation in the knowledge and practice of health professionals in relation to breastfeeding. Health workers currently receive breastfeeding information during their initial training, through continuing education, and through interaction with their colleagues.

The Committee makes the following recommendations in relation to the training of nursing and medical personnel.

Undergraduate Training

The concept of the 10 Steps to Successful Breastfeeding² should form the basis of an education programme for all nursing/midwifery and medical personnel at undergraduate level. Due attention should be paid in the curricula 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.

In-Service Training

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 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 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 co-ordinate 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.

Manual of Best Practice

To help ensure consistency in training and in practice, the 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 Committee recommends the Royal College of Midwives publication “Successful Breastfeeding” (2nd Edition 1991)³ as the manual of best practice, with “The Breastfeeding Answer Book” (La Leche League International, 2nd Edition 1992), as an additional resource.⁴



Chapter 6:

Promoting breastfeeding in the wider community

Chapter 6

Promoting breastfeeding in the wider community

While the contacts between pregnant and breastfeeding mothers and health professionals and voluntary support groups are a key ingredient in any policy to promote breastfeeding, the issue also needs to be addressed in a wider socio-cultural context. As has already been stated in Chapter 4, many women have already made their decision about breastfeeding before they become pregnant. A study of Irish mothers in the early 1980s found that when asked about the timing of their decision on feeding method, 54% of breastfeeders and 43% of bottlefeeders said they “always knew”.¹ The decision on feeding method is made against the background of the attitudes prevailing in the wider society as well as those of the mother’s more immediate network of family and friends.

The behaviour and attitude of the mother’s own mother would appear to be important. An Irish study found that 50% of breastfeeders had been themselves breastfed compared to 31% of bottlefeeders.² In terms of attitudes, 51% of the breastfeeders compared to 18% of the bottlefeeders rated their own mother’s attitude to breastfeeding as positive. A recent national survey of breastfeeding in the UK showed a similar pattern with 75% of those who were themselves breastfed planning to breastfeed their babies, compared with 70% who were fed by both bottle and breast and 48% of those who were entirely bottlefed.³ Interestingly, among those who did not know how they had been fed, 49% planned to breastfeed. The authors state that “this suggests that it may be discussions with their own breastfeeding mothers about the way they were fed which influences women to choose to breastfeed”.⁴

Research also suggests that a baby’s father plays a significant role in a mother’s decision about infant feeding method. A study of Irish mothers found that 81% of breastfeeders said their husband preferred breastfeeding, 2.5% preferred bottlefeeding and 16.5% described him as non-committal.⁵ Among bottlefeeders 25.5% said their husbands preferred breastfeeding with 66.5% saying he was non-committal and 5% of the husbands not discussing the subject at all. Studies in other countries have also found that fathers influence the decision.^{6,7,8} One study found that a mother’s choice of infant feeding method was strongly associated with her husband’s opinion if he had a definite preference.⁹ There is also evidence that the baby’s father’s support of breastfeeding is associated with its duration.¹⁰ Similarly an association has been found between the giving of information to the father and the duration of breastfeeding.¹¹

There is some evidence of an association between the feeding method of a women’s wider social network of friends and acquaintances and her own decision. One longitudinal study in the UK of primagravida found that most mothers used the method advocated by their “lay advisors”.¹² A more

recent national survey in the UK found that the way a woman's friends and acquaintances fed their babies was strongly associated with her own choice.¹³ In a low income population in the US, the lack of support for breastfeeding from a close source such as husband, mother, other relative or friend was a most significant factor in influencing a mother to bottlefeed.¹⁴ In an Irish context, mothers were asked how most other mothers they knew with young children fed their babies. Thirty seven (37.5%) per cent of the breastfeeders and 16% of the bottlefeeders said these were mainly breastfeeders. About 20% in each group said they knew roughly equal numbers of breast and bottlefeeders. The remainder, 63.5% in the case of bottlefeeders and 40% in the case of breastfeeders, were mainly in contact with bottlefeeders.¹⁵

A strong association has also been found in many studies between socio-economic group and whether or not a mother breastfeeds. In a national sample of Irish mothers who were breastfeeding at discharge in 1990, 64.7% of those in the higher professional group were doing so, compared to 31.8% of those in the skilled manual group, 17.9% in the semi-skilled manual group and 8.2% of those where the baby's father was unemployed.¹⁶ National surveys in the UK have also found a strong social class gradient in breastfeeding.¹⁷

Research also indicates a very different educational experience of breastfeeding and bottlefeeding mothers. In an Irish study in the early 1980s, one third of the bottlefeeders had left school at or before 15 years of age compared to only 10% of the breastfeeders. The great majority (78%) of the breastfeeders stayed at school to age 17 and beyond compared to 42% of the bottlefeeders.¹⁸ A similar pattern has been found in surveys in the UK.¹⁹ One would expect a very considerable overlap between socio-economic group and educational level, though the Irish study referred to earlier in the paragraph, concluded that "educational level may be an even more powerful discriminator (in relation to breastfeeding) than social class".²⁰

In examining the background socio-cultural variables associated with breastfeeding or bottlefeeding, care is necessary that associations found between certain variables and these behaviours are not interpreted as proving causation. This is particularly important where there is potential for overlap between associated factors e.g. some of the association between socio-economic group and feeding method might prove to be explained by younger age at giving birth in lower socio-economic groups or by lower rate of attendance at ante-natal classes.

One general attitude which has surfaced in research on reasons for choice of bottlefeeding is embarrassment about breastfeeding. In an Irish study conducted in the early 1980s, 10.5% of the bottlefeeders specifically mentioned embarrassment about breastfeeding as the reason they chose to bottlefeed and another 7% mentioned lack of privacy to breastfeed.²¹ (In a survey in the UK around the same time 11% of bottlefeeders mentioned

embarrassment as a reason for not breastfeeding. This had decreased to 7% by 1990).²² In a separate question the respondents in the Irish study were asked what they felt were the disadvantages of breastfeeding. Thirteen (13%) per cent mentioned embarrassment and 17% either the need for privacy in the home (8.5%) or the lack of special facilities for breastfeeding outside the home. Both bottlefeeding and breastfeeding mothers were asked whether they would mind breastfeeding in various situations e.g. in front of their husband, their mother or in a public park or restaurant. The two groups differed quite clearly in the levels of embarrassment regarding breastfeeding, with embarrassment rates less but still substantial, among breastfeeders.²³

The Committee recommends that there should be no discrimination against breastfeeding over bottlefeeding babies in public places.

In the context of the above research, it would appear that education about breastfeeding needs to extend beyond pregnant women and indeed beyond women, to include the community at large.

Since breastfeeding is recognised as the optimal health care for the normal term baby, the Committee recommends that the media support and promote a positive image of breastfeeding and portray it as the norm.

One of the factors credited with enabling Norway to achieve its high incidence of breastfeeding is a relaxed attitude to the female body, including the shape of the female breasts, which may make women less apprehensive about breastfeeding.²⁴ Increased female self-confidence as a result of the formation of both breastfeeding mothers' support groups and the feminist movement is also considered to have been an enabling factor.²⁵

In an Irish context

the Committee recommends that 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.

Maternity Leave

While psycho-social factors may be important influences on decisions about initiation and duration of breastfeeding, practical considerations also need to be addressed. In modern society one of the most important of these is the balance which many women are trying to achieve between the demands of the family and work outside the home. In structural terms this issue is

addressed in maternity protection legislation (maternity leave, job protection and nursing breaks), workplace facilities for expressing milk or child care facilities which enable employed mothers to feed their children. The interplay between general attitudes to breastfeeding in a society and structural constraints on, or facilitation of, the practice of breastfeeding is recognised.

Though generalisation is difficult because of the different structural provisions in different societies, there is some evidence of an association between shorter duration of breastfeeding and return to fulltime employment. A national survey in the UK in 1990 examined reasons why breastfeeding mothers stopped feeding at different ages of their baby. The survey found that after the baby reached two months old, mothers were increasingly likely to stop breastfeeding because of returning to work. This was significantly more likely to be given as a reason than it had been in surveys earlier in the 1980s but, as the authors point out, substantially more mothers were on paid maternity leave in 1990 than in previous years.²⁶

A survey in the US of over 500 women, predominantly white, well-educated and married who replied to a questionnaire placed in women's magazines and who had breastfed while being employed found that weaning before 1 year of age was associated with early postpartum employment (Before 16 weeks) as well as fulltime employment. When the mother returned to work appeared to have a greater effect than how many hours she worked per week.²⁷

Maternal employment was found to be a significant predictor of cessation of breastfeeding among a heterogenous US population.²⁸ Another US study also found that mothers who returned to work in the early postpartum period were more likely to wean.²⁹ In the Irish national survey in 1986, a quarter of women who breastfed said that the duration of their breastfeeding was decided by their return to work.³⁰

It is of interest to note that Norway, the European country with the highest known incidence and prevalence of breastfeeding (90% at birth, 70% at 3 months), has very generous structural supports for breastfeeding. Paid maternity leave has gradually been extended from 12 weeks in the early 1970s up to 46 weeks in 1993 for those who have been employed for 6 of the 10 months prior to delivery.³¹ Working mothers who are breastfeeding are entitled to a 2 hour nursing break daily.³² The Committee recognises the importance of such structural supports for breastfeeding.

At present Irish legislation provides for a period of 14 weeks paid maternity leave, with provision for a further period of 4 weeks unpaid leave at the end of the paid period. Maternity leave must begin no later than 4 weeks before the end of the expected week of confinement. The Committee is aware that in order to have a longer period of leave postpartum, many mothers pressurise their obstetrician to falsify the expected delivery date. The Committee considered whether it should recommend greater

legislative flexibility on the ante-natal leave period. The Committee decided against this on the grounds that mothers who took ante-natal leave of less than 4 weeks could end up exhausted after their delivery and perhaps be less likely to breastfeed.

The Committee instead recommends greater legislative flexibility in relation to post-natal leave. Initially this might involve more extended optional unpaid leave with a gradual extension in the longer term of the length of paid leave. The Committee recommends that employers provide facilities where breastfeeding mothers who are working can express milk. The Committee also recommends the extension of workplace creche facilities along the lines recommended in the Second Report of the Council for the Status of Women. The public sector, and in particular, the health sector, should give a lead in providing creche facilities and lactation breaks.



Chapter 7:

Targets, implementation and
monitoring

Chapter 7

Targets, implementation and monitoring

Introduction

Despite various initiatives in terms of provision of literature, the Voluntary Code of Practice on the Marketing of Infant Formulae, and the existence of mother-to-mother breastfeeding support groups, the incidence of breastfeeding at discharge from hospital has changed little in Ireland since the early 1980s.^{1,2} The Committee is of the view therefore that if the objectives of this Report are to be achieved there is need for a co-ordinated approach to the implementation of its recommendations and the monitoring of progress on them and on the objectives of increasing

- (a) the percentage of mothers who initiate breastfeeding and
- (b) the percentage who practise exclusive breastfeeding to at least four months and thereafter with appropriate weaning foods.

Targets

The Committee is of the view that, in pursuit of the two general objectives outlined above, it is helpful to set more specific targets which make it possible to identify and quantify progress towards the achievement of those objectives. In that context the Committee recommends the following targets:

- 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 4 months by the year 2000.

In order to achieve the above medium and longterm 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 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 creche facilities and lactation breaks.

The Baby Friendly Hospital Initiative

The Committee is cogniscent of the launch, in 1991, by WHO and UNICEF of a Baby Friendly Hospital Initiative (BFHI).³ This initiative provides for the designation of maternity hospitals and units as “Baby Friendly” when they have been assessed and found to be carrying out all the “Ten Steps to Successful Breastfeeding” (see Appendix G). When a hospital considers that it is doing this, it can apply for external assessment organised by a National Designation Authority and carried out by a Board of Assessors. If these are satisfied that the hospital is truly “Baby Friendly” it is awarded a plaque stating this. If the assessors are not satisfied that the hospital fulfills all the criteria, the hospital may still request a “Certificate of Commitment” which states the hospital’s commitment to become truly “Baby Friendly” in the near future.

The Committee is aware that the Department of Health has been approached by both WHO and UNICEF urging Ireland’s participation in the Baby Friendly Hospital Initiative.

Given that the recommendations of this Committee on promoting breastfeeding at hospital level are in line with the “Ten Steps to Successful Breastfeeding” advocated by the BFHI, the Committee is recommending Ireland’s participation in this initiative. However the Committee wishes to emphasise that this designation should not be taken to insinuate that hospitals not so designated are not friendly to babies.

The Committee sees the BFHI as potentially an additional catalyst to mobilise support to help achieve the objectives of this Report.

The Committee recommends that the Department of Health takes responsibility for ensuring that the structures necessary for Ireland's participation in the initiative i.e. a National Designation Authority and a Board of Assessors, are put in place.

Co-ordination of the Implementation of the Report's Recommendations

The Committee recognises the need for a statutory agency to oversee and co-ordinate the implementation of its recommendations.

The Committee recommends that the lead role in this be undertaken by the Health Promotion Unit of the Department of Health in conjunction with other relevant divisions within the Department e.g. 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, is 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.**

Dissemination of the Committee's Recommendations

The Committee recommends that the Health Promotion Unit disseminate this Report to relevant organisations including all maternity hospitals and units both public and private, the health boards, An Bord Altranais, 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, of 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, the Department of Equality and Law Reform, the Department of Enterprise and Employment, the Irish Congress of Trade Unions, the Irish Business and Employers Confederation, La Leche League, 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.

An accompanying letter should request the organisation to reply within 6 months to the Health Promotion Unit on the steps that are being taken to implement recommendations relevant to that organisation.

National Resource Centre for Breastfeeding Materials

The Health Promotion Unit currently produces two main publications which address the issue of infant feeding – Food and Babies and the Book of the Child. These are distributed to mothers through maternity hospitals and units. The Health Promotion Unit also provides some funding for the educational materials of mother-to-mother support groups. The Committee is aware that there is need for stand alone leaflets on specific topics which public health nurses and GPs could give to breastfeeding mothers as required. A need has also been expressed for attractive posters for GP's surgeries, health centres and ante-natal clinics.

The Committee recommends that the Health Promotion Unit act as a Resource Centre for Breastfeeding Materials which have a national application.

Research

National data on the percentage of mothers breastfeeding at discharge are now published annually by the Planning Unit of the Department of Health in its Report on Perinatal Statistics. These data are based on the birth notification form routinely returned to the Department. The data are currently published in aggregated form for the country as a whole, but they could also be provided separately for each maternity hospital and unit. In addition, updated systems will, within the next year or two, considerably lessen the time lag before publication of the data for a given year.

The Committee recommends, that with these improvements, the Perinatal Statistics Report compiled by the Planning Unit of the Department of Health should continue to be the main instrument for monitoring the national incidence of breastfeeding at discharge. These statistics, currently published in aggregated form for the country as a whole, should also be provided separately for each maternity hospital and unit.

It is recognised that, while the postpartum hospital stay is quite short, there may still be a number of mothers who attempt to initiate breastfeeding but have abandoned it by the time they leave hospital and are therefore not recorded in national statistics.

The Committee recommends that each maternity hospital and unit maintain its own data on these mothers. These data can be used by the hospital to monitor its own performance.

There is currently no routine data collection on the duration of breastfeeding. Since one of the objectives of the Committee is to increase the percentage of mothers who breastfeed for 4 months, and thereafter with appropriate weaning foods, it will be necessary to monitor periodically progress towards this objective. The Committee has already recommended that each Community Care Area collect data on prevalence of breastfeeding at 4 months for the purposes of monitoring and evaluation at local level.

The Committee recommends that the appropriate health board medical officer in each Community Care Area submit an annual return to the Department of Health on the total number of births in his/her area and the percentage of mothers breastfeeding at hospital discharge and at 4 months. The Department will have responsibility for collation and publication of the data at national level. The Department should also ensure standardisation in the way the data are collected, for instance, definitions of breastfeeding, whether it is exclusive or with supplements.

In addition to collecting basic statistical data on a routine basis as outlined above, the Committee recognises that periodically it may be necessary to do more indepth surveys of both breastfeeding and bottlefeeding mothers to obtain up-to-date information on the factors influencing initiation and duration of breastfeeding.

The Committee recommends that the Health Promotion Unit keep under constant review the need for such research.



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Chapter 7

Targets, implementation and monitoring

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Appendices

Appendix A

*International Code of Marketing
of Breast-milk Substitutes*



World Health Organization

Geneva
1981

International Code of Marketing of Breast-milk Substitutes

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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 breast-feeding;

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 breast-feeding, 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 article 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:

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| “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”. |

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| “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”. |

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| “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 organisations 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 the 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 B

Article 1.0 Aim of the Code

The aim of the Code is to contribute to the provision of safe adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper uses of Infant Formulae when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

Article 2.0 Scope of the Code

This Code applies in the Republic of Ireland to the marketing of Infant Formulae, as suitable for use as a partial or total replacement for breastmilk. It also applies to information concerning their use.

Article 3.0 Definitions

For the purpose of this Code, the following terms have the meanings as detailed below:

| | | |
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| Artificially-Fed Infants | <i>means</i> | those infants fed with Infant Formulae either exclusively or as a supplement to breastfeeding. |
| Breast Milk Substitutes | <i>means</i> | any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose. |
| Code Monitoring Committee | <i>means</i> | the Committee established within the Confederation of Irish Industry in accordance with the Schedule to this Code. |
| Distributor | <i>means</i> | a person, corporation or any other entity engaged in distributing Infant Formulae at wholesale or retail level in the course of trade or business. |
| General Advertising | <i>means</i> | the communication to the general public of a promotional message through mass media, e.g., radio, television, national and local newspapers, magazines and posters. Price information is excluded. |
| Health Care Systems | <i>means</i> | governmental or private institutions or organisations engaged directly or indirectly in health care for mothers, infants and pregnant women, including nurseries or child-care institutions. It also includes health workers in private practice. |
| Health Care System Advertising | <i>means</i> | advertising which is communicated or disseminated under the supervision or care of the health care system to mothers of infants or their families. This includes, for example, advertising in specialist publications published by or for such professional |

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| | | bodies as the Irish Medical Organisation, the Irish Paediatric Association, the Irish Nurses' Organisation and public health nurses. It also includes bought space in the medical press or other relevant specialist publications intended for a professional and health care readership. |
| Health Worker | means | a person working in the field of health under the authority of a health care system. |
| Infant | means | a child who has not attained the age of one year. |
| Infant Formulae | means | manufactured products either in ready-to-feed or concentrated liquid or dried form, which, after reconstitution if necessary, can be used as the sole source of nourishment for an infant. It does not include products used as weaning food. |
| Labelling | means | brand names, pictorial or other descriptive matter, words or particulars appearing on the packaging of Infant Formulae products offered for retail sale. |
| Manufacturing | means | a person or corporation or any other entity engaged in the business of manufacturing Infant Formulae either directly or indirectly. |
| Samples | means | single or small quantities of Infant Formulae provided free of charge. |
| Subsidised Supplies | means | donations or low-priced sales to institutions or organisations or individuals of supplies of infant formulae or other products within the scope of this Code, whether for use in institutions or for distribution outside them. |
| Weaning Food | means | a food used as part of the mixed diet during the time when breast or bottle feeding becomes insufficient to satisfy the nutritional requirements of the infant, usually from about the age of twelve weeks onwards but excluding Infant Formulae. |

Article 4.0 Information and Education

- 4.1 Objective and consistent information on infant feeding must be provided for use by mothers and others responsible for the care of infants.
- 4.2 Informational and educational materials, including those intended to reach pregnant women and mothers of infants, whether written, audio or visual, dealing

with the feeding of infants with Infant Formulae should emphasise the benefits and superiority of breastfeeding, without however using terms which would or could cause anxieties to mothers who are unable to breastfeed their babies.

- 4.3 Explicitly worded instructions must be given to guide mothers on the appropriate and correct use of Infant Formulae. Members of the health profession and those members of the public who request it must be provided with accurate and relevant information about Infant Formulae which should accurately reflect current knowledge and responsible opinion.
- 4.4 Any information or education equipment or material provided by manufacturers or distributors should be in conformity with the overall policies promoted by the Department of Health.

Article 5.0 The Marketing of Infant Formulae to the General Public

- 5.1 There must be no general advertising or advertising at point of sale of Infant Formulae to the general public.
- 5.2 Labelling or promotional literature should not imply that Infant Formulae are equivalent or superior to the milk of a healthy mother or include words or pictures designed to discourage a mother from breastfeeding, or suggest by any means that artificially-fed infants are more likely to be contented or to grow faster or larger than adequately breast-fed babies.
- 5.3 Samples of Infant Formulae should not be distributed by manufacturers or distributors directly to pregnant women, mothers of infants or their families.
- 5.4 Gifts of utensils or other articles that may discourage a mother from breastfeeding her infant should not be distributed to pregnant women, mothers of infants or their families.
- 5.5 Educational services and information related to Infant Formulae should be provided only through the health care system and by appropriately trained personnel. This will be without prejudice to the rights of mothers as consumers to seek information from manufacturers or distributors on Infant Formulae and on artificial feeding. Manufacturers and distributors may meet such requests for information, provided that they conform to the provisions of Articles 4 and 5 of this Code.

Article 6.0 Marketing of Infant Formulae to Health Care Systems

- 6.1 No facility of a health care system shall be used for the purpose of advertising Infant Formulae to the public. This Code does not, however, preclude the dissemination of information and materials to health professionals as provided for in Articles 6 and 7.
- 6.2 Health care system advertising of Infant Formulae is permitted; however, no advertising should imply that Infant Formulae are equivalent or superior to the milk of a healthy mother.

- 6.3 Scientific, factual and relevant information regarding Infant Formulae should be supplied to the health care system through appropriately trained personnel.
- 6.4 Equipment and materials, in addition to those referred to in Article 5.4, donated to a health care system, should be in accordance with the normal policies of the health care system.
- 6.5 Information and educational materials referred to in Article 4 of this Code may be used at the discretion of the health care system authorities.
- 6.6 The use of subsidised supplies should not be permitted. Rather supplies should be made available through normal procurement channels.

Article 7.0 Health Workers

- 7.1 Information provided by manufacturers and distributors to health care professionals regarding Infant Formulae should be restricted to scientific and technical matters. Such information should not imply or create a belief that formula feeding is equivalent or superior to breastfeeding. It should also comply with the provisions of Article 4.2.
- 7.2 No financial or material inducement to promote Infant Formulae should be offered by manufacturers or distributors to health care professionals or members of their families. However, articles of general utility may be distributed to members of the health care system provided they are inexpensive and relevant to the practice of medicine and general health care.
- 7.3 Samples of Infant Formulae 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 formulae to pregnant women, mothers of infants and young children or members of their families.

Article 8.0 Persons Employed by Manufacturers and Distributors

- 8.1 Persons engaged in marketing Infant Formulae should not be involved directly in the instruction or education of pregnant women or mothers of infants unless requested to do so by the appropriate health care system authority.
- 8.2 Manufacturers and distributors of Infant Formulae should appraise their personnel of their responsibilities under the Code.

Article 9.0 Labelling

- 9.1 Labelling of Infant Formulae must comply with Irish food labelling regulations.
- 9.2 The labelling of Infant Formulae should provide the necessary information about the correct use of the product and should not discourage breastfeeding. Infant

Formulae offered for retail sale should have a clear conspicuous message stating the following points:

- (a) the superiority of breastfeeding
- (b) the words “important notice” or their equivalent
- (c) that personnel of the health care system be consulted about infant feeding
- (d) clear and precise instructions on the use of Infant Formulae including the use of previously boiled water
- (e) warning against incorrect reconstitution of Infant Formulae, particularly against over-concentration or dilution of preparation.

- 9.3 Specialised products for metabolic disorders are exempt from the provisions of 9.2 (a) above.

Article 10.0 Composition

Infant Formulae shall comply with the relevant Irish food regulations regarding hygiene, additives and contaminants.

Article 11.0 Implementation

- 11.1 The administration of this Code is the responsibility of the Code Monitoring Committee.
- 11.2 All persons concerned in any way with the marketing of Infant Formulae should co-operate with the Code Monitoring Committee to ensure that the Code is applied and enforced as effectively as possible.
- 11.3 The Third Edition of this Code comes into effect on 1st January 1991.

Appendix C

COMMISSION DIRECTIVE
of 14 May 1991
on infant formulae and follow-on formulae
(91/321/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses, and in particular Article 4 thereof,

Whereas the essential composition of the products in question must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data;

Whereas on the basis of these data the essential composition of infant formulae and follow-on formulae manufactured from cows' milk protein and soya proteins alone or in a mixture can already be defined; whereas the same is not true for preparations based wholly or partly on other sources of protein; whereas for this reason specific rules for such products, if necessary, will therefore have to be adopted at a later date;

Whereas this Directive reflects current knowledge about these products; whereas any modification, to allow innovation based on scientific and technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas because of the persons for which these products are intended it will be necessary to lay down microbiological criteria and maximum levels for contaminants; whereas given the complexity of the subject these will have to be adopted at a later stage;

Whereas infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants

during the first four to six months of life; whereas in order to safeguard the health of such infants it is necessary to ensure that the only products marketed as suitable for such use during the period would be infant formulae;

Whereas pursuant to Article 7 (1) of Directive 89/398/EEC the products covered by this Directive are subject to the general rules laid down by Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer; as last amended by Directive 89/39/EEC; whereas this Directive adopts and expands upon the additions and exceptions to those general rules, whereas it is appropriate, in order to promote and protect breast-feeding;

Whereas, in particular, the nature of destination of the products covered by this Directive require nutritional labelling for the energy value and principal nutrients they contain; whereas, on the other hand, the method of use must be specified in conformity with Article 3 (1) (8) and Article 10 (2) of Directive 79/112/EEC, in order to prevent inappropriate uses likely to be detrimental to the health of infants;

Whereas, pursuant to Article 2 (2) of Directive 79/112/EEC, and in order to supply objective and scientifically verified information, it is necessary to define the conditions under which claims about the particular composition of an infant formula are authorised;

Whereas, in an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code of Marketing of Breast-Milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community;

Whereas given the important role which information on infant feeding plays in choosing, by pregnant women and mothers of infants, the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information ensures an adequate use of the products in question and is not counter to the promotion of breast-feeding;

Whereas this Directive does not concern the conditions of sale of publications specializing in baby care and of scientific publications;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

Whereas issues relating to products intended for export to third countries should be dealt with in a coherent and homogeneous manner in a separate measure;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health in the Community. It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-Milk Substitutes dealing with marketing, information and responsibilities of health authorities.

2. For the purposes of this Directive,

- (a) 'infants' means children under the age of 12 months;
- (b) 'young children' means children aged between one and three years;
- (c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;
- (d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons.

Article 2

Member States shall ensure that the products referred to in Article 1 (2) (c) and (d) may be marketed within the

Community only if they conform to the definitions and rules laid down in this Directive. 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.

Article 3

1. Infant formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

2. Follow-on formulae shall be manufactured from protein sources defined in the Annexes and other food ingredients as the case may be whose suitability for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.

3. The prohibitions and limitations on the use of food ingredients laid down in Annexes I and II shall be observed.

Article 4

1. Infant formulae must comply with the compositional criteria specified in Annex I.

2. Follow-on formulae must comply with the compositional criteria specified in Annex II.

3. In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

Article 5

1. Only the substances listed in Annex III may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

- mineral substances.
- vitamins,
- amino acids and other nitrogen compounds,
- other substances having a particular nutritional purpose.

The purity criteria for these substances shall be stipulated at a later stage.

2. The provisions relating to the use of additives in the manufacture of infant formulae and follow-on formulae shall be laid down in a Council directive.

Article 6

1. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants. Where necessary the maximum levels of any such substances shall be stipulated at a later date.
2. Microbiological criteria shall be established at a later date.

Article 7

1. The name under which the products covered by Article 1 (2) are sold shall be, respectively:

- in English:
'infant formula' and 'follow-on formula',
- in Danish:
'Modermælkserstatning' and 'Tilskudsblanding',
- in German:
'Säuglingsanfangsnahrung' and 'Folgenahrung',
- in Greek:
'Παρασκευάσμα για βρεψη' and 'Παρασκευάσμα δεύτερης βρεψικης ηλικίας',
- in Spanish:
'Preparado para lactentes' and 'Preparado de continuación',
- in French:
'Préparation pour nourrissons' and 'Préparation de suite',
- in Italian:
'Alimento per lattanti' and 'Alimento di proseguimento',
- in Dutch:
'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',
- in Portuguese:
'Fórmula para lactentes' and 'Fórmula de transição',

However, the name of products manufactured entirely from cows' milk proteins, shall be respectively:

- in English:
'Infant milk' and 'follow-on milk',
- In Danish:
'Modermælkserstatning udelukkende baseret på mælk' and 'Tilskudsblanding udelukkende baseret på mælk',

- in German:
'Säuglingsmilchnahrung' and 'Folgemilch',
- in Greek:
'Γάλα για βρέψη' and 'Γάλα δεύτερης βρεψικης ηλικίας',
- in Spanish:
'Leche para lactentes' and 'Leche de continuación',
- in French:
'Lait pour nourrissons' and 'Lait de suite',
- in Italian:
'Latte per lattanti' and 'Latte di proseguimento',
- in Dutch:
'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',
- in Portuguese:
'Leite para lactentes' and 'Leite de transição'.

2. The labelling shall bear, in addition to those provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

- (a) in the case of infant formulae, 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) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first four months of life;
- (d) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, lipids and carbohydrates per 100 ml of the product ready for use;
- (e) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol and carnitine, per 100 ml of the product ready for use;
- (f) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.

3. The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding. The use of the terms 'humanized', 'maternalized', or similar terms shall be prohibited. The term 'adapted' may only be used in conformity with paragraph 6 and Annex IV, point 1.

4. The labelling of infant formulae shall in addition bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

- (a) a statement concerning the superiority of breast-feeding;
- (b) a statement recommending that the product be used only on the advice of independent persons having qualification in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care;

5. The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealize the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

6. The labelling may bear claims concerning the special composition of an infant formula only in the cases listed in Annex IV and in accordance with the conditions laid down therein.

7. The requirements, prohibitions and restrictions referred to in paragraphs 3 to 6 shall also apply to:

- (a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;
- (b) advertising.

Article 8

1. Advertising of infant formulae shall be restricted to publications specializing in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 7 (3), (4), (5), (6) and (7) (b) and contain only information 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.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

Article 9

1. Member States shall 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 covering the planning, provision, design and dissemination of information and their control.

2. Member States shall ensure that informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall 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 possible negative effect on breast-feeding of introducing partial bottle-feeding;
- (d) difficulty of reversing the decision not to breast-feed;
- (e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formulae, they shall 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 improper use of infant formulae. Such material shall not use any pictures which may idealize the use of infant formulae.

3. Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

4. Member States shall ensure that 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 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.

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof. Those provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive, by 1 December, 1992.
- prohibit trade in products which do not comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, these shall

contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 14 May 1991.

For the Commission
Martin BANGEMANN
Vice-President

ANNEX 1

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 (60 kcal/100 ml) | 315 kJ (75 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.

2.1 *Formulae manufactured from unmodified cows' milk proteins*

| Minimum | Maximum |
|------------------------------------|--------------------------------|
| 0,56 g/100 kJ (2,25 g/100 kcal) | 0,7 g/100 kJ (3 g/100 kcal) |

The chemical index of the proteins present shall be equal to at least 80% of that of the reference protein (breast milk), as defined in Annex VI); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

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.

2.2 *Formulae manufactured from modified cows' milk proteins (alteration of the casein/whey protein ratio)*

| Minimum | Maximum |
|-----------------------------------|--------------------------------|
| 0,45 g/100 kJ (1,8 g/100 kcal) | 0,7 g/100 kJ (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 to that contained in the reference protein (breast milk, as defined in Annex V).

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

| Minimum | Maximum |
|------------------------------------|--------------------------------|
| 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% that of the reference protein (breast milk, as defined in Annex 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 Annex V).

The L-camitine content shall be at least equal to 1,8 µmoles/100 kJ (7,5 µmoles/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

| 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 oil,
- cotton seed oil,
- fats containing more than 8% trans isomers of fatty acids.

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

4. Carbohydrates
Minimum 1,7 g/100 kJ (7 g/100 kcal) Maximum 3,4 g/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
— gelatinized starch }

4.2 *Lactose*
Minimum 0,85 g/100 kJ (3,5 g/100 kcal) Maximum —

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 | — |
| Phosphorous (mg) | 6 | 22 | 25 | 90 |
| Magnesium (mg) | 1,2 | 3,6 | 5 | 15 |
| Iron (mg) (¹) | 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 | — |

(¹) Limit applicable to formulae with added iron.

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 (µg-RE) ⁽¹⁾ | 14 | 43 | 60 | 180 |
| Vitamin D (µg) ⁽²⁾ | 0,25 | 0,65 | 1 | 2,5 |
| Thiamin (µg) | 10 | — | 40 | — |
| Riboflavin (µg) | 14 | — | 60 | — |
| Nicotinamide (µg-EN) ⁽³⁾ | 60 | — | 250 | — |
| Pantothenic acid (µg) | 70 | — | 300 | — |
| Vitamin B ₆ (µg) | 9 | — | 35 | — |
| Biotin (µg) | 0,4 | — | 1,5 | — |
| Folic acid (µg) | 1 | — | 4 | — |
| Vitamin B ₁₂ (µg) | 0,025 | — | 0,1 | — |
| Vitamin C (µg) | 1,9 | — | 8 | — |
| Vitamin K (µg) | 1 | — | 4 | — |
| Vitamin E (mg α-TE) ⁽⁴⁾ | 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 kJ | — |

⁽¹⁾ RE = all trans retinol equivalents.

⁽²⁾ In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

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

⁽⁴⁾ α-TE = d-α-tocopherol equivalent.

ANNEX 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 (60 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 (2,25 g/100 kcal) | 1g/100 kJ (4,5 g/100 kcal) |

The chemical index of the proteins present shall be equal to at least 80% of that of the reference protein (casein as defined in Annex 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.

| | | |
|----|----------------------------------|----------------------------------|
| 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 oil,
 - cotton seed oil,
 - fats containing more than 8% trans isomers of fatty acids.

| | | |
|-----|--------------------|------------------------------|
| 3.2 | <i>Lauric acid</i> | |
| | Minimum | Maximum |
| | — | 15% of the total fat content |

| | | |
|-----|----------------------|------------------------------|
| 3.3 | <i>Myristic acid</i> | |
| | 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 | |

| | | |
|----|--------------------------------|---------------------------------|
| 4. | Carbohydrates | |
| | Minimum | Maximum |
| | 1,7 g/100 kJ (7 g/100 kcal) | 3,4 g/100 kJ (14 g/100 kcal) |

- 4.1 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 proteins 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 (0,75 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 Annex VIII.

5.4 The calcium/phosphorus ratio shall not exceed 2.0.

6. Vitamins

| | Per 100 kJ | | Per 100 kcal | |
|------------------------------------|--|---------|--|---------|
| | Minimum | Maximum | Minimum | Maximum |
| Vitamin A (µg-RE) ⁽¹⁾ | 14 | 43 | 60 | 180 |
| Vitamin D (µg) ⁽²⁾ | 0,25 | 0,75 | 1 | 3 |
| Vitamin C (µg) | 1,9 | — | 8 | — |
| Vitamin E (mg α-TE) ⁽³⁾ | 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 kJ | — |

⁽¹⁾ RE = all trans retinol equivalent.

⁽²⁾ In the form of cholecalciferol, of which 10 µg = 400 u.i. of vitamin D.

⁽³⁾ α-TE = d-α-tocopherol equivalent.

ANNEX III

NUTRITIONAL SUBSTANCES

1. Vitamins

| Vitamin | Vitamin formulation |
|-------------------------|--|
| Vitamin A | Retinyl acetate Retinyl palmitate Beta-carotene Retinol |
| Vitamin D | Vitamin D ₂ (ergocalciferol) Vitamin D ₃ (cholecalciferol) |
| Vitamin B ₁ | Thalmin hydrochloride Thalmin mononitrate |
| Vitamin B ₂ | Riboflavin Riboflavin-5'-phosphate, sodium |
| Niacin | Nicotinamide Nicotinic acid |
| Vitamin B ₆ | Pyridoxine hydrochloride Pyridoxine-5'-phosphate |
| Folate | Folic acid |
| Pantothenic acid | D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol |
| Vitamin B ₁₂ | Cyanocobalamin Hydroxocobalamin |
| Biotin | D-biotin |
| Vitamin C | L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbin 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) |

2. 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 |

| Mineral substances | Permitted salts |
|--------------------|--|
| 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 |
| 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 |

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-cysteine and its hydrochloride
L-methionine
L-phenylalanine
L-threonine
L-tryptophan
L-tyrosine
L-valine
L-carnitine and its hydrochloride
Taurine

4. Others

Choline
Choline chloride
Choline Citrate
Choline bitartrate
Inositol

ANNEX 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 ⁽¹⁾ . |
| 6. Iron enriched | Iron is added. |

⁽¹⁾ When determined by a method the detection limits of which will be established at a later stage.

ANNEX 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 ⁽¹⁾ | 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 |

⁽¹⁾ 1 kJ = 0,239 kcal.

ANNEX VI

Amino acid composition of casein and breast milk protein

The amino acid composition of casein and breast milk protein:

(g/100 g of protein)

| | Casein (°) | Breast milk (°) |
|---------------|------------|-----------------|
| 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 |

(°) Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No. 24, Rome 1970, items 375 and 383.

ANNEX VII

The mineral elements in cows' milk

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat and per g of proteins are the following:

| | Per 100 g SNF (°) | 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 (µg) | 225 | 6 |
| Iodine | NS (°) | NS |

(°) SNF: 'solids-no fats'.

(°) NS: non-specified, varies widely according to season and stock farming conditions.

Appendix D

COUNCIL DIRECTIVE 92/52/EEC

of 18 June 1992

on infant formulae and follow-on formulae intended for export to third countries

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas Community rules concerning infant formulae and follow-on formulae are laid down by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses in Commission Directive 91/321/EEC;

Whereas given the nature of the products in question it is desirable that Community rules or international standards relating to their composition are made applicable to such products intended for export to third countries;

Whereas in order to prevent inappropriate use of these products which could prejudice the health of infants it is also desirable to extend the application of the Community rules on labelling of infant formulae and follow-on formulae to those products intended for export to third countries;

Whereas the products complying with Directive 91/321/EEC may be marketed in the Community as from 1 December 1992; whereas no legislation prohibits the export of such products to third countries,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive concerns infant formulae and follow-on formulae, as defined by Article 1 (2) (c) and (d) of Directive 91/331/EEC, intended for export to third countries.

Article 2

Member States shall ensure that the products referred to in Article 1 may be exported from the Community only if they comply with the Directive.

Article 3

1. No produce other than infant formulae 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.
2. In addition to products referred to in Article 1 must comply:
 - (a) with Articles 3, 4, 5 and 6 of Directive 91/321/EEC or with relevant applicable world standards established by Codex Alimentarius;
 - (b) with Article 7 (2) to (6) of Directive 91/321/EEC;

(c) with the provisions of Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs,

unless otherwise requested or stipulated by provisions established by the importing country.

3. These products shall be labelled in an appropriate language and in such a way as to avoid any risk of confusion between infant formulae and follow-on formulae.

4. The stipulations, prohibitions and restrictions laid down in Article 7 (2) to (6) of Directive 91/321/EEC shall also apply to the presentation of the products concerned and in particular their form, aspect of packaging and the packaging materials used.

Article 4

Member States shall take the necessary measures to comply with this Directive. They shall forthwith inform the Commission thereof. Those measures shall be applied in such a way as to prohibit exports of products which do not

comply with this Directive, with effect from 1 June 1994.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 5

This Directive is addressed to the Member States.

Done at Luxembourg, 18 June 1992.

For the Council

The President

Vitor MARTINS

Appendix E

Protection afforded by breastfeeding against acute infectious diseases

In developing countries, there is much epidemiological evidence that breastfeeding protects against gastrointestinal infection and mortality, and though the mechanisms are unclear, against respiratory disease too.¹ In contrast to this, the results of studies from modern industrialised countries have been far less consistent.² A review of all the studies written in English since 1970 was carried out by BAUCHNER et al in the mid 1980s.³ They concluded that most of the studies had major methodological flaws and that breastfeeding had at most a minimal protective effect in industrialised countries. A study conducted in Dundee and designed in keeping with the methodological criteria recommended by BAUCHNER et al, concluded that breastfeeding during the first 13 weeks of life confers protection against gastrointestinal illness that persists for up to one year of age.^{4,5} Other evidence showing a protective effect of breastfeeding comes from the US.^{6,7} A recent Dutch study found evidence that breastfeeding confers modest beneficial health effects in early childhood in a well-developed country.⁸

Breastfeeding is also considered to have a protective effect against respiratory tract disease. Protection is most evident against serious respiratory illness (bronchitis, bronchiolitis, pneumonia) rather than uncomplicated respiratory illness.^{9,10} The protection afforded by breastfeeding is greatest when bottlefeeding is excluded.^{11,12} Breastfeeding has been found to reduce the duration of secretory otitis media and if prolonged to act as prophylaxis against recurrent otitis media.^{13,14} A recent study in Sweden however, found no connection between the duration of breastfeeding and the number of antibiotic-treated respiratory tract infections in the infants.¹⁵

A number of studies in the US have shown that bottlefeeding imposes a 4 to 16 fold risk of *H. influenzae* bacteraemia and meningitis.^{16,17} In Finland where breastfeeding is common and prolonged, *H. Influenzae* infection is much less frequent during the first year of life.¹⁸ Some studies have also suggested that breastfed babies have fewer urinary tract infections.^{19,20}

A Canadian study showed that breastfeeding significantly enhances cell-mediated immunity to BCG vaccine if given at birth but not at one month.²¹ Further work by PABST showed that breastfeeding significantly enhanced the active immune response to conjugate *Haemophilus influenzae* type b vaccine at 7 and 12 months of age.²² An Italian study suggests that breastfeeding has a protective role against paralytic poliomyelitis during the first 6 months of life.²³

Appendix E

Other factors regarding breastfeeding

An objective assessment of the benefits of breastfeeding must pay due regard to the concerns relating to breastfeeding highlighted in the literature. These concerns can be summarised under a number of headings as follows.

Iron Status in Breastfed Babies: Iron in breastmilk, despite its low concentration, has a high bioavailability which maintains adequate iron nutrition for the infant for 6 months.^{1,2} Studies on infants older than 6 months have noted that both a decline in haemoglobin content and evidence of iron deficiency become increasingly common between 6 and 9 months of age.^{3,4} One reason postulated for this is that the iron content in human milk is not sufficient to meet the iron demands for growth.⁵ Another possible reason is that the high bioavailability of breastmilk iron is modified by the introduction of solid foods.⁶ Complementary foods for breastfed infants should emphasise the use of appropriate iron-fortified weaning foods.⁷

Cholesterol Levels in Breastfed Babies: A number of studies have shown a higher cholesterol level in exclusively breastfed babies relative to partially breastfed or bottlefed babies.^{8,9} However the cholesterol level has been found to drop off on weaning.^{10,11} In a follow up study, which included adolescents up to 19 years of age, no beneficial effects of plasma cholesterol levels in the longterm were observed.¹² One study did, however, report a lower mean cholesterol in 32 year old women (but not in men) who had been breastfed versus those women who had been bottlefed.¹³

Growth Rates of Breastfed Babies: Studies have shown that weight gain for bottle and breastfed babies are similar for the first 3 months but that breastfed babies gain weight less rapidly during the remainder of the first year.^{14,15} On the other hand length and head circumference seem to be unaffected.^{16,17} If the growth of breastfed babies is plotted on current growth charts, it may seem that they are falling behind and mothers may be advised to supplement their food.^{18,19} A review of the infants in one study showed that despite lower energy intakes and growth rates of breastfed babies, morbidity, activity level or behavioural development is not affected.²⁰ In a recent study in France, it was postulated that among infants breastfed for longer than 4 months, decreases in growth velocity may result partly from inadequate zinc intake.²¹

Transmission of Human Immunodeficiency Virus (HIV) through Breastmilk: HIV may be transmitted in colostrum and breastmilk during lactation, although the exact mode of transmission remains unclear.²² Nipple cracking and bleeding has been suggested as a possible source of transmission associated with breastfeeding.²³ In developed countries the infants of HIV positive mothers should not be breastfed.²⁴ However, for developing countries, it has been concluded that the risk of death in children is less from breastfeeding by HIV positive mothers than from not breastfeeding.²⁵

Breastfed Jaundice: Two different clinical conditions associating breastfeeding and jaundice exist.²⁶ The most common, called early breastmilk jaundice, which occurs in the first days after birth, is thought to be caused by the breastfed baby's decreased caloric intake and failure to form stool rather than by the breastfeeding process per se.²⁷ This type of jaundice can be prevented and treated by encouraging the mother to nurse as frequently as possible.²⁸ The second which occurs in 2-4% of breastfed babies, is known as the breastmilk jaundice syndrome, in which the bilirubin level rises progressively from the fourth day and reaches a maximum level by 5 to 15 days, and is thought to be caused by breastmilk abnormalities whose nature is unclear.²⁹ While the incidence of late onset breastmilk jaundice cannot be prevented by nursing practices such as frequent feeding, its severity can be reduced by preventing bilirubin accumulation due to early onset breastfeeding jaundice.³⁰ The breastmilk jaundice syndrome, once differentiated from other causes of prolonged unconjugated hyperbilirubinaemia generally needs no therapy if the bilirubin level remains below 270 mol/l in healthy full-term infants.³¹

Appendix E

Ten steps to successful breastfeeding

Every facility providing maternity services and care for newborn infants should :

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half-hour of birth.
5. Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breastmilk, unless medically indicated.
7. Practise rooming-in – allow mothers and infants to remain together – 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

From:

Joint WHO/UNICEF Statement, **Protecting, Promoting and Supporting Breastfeeding: The Special Role of Maternity Services**, WHO, Geneva, 1989.

