Infant milks in the UK

Helen Crawley and Susan Westland

THE CAROLINE WALKER TRUST

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This report is provided for information only and individual advice on diet and health should always be sought from appropriate health professionals.

We have attempted to provide accurate information on the current composition of infant milks sold in the UK in this report, and do so in good faith. However, it is likely that composition will change and new scientific evidence will emerge so **please refer to the specific manufacturers for up-to-date information**.

This is a draft report for discussion. If there is any information in the report that is incorrect, we are happy to receive information about this for the final report.

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The Caroline Walker Trust

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Acronyms

AA	Arachidonic acid
ACBS	Advisory Committee on Borderline Substances
CMPA	Cows' milk protein allergy
COMA	Committee on Medical Aspects of Food and Nutrition Policy
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
DH	Department of Health
EAR	Estimated average requirement
EC	European Commission
EFSA	European Food Safety Authority
ESPGHAN	European Society of Paediatric Gastroenterology, Hepatology and Nutrition
EU	European Union
FAs	Fatty acids
FOF	Follow-on formula
FOS	Fructo-oligosaccharides
FSA	Food Standards Agency
GOS	Galacto-oligosaccharides
GUL	Guidance upper level
IBFAN	International Baby Food Action Network
IF	Infant formula
LA	Linoleic acid
LACORS	Local Authorities Co-ordinators of Regulatory Services (now called Local Government Regulation)
LBW	Low-birthweight
LCPs	Long chain polyunsaturated fatty acids
PAH	Polycyclic aromatic hydrocarbons
PC	Phosphatidyl choline
PRC	Pesticide Residues Committee
PUFAs	Polyunsaturated fatty acids
RCN	Royal College of Nursing
RNI	Reference nutrient intake
RTF	Ready-to-feed
SACN	Scientific Advisory Committee on Nutrition
SCF	Scientific Committee on Food
SGA	Small for gestational age
TPAN	Total potentially available nucleotide
WHO	World Health Organization

Executive summary and recommendations

This report provides information about infant milks available in the UK. The stimulus to produce this report was the lack of any clear, objective and comprehensive information for health professionals about the composition of infant milks and how they are monitored and regulated. The main aim of producing the report is to encourage the relevant health departments of the UK to take greater responsibility in advising health professionals about infant milks, to ensure parents and carers have consistent information when making choices about infant feeding. The world infant formula market is rapidly expanding with a 9% per annum increase globally, reflecting changing infant feeding patterns across the world, and in particular in Asia. It is important that manufacturers in this global market are held to account about the composition of their products which are the sole source of nutrition for many millions of infants around the world.

Babies should wherever possible be exclusively breastfed for the first 6 months of life, and throughout the first year of life, or longer if the mother wishes, alongside complementary food from the age of 6 months. A safe alternative to breast milk, however, remains an essential product as some infants may not be able to receive breast milk for a variety of reasons. Those who use infant milks should be reassured that, whilst we believe that there needs to be greater transparency in the reporting of the composition and safety of infant milks, we are not suggesting that parents and carers should use anything other than a suitable formula milk as an alternative to breast milk in the first year of life.

There are a relatively small number of manufacturers that produce infant milks for the UK market. We have provided information on the types of milks that are available and made comments on their composition. It can be argued that there is little need for some products – for example, follow-on formula, hungry baby milks, partially hydrolysed milks, milks to help with digestion, and goodnight milks – as there is little evidence to support their usefulness. They appear to fulfil a perceived need, rather than an actual need. It can also be argued that some milks that are freely available on the market should not be – for example, infant soya milks and milks based on goats' milk. In addition there needs to be further debate on the usefulness of growing-up milks and toddler milks. Nutritional requirements for infants aged 12 months and older should be met from a varied, mixed diet rather than from expensive fortified products.

There is insufficient independent information about the nutritional composition of infant milks for sale in the UK. Manufacturers of infant milks were asked, as part of this project, to provide us with information on how they monitor the composition of their milks. Those who did reply said that they have rigorous and regular monitoring procedures in place, but we were not provided with any detailed information about how this is undertaken or how frequently, nor were we provided with any recent results from any manufacturer who sells their products in the UK. Limited data from analytical studies suggest there may be

differences between the declared and actual composition of some components of some infant milks. It is also unclear how companies ensure that nutrients are present in the right amounts at point of manufacture and at the end of shelf-life.

Manufacturers are not currently asked to provide annual monitoring information to the Food Standards Agency or to the relevant health departments in the UK. Furthermore, limited data from European surveillance surveys suggest that, in some countries which produce infant milks subsequently sold in the UK, there may be some limitations in the monitoring operations.

The rationale for companies' reformulating infant milk or making compositional changes is not clear. It would seem reasonable that manufacturers seek agreement with the regulatory authorities before new products are made available. The safety, efficacy and suitability of new ingredients used may be within the current regulations, but there are questions over the safety of allowing their use before an independent committee has checked appropriate evidence. Member states of the European Commission (EC) have requested that all new ingredients are pre-authorised by the European Food Safety Authority (EFSA), and the EC should re-consider this issue.

In this report we have made a number of observations and recommendations that aim to ensure greater transparency about the composition of infant milk. This report has limitations, however. In a dynamic market of considerable size, keeping up to date remains a challenge. It is therefore vital that an expert group takes responsibility for updating infant milk data and for making it readily available to all.

Recommendations

To Government, professional and regulatory bodies

- Relevant Government departments and professional bodies responsible for infant feeding should take responsibility for funding the preparation and distribution of a regularly updated, independent source of information on infant milks available in the UK, including information on their nutritional composition.
- There should be annual independent monitoring of the nutritional composition of all infant formula available on the UK market. These data should be made freely available.
- Health claims on infant milks undermine breastfeeding and an independent and objective body in the UK should review all evidence relating to claims made for infant milks, to support the European Food Safety Authority (EFSA) in objective review of any health claims submitted.
- New infant milks should not be made available on the UK market until their nutritional composition has been independently checked and agreed with the relevant competent authority.
- The UK-wide Infant Feeding Survey, conducted every five years, should collect detailed information from parents on the types and brands of infant formula used from birth and in the first weeks of life.
- Research should be commissioned to consider how parents use ready-to-feed infant milks with regard to quantities used at different ages and whether using prepared milk encourages greater energy consumption by infants.

- Qualitative research should be commissioned which explores parental knowledge and attitudes to infant feeding and infant formula currently available, as well as exploring anxieties about normal infant feeding patterns and behaviour.
- The UK health departments should adopt in full the World Health Assembly recommendation that there should be no advertising of infant formula or follow-on formula to health professionals, parents or carers.

To manufacturers

- Manufacturers should be required to have fully transparent monitoring procedures and provide regular updates to the Food Standards Agency or relevant UK health departments regarding how and when infant milk composition and safety are checked. This should include both nutritive and non-nutritive components.
- Manufacturers should be required to provide evidence of the efficacy of their products using studies that are fully relevant to the group for which the product is indicated and that reflect the composition of their product. Evidence should be agreed and checked by an independent body before it is made available to health professionals and others.
- A pooled fund from all manufacturers of infant milks in the EC, based on a percentage of profits made from the sale of infant milks, should be made available to facilitate objective research on infant milks.
- Manufacturers should ensure that the information available on their websites reflects the composition and nature of the products currently available on the market and that all information provided is in line with current recommendations from the relevant health departments of the UK.
- All infant milk producers should adapt their feeding guidelines so they are consistent with the feeding guidelines for infant age and weight agreed by health professional bodies in the UK.
- All infant milk powders should be clearly labelled that they are non-sterile and may contain pathogenic micro-organisms, as recommended by the World Health Assembly (2005).
- All information given to parents and carers on product packaging, in supporting literature, on websites and from careline staff about how to make up infant milks safely should be in line with current Government guidance.

To health professionals

- Health professionals and others who support parents and carers to make choices about infant feeding should request, and use, objective, independent and up-to-date information about infant milk from their professional body or from their relevant health department.
- All those involved in supporting parents and carers to make choices about how to feed infants should receive mandatory training which clearly explains the differences between breast milk and formula milk, the types of formula available, any implications of their compositional differences, and their indications for use.
- Clear and consistent information should be provided to all parents and carers about how to make up infant milks safely.

1 Introduction

With few exceptions, the World Health Organization (WHO, 2003) and health departments across the developed and developing world recommend exclusive breastfeeding for the first six months of life as the best way to feed infants. Where mothers cannot or choose not to breastfeed, breastmilk substitutes, predominantly infant formula milks, are available. However, infant formulas are an imperfect approximation of breast milk, for the following reasons.

- The exact chemical properties of breast milk are still unknown and cannot be reproduced.
- A mother's breast milk changes in response to the feeding habits of her baby and over time, thus adjusting to the infant's individual growth and development needs.
- Breast milk includes a mother's antibodies and many other defensive factors that help the baby avoid or fight off infections, and gives the baby's immature immune system the benefit of the mother's mature immune system.

It is essential that alternatives to breast milk are available and that these are well regulated as food products. Infant milk is unique among foods as it is the sole source of nutrition for infants. It is vital that all those who give advice to parents and carers about infant feeding have access to clear and objective information about the different types of infant formula and other infant milks currently available. (For definitions of the terms infant formula and infant milk, see page 14.)

Breastfeeding

This report is about infant milks, a variety of which are available to replace or complement breastfeeding during the first two years of a child's life.

However, The Caroline Walker Trust (CWT) strongly believes that every infant in the UK should, wherever possible, be breastfed for the first six months of his or her life, and that breastfeeding should then continue alongside the introduction of complementary foods for the first year, or longer if the mother so chooses. CWT strongly supports greater investment to support women to breastfeed their infants. For more information about the benefits of breastfeeding for infants and for mothers, and for details of organisations that support breastfeeding, see section 8.

For more information on appropriate infant feeding, see the Caroline Walker Trust reports *Eating Well for Under-5s in Child Care* (2006), *Eating Well for Under-5s in Child Care: Training Materials* (2006) and the photo resources *Eating Well: First Year of Life* (2011) and *Eating Well for 1-4 Year Olds* (2010).

1.1 Why have we written this report?

The stimulus for writing this report was the lack of a clear, objective summary which documented what infant milks are available in the UK, their composition, the differences between them and when they might be appropriate for use. We spoke informally to a number of health professionals in a range of disciplines responsible for advising parents on infant feeding. They reported receiving most of their information about infant milks from the manufacturers of the products available. The WHO International Code of Marketing of Breast-milk Substitutes (WHO, 1981) makes a series of recommendations to promote safe and adequate nutrition for infants. Among the recommendations are two that are relevant to this report:

- *"Governments should ensure that objective and consistent information is provided on infant and young child feeding."*
- *"Only scientific and factual information should be given to health workers."*

Although these recommendations do not appear directly in the European Commission Directive on Infant Formulae and Follow-on Formulae, which is the legal framework within which EU member states must work, the Directive does state that:

"The rules on composition, labelling and advertising are in line with the principles and aims of the International Code of Marketing of Breast-Milk Substitutes ('the Code')."

In addition the Directive states that there should be:

"Provision of information on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition."

In 2008, NICE guidelines from the panel reviewing maternal and child nutrition (NICE, 2008) also recommended that advice on the use of infant formula and follow-on formula should be made available to health professionals.

Despite these recommendations, there does not appear to be a comprehensive and independent summary of infant milks for sale in the UK that health professionals and others can use to advise parents and carers appropriately about infant feeding. A recent systematic review examining mothers' experiences of bottle feeding reported that mothers felt they received little information about bottle feeding and that mistakes in how milks are used were common. The authors of that review concluded that inadequate information and support for mothers who decide to bottle feed may put the health of their babies at risk (Lakshman et al, 2009).

The Food Standards Agency in a recent review on the controls of infant formula and follow-on formula (Food Standards Agency, 2010) commented that:

"The panel was struck by the findings of the qualitative research that healthcare professionals did not always provide information on formula feeding and as a result parents, parents-to-be and carers sought information from other sources including company carelines. The research also highlighted that the terms 'infant formula' and 'follow-on formula' are not immediately understood."

We have attempted to gather as much information on infant milks as possible for this preliminary report. It is important to note, however, that the main aim of this report is to stimulate UK Government departments and professional organisations who lead on infant feeding to ensure that comprehensive information about infant milks is regularly updated and made easily accessible to all.

1.2 The objectives of this report

The objectives of this report are:

- to provide a summary of the composition of infant milks currently sold in the UK and to provide independent information to health professionals and others who give advice to parents and carers about infant feeding
- to review how the composition and safety of infant milks are currently monitored
- to consider evidence used to support claims made by manufacturers about ingredients used in infant milks, and to review whether the Department of Health's *Guidelines on the Nutritional Assessment of Infant Formulas* (Department of Health, 1996) have been met.

1.3 Who the report is for

- Individuals or groups responsible for ensuring that families are given the best possible advice about how to feed their infant. This includes paediatricians, GPs, midwives, health visitors, nursery nurses, early years workers in children's centres, nurseries and other childcare settings, dietitians and other health professionals, teachers, support workers and volunteers.
- Policy makers, civil servants, trading standards officers, environmental health officers, food safety officers, public analysts and all those involved in ensuring we have a safe and appropriate food supply.
- Campaigners, journalists and others who wish to highlight the importance of clear and objective information about infant milks, and parents and carers who may wish to know more about the infant milks available in the UK.

Terminology

There are a number of names and terms used for infant milks. Some people call them 'breastmilk substitutes', while others prefer the term 'artificial milks' or 'formula milks'. The term 'breastmilk substitute' refers to all products which are marketed in a way which suggests they should replace breastfeeding, even if the product is not suitable for that purpose. This may include infant formula, baby foods, gruel, tea, juice, bottles, teats/nipples and related equipment.

For clarity we are using the following terms throughout this report:

What do we mean by infant milk?

We use the term 'infant milk' as an umbrella term for all milk-based drinks provided commercially for infants and young children.

What do we mean by infant formula?

We use the term 'infant formula' to mean a food that can provide an infant with all its nutritional needs during the first 6 months of life.

What do we mean by follow-on formula?

We use the term 'follow-on formula' for those milks that are suitable as the main milk drink for infants from 6 months of age.

A glossary of terminology surrounding infant formula can be found on page 89.

2 Background

2.1 A brief history of infant milks

Before the 20th century, infants not fed on human milk were unlikely to reach their first birthday. Many infants who were unable to be breastfed by their mothers were wet-nursed (given breast milk by a woman other than the child's mother). Other less fortunate infants were 'dry-nursed'. Dry nursing involved feeding an infant on a home-prepared mixture based on a liquid, either water or milk, mixed with finely ground grains. However, the majority of infants died if they did not have access to breast milk.

The first commercial infant formula was produced in 1867, devised by Justus von Liebig, a German chemist, and sold as Liebig's Perfect Infant Food. This consisted of wheat flour, cows' milk, malt flour and potassium bicarbonate. The product was initially sold in liquid form but soon became available as a powder with added pea flour and a lower milk content. The commercial success of this product quickly gave rise to competitors such as Mellin's Infant Food, Ridge's Food for Infants and Nestlé's Milk made from milk and cereal in Switzerland, and often credited as the first international formula milk brand. The term 'formula' is derived from Thomas Morgan Botch's approach to 'percentage feeding'. He coined the term when he was trying to devise the best mix of the various constituents that make up baby formula in the mid 19th century.

During the 19th and 20th centuries, nutrition scientists continued to analyse human milk and attempt to make infant formulas that more closely matched the composition of human milk. Maltose and dextrins were believed to be nutritionally important (even though these are not present in breast milk), and in 1912 the Mead Johnson Company released a milk additive called Dextri-Maltose. This formula was only made available to mothers by doctors. In 1919, milk fats were replaced with a blend of animal and vegetable fats as part of the continued drive to simulate human milk more closely. This formula was called SMA, which stood for 'simulated milk adapted'.

In the late 1920s, Alfred Bosworth released Similac (for 'similar to lactation'), and Mead Johnson released Sobee. In 1941 National Dried Milk was introduced in the UK. This was a dried, full-fat, unmodified cows' milk powder fortified with vitamin D. The milk was introduced by the Government as part of the Welfare Food Service and was intended for families with babies or children who could not afford or otherwise obtain fresh milk during the period of milk rationing; however, it continued to be used well into the 1970s. Commercial formulas did not begin to seriously compete with breastfeeding or home-made formula until the 1950s. Home-made formulas commonly used before this were based on diluted evaporated or sterilised milk and had the advantages of being readily available and inexpensive, although evaporated and sterilised milk are now recognised as being unsuitable for babies.

The reformulation of Similac in 1951, and the introduction (by Mead Johnson) of Enfamil in 1959, were accompanied by marketing campaigns and the provision of inexpensive formula to hospitals. By the early 1960s the use of commercial formulas was widespread.

By the mid-1960s most infant formulas were fortified with iron, differences in the whey:casein ratio of cows' milk and human milk were recognised, and most infant formula became whey-based. The renal solute load of infant formula was also considered in the 1960s and recommendations were made to reduce the potential renal solute load in an effort to reduce the prevalence of hypernatraemic dehydration. This condition had been associated with unmodified cows' milk formula with a high sodium content. The high phosphate content of formulas based on unmodified cows' milk caused problems of tetany and convulsions in some infants. In the UK, recommendations on infant feeding in the 1970s lowered the acceptable levels of sodium, phosphate and protein in infant formulas, and National Dried Milk, which was based on unmodified cows' milk, was withdrawn in 1976.

Since the early 1970s, industrial countries have witnessed an increase in breastfeeding among children from newborn to 6 months of age. This upward trend in breastfeeding has been accompanied by a deferment in the average age of introduction of other foods and cows' milk as the main drink, resulting in increased use of both breastfeeding and infant formula between the ages of 3-12 months. Later weaning and concerns over iron deficiency have also led to the development of other infant milk drinks for use into the second year of life. The last 25 years have also seen further changes in infant milk composition, with the addition of individual ingredients, which aim to make infant milk closer in composition to breast milk. For example, taurine was first added in 1984, nucleotides in the late 1990s and long chain polyunsaturated fatty acids and prebiotics in the early 2000s. However, despite considerable advancements in the composition of infant milks, breast milk contains over 300 components, which contribute to the health and well being of infants, compared with only about 75 at most in typical infant formula. The cells that pass from the mother and the wide range of other immunomodulatory factors in breast milk cannot be recreated, and it is also likely that there are other important components in breast milk yet to be identified.

Further information on the history of infant milks can be found in *The Politics of Breastfeeding* by Gabrielle Palmer (Palmer, 2009).

2.2 Development of the regulation of infant milk composition

In 1974, the report *Present Day Practice in Infant Feeding* (Department of Health and Social Security, 1974) highlighted the decline in breastfeeding in the UK and the unsatisfactory composition of artificial milks then available. Following the publication in 1977 of a report on *The Composition of Mature Human Milk* (Department of Health and Social Security, 1977), which attempted to provide a basis for a compositional profile of human milk, the need for a standard for the composition of artificial milks was realised. Clear guidance on the composition of artificial feeds for the young infant were published by the Department of Health and Social Security in 1980 (Department of Health and Social Security, 1980), and in this report it was acknowledged that adequacy of artificial feeds should be assessed not only on nutrient content but also on the bioavailability of nutrients, nutrient balance and clinical and metabolic outcomes.

From 1989, legislation relating to infant milk composition has been made by the Council of Europe, and the first European Commission Directive on Infant Formulae and Follow-on Formulae was adopted in 1991. This specified the compositional and labelling requirements for milks for infants in good health during the first 4-6 months of life that all infant formulas sold in the European Union countries must comply with.

In addition, the Codex Alimentarius of the United Nations Food and Agriculture Organization and the World Health Organization also provides guidance on the composition of infant formula and these standards are used widely internationally

(Codex Alimentarius Committee, 2006). Because all Codex standards must be 'consensus' standards, with near unanimous consent, Codex faces difficult negotiations between countries and between competing interests before recommendations can be agreed. Codex has a committee which reviews Nutrition and Foods for Special Dietary Uses and the process of agreeing standards can often be long as compromise is preferred over voting, making meetings vulnerable to lobbying by commercial interests. Codex also produces international standards for food safety, including standards on microbiological specifications for infant formula (see www.codexalimentarius.net/web/standard_list.do).

2.3 The International Code of Marketing of Breast-milk Substitutes

By the early 1970s, the majority of babies in many developed countries were not being breastfed and most infant milks used were commercially produced. The increased use of infant milks was attributed not only to improvements in their nutritional composition but also to vigorous promotion by the manufacturing industry. The WHO International Code of Marketing of Breast-milk Substitutes was adopted by a Resolution of the World Health Assembly in 1981 (WHO, 1981). The Code bans all promotion of bottle feeding and sets out requirements for labelling and information on infant feeding. Also, any activity which undermines breastfeeding violates the aim and spirit of the Code. The Code and its subsequent World Health Assembly Resolutions are intended as a minimum requirement in all countries. The Code covers all products marketed in a way which suggests they should replace breastfeeding, including all types of formula milks, baby foods, teas and juices, and equipment such as bottles, teats/nipples and other related equipment. Organisations such as Baby Milk Action in the UK, which is part of an international network (IBFAN), review compliance with the WHO Code and highlight examples of non-compliance.

The UK was one of the strongest supporters of the International Code when it was adopted in 1981. Also, as a signatory to the 1990 Innocenti Declaration, the UK Government committed itself to *"taking action to give effect to the principles and aim of all the articles of the International Code ... in their entirety ..."* and to enacting *"imaginative legislation protecting the breastfeeding rights of working women ... by the year 1995."*

At the 1994 World Health Assembly, UK support for the Code was reiterated once again and the Government 1995 White paper, *The Health of the Nation*, called for an increase in breastfeeding rates (Department of Health, 1992). The Government officially supported the UK Baby Friendly Initiative in which the International Code is the pivotal recommendation. Despite this, in March 1995, the Infant Formula and Follow-on Formula Regulations were adopted as law in the UK, with this law falling short of the International Code in important respects. Most notably, it allows advertising of products through the healthcare system, in direct contravention of the WHO International Code.

Amongst the provisions of the 1995 legislation is a ban on the advertising and promotion of infant formula, but these measures are regarded as ineffectual by many breastfeeding advocacy groups and health professionals. Their view is that manufacturers have taken advantage of limitations in the scope of the regulations that have enabled them to advertise and promote follow-on formula in such a way that it is unclear whether the product being promoted is infant formula or follow-on formula. The new legislation (the Infant Formula and Follow-on Formula Regulations 2007) attempts to impose a few further limits on the advertising and promotion of infant milks, but has not prevented generic promotion of brand name, or the promotion of follow-up formula.

2.4 Infant feeding patterns in the UK

Data from the most recently available national Infant Feeding Survey of parents across the UK (Bolling et al, 2007) show that, in 2005:

- Just under a quarter of mothers (24%) did not initiate breastfeeding at birth but used infant formula as the sole source of nutrition.
- 35% of parents introduced infant formula on the first day of life.
- By 1 week of age, more than half of infants had had some infant formula and by 6 weeks of age, 76% of infants had been given infant formula.
- By 4-10 weeks, more than half (53%) of infants were entirely fed on infant formula.
- By 4-6 months of age, 83% of infants had been given some infant formula and 68% were entirely fed on infant formula.
- By 8-10 months, 91% of infants had had some infant milk and 83% of infants were entirely fed on infant milk.

Among those mothers who use both breastfeeding and infant milk, the majority (64%) said that infant milk was the predominant method of feeding.

The majority of infants in the UK are therefore likely to be given infant formula during the first six months of life, despite Department of Health recommendations that breastfeeding should be the source of nutrition during this period. The Infant Feeding Survey does not ask parents what type of milk they offer their infant during the first few weeks of life (stage 1 of the survey covers the period 4-10 weeks but the majority of infants in the survey are 4-6 weeks of age) as there is an assumption that this will be an appropriate first milk. When mothers were asked when they first used follow-on formula, 4% reported doing so in the first 8 weeks, 10% by 4 months and 12% by 4-6 months of age. This is despite recommendations on follow-on formula packaging that follow-on formula is not appropriate for infants under 6 months of age and advice from the majority of health professionals that a change to follow-on formula is not necessary at any stage.

Mothers who did use follow-on milk by 4-6 months said they did so on the advice of a health professional (25%) or because they thought it was better for the baby (24%). By the time their babies were 8-10 months of age, the majority of mothers were using follow-on milk. It is not clear what proportion of parents know the difference between first milk and follow-on milk. In the Infant Feeding Survey, 30% of mothers claimed not to know the difference and of those who claimed to know, this could not be verified. This may mean that there is some mistaken reporting in the types of milks infants were given.

2.5 The infant milk market in the UK

The infant milk market in the UK is dominated by five major brands:

- **Aptamil** (Nutricia, owned by Danone)
- **Cow & Gate** (Nutricia, owned by Danone)
- **SMA Nutrition** (Wyeth, owned by Pfizer)
- **Nurture** (previously Farley's, owned by Heinz)*, and
- **Hipp Organic** (owned by Hipp).

* Nurture was a major player in the infant milk market until very recently, but withdrew in 2010 citing the desire to focus on infant foods and other products. However, some data about their products are included in this report as they illustrate some of the issues around infant milk composition.

TABLE 1

Main brands of infant milks in the UK, their market share (2009), and amounts spent on marketing (2008)

Parent company	Brands of milk	Market share of infant milk sales 2009	Amount spent on marketing in 2008
Danone	Aptamil Cow & Gate	54%	£2.4 million – Aptamil follow-on formula £3 million – Cow & Gate follow-on formula £335,000 – Cow & Gate goodnight milk
Pfizer	SMA Nutrition	40%	£3.3 million – SMA follow-on formula
Heinz	Nurture	3%	£1.1 million – Nurture follow-on formula
Hipp	Hipp Organic	2%	£56,000 – Goodnight milk

Source: Business Insights, 2009

In 2009 the infant milk market in the UK was worth £263 million, and had grown by 73% since 2004 (Business Insights, 2009). Market growth has been attributed to various factors including the upward trend in live births in the UK and, it could be suggested, by more consistent advice to continue formula feeding throughout the first year of life. Mintel (2007) in their analysis of the infant milk market, suggested that the Healthy Start voucher scheme – which replaced the Welfare Food Scheme and now gives parents vouchers to buy milk in supermarkets and other retailers rather than giving milk free at clinics – has also contributed to the increase in sales. Mintel suggested that between £15 million and £20 million of infant milk sales were through the Healthy Start scheme in 2007. (For more information about Healthy Start, see www.healthystart.nhs.uk)

A summary of the main brands, their market share in 2009 and the amount that they spent on promoting their brands in 2008, is shown in Table 1.

Of all the money spent on advertising of all baby foods, infant milks and drinks, 62% is spent on advertising infant milks and 82% of this spend is on television advertising. This suggests that, in 2008, approximately £8 million was spent on advertising infant milks on television in the UK (Business Insights, 2009).

Powdered milks suitable from birth, and milks for hungrier babies suitable from birth, accounted for the majority of infant milks sold in 2009, with sales of these products representing about 44% of sales of all infant milks. Follow-on milks accounted for 21% of sales, and ready-to-feed milks represented 14% of all sales in 2009 (Business Insights, 2009). Sales of ready-to-feed milks have shown an increase of 81% since 2004.

Other infant milks such as Babynat and Holle formula have a negligible market share and are generally sold through health food shops and small retailers. Other milks from overseas may be available in UK retail outlets that cater for specific immigrant communities, and some shops may offer milks that are directly imported and which may not conform to EC regulations on infant formula and follow-on formula. While writing this report we came across an infant milk available for sale from Poland, for example, that did not comply with EC labelling regulations. Infant milks from around the world are also sold on websites such as ebay. Parents should be strongly discouraged from purchasing any milk that has not been recommended to them by a health professional.

2.6 The international infant milk market

Infant milk sales form the largest part of the baby food market worldwide, with a share of 40%. The world infant milk market was evaluated at 907,000 tons in 2007, worth $9 billion (UBIC Consulting, 2010). Together, Europe and North America represent 33% of the worldwide infant milk market, but the fastest developing area is the Asian market, which is also the largest (53%). The US market is dominated by Ross Abbott and Mead Johnson, accounting for 80% of products sold, and more than half of infant milks sold in the US are sold through supported government welfare programmes (Kent, 2006). The Western European market is approximately the same size as the US market in volume terms, and the leading companies are Nestlé and Danone. The Chinese market is growing very fast at over 20% per year, despite recent contamination scandals (see section 6.2).

It is not easy to find information about where formula milks are made, as ingredients can be sourced from one country and processed elsewhere. Ireland produces 15-20% of infant formula milk globally and in 2010 the Irish Government announced that Danone was investing €50 million to expand the production of infant milk in Ireland by 300%, and that this would be exported to over 60 countries worldwide. Milks sold in the UK are also likely to be made in a number of other European countries, primarily France and Germany. Increasingly companies are setting up infant formula production in parts of Eastern Europe and Asia. More information on the global infant formula market can be found through The International Baby Food Action Network (www.ibfan.org).

2.7 European legislation on infant formula and follow-on formula

Infant formula and follow-on formula available in the UK must comply with all relevant food legislation and also with the requirements of European Commission Directive 2006/141/EC on Infant Formulae and Follow-on Formulae. The Directive required member states of the European Union to adopt and publish, by 31 December 2007 at the latest, laws and administrative provisions to implement the Directive at a national level. In England this Directive and Council Directive 92/52/EEC (regarding infant formula and follow-on formula intended for export to third countries) have been given effect by the Infant Formula and Follow-on Formula (England) Regulations 2007 and a subsequent amendment, which replace the Infant Formula and Follow-on Formula Regulations 1995. Similar regulations are in effect in Scotland, Wales and Northern Ireland.

The compositional standards established by Commission Directive 2006/141/EC were based on scientific reviews carried out by the Scientific Committee on Food (SCF) which from 2003 became part of the European Food Safety Authority (EFSA). The goal of setting minimum and maximum values of nutrients is to provide safe and nutritionally adequate infant formula products that meet the normal nutritional requirements of healthy babies. EFSA is an EC Committee of independent scientists whose mandate is to answer scientific and technical questions concerning consumer health and food safety associated with the consumption of food products. The compositional revisions included in Directive 2006/141/EC are based on the SCF's 2003 report on the revision of essential requirements of infant and follow-on formula which took into account scientific and technical developments in infant feeding (Scientific Committee on Food, 2003). Their review adopted certain principles, including the principle that the composition of human milk from healthy, well nourished mothers is highly variable as the content of many nutrients changes during lactation, or differs between women and throughout the day. Additionally there are considerable differences in the bioavailability and metabolic effects of similar contents of many specific nutrients in human milk and in infant formula. Conclusions on the suitability

and safety of nutrient contents in infant formula cannot therefore be simply based on its similarity to human milk. They suggest that a more useful approach to evaluate the adequacy of infant formula composition is the comparison of physiological (eg. growth patterns), biochemical (eg. plasma markers), and functional (eg. immune response) outcomes in infants fed formula with those in populations of healthy infants who have been exclusively breastfed for 4-6 months.

The European Commission Directive on Infant Formulae and Follow-on Formulae states that (Food Standards Agency, 2007a):

Minimum and maximum values for nutrients should:

- Be based on adequate scientific data that establishes needs for practically all infants in the target population and the absence of adverse effects or, in the absence of such data should:
  - be based on an established history of apparently safe use
  - take into account other factors such as bioavailability and losses during shelf-life
  - refer to total nutrient contents of IF (infant formula) and FOF (follow-on formula) as prepared ready for consumption according to the manufacturer's instructions.

The Directive itself aims to ensure that:

- The essential composition of infant formula and follow-on formula satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data
- The labelling of infant formula and follow-on formula allows the proper use of such products and promotes and protects breastfeeding
- The rules on composition, labelling and advertising are in line with the principles and aims of the International Code of Marketing of Breast-milk Substitutes ('the Code')
- Information provided to carers about infant feeding does not counter the promotion of breastfeeding.

Other main provisions of the Directive are that:

- 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 months of life until the introduction of complementary feeding
- Infant formula and follow-on formula shall not contain any substance in such quantity as to endanger the health of infants and young children
- There are detailed requirements for the essential composition of infant formula and follow-on formula
- There are limits on the level of any individual pesticide residue that may be present in infant formula and follow-on formula and specific lower limits for very toxic pesticides
- There are mandatory and non-mandatory particulars for the labelling of infant formula and follow-on formula
- Requirements are made for the labelling of infant formula and follow-on formula to apply to presentation and advertising

- There are restrictions on nutrition and health claims that can be made in relation to infant formula
- The labelling, presentation and advertising of infant formula and follow-on formula should avoid risk of confusion by the consumer between these two products
- There should be restrictions on the advertising of infant formula
- Information should be provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition.

A summary of the regulatory standards for the composition of infant formula can be found in Appendix 1.

The Food Standards Agency (FSA) has recently reviewed whether the new controls on the way in which follow-on formula is presented and advertised have been effective in making clear to parents, parents-to-be and carers that advertisements for follow-on formula are meant only for babies over 6 months and are not perceived or confused as infant formula advertising, which is prohibited (Food Standards Agency, 2010). The review found that the controls are having the desired effect in the main, but some adverts are not always clearly understood as being for follow-on formula rather than infant formula. There was not sufficient evidence of confusion between infant formula and follow-on formula to justify a ban on the advertising of follow-on formula, but it was recommended that manufacturers should make changes to advertising, to make it clear that follow-on formula is intended for babies over 6 months. This includes clearly representing the age of babies in the adverts. The panel specifically recommended that:

"In order to increase the chances of achieving clarity, it is recommended that manufacturers make all the following changes to advertising:

- Provide text relating to age suitability in a box, in bold or underlined
- Specify, unambiguously, the age of the child for whom the product is intended in the voiceover of television advertisements
- Ensure that the infants shown in follow-on formula advertising are unambiguously aged six months and over: for example by demonstrating features such as good head and arm control; sitting upright; having hair and teeth; showing emotional facial expression; being in an outdoor environment; self-feeding
- Increase the size and enhance the clarity of product images (ie. packshots)."

A qualitative study undertaken in Australia (Berry et al, 2010), which investigated how women expecting a first baby perceived print advertisements for toddler milks, found that women clearly understood toddler milk advertisements to be promoting a range of products that included infant formula and follow-on formula. These adverts functioned as indirect advertising for infant formula and women accepted their claims quite uncritically. The FSA panel also acknowledged the brand extension that advertising of follow-on formula allowed and agreed that, whilst the current controls outlined by the Infant Formula and Follow-on Formula Regulations are fulfilling their objective to some degree, there remains confusion among some parents, carers and parents-to-be (Food Standards Agency, 2010).

3 What is infant milk made from?

The basic components of any infant milk, regardless of the format (powder or ready-to-feed), are proteins, fats, carbohydrates, vitamins and minerals. The major infant formula producers develop their own brands with a combination of each of these components. However, this must be achieved in accordance with the regulatory framework of the Infant Formula and Follow-on Formula Regulations 2007. The basic nutritional profile of the majority of infant milks is therefore very similar.

The majority of infant milks start with a base of cows' milk (skimmed or full-fat, liquid or powder, or using whey protein concentrates) with added lactose or other carbohydrates, vegetable and other oils, vitamins and minerals. These infant milks are suitable for most full-term, healthy infants. Other milks may be based on soy protein from soya beans with added vegetable and other oils and maltose, maltodextrins or glucose polymers. A third category of infant milks are those containing no milk components at all. These include elemental formulas which are based on synthetic free amino acids (the building blocks of proteins). The current legislation specifically states that only products based on cows' milk protein, hydrolysed protein or soy protein may be marketed as infant and follow-on formula.

3.1 Protein

Cow's milk protein and soy protein are the main protein sources of most infant milks. Proteins are composed of many amino acids, eight of which are essential (cannot be synthesised by the human body), and must be provided in adequate proportions in the diet.

Protein requirements for infants are based on the concentrations of amino acids in mature human milk. The majority of infant formulas are based on highly modified cows' (bovine) milk. Both the protein quantity and protein composition differ between bovine milk and mature human milk. The total protein content of bovine milk is higher than that of mature human milk (3.3g/100ml vs. 1.3g/100ml respectively) (Poskitt and Morgan, 2005). Regulations require infant formula to contain an available quantity of each amino acid at least equal to that found in human breast milk (for an equal energy value). Casein and whey are the two major proteins of human milk. Casein is the major protein source, and whey contains many different proteins and non-protein nitrogen. Colostrum is predominantly whey, and early breast milk is whey-dominant (60:40) but the proportions of casein and whey become approximately equal late in lactation (Jensen, 1995). Whey and casein are present in bovine milk in different proportions to those found in breast milk, with casein the predominant protein source (whey:casein ratio typically 20:80). First infant formula has an altered whey:casein ratio (60:40) to bring it closer to that found in breast milk which is whey-dominant. Formula aimed at 'hungrier babies' has a whey:casein ratio of 20:80.

The predominant whey proteins in mature human milk and bovine milk are α-lactalbumin and β-lactoglobulin respectively. Infant formulas based on bovine milk therefore have a lower concentration of α-lactalbumin than human milk.

The concentration of some essential amino acids in bovine milk are lower than in human milk, and the concentrations of tryptophan and cysteine in bovine milk are approximately half of those in mature human milk (Heine et al, 1991). Therefore, in order for formula milk based on bovine milk to meet the amino acid requirements of infants, the total protein content of most infant milks is higher than that of breast milk. Research supported by Wyeth Nutrition (SMA) suggested that, whilst infant milks with a whey:casein ratio of 60:40 are nutritionally complete, the proportion of specific amino acids is still lower than in breast milk, particularly of the amino acids tryptophan and cysteine (Lien et al, 2004; Davis et al, 2008). Formula milks with an increased proportion of the protein α-lactalbumin, which is rich in tryptophan and cysteine, have since been developed (SMA First Infant Milk and Nurture Newborn). It is suggested that milks with a higher proportion of α-lactalbumin are advantageous as they have a reduced total protein content, which reduces the solute load on developing infant kidneys (Lien et al, 2004) and are tolerated better by the infant, with the gastrointestinal tolerance profile of healthy term infants fed with α-lactalbumin enriched formula closer to that for infants fed with human milk (Davis et al, 2008). Feeding-related gastrointestinal events such as constipation and regurgitation have also been reported to be significantly higher in infants fed on a standard formula compared to infants fed α-lactalbumin enriched formula (Davis et al, 2008). It has been suggested elsewhere, however, that higher levels of protein found in formula milk may be linked to higher bodyweight in later life. Data from a large randomised study of 1,000 infants in Europe given either standard infant formula, low protein formula closer in protein content to breast milk, or breast milk, showed that those fed standard formula were heavier in later years (Koletzko et al, 2009a).

3.1.1 Nucleotides

Nucleotides are substances that can be synthesised in the body from amino acids and which form the basis of DNA and RNA. These substances are important metabolic regulators, involved in energy transfer and breaking down large molecules for example, and are particularly important in tissues with rapid turnover. Nucleotides are not considered essential in the diet as they can be synthesised in the body, but it is thought that at certain times (such as during periods of rapid growth or in disease) the process of synthesis of nucleotides may not be able to keep up with demand and that the body relies on dietary sources.

Breast milk is a source of nucleotides although the amount present is variable and the analysis methods to determine composition can also be variable. Colostrum has the highest concentration of free nucleotides and during the first four weeks of lactation the concentration falls by about half. Mature human milk contains at least 1.0mg/100ml of free nucleotides. But the total potentially available nucleotide (TPAN) content of breast milk was determined by Leach et al (1995) to be 7.2mg/100ml. Cows' milk contains considerably lower amounts and the chemical composition of the nucleotides also differs from that of human milk. Heat treatment during infant milk production also degrades the nucleotides present. European regulations permit a maximum concentration of 5mg/100kcal (equivalent to about 3.4mg/100ml) of nucleotides to be added to infant formula (with variable amounts for each specific nucleotide).

In the UK, all non-organic standard infant formulas for healthy term infants are supplemented with nucleotides at around 3.1mg/100ml. Studies examining the clinical effects of nucleotides have used formula supplemented with nucleotides at concentrations ranging from just over 1.1mg/100ml to 7.2mg/100ml (TPAN) and have examined healthy full-term infants, premature infants, small for gestational age infants, and infants living in relatively contaminated environments, so it is not always easy to compare the data.

Studies in infants suggest that dietary nucleotides may have a role to play in both the immune and gastrointestinal systems. The most frequently reported effects of feeding

infants formula supplemented with nucleotides include a lower incidence of episodes of diarrhoea and increased plasma antibody response to immunisation with *Haemophilus influenzae* type b polysaccharide (Hib) and diphtheria and tetanus toxoids. The mechanisms by which nucleotides achieve these effects are still largely unknown. The SMA range of standard infant and follow-on formulas is supplemented with nucleotides at 3.0mg/100ml. SMA restricts their suggestions for the health benefits of nucleotide supplementation in their standard range of formula milks to a possible improvement in immune function. The clinical trial which SMA refers to on its website used a test formula supplemented with 3.3mg/100ml of nucleotides and was supported by Wyeth Nutrition. This relatively large trial, conducted in healthy term infants, showed a modest improvement in antibody response to tetanus toxoid at 7 months for infants fed the supplemented formula. There was no difference between groups for antibody response to diphtheria toxoid (Hawkes et al, 2006). Whilst an improvement in immune function can be observed, this does not necessarily alter the incidence and severity of infection between groups, and this is not always measured.

The Aptamil range of standard infant and follow-on formulas is supplemented with nucleotides at 3.2mg/100ml. Aptamil supports the use of their product by reference to research which has shown that babies fed formula containing nucleotides have improved growth and enhanced immune systems. In a large 12-month trial by Yau et al (2003), using a test formula supplemented with nucleotides at 7.2mg/100ml, the incidence of diarrhoea and respiratory tract infections and immune response were measured. At 8-28 weeks, infants fed the supplemented formula were shown to have a 25.4% lower risk of diarrhoea than infants fed the control formula. Infants fed the supplemented formula also had higher concentrations of serum IgA throughout the study. Both groups had a similar antibody response to hepatitis B immunisation. Whilst both groups also had a similar incidence of lower respiratory tract infections, the risk of upper respiratory tract infections was 1.13 times higher in the group fed supplemented formula. It is interesting to note that, although the protein and micronutrient profiles of the test and control formulas were very similar, the whey:casein ratios were quite different. The control formula had a whey:casein ratio of 18:82, and the test formula 48:52. Differences in the formula used in trials and between groups in trials makes it difficult to interpret evidence related to claimed benefits.

Cow & Gate supplement their range of standard infant and follow-on formulas with nucleotides at 3.2mg/100ml. However, they do not suggest specific health benefits for the inclusion of nucleotides in formulas for healthy term infants.

The studies used to support the use of nucleotides in standard infant formula have shown conflicting results, particularly in respect of their effects on response to specific immunisations. The optimal level of supplementation is also unclear as a wide range of nucleotide concentrations have been shown to have beneficial effects in term infants.

3.2 Fat

The fat component of human milk is highly variable and changes according to certain factors including the duration of feed, stage of lactation and the dietary habits of the mother (Agostoni et al, 1999). Where infants are exclusively fed on mature human milk, fats supply 50% of their energy. Fats are also added to supply 50% of the energy in formula milks, and vegetable oils are typically included, although oils from fish and fungal sources are also used. Canola oil (a variety of rapeseed oil low in erucic acid) has been widely used as an ingredient in infant formula in Europe, but not in North America due to safety concerns. Evidence from a recent randomised control trial considering normal growth of infants fed formula with and without canola oil, however, found no differences in weight or length gain between 4 weeks and 7 months of age (Rzehak et al, 2010). The quantity of fat

in cows' milk and human milk is similar, but the component fatty acids are very different. Human milk is higher in unsaturated fats, particularly linoleic and α-linolenic acids. Human milk also contains the long chain polyunsaturated fatty acids (LCPs) arachidonic acid, eicosapentaenoic acid and docosahexaenoic acid. Non-organic infant formula are fortified with LCPs but there is no organic source of these oils available. Structured triglycerides are also used in some infant formulas. Betapol is a patented synthetic structured triglyceride, produced by Martek Laboratories, which is used in some brands of infant milks.

3.2.1 Long chain polyunsaturated fatty acids (LCPs)

Humans have the capacity to synthesise long chain polyunsaturated fatty acids (LCPs) from simpler fatty acid precursors. However, they cannot synthesise fatty acids with a double bond at the n-3 or n-6 position and therefore rely on these fatty acids (FAs) to be supplied in the diet. Linoleic acid (LA, C18:2 n-6) and α-linolenic acid (ALA, C18: n-3) are the most commonly occurring dietary sources of n-3 and n-6 PUFAs (polyunsaturated fatty acids). In mammals these FAs are further metabolised by enzyme systems to LCPs. The most important metabolites of LA are dihomo-gamma-linolenic acid (DHGLA, C20:3 n-6) and arachidonic acid (AA, C20:4n-6) and those of ALA are eicosapentaenoic acid (EPA, C20:5 n-3) and docosahexaenoic acid (DHA, C22:6n-3) (Lauritzen et al, 2001).

AA and DHA are the main n-3 and n-6 FAs of neural (brain) tissues and DHA is a major FA in phospholipids of the photoreceptor cells of the retina in the eye. There is evidence to suggest that pre-term infants may have a greater capacity to synthesise LCPs than term infants, but this may still be insufficient to meet the needs of all pre-term infants. Human milk contains small concentrations of DHA and AA whereas some infant formulas contain only the precursors ALA and LA and some now have added LCP.

Trials which have examined the potential beneficial effects of using formula supplemented with DHA and AA on visual function and neurodevelopmental outcomes in either pre-term and/or term infants have had mixed results, and there is a lack of consistency between the recommendations of several expert panels and committees on whether or not infant formula for term infants should contain added DHA and AA (Koletzko et al, 2001; LSRO, 1998; FAO/WHO, 1994). The report of the Scientific Committee on Food (Scientific Committee on Food, 2003) suggested that, whilst DHA may have a potentially beneficial effect on visual acuity, no consensus could be reached that DHA or AA, or both, are indispensable nutrients for term infants, nor that a dietary supply is beneficial (Lauritzen et al, 2001; Jensen and Heird, 2002; Lucas et al, 1999). A Cochrane systematic review of the safety and benefits of adding LCP to formula milk for term infants, completed in 1998 and reviewed in 2007, found that feeding term infants with formula milk enriched with LCP had no proven benefit regarding vision, cognition or physical growth (Simmer et al, 2007).

In 2010 the European Food Safety Authority (EFSA) approved the claim that "*DHA has a structural and functional role in the retina and DHA intake contributes to the visual development of infants up to 12 months of age*". In March 2011, however, the European Parliament's all-party environment and public health committee said in a vote on a draft resolution by British Labour MEP Glenis Willmott that this claim is "misleading", and so the claim is likely to be disallowed across Europe. Some of the problems with using evidence to make health claims about constituents of artificial infant milks are discussed in section 6.12.

Longer term impacts of supplemented milks have not yet been established. PUFAs in infant milk can react with lysine (an amino acid) upon oxidation and this may lead to the production of undesirable compounds such as furfurals (which can modify the nutritional value of proteins and change the taste and smell of milk). There are at present no established limits for furfural concentrations in infant formula, and few studies look at

long-term implications of additions to infant formula. A recent 10-year follow-up of a randomised control trial of DHA-supplemented formula in pre-term infants also found that girls were heavier and had higher blood pressure than the breastfed group (Kennedy et al, 2010), suggesting that the long-term implications of formula additions may not always be known.

A number of infant milks available in the UK contain these long chain fatty acids. The sources of LCPs in Cow & Gate and Aptamil products are vegetable and fish oils whilst the sources of LCPs in SMA products are fungal and algal oils. The use of fish oils means that many milks are not suitable for vegetarians.

Hipp Organic is the most recent company to have added LCPs to their products. A representative of the company told us that clinical trials using their product are currently underway in Europe. The decision to market the product in advance of clinical trials was based on a history of safe useage of LCPs, at the same level, in infant milks produced by other manufacturers. The source of LCPs in Hipp powdered formula milk is fish oils whilst LCPs in the RTF formula are algal.

Supplementation of formula with LCP can increase the retail price by 5%-25% and single cell oils produced by micro-organisms are likely to be the oils of choice commercially in future (Chávez-Servín et al, 2008). There are therefore considerable cost implications for welfare food schemes and families if these fats are considered essential ingredients in all infant formula.

3.2.2 Structured triglycerides

Apart from the chain length of fatty acids, their function is also impacted by the structure and position of the fatty acids in the triacylglycerol molecule. In human milk the fatty acid palmitate accounts for about 25% of the fatty acids, and 70% of these fatty acids are attached in the middle (sn-2) position of the triacylgylcerol molecule. The advantage of this position is that the enzyme pancreatic lipase cleaves the fatty acid molecules at the sn-1 and sn-3 positions, and the remaining free fatty acids and palmitate still attached to the backbone of the fat molecule are easily absorbed through the intestine. In cows' milk, and therefore in standard formula milk, the palmitate fatty acids are predominantly in the sn-1 and sn-3 positions so that, when they are hydrolysed by lipase, they become free palmitate in the intestine. The disadvantage of this is that the free palmitate can form complexes with calcium in the lumen of the intestine, and these complexes are poorly absorbed (Kennedy et al, 1999). The formation of these complexes may reduce the amount of energy available from fatty acids and reduce calcium absorption due to bound calcium being excreted from the intestine. This may also have the effect of hardening the stools, leading to constipation and colic.

Structured triglycerides have been used in infant formula for some time. Betapol is a structured lipid manufactured by Lipid Nutrition for use in infant formula, where 40%-70% of the palmitic acid is attached at the sn-2 position. Cow & Gate was the first formula milk company in the UK to introduce Betapol to their milks in about the early 2000s and its use appears to have been confined to formula designed to relieve minor digestive problems. Evidence for the efficacy of Betapol in aiding constipation and improving calcium absorption has come from a number of studies. In a double-blind, randomised clinical trial using formula milk supplied by Nutricia (Kennedy et al, 1999), 203 term infants were randomly assigned to receive one of two formula milks, each with a similar concentration of palmitate as a percentage of total fatty acids. The test formula contained synthetic triacylglycerol (Betapol) with 50% of the palmitate in the sn-2 position. In the control formula 12% of the palmitate was in the sn-2 position. A control group of 120 breastfed infants was included in the study. The study concluded that changing the stereoisomeric structure of the palmitate in infant formula resulted in higher whole body bone mineral

content, reduced stool fatty acids and softer stools, more like those of breastfed infants. Improved fatty acid and calcium absorption were also recorded in similar studies by Carnielli et al (1996) and Lucas et al (1997) for term and pre-term infants respectively. Other studies have not provided consistent evidence, however. A study by Bongers et al (2007) found no significant difference in defecation frequency or constipation, and in one study a number of parents reported concern about runny stools after feeding formula containing Betapol to their babies (Kennedy et al, 1999).

Whilst Nutricia have supported clinical trials examining the nutritional efficacy of products containing Betapol, they do not market their products as containing Betapol. Cow & Gate lists structured triglycerides in the ingredients lists for some products but Milupa do not, although they do refer to the study by Kennedy et al (1999) to support the suggested benefits of Betapol in reducing constipation.

Heinz Nurture products (now discontinued) contained Betapol across their entire standard infant milk range and claims were made that this led to softer stools, increased energy release and improved bone density and development. However, much of the evidence used to support these claims was weak, or related to research using other milk products. Some of this is discussed in section 6.12.

3.3 Carbohydrate

Lactose is the major carbohydrate of human milk and cows' milk and is found in most infant milks. In general, infant milks based on soy protein have glucose, maltose or glucose polymers added as a source of carbohydrate. Maltodextrin used in some milks is usually derived from maize or potatoes and some milks have added glucose, glucose syrups, sucrose or corn syrup. Infant milk with glucose sugars is likely to contribute to higher levels of dental decay in infants (Grenby and Mistry, 2000).

3.4 Vitamins and minerals

Vitamins and minerals are micronutrients – substances that are essential in the diet in minute quantities for growth, maintenance and functioning. Most vitamins cannot be produced by the body and must therefore be provided in food. As some vitamins can be harmful if supplied in excess, the European Commission Directive specifies minimum and maximum levels of vitamins that must be present in infant and follow-on formula milks. Some minerals and trace elements are added to infant formula, but some micronutrients and other elements will be present within the raw ingredients used in the formula. Vitamins and minerals in breast milk are absorbed more efficiently than those in formula milks, and therefore more has to be added to infant milks than would be found in breast milk, to allow for reduced absorption levels. For example: breastfed infants can absorb 50% of the iron and zinc in breast milk, compared to only 10% of iron and 30% of zinc from formula milk; calcium absorption from breast milk is about 66% and from formula milk 40%; and absorption of many other micronutrients such as copper and selenium has been reported to be significantly lower from formula milk (Department of Health, 1991).

As some vitamins deteriorate during storage, infant milk has to allow for this in the amounts added at manufacture, or include additives which reduce the deterioration. There has been a suggestion by the FAO/WHO Codex Alimentarius Committee that whenever foods are given to infants under 12 weeks of age, they should be made up from fresh ingredients every day, as infants may not have developed to a point where they are able to cope with substances used to prolong shelf-life that present no problem to adults (Codex Alimentarius Committee, 2006). This is obviously not possible, but highlights the fact that additives used for preservation in infant formula are unregulated in relation to

their effects on infants. It has also been suggested that babies given the freshest milks might get dangerously high doses of some vitamins and those getting products stored for long periods might get dangerously low doses (Koletzko and Shamir, 2006). It is therefore essential that there is regular compositional testing of milks purchased off the shelf at a variety of outlets in the UK.

It is interesting to note that there are some anomalies between levels set by the European Commission Directive on Infant Formulae and Follow-on Formulae and UK national dietary recommendations. All infant formulas available in the UK contain levels of calcium which are within the levels set by the Directive. However, the UK dietary reference values set the estimated average requirement (EAR) for calcium for infants aged 0-12 months at 400mg/day and the reference nutrient intake (RNI) (which meets the needs of 97.5% of the population) at 525mg/day (Department of Health, 1991). Based on a typical first infant milk containing about 70mg calcium/100ml, an infant would be required to consume about 570ml of formula milk a day to achieve the EAR calcium intake, or about 750ml a day to meet the RNI. Based on Royal College of Nursing feeding guidelines for infants by age, the EAR could be achieved on average at 2-6 weeks and beyond, but the RNI not until 2-3 months and beyond.

More information on feeding guidelines is given in section 5 and Tables 15 and 16.

3.5 Other ingredients

3.5.1 Carnitine

Carnitine is the generic term for a number of compounds that include L-carnitine, acetyl-L-carnitine, and propionyl-L-carnitine. Carnitine plays a critical role in energy production and is concentrated in tissues like skeletal and cardiac muscle. The body makes sufficient carnitine to meet the needs of most people. However, some individuals, including pre-term infants, cannot make enough and carnitine must be supplied in the diet. Cows' milk contains more carnitine than human milk. Legislation sets minimum and maximum levels for L-carnitine in infant formula which have been manufactured from soy protein isolates or hydrolysed protein.

3.5.2 Inositol

Inositol is an essential growth factor which is synthesised in the body but may need to be provided in the diet under certain conditions. Inositol is present in high concentration in human milk, and decreases over the course of lactation. Inositol levels in blood are high among neonates, leading to the suggestion that inositol plays an important role in early development (Scientific Committee on Food, 2003). In the UK, legislation sets minimum and maximum levels for inositol in infant formula suitable from birth.

3.5.3 Taurine

Taurine is a free amino acid found abundantly in human milk and in only small amounts in cows' milk. Most infant formulas are enriched with taurine, although it is an optional ingredient. Interestingly, taurine has been added to formula for many years because it was found in human milk and the patent protection of the addition to formula made it economically beneficial to some, despite there being little scientific rationale for it. Many decades later it appears that taurine is a safe addition to formula milk, but there remains no clear clinical benefit for it (Koletsko et al, 2009b).

3.5.4 Choline

Choline is an amine which is distributed in tissues throughout the body. It is synthesised in the body, but may need to be provided in the diet under certain conditions. Choline serves as the precursor for the synthesis of phosphatidyl choline (PC), the main phospholipid in brain, liver and other tissues. PC plays a role in normal membrane composition and signalling processes, lipid metabolism, and normal brain development.

3.5.5 Lutein and zeaxanthin

Lutein and zeaxanthin are carotenoids found in common foods such as broccoli, peas and spinach, and are important antioxidants which might help to protect against oxidative damage to the eye. Although there are no data that suggest that lutein supplementation can influence visual acuity in infants, some studies have shown modest benefits to visual disorders in adults. Breast milk contains lutein derived from the mother's diet and, whilst this carotenoid is not currently added to formula milk available in the UK, it may be a potential new ingredient in the future and has been trialled by Wyeth in the US in a sample of infants to ensure that the addition of lutein does not impact on growth (Capeding et al, 2010).

3.6 Prebiotics

Prebiotics are non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth and/or activity of one or several bacteria in the colon and by so doing improve host health (Gibson and Roberfroid, 1995). Colonic bacteria produce a wide range of compounds which may have both positive and negative effects on the host. The bacterial genera *Bifidobacterium* and *Lactobacillus* are generally accepted as being amongst the beneficial species of gut bacteria. *Staphylococci* and *Clostridium* are considered pathogenic and *Enterococci*, *Bacteroides* and *Streptococci* are amongst the genera considered to have both beneficial and harmful effects (Gibson and Roberfroid, 1995). There is evidence to suggest that postnatal immune development may be altered by influencing the constitution of gastrointestinal bacterial flora (Moro et al, 2006).

Human breast milk contains over 200 different oligosaccharides which account for approximately 1% of its composition and different mothers produce different sets of human milk oligosaccharides (Petherick, 2010). The complex mixture of oligosaccharides present in human milk is thought to have a bifidogenic effect on the colonic microflora of infants to protect them from the specific hazards in their environment. Infant formula made from bovine milk is virtually free of prebiotic oligosaccharides (Costalos et al, 2008). It has been shown that the colonic microflora of infants fed on human milk is dominated by *Bifidobacterium*, whilst that of formula-fed infants is more diverse with *Bifidobacterium*, *Bacteroides*, *Clostridium* and *Streptococci* all prevalent (Yoshiota et al, 1991).

There are no commercially available analogues of human milk oligosaccharides. However, in adults, mixtures of long-chain fructo-oligosaccharides (FOS) and galacto-oligosaccharides (GOS) have been shown to enhance the growth and proliferation of *Bifodobacterium* and *Lactobacillus* in the colon at the expense of potentially harmful bacteria such as *Clostridium* and *Staphylococci*. More recently, mixtures of FOS and GOS have been used in infant formula in an attempt to reproduce the bifidogenic activity of breast milk (Moro and Arslanoglu, 2005). Whilst FOS and GOS do not mimic the oligosaccharide content of breast milk, they have a similar molecular weight and high galactose content.

Immunofortis is a patented mix of prebiotics used by Milupa in their Aptamil infant and follow-on formula. The specific blend of oligosaccharides used has been subject to a wide range of clinical trials carried out by or sponsored by the then parent company Numico. (Numico no longer exists; the parent company is now Danone.)

A large number of pieces of research have been compiled by companies promoting formula with added prebiotics to show health benefits. The most recent research used to support the use of Immunofortis comes from a study of healthy term infants who had a parental history of atopic eczema, allergic rhinitis or asthma (Arslanoglu et al, 2008). Mothers who started formula feeding within the first 2 weeks of life (and had ceased to breastfeed by 6 weeks of age) were recruited and 134 infants either in the test formula or placebo group were followed for two years. Those infants who were fed in the first 6 months of life with a formula containing extensively hydrolysed proteins and prebiotic oligosaccharides had significantly fewer infections (as diagnosed by a doctor), fewer episodes of fever (as recorded by parents), and fewer incidents of atopic dermatitis, allergic wheezing and urticaria. However, this research may not be generalisable to all infants and, although differences between the groups were significant, the actual reductions in episodes of illness in some cases was small (for example, a mean of 0.5 episodes of ear infection among the supplemented groups compared with a mean of 0.7 among the placebo group). Cow & Gate products use the same prebiotic mixture as Milupa products.

In February 2010 the European Food Safety Authority (EFSA) refused to allow the health claim for prebiotics in infant formula put forward by Danone. EFSA found insufficient evidence linking consumption of Danone's Immunofortis prebiotic formula and a claim to "*naturally strengthen the baby's immune system*". This ruling applies to infant milk products for babies up to 12 months of age. EFSA also reported that they found Danone's 30-trial dossier "*wanting for containing limited, inconsistent and irrelevant trial data*".

Prebiotics have been added to Hipp organic formula milks since January 2010. The prebiotic mixture used contains only galacto-oligosaccharides and no clinical trials using their reformulated product have been completed to date.

SMA does not add oligosaccharides to any of their infant or follow-on formula. However, they suggest that enriching formula with α-lactalbumin has been shown to have a prebiotic effect by increasing the development of a bifidobacteria-dominant flora. This suggestion is supported by a single journal abstract which describes a prospective, blinded, parallel study carried out by Wyeth, USA in which 154 healthy term infants were enrolled and randomised to receive either formula enriched with α-lactalbumin or α-lactalbumin and fructo-oligosaccharide. At the end of an eight-week period, the faecal flora of both groups were similar to that of infants fed human milk (Bettler and Kullen, 2007). In order for a foodstuff to qualify as a prebiotic, it must induce luminal or systemic effects that are beneficial to the host health (Gibson and Roberfroid, 1995). In this instance a bifidogenic effect has been observed, but no evidence of beneficial effects to host health have been recorded and therefore it is incorrect to suggest that α-lactalbumin has a prebiotic effect.

Prebiotics should not be confused with probiotics, which are live micro-organisms, usually lactobacilli or bifidobacterium, that can be added directly to a food for human consumption. There is insufficient evidence to recommend the addition of probiotics to infant feeds for prevention of allergic disease, food hypersensitivity or diarrhoea (Osborn and Sinn, 2007; Szajewska and Mrukowicz, 2001) and no infant milks currently contain probiotics.

A further discussion of evidence used to support claims made around specific ingredients in infant milks can be found in section 6.12.

3.7 Powdered and ready-to-feed milks

Infant formulas are available in powder and ready-to-feed (RTF) formulations and the composition may vary between the two. RTF milks are, however, rapidly growing in popularity as consumers look for increasingly convenient food and drink products. There has been concern over a number of years that errors in the reconstitution of powdered

milks might contribute to overfeeding of infants (Lucas, 1992) and the main advantage of RTF formula is that no errors can be made when making up the milk. In addition, RTF formula is sterile until opened, whilst powdered milks are not. Infants may also accept RTF milk straight from the carton without being warmed, which some parents may see as an advantage. The disadvantages are that RTF milks are very expensive, and considerable numbers of cartons are required which can be bulky to purchase and increases packaging waste. There is also reduced flexibility on serving sizes. More research is needed on how RTF formulas are used by parents (see section 6.5.1).

The potential for harm to infants from making up powdered formula milk feeds incorrectly is serious. Over-concentration of feeds may lead to hypernatraemic dehydration or obesity, while under-concentration may lead to growth faltering (Department of Health and Social Security, 1974; Chambers and Steel, 1975). A systematic review of formula feed preparation (Renfrew et al, 2008) reported that errors in reconstituting feeds were commonly reported and that there was considerable inconsistency in the size of scoops between milk brands. In addition there appears to be little information provided to parents antenatally on how to make up bottles appropriately. A study in which mothers at clinics were asked to measure powdered milk with the same scoop found wide variations in the amount of powder used, ranging from 2.75g to 5.2g per levelled scoop (Jeffs, 1989). Pre-weighed sachets of milk powder have been suggested as a way to reduce volume errors, although where part packets are required to make up smaller or larger feeds, it is likely that errors will still occur. Renfrew et al (2008) recommended that there should be a consistent approach in terms of uniform instructions in the making up of feeds and in scoop sizes to avoid confusion, led by the Food Standards Agency and the Department of Health, but these recommendations do not appear to have been taken forward. When preparing this report we made up powdered formula for the main first milk brands following the manufacturers' instructions, and 900g of dried powder made between 6625ml and 7520ml of milk, suggesting some varieties in the energy density of milks per scoop if the final products meet similar compositional standards.

3.7.1 Water used to make up powdered milk, and fluoride intakes

It is recommended that powdered formula milks are made up using fresh tap water and that bottled water is only used if it specifically states that it is appropriate for making up infant formula, as some bottled waters have a high level of some minerals. It is recommended that bottled waters used to make up formula should have less than 200mg sodium per litre and less than 250mg sulphite (SO_4) per litre and that they are boiled before for use for infants under 6 months of age (NHS, 2011).

There has been some discussion of the risks of using bottled water should an emergency arise and mains water supplies are disrupted. Often in these circumstances bottled water is made available to households and it is important that clear information is given to parents and carers in emergency situations on whether it is safe to use this. A review of the safety of bottled water for making up infant formula concluded that this is likely to be a safe alternative to mains water in the event of an emergency and this should be made clear in appropriate guidance (Osborn and Lyons, 2010).

Most RTF formula milks use demineralised tap water as the diluent. This has the advantage of allowing tighter control over the final mineral content of the product. The final mineral content of reconstituted powder formulas will depend on the mineral content of the water used as a diluent. The mineral content of tap water is subject to considerable geographical variation. In the UK some, although not all, water supplies are fluoridated. Whilst no essential function of fluoride has been proven in humans, it protects against dental caries. However, an excess of fluoride during the development of teeth may cause dental fluorosis (an enamel development defect causing brown mottling and pitting). The panel on dietary

reference values of COMA recommends that water is fluoridated to a level of 1ppm (1 part per million). Consumption of water fluoridated to this level results in a daily consumption of oral fluid intake of 0.22mg/kg of body weight in formula-fed infants aged 1 month. This falls within the levels of safe intakes for infants aged up to 6 months (Department of Health, 1991). EC regulations specify only maximum levels for fluoride in infant or follow-on formula.

A recent analysis of the fluoride content of infant milks showed that there was considerable variation, with the fluoride concentration of powdered infant milks in this study ranging from 0.012 to 0.210mg/ml when reconstituted with non-fluoridated water, and from 0.346 to 1.210mg/ml when reconstituted with fluoridated water (Zohouri et al, 2009). The fluoride concentration of the water used to prepare infant milk is a more important determinant of fluoride intake than the content of the infant milks themselves. However, infants fed on infant milks in fluoridated areas will receive considerably more fluoride than breastfed babies. Since there is a lack of agreement among expert groups on the appropriate upper intake of fluoride in relation to dental fluorosis in children, it is difficult to conclude whether infants living in fluoridated areas are potentially at risk of receiving excessive amounts of fluoride from infant milks. Data from the recent analysis by Zohouri et al (2009) suggest that fluoride intakes among formula-fed infants in fluoridated areas are likely to be below the safe fluoride intake threshold of 0.22mg/kg bw/day in infants under 6 months suggested by COMA (Department of Health, 1991), but higher than the Tolerable Upper Intake Level of 0.1mg/kg bw/day defined by EFSA for 1-8 year olds (European Food Safety Authority, 2005). Further work in this area is needed to examine actual fluoride intakes by infants during the first year of life and the contribution made by infant milks to this.

3.8 Milks suitable for specific population groups

Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, manufacturers of infant formula do not typically use them. We have indicated in Tables 3-14 if milks are suitable for vegetarians.

Vegan parents or carers who wish to avoid all animal products for their infants and who choose not to breastfeed, can use soy protein based milks if recommended to do so by a health professional, as these are suitable for vegans.

Many infant milks have sought approval for use by communities who require halal products, and we have indicated where this is the case in Tables 3-14. Many of those who choose a kosher diet will use infant milks which are vegetarian or halal approved, but some groups who choose a stricter kosher diet may seek products that are approved by a Rabbi or other religious organisation. This may be particularly the case during Passover.

Parents and carers who do not have English as a first language and who may have access to infant milks that have been imported to the UK from elsewhere should be strongly advised to use milks which are manufactured for use in the UK and which are known to comply with EC compositional and labelling regulations.

3.9 Goats' milk

Goats' milk based formulas are excluded from the current European Commission Directive on Infant Formulae and Follow-on Formulae on the basis of recommendations made by the European Food Safety Authority (EFSA, 2006). Their recommendation was based on the grounds of there being insufficient evidence to support the nutritional adequacy and safety of goats' milk as a protein source in infant and follow-on formula. The evidence assessed suggested that the protein in unmodified goats' milk failed to provide amino acids in the

concentration required relative to the energy value. In 2005, after the Directive had been issued, further information was provided by Vitacare, a manufacturer of goats' milk formula, and EFSA was asked by the EC to review its original assessment. In 2006 they published their opinion which concluded that, according to the additional amino acid analysis provided, the goats' milk formula fulfilled the requirements of Directive 91/321/EEC which is to provide, per energy value, at least the same amounts of indispensable and conditionally indispensable amino acids as the reference protein, human milk. However, EFSA also pointed out that the results of the clinical trial which had been submitted were insufficient to establish the nutritional adequacy and safety of goats' milk formula due to flaws in the methodology, including insufficient sample size, restriction to anthropometric parameters only, absence of a breastfed reference group, and non-adherence to the study's protocol (EFSA, 2006). Their overall conclusion was that there was still insufficient data to establish the suitability of goats' milk protein as a protein source in infant formula.

EFSA also concluded that there was insufficient data to support the belief that the incidence of allergic reactions is lower when feeding goats' milk based formula compared with cows' milk based formula. The protein in goats' milk is very similar to that found in cows' milk and most babies who react to cows' milk protein will also react to goats' milk protein. The Department of Health recommends that infants with proven cows' milk protein intolerance can be prescribed an extensively hydrolysed infant formula. Goats' milk based formula is also unsuitable for babies who are lactose-intolerant as it contains similar levels of lactose to cows' milk based infant formulas (Department of Health, 2007). The EFSA report can be found at: http://www.efsa.europa.eu/cs/BlobServer/Statement/milk_en1.pdf?ssbinary=true

Some goats' milk infant milks are sold on the UK market, but these are not recommended for the first year of life. Holle Infant Goat Milk Follow-on Formula, for example, is marketed as suitable from 6 months of age, but this milk does not comply with EU recommendations.

3.10 Other milks unsuitable for infants and toddlers

Infants should be breastfed or given appropriate infant formula milks during the first year of life. Cows' milk or milk from any other animal (eg. goat, sheep or buffalo), unmodified soya milks or milk substitutes such as oat milk, rice milk or almond milk are not suitable as the main drink for infants in the first year of life.

The majority of toddlers will be able to have whole cows' milk as their main milk drink during the second year of life and beyond, and there are no nutritional advantages to having other milks if cows' milk is tolerated. From 1 year of age, however, whole goats' milk, sheep's milk or buffalo milk or calcium-fortified unsweetened soya milks can be used as the main drink if desired alongside a good mixed diet which will meet the majority of the child's energy and nutrient needs.

There are particular concerns about rice milks which can contain high levels of arsenic. The current recommendation from the Food Standards Agency (2009a) is:

"The Agency advises against the substitution of breast milk, infant formula or cows' milk by rice drinks for toddlers and young children. This is both on nutritional grounds and because such substitution can increase their intake of inorganic arsenic, which should be kept as low as possible. If toddlers and young children (ages 1 - 4.5 years) consume rice drinks instead of breast milk, infant formula or cows' milk, the Agency estimates that their intake of inorganic arsenic could be increased by up to four fold."

3.11 How are formula milks made?

The manufacturing processes for most powdered milks are very similar. Powdered infant formula is manufactured using two general types of processes: a dry blending process and a wet-mixing/spray-drying process. Some manufacturers use a combination of these processes, and each has different risks and benefits with respect to the potential for product contamination by bacteria such as *Enterobacter sakazakii* (now known as *Cronobacter sakazakii*) or other harmful bacteria.

In the dry blending process, the ingredients are received from suppliers in a dehydrated powdered form and are mixed together to achieve a uniform blend of the macronutrients and micronutrients necessary for a complete infant formula product. Dry blending is less capital-intensive and more energy-efficient than wet-mixing/spray-drying and, as it does not involve the use of water in the manufacturing process, a dry environment reduces the chance that harmful bacteria will become established in the plant environment in sufficient numbers to cause product contamination. However, the microbiological quality of a dry-blended product is largely determined by the microbiological quality of the constituent dry ingredients. In a dry blending process there is no heat treatment to destroy bacteria in the final product. Thus, if one or more ingredients in a dry-blended product are contaminated by even low numbers of harmful bacteria, these bacteria are likely to be present in the finished product. Dry ingredients are generally blended in large batches until the nutrients are uniformly distributed throughout the batch. The blended product is then passed through a sifter to remove oversize particles and is then transferred to drums for storage or transferred directly to the powder packaging line. The powder is transferred to a filler hopper that feeds powder into cans, which are then flushed with inert gas, seamed, and coded.

In the wet-mixing/spray-drying process, ingredients are blended together, homogenised, pasteurised and spray-dried to produce a powdered product. The pasteurisation step destroys harmful bacteria that may be present in the ingredients, so this process is much less dependent on the microbiological quality of ingredients. This process also has the advantage of ensuring a uniform distribution of nutrients throughout the batch. However, the wet-mixing/spray-drying process requires that processing equipment, including the spray dryer and fluidised bed, be regularly wet-cleaned. This frequent wet-cleaning provides the moisture needed by bacteria to grow and become established in the plant environment. If not controlled, these bacteria can be a source of product contamination. Ingredients are blended with water in large batches, and pumped to a heat exchanger for pasteurisation. Some nutrients are added after pasteurisation and the microbiological quality of these nutrients is critical, since the product may not receive further heating sufficient to destroy harmful bacteria. After the addition of micro-nutrients, the liquid may be concentrated by passing it through an evaporator, or it may be pumped directly to the spray dryer. After spray drying, the product may be agglomerated to increase the particle size and to improve its solubility.

3.12 Are formula milks expensive to make?

The cost of manufacturing infant formula from the ingredients used is not known, but it has been estimated, from information collected in 1998 by the General Accounting Office in the US, that wholesale prices of infant formula appear high in relation to the costs of production, indicating 'the likelihood of a high proft margin' (United States General Accounting Office, 1998). In 1994, retail prices of infant formula in the US were estimated to be as much as five times the cost of manufacture, and it is likely that this is common to manufacture elsewhere in the world (Kent, 2006). Manufacturers of ingredients for formula milks such as Martek Biosciences, who provide DHA for addition to formula milks, also make substantial profits from these ingredients, with Martek Biosciences estimating gross profits of nearly 50% for 2010 (Martek Biosciences, 2010).

4 Infant milks available in the UK

This section describes the types of infant milk available in the UK in 2010/11 and the basic composition of those milks.

The infant milk market is very dynamic and the majority of companies have reformulated their entire range of milks during the time in which we have carried out this review, primarily in response to the deadline for meeting the compositional requirements of the Infant Formula and Follow-on Formula Regulations 2007 (see section 2.7). When a new product is placed on the market, or when the reformulation of an existing product requires a labelling change, infant milk manufacturers and importers are required by the 2007 regulations to notify the competent authority of the member state where it is to be marketed. (In the UK, the competent authority is the Food Standards Agency.) However, as there is no requirement to provide notification of the withdrawal of a product, notifications do not reflect the current milk market. In addition there are often compositional differences between ready-to-feed formula and powdered formula of the same name. Where we have been given information about infant milks from manufacturers, this information has been taken from the most recent website information or promotional material designed for health professionals or from conversations with consumer carelines.

It should be noted that the nutritional composition information on company websites is often out of date. Also, the nutritional composition information on packaging is not always complete and it cannot be assumed that the absence of a nutrient from the listing means that it is not present. The majority of company websites offer full nutritional listings only to healthcare professionals who register with them.

The information on milk composition used in this report has not been compiled easily. It should be noted, however, that all infant milk manufacturers approached for product information were willing and able to provide us with up-to-date information on request. We recommend that an appropriate independent body should use this information as a starting point to maintain a current record of the UK infant milk market. This could be used as a reference tool for individuals and groups with an interest in infant nutrition. We cannot guarantee that the information has not changed between our collection of it and publication of this draft report.

For the purposes of this report we have divided infant milks available into the categories shown in Table 2. Sections 4.1 to 4.10 give basic information and nutritional composition information about each category.

TABLE 2

Infant milks commonly available in the UK

Category of infant milk	Names of infant milks included in this category
Infant milks suitable from birth (cows' milk based)	Aptamil 1 Babynat Infant Formula (discontinued) Cow & Gate 1 Hipp Organic First Infant Milk Holle Organic Infant Formula 1 Nurture Newborn (discontinued) SMA First Infant Milk
Infant milks marketed for hungrier babies, suitable from birth (cows' milk based)	Aptamil Hungry Milk Cow & Gate Infant Milk for Hungrier Babies 2 Hipp Organic Hungry Infant Milk Nurture Hungry Baby (discontinued) SMA Extra Hungry
Thickened infant milks suitable from birth	Enfamil AR SMA Staydown
Soy protein based infant milks suitable from birth	Abbott Isomil (discontinued) Cow & Gate Infasoy Nurture Soya (discontinued) SMA Wysoy
Lactose-free infant milks suitable from birth	Enfamil O-Lac SMA LF
Partially hydrolysed infant milks suitable from birth	Aptamil Comfort Cow & Gate Comfort Nurture Gentle Infant Milk (discontinued)
Follow-on formula suitable from 6 months of age	Aptamil 3 Follow-on Milk Babynat Follow-on Milk Cow & Gate 3 Follow-on Milk Hipp Organic Follow-on Milk Holle Organic Infant Formula 2 Nurture Growing Baby Follow-on Milk (discontinued) SMA Follow-on Milk
Partially hydrolysed follow-on formula suitable from 6 months of age	Cow & Gate Comfort Follow-on Milk (discontinued) Nurture Gentle Follow-on Milk (discontinued)
Goodnight milks	Cow & Gate Good Night Milk (discontinued) Hipp Organic Good Night Milk
Growing-up milks and toddler milks	Aptamil Growing Up Milk Cow & Gate Growing Up Milk Hipp Organic Growing Up Milk Holle Organic Infant Formula 3 Nurture Toddler Milk (discontinued) SMA Toddler Milk

Notes

We have highlighted where infant milks have recently been discontinued. This highlights the dynamic nature of the infant milk market and the need for a regularly updated independent source of information on infant milks available in the UK.

Details of the manufacturers of these infant milks, and their contact details, can be found in section 8.

A number of other milks can be purchased in the UK in shops which sell foods for specific population groups, and some of these milks may be imported to the UK without appropriate product translation into English. We have not included these products in this review and strongly recommend that any formula milks found for sale in the UK which are not included in this report are reported to local trading standards officers for investigation.

There are also a number of specialist infant milks that are either available on prescription from pharmacies, or are for hospital use only. These should not be given to an infant without specialist advice from a paediatric dietitian or paediatrician. A list of these specialist formulas can be found in Appendix 2.

4.1 Infant milks suitable from birth (cows' milk based)

Infant milks suitable from birth are designed to fully meet the nutritional requirements of healthy term infants from birth to 6 months old and aim to be closest in composition to breast milk. Based on modified cows' milk, these infant milks have whey:casein ratios of 60:40. There is little variation between brands in the macronutrient and micronutrient content, but there is some variation in the additional ingredients used which are permissible but not considered mandatory (under the Infant Formula and Follow-on Formula Regulations 2007). These include long chain polyunsaturated fatty acids (LCPs) and prebiotics. (See sections 3.2 and 3.6 for more information about these ingredients.) Organic products are also regulated by EC regulation 834/2007 on organic production and labelling.

The nutritional composition and ingredients used in infant milks based on cows' milk suitable from birth are given in Table 3.

TABLE 3

The nutritional composition of infant milks suitable from birth (cows' milk based)

Nutrients per 100ml	Aptamil 1	Babynat Infant Formula (discontinued)	Cow & Gate 1	Hipp Organic First Infant Milk	Holle Organic Infant Formula 1	Nurture Newborn (discontinued)	SMA First Infant Milk
Macronutrients							
Energy *kcal*	66	67	66	67	67	67	67
Protein *g*	1.3	1.35	1.3	1.4	1.5	1.4	1.3
Whey:casein ratio	60:40	60:40	60:40	60:40	60:40	60:40	60:40
Carbohydrate *g*	7.3	8.1	7.3	7.1	8.3	7.0	7.3
– of which lactose *g*	7.0	5.0	7.0	6.8	6.0	6.9	7.3
Fat *g*	3.5	3.24	3.5	3.6	3.1	3.7	3.6
Added LCPs AA	✓	✗	✓	✓	✗	✓	✓
DHA	✓	✗	✓	✓	✗	✓	✓
In approved ratio	✓	N/A	✓	✓	N/A	✓	✓
LCP source	Vegetable and fish oils	N/A	Vegetable and fish oils	Vegetable and fish oils	N/A	Fungal and fish oils	Fungal and algal oils (vegetable source)
Micronutrients							
Vitamins meeting regulations	✓	✓	✓	✓	✓	✓	✓
Minerals meeting regulations	✓	✓	✓	✓	✗[1]	✓	✓
Other							
Structured vegetable oils	✗	✗	✗	✗	✗	✓	✗
Prebiotics	✓	✗	✓	✓	✗	✓	✗
Nucleotides	✓	✗	✓	✗	✗	✓	✓
Inositol	✓	✗	✓	✓	✗	✓	✓
Taurine	✓	✗	✓	✗	✗	✓	✓
Choline	✓	✗	✓	✓	✗	✓	✓
Added antioxidants	✓	✓	✓	✓	✓	✓	✓
Contains soya	✓	✗	✓	✓	✗	✓	✓
Contains fish oil	✓	✗	✓	✓	✗	✓	✗
Suitable for vegetarians[2]	✗	✗	✗	✗	✗	✗	✗
Halal approved	✓	✗	✓	✗	✓	✓	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid N/A = not applicable

1 Information provided to us suggested copper was present in lower amounts in this milk than regulations state, and selenium was not added.

2 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

4.2 Infant milks marketed for hungrier babies, suitable from birth (cows' milk based)

In addition to first infant formula, most manufacturers also offer an infant formula for 'hungrier babies'. These milks are predominantly casein-based and the rationale for their use is that the whey:casein ratio of approximately 20:80 (which is similar to that in cows' milk) is thought to result in slower gastric emptying, resulting in greater satiety. Studies used to support this suggestion have, however, been from small studies of infants with reflux difficulties (Billeaud et al, 1990; Tolia et al, 1992) and these findings are not supported by all studies. It has also been suggested that the use of these milks may help delay weaning, but there is no scientific evidence to support this. Cow & Gate suggest on their website that infants under 6 months may get a better night's sleep if they have hungry baby formula in the evening, but give no evidence to support this claim. The higher casein content of hungrier baby formula is likely to cause larger and more indigestible curds to form in the stomach, but there is no evidence that this helps a baby to settle better or sleep longer (Taitz and Scholey, 1989; Thorkelsson et al, 1994).

The nutritional composition of hungry baby formulas does not differ significantly from those of standard infant formulas, but they have a slightly higher carbohydrate and protein content balanced by a slightly lower fat content which maintains the total energy value at recommended levels. The vitamin and mineral content of these milks also differs slightly from those in first infant formula. However, all milks available report vitamin and mineral contents within the recommended levels.

The nutritional composition and ingredients used in infant milks marketed for hungrier babies suitable from birth are given in Table 4.

TABLE 4

The nutritional composition of infant milks marketed for hungrier babies, suitable from birth (cows' milk based)

Nutrients per 100ml	Aptamil Hungry Milk	Cow & Gate Infant Milk for Hungrier Babies 2	Hipp Organic Hungry Infant Milk	Nurture Hungry Baby (discontinued)	SMA Extra Hungry
Macronutrients					
Energy *kcal*	66	66	67	68	67
Protein *g*	1.6	1.6	1.6	1.7	1.6
Whey:casein ratio	20:80	20:80	20:80	20:80	20:80
Carbohydrate *g*	7.7	7.7	7.7	7.5	7.0
– of which lactose *g*	7.6	7.4	7.2	7.4	7.0
Fat *g*	3.2	3.2	3.3	3.5	3.6
Added LCPs AA	✓	✗	✓	✓	✓
DHA	✓	✗	✓	✓	✓
In approved ratio	✓	N/A	✓	✓	✓
LCP source	Vegetable and fish oils	N/A	Vegetable and fish oils	Fungal and fish oils	Fungal and algal oils (vegetable source)
Micronutrients					
Vitamins meeting regulations	✓	✓	✓	✓	✓
Minerals meeting regulations	✓	✓	✓	✓	✓
Other					
Structured vegetable oils	✗	✗	✗	✓	✗
Prebiotics	✓	✓	✓	✓	✗
Nucleotides	✓	✓	✗	✓	✓
Inositol	✓	✓	✓	✓	✓
Taurine	✓	✓	✗	✓	✓
Choline	✓	✓	✓	✓	✓
Added antioxidants	✓	✓	✓	✓	✓
Contains soya	✓	✓	✓	✓	✓
Contains fish oil	✓	✗	✓	✓	✗
Suitable for vegetarians[1]	✗	✗	✗	✗	✓[2]
Halal approved	✓	✓	✗	✓	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid N/A = not applicable

1 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

2 Powder formulation only.

4.3 Thickened infant milks suitable from birth

These products have been formulated to help improve gastro-oesophageal reflux (bringing up milk or being sick) in formula-fed infants. Whilst reflux does not generally result in pathologic consequences and resolves spontaneously by about 3 months of age in the majority of cases, many parents seek remedies (Vanderhoof et al, 2003) and these milks have been developed to meet this actual or perceived need. In the UK there are two thickened milks available – Enfamil AR (Mead Johnson) and SMA Staydown (SMA Nutrition). Both formulas are available on prescription and over the counter at pharmacies. Both milks can be used from birth and contain added gelatinised corn starch or rice starch. SMA Staydown has a whey:casein ratio of 20:80 to slow gastric emptying; it is suggested that the added pre-cooked corn starch thickens on contact with stomach acid, increasing the time taken for the milk to pass through the stomach. SMA supports the use of this milk by reference to clinical trials (Ramirez-Mayans et al, 2003; Xinias et al, 2003), although the role of gastric emptying in the pathogenesis of gastro-oesophageal reflux in infants is considered to be controversial (Tolia et al, 1992). In a systematic review of non-pharmacological and non-surgical therapies for gastro-oesophageal reflux in infants, Carroll et al (2002) concluded that thickened milks do not appear to reduce measurable reflux, although they may reduce vomiting.

The thickening agent in SMA Staydown is corn starch, whilst that of Enfamil AR is rice starch. SMA Nutrition suggests that rice starch is associated with constipation, whilst Enfamil suggest that rice starch is the natural choice for thickening milks as it is typically used as a first weaning food. The study by Vanderhoof et al (2003) concluded that Enfamil AR did not cause constipation, while in the study by Ramirez-Mayans et al (2003), 3 out of 24 infants being fed milk containing 5% (5g/100ml) rice starch suffered constipation.

It has been suggested that commercially prepared thickened milks have an advantage over thickeners added to milk at home as the latter type may lead to inconsistencies in composition (Ramirez-Mayans et al, 2003). Milk thickeners to add to milk include Instant Carobel (Cow & Gate), which uses carob bean gum as a thickening agent.

Whilst some studies have shown that thickened milks can reduce regurgitation in some infants, their use in infants with simple reflux is not supported by the ESPGHAN Committee on Nutrition on the grounds that there is no conclusive information available on the potential effects of thickening agents on the bioavailability of nutrients and growth of children, or on mucosal, metabolic and endocrine responses (Aggett et al, 2002a). There is also very little evidence to suggest that these milks confer any benefits with respect to acid exposure of the oesophageal mucosa or bronchopulmonary complications of gastro-oesophageal reflux. It is suggested that, where infants have simple reflux and no complications, parents and carers require advice and information rather than a different type of formula (Aggett et al, 2002a).

The nutritional composition and ingredients used in thickened infant milks suitable from birth are given in Table 5.

TABLE 5

The nutritional composition of thickened infant milks suitable from birth

Nutrients per 100ml	Enfamil AR	SMA Staydown
Macronutrients		
Energy *kcal*	68	67
Protein *g*	1.7	1.6
Whey:casein ratio	20:80	20:80
Carbohydrate *g*	7.6	7.0
– of which lactose *g*	4.6	5.2
Carbohydrate source	Lactose, glucose polymers, rice starch	Lactose, maltodextrin, dried glucose syrup, pre-cooked corn starch
Fat *g*	3.5	3.6
Added LCPs AA	✓	✗
DHA	✓	✗
In approved ratio	✓	N/A
LCP source	Single cell oils (vegetable source)	N/A
Micronutrients		
Vitamins meeting regulations	✓	✓
Minerals meeting regulations	✓	✓
Other		
Structured vegetable oils	✗	✗
Prebiotics	✗	✗
Nucleotides	✗	✓
Inositol	✗	✓
Taurine	✓	✓
Choline	✓	✓
Added antioxidants	✓	✓
Contains soya	✓	✓
Contains fish oil	✗	✗
Suitable for vegetarians[1]	✓	✓
Halal approved	✗	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid N/A = not applicable

1 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

4.4 Soy protein based infant milks suitable from birth

Soy protein based milks are free of any animal products and use glucose, corn syrup or sucrose as the carbohydrate source. The amino acid profile of soy protein is deficient in sulphur-containing amino acids, and soy protein based milks must therefore be fortified with the sulphur-containing amino acid L-methionine. Soy protein based milks are available both over the counter and by prescription and may be used from birth. They have sometimes been used for children who require an alternative to cows' milk based infant milks because they have an allergy or intolerance to cows' milk, or because they have a specific condition such as galactosaemia or galactokinase deficiency, or because parents or carers have elected to feed them a vegan diet.

There is currently controversy over the use of soy protein based infant milks for children aged under 6 months. Concerns have been raised over the potential allergenic effect of soy protein based milks in infants at high risk of atopy and the effects that the phyto-oestrogens present in soy protein based milks might have on future reproductive health (Committee on Toxicity, 2003).

In a systematic review of clinical studies examining measures of infant health and development and comparing soy protein based infant milk with cows' milk protein based infant milk and/or human milk, Mendez et al (2002) concluded that modern soy protein based milks (supplemented with methionine) support normal growth and development in healthy-term infants during the first year of life.

Soy protein based infant milks have often been used as an alternative to cows' milk protein based infant milks in children with cows' milk protein allergy (CMPA). In a review of trials comparing the effect of prolonged feeding of soy protein based infant milk to cows' milk protein based infant milk, meta-analysis found no significant difference in childhood asthma incidence, childhood eczema incidence or childhood rhinitis. The authors concluded that soy protein based milks cannot be recommended for allergy prevention or food intolerance in infants at high risk of atopy (Osborn and Sinn, 2006).

It is recognised that a proportion of children with CMPA are also allergic to soy protein. The Chief Medical Officer has recommended that soy protein based milks should not be used as the first line of treatment for infants under 6 months of age who have CMPA or cows' milk protein intolerance, as this is the period when they are most likely to become sensitised to soy protein (Chief Medical Officer, 2004). ESPGHAN recommends that soy protein based formulas should not be used for infants under 6 months of age and that the use of therapeutic milks based on extensively hydrolysed proteins (or amino acid preparations if hydrolysates are not tolerated) should be preferred to the use of soy protein milks in the treatment of cows' milk protein allergy (Agostoni et al, 2006).

Soy protein based milks contain much higher levels of phyto-oestrogens than milks based on cows' milk protein. Setchell et al (1998) estimated that infants aged 1 to 4 months who were fed soy protein based milks would receive 6-12mg/kg of body weight of phyto-oestrogens per day, compared to 0.7-1.4mg/kg per day for adults consuming soy protein based products. There has been very little research into the effects of consumption of phyto-oestrogens from soy protein based milks in very young infants. However, research in animals suggests that phyto-oestrogens can have detrimental effects on reproductive function, immune function and carcinogenesis. In a review of the scientific evidence on soy protein based milks, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) concluded that the high levels of phyto-oestrogens present in soy protein based milks posed a potential risk to the future reproductive health of infants

(Committee on Toxicity, 2003). Advice in the UK is that parents should always seek advice before feeding their infant soy protein based infant milk.

The nutritional composition and ingredients used in soy protein based infant milks suitable from birth are given in Table 6.

TABLE 6

The nutritional composition of soy protein based infant milks suitable from birth

Nutrients per 100ml	Abbott Isomil (discontinued)	Cow & Gate Infasoy	Nurture Soya (discontinued)	SMA Wysoy
Macronutrients				
Energy *kcal*	68	66	69	67
Protein *g*	1.8	1.6	1.95	1.8
Carbohydrate *g*	6.9	7.0	6.8	6.9
Carbohydrate source	Corn syrup solids, sucrose	Glucose syrup	Glucose syrup	Dried glucose syrup
Fat *g*	3.7	3.5	3.8	3.6
Added LCPs AA	✗	✗	✗	✗
DHA	✗	✗	✗	✗
Micronutrients				
Vitamins meeting regulations	✓	✓	✓	✓
Minerals meeting regulations	✗	✓	✓	✓
Other				
Structured vegetable oils	✗	✗	✗	✗
Prebiotics	✗	✗	✗	✗
Nucleotides	✗	✗	✗	✗
Inositol	✗	✓	✓	✓
Taurine	✓	✓	✓	✓
Choline	✓	✓	✓	✓
Added antioxidants	✓	✓	✓	✓
Contains soya	✓	✓	✓	✓
Contains fish oil	✗	✗	✗	✗
Suitable for vegetarians[1]	✓	✓	✓	✓
Halal approved	✓	✓	✓	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid

1 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

4.5 Lactose-free infant milks suitable from birth

The main difference between lactose-free and standard cows' milk based formulas is that in lactose-free formula the carbohydrate is glucose rather than lactose. Lactose intolerance is a clinical syndrome which can cause abdominal pain, diarrhoea, flatulence and/or bloating after ingestion of food containing lactose. The underlying physiological problem is lactose malabsorption which is caused by an imbalance between the amount of lactose ingested and the capacity of the enzyme lactase to hydrolyse it, and therefore the amount of lactose that can cause symptoms varies (Heyman et al, 2006).

Heyman et al (2006) identify the following different types of lactose intolerance.

- Primary lactose intolerance is caused by an absolute or relative lack of the enzyme lactase and is the most common cause of lactose malabsorption worldwide. It is known to be more prevalent amongst black and Asian populations but is extremely rare in infants.
- Secondary lactose intolerance results from injury to the small bowel such as might occur during acute gastroenteritis and persistent diarrhoea.
- Congenital lactase deficiency is a rare condition in infants, in which the infant develops persistent diarrhoea as soon as any lactose, from human milk or formula, is introduced.
- Developmental lactase deficiency is observed amongst premature infants. Lactase production is deficient in the immature gastrointestinal tract until at least 34 weeks' gestation.

In primary lactose intolerance, the degree of lactase deficiency varies and the use of lactose-free milks may help to relieve the symptoms of lactose intolerance.

Congenital lactase deficiency can only be treated by excluding lactose from the diet. In infants this can be achieved by using lactose-free infant milks or incubating feeds (human milk or formula) with lactase. Developmental lactose intolerance can be treated in a similar manner, but the continued use of breast milk does not seem to have any adverse effects on pre-term infants (Shulman et al, 1995).

In the UK, the lactose-free infant milks Enfamil O-Lac (Mead Johnson) and SMA LF (Wyeth) are available over the counter from pharmacies. Both products are approved by the Advisory Committee on Borderline Substances (ACBS) for proven lactose intolerance. They are both nutritionally complete for infants up to 6 months of age and can be used alongside complementary feeding after that. SMA LF is presented as being suitable not only for infants with congenital lactose intolerance, but also for infants who have been diagnosed with lactose intolerance following a bout of gastroenteritis. It is also suggested to help in the dietary management of post-infectious diarrhoea in infants who are not breastfed. Similarly, Enfamil O-Lac is reported to manage both primary and secondary lactose intolerance and digestive problems such as colic, diarrhoea, bloating and wind associated with lactose intolerance. In developed countries, with the exception of very malnourished children, the use of lactose-free infant milks as a treatment for acute gastroenteritis has been shown to have no clinical advantage over standard lactose-containing formula (Kukuruzovic and Brewster, 2002). The use of lactose-free formula for the treatment of acute diarrhoea is considered by ESPGHAN to be unjustified. Despite this assertion, in a multi-centre study conducted in 29 European countries in 2000, when doctors were asked, in a questionnaire, what they would recommend for an infant with acute diarrhoea, 36% said they would use normal lactose-containing infant milk, 35% would use lactose-free infant milk, and 19% would use a lactose and milk protein free product (Szajewska et al, 2000). This suggests there may be considerable confusion among health professionals about the treatment of lactose intolerance in infants.

Lactose-free infant milk has a greater potential to cause dental caries than milks where the main source of carbohydrate is lactose. This is because lactose is a non-cariogenic sugar whereas the common replacement carbohydrate, glucose, is cariogenic (Bowen et al, 1997). It is therefore vital that parents using lactose-free infant milks follow advice to avoid prolonged contact of milk feeds with their baby's teeth and ensure that they clean their baby's teeth after the last feed at night.

The nutritional composition and ingredients used in lactose-free infant milks suitable from birth are given in Table 7.

TABLE 7

The nutritional composition of lactose-free infant milks suitable from birth

Nutrients per 100ml		Enfamil O-Lac	SMA LF
Macronutrients			
Energy *kcal*		68	67
Protein *g*		1.42	1.5
Whey:casein ratio		N/K	60:40
Carbohydrate *g*		7.2	7.2
– of which lactose *g*		less than 7	less than 0.1
Carbohydrate source		Glucose polymers, citrate	Dried glucose syrup
Fat *g*		3.7	3.6
Added LCPs	AA	✓	✗
	DHA	✓	✗
In approved ratio		✓	N/A
LCP source		Single cell oils (vegetable source)	N/A
Micronutrients			
Vitamins meeting regulations		✓	✓
Minerals meeting regulations		✓[1]	✓
Other			
Structured vegetable oils		✗	✗
Prebiotics		✗	✗
Nucleotides		✗	✗
Inositol		✓	✓
Taurine		✓	✓
Choline		✓	✓
Added antioxidants		✓	✓
Contains soya		✓	✓
Contains fish oil		✗	✗
Suitable for vegetarians[2]		✓	✓
Halal approved		✗	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid
N/A = not applicable N/K = not known

1 Iron content in line with the regulations for milks for special medical purposes.

2 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

4.6 Partially hydrolysed infant milks suitable from birth

Infant milks containing partially hydrolysed proteins are marketed as 'easier to digest'. In the UK there are two partially hydrolysed infant formulas available: Aptamil Comfort and Cow & Gate Comfort. Nurture Gentle Infant Milk (Heinz) has been discontinued. Aptamil Comfort and Cow & Gate Comfort are based on 100% whey protein, whilst the protein component of Nurture Gentle Infant Milk was 50% whey and 50% casein. All products contain lactose.

Aptamil Comfort, launched in 2007, is suggested as suitable for infants experiencing 'feeding discomfort' and the range of conditions it is claimed to help improve include colic, lactose intolerance, constipation and regurgitation (also known as possetting or reflux). The product contains partially hydrolysed proteins, a special blend of vegetable oils, reduced lactose, and a patented mix of prebiotics known as Immunofortis. Cow & Gate Comfort is formulated for 'comfortable digestion' and is claimed to help protect the immature, sensitive digestive system. This milk contains partially hydrolysed protein, reduced lactose, structured vegetable oils and prebiotics. It has an identical nutrient profile to Aptamil Comfort. Nurture Gentle Infant Milk claimed to have been formulated specifically to help aid digestion of protein and lactose, and help ease tummy spasms, flatulence and bloating. This milk contained acidified milk, a patented blend of structured vegetable oils known as Betapol, and prebiotics.

Acidification of milk is achieved by fermenting the milk with lactic-acid-producing bacteria during the production process. This is followed by heat treatment to ensure that there are no viable (live) bacteria in the final product. There is only limited evidence available on the effects of acidified milk in infant formula, but a large randomised, double-blinded, placebo-controlled clinical trial suggests that using acidified milk products may reduce the severity, but not the incidence, of diarrhoea in healthy infants (Thibault et al, 2004). The suggested mechanism for action is that active fermentation metabolites may have a bifidogenic effect and may interact with the intestinal immune system (Thibault et al, 2004). The health benefits of bifidogenic products are discussed in more detail in section 3.6. However, there does not appear to be any evidence that acidified milk aids digestion of protein and lactose.

None of these partially hydrolysed formulas are available on prescription. They represent the trend towards manufacturers 'medicalising' infant formula. They also demonstrate that, in the absence of a consensus of scientific opinion on the most effective method to manage minor digestive problems, manufacturers are able to manipulate the composition of formula within the regulations to produce a range of formulations, each of which purports to be the most effective method of easing common conditions in infants. A recent paper from a large randomised trial of healthy term infants given either a standard full-lactose non-hydrolysed cows' milk protein based infant milk or a 70% lactose, partially hydrolysed whey protein formula over 60 days reported that there was no difference in tolerance of intact compared to partially hydrolysed protein (Berseth et al, 2009). The authors noted that parents may mistake behaviours common in early infancy such as regurgitation and excessive crying as manifestations of intolerance to their infant milk and unnecessarily switch brands or types of milk.

The National Institute of Health and Clinical Excellence considers that there is insufficient evidence to suggest that infant formulas based on partially or extensively hydrolysed cows' milk protein can help prevent allergies (NICE, 2008).

The nutritional composition and ingredients used in partially hydrolysed infant milks suitable from birth are given in Table 8.

TABLE 8

The nutritional composition of partially hydrolysed infant milks suitable from birth

Nutrients per 100ml	Aptamil Comfort	Cow & Gate Comfort	Nurture Gentle Infant Milk (discontinued)
Macronutrients			
Energy *kcal*	66	66	68
Protein *g*	1.5	1.5	1.4
Whey:casein ratio	100:0	100:0	50:50
Carbohydrate *g*	7.1	7.1	7.2
– of which lactose *g*	3.3	3.3	4.8
Carbohydrate source	Lactose, glucose syrup, corn starch	Lactose, glucose syrup, corn starch	Lactose, maltodextrin, corn starch
Fat *g*	3.5	3.5	3.7
Added LCPs AA	✗	✗	✗
DHA	✗	✗	✗
Micronutrients			
Vitamins meeting regulations	✓	✓	✓
Minerals meeting regulations	✓	✓	✓
Other			
Structured vegetable oils	✓	✓	✓
Prebiotics	✓	✓	✓
Nucleotides	✓	✓	✓
Inositol	✓	✓	✓
Taurine	✓	✓	✓
Choline	✓	✓	✓
Added antioxidants	✓	✓	✓
Contains soya	✗	✗	✓
Contains fish oil	✗	✗	✗
Suitable for vegetarians[1]	✗	✗	✗
Halal approved	ANS	ANS	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid
ANS = approval not sought

1 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

4.7 Follow-on formula suitable from 6 months of age

Follow-on formula is defined by the European Commission Directive 2006/141/EC as "*foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet*". It is intended for infants over the age of 6 months who are receiving complementary foods and contains relatively more protein, micronutrients and iron than infant milks designed for use from birth. As infant formulas are designed for use by infants from birth to 1 year of age, those receiving complementary foods with adequate protein, carbohydrate, fat and iron do not need to have their infant formula replaced by follow-on formula. The Scientific Advisory Committee on Nutrition (SACN), in their 2007 review of infant feeding, stated that "*There is no published evidence that the use of any follow-on formula offers any nutritional or health advantage over the use of whey-based infant formula among infants artificially fed*" (SACN, 2007). For this reason follow-on formula are not included in the UK Healthy Start Scheme.

Follow-on formula have been vigorously marketed as a good source of iron for older infants, but increasing the iron content of follow-on formula beyond that typically found in first formula has only a limited effect on increasing the net amount of iron absorbed, and it is generally agreed that follow-on formula offers no advantage over standard infant formula after the age of 6 months (Moy, 2000). There is also some evidence that exessive iron intakes may result in a reduced uptake of other trace metals including copper and oxidation of lipids, due to the pro-oxidant effects of excess iron (Aggett et al, 2002b).

Current UK infant feeding guidelines recommend that the weaning diet should include iron-rich foods, that exclusive breastfeeding should continue for at least 6 months and that the introduction of cow's milk, which has a lower iron content than breast milk, should be postponed until 12 months of age. There is some evidence that high iron intakes among iron-replete toddlers may actually have an adverse affect on growth (Idjradinata et al, 1994) and a large trial of nearly 500 infants and toddlers given follow-on formula between 9-18 months of age in the UK found that there were no developmental or growth advantages in children given iron-supplemented follow-on formula (Morley et al, 1999). Whilst there may be nutritional and health advantages to continuing formula milk intake into the second year for those infants considered at high risk of iron deficiency because of poor diet or other difficulties, it is advised that first milks remain the milk of choice during the first year.

Some of the differences between infant milks suitable from birth and follow-on formulas are shown in Table 9.

The nutritional composition and ingredients used in follow-on formula suitable from 6 months of age are given in Table 10.

TABLE 9

Summary of some of the differences between selected nutrients in major-brand first infant milks suitable from birth and follow-on formulas suitable from 6 months of age

	Energy kcal/100ml	Protein g/100ml	Carbohydrate g/100ml	Fat g/100ml	Vitamin D µg/100ml	Calcium mg/100ml	Iron mg/100ml	Zinc mg/100ml
Aptamil 1	66	1.3	7.3	3.5	1.2	50	0.53	0.5
Aptamil 3 Follow-on Milk	68	1.4	8.6	3.2	1.4	62	1.0	0.52
Cow & Gate 1	66	1.3	7.3	3.5	1.2	50	0.53	0.5
Cow & Gate 3 Follow-on Milk	68	1.4	8.6	3.2	1.4	62	1.0	0.52
Hipp Organic First Infant Milk	67	1.4	7.1	3.6	1.1	60	0.5	0.7
Hipp Organic Follow-on Milk	69	1.5	7.7	3.5	1.2	74	1.0	0.7
Nurture Newborn (discontinued)	67	1.4	7.0	3.7	1.0	47	0.7	0.4
Nurture Growing Baby Follow-on Milk (discontinued)	68	1.8	7.3	3.5	1.1	75	1.2	0.7
SMA First Infant Milk	67	1.4	7.3	3.6	1.1	42	0.8	0.6
SMA Follow-on Milk	67	1.9	7.4	3.3	1.5	90	1.3	0.9

TABLE 10

The nutritional composition of follow-on formula suitable from 6 months of age

Nutrients per 100ml	Aptamil 3 Follow-on Milk	Babynat Follow-on Milk	Cow & Gate 3 Follow-on Milk	Hipp Organic Follow-on Milk	Holle Organic Infant Formula 2	Nurture Growing Baby Follow-on Milk (discontinued)	SMA Follow-on Milk
Macronutrients							
Energy *kcal*	68	66	68	69	75[1]	68	67
Protein *g*	1.4	1.62	1.4	1.5	1.8	1.8	1.5
Whey:casein ratio	50:50	40:60	50:50	40:60	N/K	30:70	60:40
Carbohydrate *g*	8.6	7.87	8.6	7.7	8.6	7.3	7.2
– of which lactose *g*	6.0	3.89	6.0	7.4	5.1	7.2	7.2
Carbohydrate source	Lactose, malto-dextrins	Lactose, malto-dextrins	Lactose, malto-dextrins	Lactose	Lactose, malto-dextrins, corn starch	Lactose	Lactose
Fat *g*	3.2	3.07	3.2	3.5	3.7	3.5	3.6
Added LCPs AA	✗	✗	✗	✗	✗	✓	✗
DHA	✗	✗	✗	✗	✗	✓	✗
In approved ratio	N/A	N/A	N/A	N/A	N/A	✓	N/A
LCP source	N/A	N/A	N/A	N/A	N/A	Fungal and fish oils	N/A
Micronutrients							
Vitamins meeting regulations	✓	✓	✓	✓	✗[2]	✓	✓
Minerals meeting regulations	✓	✓	✓	✓	✗[3]	✓	✓
Other							
Structured vegetable oils	✗	✗	✗	✗	✗	✓	✗
Prebiotics	✓	✗	✓	✓	✗	✓	✗
Nucleotides	✓	✗	✓	✗	✗	✓	✓
Inositol	✓	✗	✓	✓	✗	✓	✗
Taurine	✓	✗	✓	✗	✗	✓	✗
Choline	✓	✗	✓	✓	✗	✓	✗
Added antioxidants	✓	✓	✓	✓	✓	✓	✓
Contains soya	✓	✗	✓	✗	✗	✓	✓
Contains fish oil	✗	✗	✗	✗	✗	✓	✗
Suitable for vegetarians[4]	✗	✗	✗	✗	✗	✗	✓[5]
Halal approved	✓	✗	✓	✗	✓	✓	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid
N/A = not applicable N/K = not known

1 Information provided to us suggested that the energy content of this milk is higher than regulations state.

2 Information provided to us suggested vitamin K, thiamin, niacin and folic acid were present in lower amounts in this milk than regulations state, and that vitamin B_6 was too high.

3 Information provided to us suggested that copper and iodine were present in lower amounts in this milk than regulations state.

4 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

5 Powder formulation only.

4.8 Partially hydrolysed follow-on formula suitable from 6 months of age

Some partially hydrolysed infant formula and formula developed to help relieve the symptoms of minor digestive problems in infants from birth were also available as follow-on formula at the time of preparing this report. The differences between these follow-on formulas and their infant formula counterparts were similar to the differences found between standard infant and follow-on formulas described in section 4.7. Cow & Gate Comfort Follow-on Milk and Nurture Gentle Follow-on Milk have, however, both been discontinued.

There does not appear to be any evidence from clinical trials in older infants to suggest better tolerance of formula milk containing partially hydrolysed protein. The Cow & Gate company website for healthcare professionals gave the following explanation for discontinuing the product:

"… as the symptoms of colic and constipation are often short lived we have decided to remove Comfort Follow-on Milk from our range. However, for those who require a sensitive formula after 6 months of age for the dietary management of colic and constipation, Cow & Gate Comfort can be used as part of a weaning diet until 12 months."

4.9 Goodnight milks and food drinks

4.9.1 Goodnight milks

Goodnight milks are another example of product diversification on the infant food market. Hipp Organic and Cow & Gate introduced 'goodnight milks' to the market but Cow & Gate Good Night Milk has since been discontinued. These products differ from standard infant and follow-on formula in that they have added ingredients which make the products thicker than standard formulas. Both products are anecdotally suggested to help settle babies at bedtime, but there is no evidence that this is the case.

The nutritional composition of Cow & Gate Good Night Milk was very similar to that of their hungrier baby formula Cow & Gate Infant Milk for Hungrier Babies 2. The principles behind the use of goodnight milks are that the 20:80 whey:casein ratio slows gastric emptying, that the addition of rice starch and potato flakes results in increased viscosity, and that the carbohydrate content makes the milk more satisfying. The total energy content is maintained within regulations by a reduction in the fat component of the milk, and the product is gluten-free.

Hipp Organic Good Night Milk has a similar nutritional composition to Hipp Organic Follow-on Milk. The addition of organic corn starch, rice flakes and buckwheat flakes results in increased viscosity and the carbohydrate content is 35% starch. This product is also gluten-free.

The Scientific Advisory Committee on Nutrition (SACN) published a statement on the risks associated with the use of goodnight milk products (SACN, 2008). Since the publication of the report, the formulation of Hipp Organic Good Night Milk has changed. The product is now gluten-free, has a lower energy density and conforms to the requirements for follow-on formula specified by European Commission Directive 2006/141/EC. Additionally, Hipp Organic used to promote the product as being a suitable replacement for a light evening meal. SACN did not agree with Hipp Organic that the product was suitable for this purpose. The literature available to health professionals on the Hipp Organic website no longer suggests that the product is a suitable meal replacement but suggests that it may be used

to replace the last follow-on formula feed at night. The Cow & Gate product conformed with the requirements for follow-on formula specified by EU Commission Directive 2006/141/EC before it was discontinued. Regardless of the nutritional composition of the products, SACN raised the following concerns over the use of 'goodnight' milks:

- SACN considers both the Cow & Gate product and the Hipp Organic product to be breastmilk substitutes and is therefore concerned that the claims made by manufacturers concerning their ability to soothe and settle babies at night might undermine breastfeeding.
- There is no published scientific evidence to support a claim that these products offer any nutritional advantage over the use of infant or follow-on formula, nor is there any scientific evidence that they offer any advantage over infant or follow-on formula in settling babies at night.
- Statements relating to settling and soothing babies at night could encourage parents to believe that it is desirable for infants to sleep longer at night, at an age where infants show marked variation in sleep patterns. Parents might be tempted to use these products to settle babies more frequently, or when infants are younger than 6 months of age.
- The products might encourage poor dental hygiene, as parents might be tempted to put their babies to bed immediately after bottle feeding. This could result in the development of nursing bottle caries. It was noted that both companies advised cleaning the baby's teeth after the last feed, although this advice appears contrary to the idea of using the milk for 'settling' babies at night.
- The manufacturer's recommendation for making up Hipp Organic Good Night Milk is different from the recommendations for making up infant and follow-on formula. The 2005 infant feeding survey (Bolling et al, 2007) showed that many parents do not follow manufacturers' recommendations for reconstituting feeds. SACN is therefore concerned that the new methods might cause further confusion and create additional risk.

Goodnight milk drinks are significantly more expensive than follow-on milk. Cow & Gate Good Night Milk was approximately 1.6 times more expensive than their standard follow-on formula, whilst Hipp Organic Good Night Milk is approximately 2.5 times more expensive than their standard follow-on formula.

The nutritional composition and ingredients used in goodnight milks are given in Table 11.

Cow & Gate Good Night Milk has now been discontinued and the formulation of Hipp Organic Good Night Milk has been changed, demonstrating again how the infant milk market is constantly changing and that new products are made available before the scientific community has the opportunity to debate any efficacy.

TABLE 11

The nutritional composition of goodnight milks

Nutrients per 100ml	Cow & Gate Good Night Milk (discontinued)	Hipp Organic Good Night Milk
Macronutrients		
Energy *kcal*	70	70
Protein *g*	1.4	1.6
Whey:casein ratio	20:80	NK
Carbohydrate *g*	9.4	8.0
– of which lactose *g*	6.6	5.0
Carbohydrate source	Lactose, potato starch, rice flakes, maltodextrin	Lactose, organic corn starch, rice flakes and buckwheat flakes
Fat *g*	3.0	3.5
Added LCPs AA	✗	✗
DHA	✗	✗
Micronutrients		
Vitamins meeting regulations	✓	✓
Minerals meeting regulations	✓	✓
Other		
Structured vegetable oils	✗	✗
Prebiotics	✓	✗
Nucleotides	✓	✗
Inositol	✓	✗
Taurine	✓	✗
Choline	✓	✗
Added antioxidants	✓	✓
Contains soya	✓	✓
Contains fish oil	✗	✗
Suitable for vegetarians[1]	✗	✓
Halal approved	✓	✗

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid

1 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

4.9.2 Food drinks

In Europe, the market for infant foods designed to be readily fed by bottle is much more established than it is in the UK, with a greater diversity of brands and products. Products are not limited to goodnight drinks but include good morning drinks and flavoured food drinks (flavoured with vanilla, chocolate and fruits). The formulation of products is generally a powder or ready-to-drink liquid, although the Plasmon brand (Heinz) offers shaped biscuits designed to be dropped into a bottle and shaken to form a paste which flows readily through the teat of the bottle. The energy density of these products sold in other European countries can be as high as 112kcal/100ml, with the majority containing gluten. Some of these products are advertised for children as young as 4 months. The German market is particularly well developed.

Table 12 summarises the features of the brands of food drinks available on the German market.

TABLE 12

Food drinks available on the German market

Brand name	kcal/100ml	Gluten	Recommended from:
Alete 1	94	No	4 months
Alete 2	74-96	Most	6 or 8 months
Bebivita	81-112	All	6 or 8 months
Hipp	86-100	Most	6 months
Milupa	103-109	Most	6 or 8 months

Source: German Society of Paediatrics (DGKJ) (2007)

The use of cereal in milks is discouraged in the UK and these products will be associated with all the risks identified by SACN for goodnight milks (see page 54).

4.10 Growing-up milks and toddler milks

Growing-up milks are offered by the infant formula manufacturers as an alternative to, or to complement, cows' milk for toddlers from about 1 year of age, although some growing-up milks are labelled as suitable from 10 months of age. Growing-up and toddler milks provide higher quantities of some micronutrients such as vitamin A, D, iron and zinc than cows' milk and infant and follow-on formula. Growing-up milks are aimed at toddlers, who should be obtaining the majority of their nutrients from the food that they eat. It is generally recommended that toddlers eat a good variety of foods to supply the majority of their nutrients, rather than relying on fortified milk products to supply them. For more information on eating well for children under the age of 5 years, see the Caroline Walker Trust (CWT) resources *Eating Well: First Year of Life* and *Eating Well for 1-4 Year Olds* (see page 12).

The change from infant formula to cows' milk involves a taste transition for infants who should become accustomed to a less sweet taste in their main milk drink. Growing-up milks contain almost twice as much sugar per 100ml as cows' milk. Given that the development of taste preference is influenced by both genetic factors and experience, parents can influence their children's taste preferences through the food choices they make for them (Savage et al, 2007; Benton, 2004). It is unclear whether repeated exposure to sweet drinks in infancy and toddlerhood might contribute to the development of a preference for sweet drinks in later life. Growing-up milks are also typically lower in calcium than cows' milk.

Full-fat cows' milk is a suitable choice as the main drink for most toddlers from the age of 1 year, alongside a varied diet. There is some evidence that organic cows' milk has higher amounts of long chain fatty acids and lower amounts of saturated fatty acids than milk from cows conventionally farmed, and that the composition is more consistent across the year, and this may have some health benefits among those who are regular milk consumers (Butler et al, 2011).

Formula milk companies have taken different approaches to the flavour of their toddler milks. Heinz's Nurture Toddler Milk (now discontinued), unlike other brands, was based on whole milk rather than skimmed milk powder with added vegetable oils. Heinz suggested that this made it taste more like cows' milk and might therefore help infants with the taste transition from formula milk to cows' milk. Aptamil, Cow & Gate, Nurture and SMA growing-up milks all contain vanilla flavouring, but only Cow & Gate and SMA include this information in their ingredients list.

Despite the fact that growing-up milks are considerably more expensive than cows' milk, growing-up milks are the fastest growing sector of the infant milk market and are being heavily advertised. It is interesting to note that in 2010 the Advertising Standards Authority found, for the second time, that television adverts for Cow & Gate toddler milks were misleading consumers in terms of the amount of iron needed by toddlers and the use of milk to supply this (ASA, 2010). Whilst it is not possible to increase the total number of infants having formula milk in many western countries, it is possible to increase the length of time that value-added products are used per child and it is being suggested within the marketing press that formula consumption among children up to the age of 5 years could be achieved. Indeed in the US a company called Simply H has launched a Toddler Health drink mix, targeting children between 13 months and 5 years with a product featuring 'brain-enhancing' nutrients, and Nestlé has launched Neslac, a honey-flavoured fortified milk drink for 2-5 year olds which was launched into the Asian market. It is important that health claims on all foods for infants and children under the age of 5 are rigorously scrutinised to ensure that parents and carers are not misled when buying unnecessary and

expensive fortified foods and drinks and that health departments consider the need for regulation of these products which will fall outside any current regulatory frameworks.

Most formula companies produce both ready-to-feed (RTF) and powder versions of their growing-up milk. Due to the differences in processing methods and ingredients between RTF and powder formulations, the same brand may have minor differences in nutritional composition between formulations.

The nutritional composition and ingredients used in growing-up and toddler milks are given in Tables 13 and 14.

TABLE 13

The nutritional composition of growing-up milks and toddler milks (RTF formulation)

Nutrients per 100ml	Full-fat cows' milk	Aptamil Growing Up Milk	Cow & Gate Growing Up Milk	Hipp Organic Growing Up Milk	Nurture Toddler Milk (discontinued)
For use from age	12 months	12 months	12 months	10 months	12 months
Macronutrients					
Energy *kcal*	67	67	67	66	66
Protein *g*	3.3	1.9	1.5	1.9	1.9
Whey:casein ratio	20:80	20:80	40:60	20:80	30:70
Carbohydrate *g*	4.8	8.1	8.5	8.5	7.8
– of which lactose *g*	3.84	7.8	6.0	8.5	N/K
Carbohydrate source	Lactose, other monosaccharides and oligosaccharides	Lactose	Lactose, maltodextrins	Lactose	Lactose, fructose, maltodextrins
Fat *g*	3.8	3.0	3.0	2.7	3.0
Added LCPs AA	✗	✗	✗	✗	✗
DHA	✗	✗	✗	✗	✗
Micronutrients					
Vitamin A *µg*	52	65	65	65	75
Vitamin C *mg*	1.0	14	14	9.0	15
Vitamin D *µg*	0.03	1.7	1.7	1.4	1.6
Calcium *mg*	115	91	84	69	90
Zinc *mg*	0.4	0.89	0.9	0.7	0.9
Iron *mg*	0.05	1.2	1.2	1.2	1.2
Other					
Prebiotics	✗	✓	✓	✗	✗
Taurine	✗	✓	✓	✗	✓
Choline	✗	✓	✓	✗	✗
Contains soya	✗	✓	✗	✗	✓
Contains fish oil	✗	✗	✗	✗	✗
Suitable for vegetarians [1]	✓	✗	✗	✓	✗
Halal approved	✓	✓	✓	✗	✓

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid
N/A = not applicable N/K = not known RTF = Ready-to-feed

1 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

TABLE 14

The nutritional composition of growing-up milks and toddler milks (those available only as powder formulation)

Nutrients per 100ml	Holle Organic Infant Formula 3	SMA Toddler Milk
For use from age	8 months	12 months
Macronutrients		
Energy *kcal*	76	66
Protein *g*	2.5	1.8
Whey:casein ratio	N/K	20:80
Carbohydrate *g*	8.9	7.4
– of which lactose *g*	4.7	7.4
Carbohydrate source	Lactose, maltodextrin, fructose, corn starch	Lactose
Fat *g*	3.4	3.3
Added LCPs AA	✗	✓
DHA	✗	✓
LCP source	N/A	Fungal and algal oils (vegetable source)
Micronutrients		
Vitamin A *µg*	93	70
Vitamin C *mg*	17.6	12
Vitamin D *µg*	1.6	1.5
Calcium *mg*	118	78
Zinc *mg*	0.6	0.93
Iron *mg*	1.5	1.2
Other		
Prebiotics	✗	✗
Taurine	✗	✓
Choline	✗	✓
Contains soya	✗	✓
Contains fish oil	✗	✗
Suitable for vegetarians [1]	✗	N/K
Halal approved	✗	N/K

AA = arachidonic acid DHA = docosahexaenoic acid LCP = long chain polyunsaturated fatty acid
N/A = not applicable N/K = not known

1 Formula milks derived from cows' milk are generally not suitable for vegetarians due to the inclusion of fish oils and/or the use of the animal-derived enzyme rennet during the production process. Rennet is used to separate curds from whey and, although vegetarian alternatives are available, they are not used by all manufacturers.

5 Feeding guidelines

The Royal College of Nursing (RCN) recommends that healthy infants are fed on demand and offered adequate food to satisfy their hunger (Royal College of Nursing, 2007). Healthy infants will naturally regulate their feeding and will take enough milk to meet their needs. Their requirements may vary from day to day, but most full-term infants will need to be fed every 2-4 hours, day and night, in the early weeks of life. All manufacturers of infant milks provide, on their packaging, guidelines which show typical volumes of formula to use according to the age and weight of the infant. They also clarify that some infants may need more or less than the amounts shown.

The RCN guidelines and the clinical guidelines on infant feeding for Great Ormond Street Hospital use data from Shaw and Lawson (2001) to suggest that healthy infants between the ages of 1 week and 3 months have a fluid requirement of 150ml per kilogram of body weight per day (150ml/kg/day). A newborn may gradually increase its intake from 20ml/kg/day in the first 24 hours after birth, to 150ml/kg/day by day 7.

There is some variation in the way manufacturers' feeding guidelines are presented which makes it difficult to compare their guidelines with those of the RCN. Manufacturers use different age and weight cut-offs when suggesting the number and volume of feeds per 24 hours, and there is variation between the daily volumes of food suggested for infants at any given age. All manufacturers' guidelines suggest, during the first weeks of life, feeding less frequently than suggested by the Royal College of Nursing. If the suggested daily volume of food is divided by the weight in kilos of the baby, it is possible to compare the suggested volume/kg/day for the different products. Table 15 summarises the daily volume of milk suggested by manufacturers depending on the age of the baby, derived from the information supplied by the manufacturers. Table 16 summarises the suggested daily volume of food suggested by manufacturers depending on the weight of the baby. The volume/kg/day suggested by manufacturers varies and for infants aged between 0 and 3 months ranges between 145ml/kg/day and 186ml/kg/day. Additionally, whilst manufacturers make it clear that individual infants have different requirements, it is not suggested on their packaging that formula-fed infants are fed on demand.

Whilst powder formula can be made up to the exact volume required, ready-to-feed (RTF) infant formula is packaged in specific volumes of either 200ml or 250ml, but can be purchased in litre containers in some cases. Whilst RTF formulas may be more convenient, they are also more expensive than using powder formula. Table 17 compares the weekly costs of using powdered milk and RTF formula. Generally the cost of using RTF formula is more than twice the cost of using powdered milk.

There is no information available on how parents use RTF cartons in terms of the volumes of milk they use – for example, whether left-over milk is stored and used at the next feed, or discarded, or whether all the milk in a carton is offered for convenience. There may be implications for the amount of energy an infant is given if whole cartons are used rather than the amounts specified in the guidance. Alternatively, parents or carers may give insufficient feed as it is more expensive, or potentially dilute the milk. Further research is required on how RTF milks are used.

TABLE 15

Guidelines for infant feeding by age

Guidance issued by:		RCN			Aptamil			Cow & Gate			SMA		
Age range	Guideline age category	Feeds/ day	ml/feed	ml/day	Feeds/ day	ml/feed	ml/day	Feeds/ day	ml/feed	ml/day	Feeds/ day	ml/feed	ml/day
Up to 2 weeks	0-2 weeks	7-8	60-70	420-560	6	85	510	6	90	540	6	100	600
2 weeks - 2 months	2-6 weeks	6-7	75-105	450-735	5	115	575	6	120	720	6	130	780
	2 months				5	150	750	5	180	900	5	170	850
2-3 months	2-3 months	5-6	105-180	525-1080	5	170	850	5	180	900	5	170	850
3-4 months	3-6 months	5	180-210	900-1050									
	3-4 months				5	170	850						
	4 months							5	210	1050	5	230	1150
4-5 months	3-6 months	5	180-210	900-1050									
	4-5 months				5	200	1000	5	210	1050	5	230	1150
5-6 months	3-6 months	5	180-210	900-1050									
	5-6 months				5	200	1000	4	240	960	4	250	1000
6 months	6 months	4	210-240	840-960	5	200	1000	4	240	960	4	250	1000
7 months+	7-12 months				3	200	600	3	210	630	3	230	690

TABLE 16

Guidelines for infant feeding by weight

Guidance issued by:	RCN			Aptamil			Cow & Gate			SMA		
Age range	Weight kg	ml/day	ml/kg/day	Weight kg	ml/day	ml/kg/ day	Weight kg	ml/day	ml/kg/ day	Weight kg	ml/day	ml/kg/day
Up to 2 weeks	-	420-560	150	3.5	510	145	3.5	540	154	3.5	600	171
2-4 weeks	-	450-735	150	3.9	575	147	4.0	720	180	4.2	780	186
1-2 months	-	450-735	150	4.7	700	149	5.0	900	180	4.7	850	181
2-3 months	-	525-1080	150	5.4	850	157	5.0	900	180	4.7	850	181
3-4 months	-	900-1050	-	6.2	850	137	6.5	1050	162	6.5	1150	177
4-5 months	-	900-1050	-	6.9	1000	145	6.5	1050	162	6.5	1150	177
6 months	-	840-960	-	7.6	1000	132	7.5	960	128	7.5	1000	133

TABLE 17

Comparison of costs of formula feeding per week for RTF and powder, using manufacturers' own feeding guidelines

Formula		Aptamil 1			Cow & Gate 1			SMA First Infant Milk		
RTF: Volume per carton/cost:*		200ml/£0.66			200ml/£0.56			250ml/£0.56		
RTF: Cost per 100ml:		33p			28p			28p		
Powder: 900g* (6000ml made-up feed):		£8.99			£7.59			£7.69		
Powder: Cost per 100ml:**		14.9p			12.7p			12.8p		
Age range	Guideline age category	ml/week	Cost/week (£) RTF	Cost/week (£) Powder	ml/week	Cost/week (£) RTF	Cost/week (£) Powder	ml/week	Cost/week (£) RTF	Cost/week (£) Powder
Up to 2 weeks	0-2 weeks	3570	£11.78	£5.32	3780	£10.58	£4.80	4200	£11.76	£5.38
2-4 weeks	2-4 weeks	4025	£13.28	£6.00				5460	£15.29	£6.99
1-2 months	4-8 weeks	4900	£16.17	£7.30						
	2 weeks - 2 months				5040	£14.11	£6.40			
	(2-4) weeks - 2 months							5460	£15.29	£6.99
2-3 months	8-12 weeks	5950	£19.63	£8.87						
	2-4 months				6300	£17.64	£8.00	5950	£16.66	£7.62
3-4 months	3-4 months	5950	£19.63	£8.87						
4-5 months	4-5 months	7000	£23.10	£10.43						
5-6 months	5-6 months	7000	£23.10	£10.43						
	4-6 months				7350	£20.58	£9.33	8050	£22.54	£10.30
6 months	6 months				6720	£18.81	£8.53	7000	£19.60	£8.96
7 months+	7-12 months	4200	£13.86	£6.26	4410	£12.35	£5.60	4830	£13.52	£6.18

RTF = Ready-to-feed

* Prices were taken from www.boots.com in January 2011.

** The cost per 100ml for powder formula is based on manufacturers' information that 900g cartons of powder formula make up to approximately 6 litres (6000ml) of feed. In practice we found that 900g powder made up between 6625ml and 7520ml of feed, depending on the brand used, so the costs of powdered formula may be cheaper than stated.

6 Monitoring the composition and safety of infant milks

There are a number of pieces of EC legislation that aim to ensure that foodstuffs are safe for the consumer and free from microbiological contamination or hazardous substances. EC Regulation 2073/2005 on the microbiological criteria for foodstuffs supports EC food hygiene rules that have applied to all food businesses since January 2006. These regulations also apply to infant formula manufacture. Annex I of the regulations sets down detailed sampling plans for each of the microbiological criteria included. Annex II sets down specific requirements for shelf-life studies. The UK Food Standards Agency (FSA) stresses that the regulation is flexible in its approach, in that sampling and testing plans should be determined on the basis of risk (eg. size and type of business). Minimum requirements for microbiological testing are not specified and food business operators are not required to wait for test results before placing food on the market. Where microbiological testing does occur, food businesses may use their food safety management processes to establish appropriate sampling regimes.

The EC Regulation also stipulates that the safety of a product or batch of foodstuffs should be assessed throughout its shelf-life and process hygiene criteria should also show that the production processes are working properly throughout every stage of manufacturing and handling. Failure to comply with food safety criteria obliges the manufacturer to withdraw the product from the market. Failure to comply with process hygiene criteria should lead to a full review of current food safety management procedures. If *Enterobacteriaceae* are found in infant formula, further testing is required.

In the UK, enforcement of the regulations is the responsibility of either local authorities or the Port Health Authorities. Food business operators are required to provide evidence that the necessary food safety management procedures are in place to ensure that all criteria are met. Assessments by enforcement officers do not necessarily involve testing, but may do so where particular problems have been identified, or for inclusion in surveys (Food Standards Agency, 2008).

Copies of EC Regulation 2073/2005 can be found at http://eur-lex.europa.eu/en/index.htm. The FSA's *General Guidance for Food Business Operators on EC Regulation No. 2073/2005* can be found at http://www.food.gov.uk/multimedia/pdfs/ecregguidmicrobiolcriteria.pdf. FSA *Guidance on the Requirements of Food Hygiene Legislation* is available at http://www.food.gov.uk/multimedia/pdfs/fsaguidefoodhygleg.pdf

6.1 European safety reviews of infant milk manufacturers

The European Commission Health and Consumer Protection Directorate General provides reports of missions carried out in member states relating to the manufacture of different food commodities (see http://ec.europa.eu/dgs/health_consumer/index_en.htm). A number of reports have been made relating to the official controls over the production and placing on the market of infant formula and follow-on formula in member states which produce milks for the UK market. In 2007 it carried out a review of milk production in Ireland (EU Commission Health and Consumer Directorate General, 2007a), where there were five manufacturers of infant formula producing 15% of the world's total production, making Ireland the largest producer at that time and a significant exporter to the developing world. The review of how these products were monitored made the following observations:

- Only *two* samples of infant formula had been analysed for mineral content in 2006.
- Only *six* samples of milk had been monitored for pesticide residues in the last national monitoring review in 2004.
- There was a low level of compliance reported as regards labelling requirements, with only 4 out of 19 infant formulas and no follow-on formula complying with relevant labelling regulations.
- Two of the dairy science laboratories used for testing samples were not accredited.
- Methods for microbiological analyses of both infant formula and follow-on formula were not recognised by the official agency and did not use validated methods, and no official testing was carried out to verify manufacturers' results.
- Despite local authority audits of manufacturers being carried out since 2001, no local authority had visited any of the manufacturers to check controls on safety for infant formula and follow-on formula.
- In a few cases, general hygiene requirements were not respected.

Similar studies were carried out in France (EU Commission Health and Consumer Directorate General, 2007b) and Poland in 2007 (EU Commission Health and Consumer Directorate General, 2007c), and in the UK in 2008 (EU Commission Health and Consumer Directorate General, 2008), and there appears to be an overall lack of use of approved safety procedures and regulations in some areas. The conclusion from the 2008 UK visit was:

"The official controls over manufacturing and placing on the market of infant formulae, follow on formulae and baby foods in the United Kingdom largely ensures that the relevant legislative requirements are complied with. ***Some deficiencies*** *were noted with regard to the organisation, coordination and audits of official controls and* ***some shortcomings*** *were noted with regard to sampling and analysis of pesticides, contaminants and for microbiological contamination."* (Our bold) (EU Commission Health and Consumer Directorate General, 2008)

Many people would be surprised to hear that there are any shortcomings at all in safety monitoring of infant milk products, particularly in light of the high-profile adulteration of infant milks in China in 2008 (see section 6.2). Whilst it is more likely that infants in poor countries will be at risk from contaminated milk products, it appears that there is insufficient independent and objective monitoring of manufacturing procedures even in the rich countries of Europe. This is particularly surprising as there is an assumption among parents that infant milk is a highly regulated product.

6.2 Lapses in production and labelling of infant milks

Infant milk production can be affected by human error in the same way as the manufacture of any other food product. Human error can lead to a number of safety lapses in food production, and there have been a number of cases of infant milk contamination worldwide, some of which are given here to illustrate the problems that can arise.

Product contamination with foreign objects, including broken glass and fragments of metal, have required product recalls. In 2006, both Nestlé and Mead Johnson recalled infant formula because of contamination with metal fragments. If ingested, these particles present a serious risk to a baby's respiratory system and throat. In September 2010, Ross Abbott Nutrition recalled certain Similac brand infant formulas in the US, Puerto Rico, Guam and some countries in the Caribbean following an internal quality review that detected the possibility of the presence of a small common beetle in the product.

Contamination with bacteria can also occur. In 2001, 400,000 tins of SMA Gold and White were recalled after a strain of the bacteria which causes botulism was traced to one of them after a 5 month old child fell ill in the UK.

Specific ingredients can also be added to excess, or left out. Carnation Follow-up Formula was recalled in 2001 as a result of excess magnesium (which can give rise to low blood pressure and irregular heartbeat). In 2003 a soy protein based formula produced specifically for the Israeli kosher market and lacking vitamin B_1 entered the marketplace, with infants suffering central nervous system damage; several suffered irreparable damage and two died. In addition, 20 children exposed to the product in infancy showed abnormalities in language and mental development at around 3 years of age (Fattal-Valevski et al, 2009). Ross Products in the US in 2006 recalled two products which were deficient in vitamin C (deficiency would result if consumed for 2-4 weeks), and in 2007 recalled products deficient in iron (anaemia would result if consumed for a month).

Products can be unfit for purpose because of manufacturing problems. For example, in 2008 SMA Gold RTF liquid was recalled in the UK following curdling of the product.

The 2008 Chinese infant milk scandal

Adulterated infant milk in the People's Republic of China in 2008 led to a reported 300,000 babies suffering kidney stones and kidney damage and six deaths, although the true numbers of infants affected are likely to be higher as the products had been available for many months before the scandal was reported. The formula milk was adulterated with melamine which was added to milk to make it appear to have a higher protein content. In a separate incident four years earlier in China, watered-down milk had resulted in 13 infant deaths from malnutrition. Chinese authorities were still reporting some seizures of melamine-contaminated dairy product in some provinces in summer 2010 and traces have been found in products exported from China across the globe.

In 2010 melamine was reported in infant formula exported to Africa, sampled in Dar-es-Salaam, the centre of international trade in East Africa. Despite bans on exports from China to East Africa after the melamine scandal, 6% of all samples tested and 11% of international brand named products revealed melamine concentrations of up to 5.5mg/kg of milk powder: twice the tolerable daily intakes suggested (Schoder, 2010).

The need for independent, rigorous inspection and regulation of infant milks remains essential in all countries to ensure that vulnerable infants are protected from both deliberate and accidental contamination, and that these milks do not find their way into other markets where testing may not be routinely carried out.

Products wrongly labelled or with misprinted labels with ingredients not listed could lead to infant allergic reactions. In 2001 Mead Johnson's Nutramigen products labelled with incorrect preparation information were widely distributed in the Dominican Republic, Guam, Puerto Rico and the US.

Whilst errors are fortunately rare, and companies act swiftly to recall products that are found to be contaminated or cause risk, the need for constant testing of products by independent bodies would seem essential as the consequences of irregularities can be life-threatening to infants.

6.3 Role of the UK Food Standards Agency

The aim of the Food Standards Agency (FSA) is to protect the health of the public and the interests of consumers in relation to food. The Food Standards Act grants the FSA the power to influence and oversee the enforcement of Food Law, which is the responsibility of local authorities. The FSA receives notifications of new or reformulated products via the compulsory forwarding of a model of the label, and they then inform the local authorities that the product has been notified. Acceptance of a notification does not imply FSA approval; it is the responsibility of the manufacturer/importer to ensure that food products comply with the relevant legislation. The FSA passes on notifications to the relevant local authorities to help them with their enforcement responsibilities.

The only evidence of analysis of infant formula carried out by the FSA that we could find was specific to imported products, which represent only a very tiny proportion of the infant formula market. The analysis was carried out as part of the FSA Imported Food Sampling and Surveillance Grants programme. The 2007/2008 sampling focussed on foods from Asia and baby/infant foods and formula. Baby/infant foods and formula were included in response to an incident of *Enterobacter sakazakii* (now known as *Cronobacter sakazakii)* contamination of Ugandan formula milk, reported in May 2007. Of the 4,156 foods sampled, only 66 were baby/infant foods, and of these only 20 were subjected to a chemical analysis, which may or may not have included an analysis of nutritional composition. No indication is given of what proportion of the samples were infant milks, but only 1 of the 20 samples was found to be adverse due to labelling irregularities. The full report can be found at http://www.food.gov.uk/multimedia/pdfs/impsamp200708.pdf

6.4 Role of other regulatory bodies

In the UK, local authorities are responsible for food safety at a local level through trading standards officers and environmental health teams, who work with public analysts to ensure food is safe and not sold fraudulently outside current legal frameworks. Local Government Regulation – formerly LACORS (Local Authorities Co-ordinators of Regulatory Services) – is the local government central body which supports local authorities to ensure food is safe and appropriate. Often milk products will be investigated only if a complaint has been made directly that a product may have caused illness, or may be being sold inappropriately or be wrongly labelled, for example. Reduced resources for public analysts and local authority inspectorates makes rigorous local checking of food commodities difficult. The Home Authority Principle means that those officers who work in areas where the head offices of infant milk companies are based take responsibility for all complaints against those products and therefore develop specific expertise in managing complaints.

Port Health Authorities may also check goods brought into the UK from outside the European Commission (EC) to check that labels and specific ingredients are in line with EC law. Port Health Authorities work with the FSA to ensure that products entering the UK are safe, but

they do not physically check all imports and the responsibility for food safety remains with the food producer. It is also possible to find on sale in the UK infant milk products that do not have any information in English on the label and that have entered without appropriate licences and checks. These should be referred to local trading standards officers.

The European Food Safety Authority (EFSA) is the EC independent scientific body responsible for assessing food safety and health claims made about food products for sale in the EC. Information about EFSA can be found at http://www.efsa.europa.eu

6.5 Bacterial contamination of infant milks

Powdered infant milks are not sterile and they may contain harmful bacteria. However, if milks are made up appropriately for infants, they should be safe (see section 6.5.1). *Salmonella* and *Enterobacter sakazakii* (now known as *Cronobacter sakazakii)* are the organisms of greatest concern in infant formula (European Food Safety Authority, 2004). Powdered infant formula milks contaminated with *C. sakazakii* or *Salmonellae* have been the cause of infection in infants. *C. sakazakii* is regarded as an emerging opportunistic human pathogen. It can be found ubiquitously in the environment, in the human and animal gut, and in foods. The widespread distribution of the bacterium suggests that in healthy infants, consuming small numbers of the bacteria in powdered infant formula milks does not lead to illness. However, younger infants are more susceptible to infection by *C. sakazakii* and *Salmonella* than older infants, and the neonates at greatest risk are pre-term or low-birthweight infants and those who are immunocompromised (European Food Safety Authority, 2004). Whilst the occurrence of infections with *C. sakazakii* is rare, the prognosis for those infected is poor, with mortality rates in infants of between 40% and 80% (Willis and Robinson, 1988). Infection can cause meningitis, necrotising enterocolitis and bacteraemia (Nazarowec-White and Farber, 1997). There are nearly 2,000 strains of the *Salmonella* bacteria that can cause illness in humans, and symptoms include diarrhoea, fever and vomiting, and infection can cause serious illness in infants. In 2008 in Spain, 31 cases of *Salmonella* infection in infants were found to be the result of infant formula contamination, and 10 of these infants needed hospitalisation (Rodríguez-Urrego et al, 2010).

Salmonella and *C. sakazakii* do not survive the pasteurisation process, but recontamination may occur during handling or from production methods where ingredients are mixed and added at different stages (see section 3.11) (Mullane et al, 2006; EFSA, 2004). Due to its ubiquitous nature, *C. sakazakii* seems to be more difficult to control in the processing environment. *Salmonella* and *C. sakazakii* can grow in the reconstituted product if stored above 5°C and can multiply rapidly at room temperature. It is therefore essential that good hygiene practices are observed during preparation, storage and feeding in order to avoid recontamination and/or multiplication in the reconstituted product (EFSA, 2004). The key recommendations from all international bodies to reduce risk to infants from bacterial infection has been to encourage the reconstitution of infant formula with water at no less than 70˚C (WHO, 2007). It has been reported that there has been considerable resistance from the infant formula industry and some segments of the medical community to this recommendation (Hormann, 2010). It is apparently argued that this temperature might destroy some nutrients present in the milk (for example, thaimin, folate and vitamin C), may carry a risk of scalding the infant if the milk is not allowed to cool sufficiently, and that powder may clump when mixed with hotter water. Hormann suggests that these arguments are used to suggest both that the risks of bacterial contaimination are small and that it is too difficult for parents and carers to make up milk safely, neither of which is true. The only nutrient significantly affected by the water temperature will be vitamin C, and the content of this vitamin is unlikely to be reduced below recommended levels during the reconstitution process (WHO, 2007).

6.5.1 How to make up infant milk safely

In 2005, the Food Standards Agency (FSA) issued guidelines on the safe preparation and storage of powdered infant formula milks and these were updated and re-issued in 2011 (FSA, 2005; NHS, 2011). Due to the ubiquitous nature of many pathogenic micro-organisms, the guidelines include recommendations for cleaning and sterilising all feeding equipment. The guidelines for making up powdered infant formula milks recommend leaving boiled water to cool for no more than 30 minutes. This step should ensure that the water used to reconstitute the feed is at a temperature above 70°C, which will kill most of the pathogenic micro-organisms present in powdered formula. Despite this recommendation, some infant formula manufacturers recommend lower temperatures, or do not make it clear that water should be left to cool for no more than 30 minutes.

Even when formula is reconstituted with water above 70°C, it may still contain bacteria which can continue to multiply during storage. Bacteria multiply most rapidly at temperatures between 7°C and 65°C. At 5°C, multiplication will continue but at a much reduced rate. The recommendations in the NHS guidelines are designed to reduce the holding time between reconstituting and using feeds in order to minimise the amount of time during which multiplication can occur. The guidelines state that:

- Individual feeds should be made up immediately prior to use rather than being made up in batches and stored in the refrigerator.
- Any prepared feed not used up within two hours should be discarded.
- All left-over feed should be discarded.

If followed, the guidelines can reduce the risk of infection from micro-organisms in powdered infant formula milks.

Data from an FSA-funded study at Nottingham Trent University (Food Standards Agency, 2009b) found that it is not feasible for those who make up formula milks to easily determine the temperature of reconstitution water in order to meet the above 70°C guideline. The advice of reconstituting milk using water which had been boiled and left for 30 minutes resulted in temperatures ranging from 46°C to 74°C depending on the volume of water boiled. This results in different degrees of lethality to bacteria. Smaller volumes of water boiled and cooled for each feed made up might help to ensure that the temperature is high enough to inhibit bacterial growth and it is important that clear, consistent advice is given to parents and carers to ensure that the water is hot enough to offer protection from bacterial infection.

The Infant Feeding Survey 2005 found that many parents and carers did not follow guidelines available at that time for the reconstitution of formula milk (Bolling et al, 2007). Just under half of all mothers who had prepared powdered infant formula in the seven days prior to being surveyed had not followed the key recommendations, either by not always using boiled water that had cooled for less than 30 minutes, or not always adding the water to the bottle before the powder. About a third of mothers did not follow the recommendations for preparing formula when away from the home, either by not keeping pre-prepared formula chilled, or by using cold or cooled water when making up feeds (Bolling et al, 2007).

The NHS guidelines on safe preparation, storage and handling of powdered infant formula are available at www.dh.gov.uk

The NCT also has a factsheet for parents – *Using Infant Formula: Your Questions Answered* – available at www.nct.org.uk

6.5.2 Should powdered infant milks be labelled as non-sterile?

There is currently some debate over the labelling of powdered infant milks as non-sterile. The World Health Assembly (2005) recommended that parents and carers should be informed, through explicit warnings on packaging, that powdered infant milks may contain pathogenic micro-organisms. Additionally, recent research funded by the FSA concluded that in the UK there is little overall awareness amongst consumers that powdered infant milk is a non-sterile food. Whilst the FSA's guidelines for parents and health professionals on the safe preparation, storage and handling of infant formula clearly state that powdered infant milks are not a sterile product, current regulations do not compel manufacturers to include this information on their packaging. It is important that parents and carers are made aware of the non-sterile status of powdered infant milks, as clearer warnings can help to reinforce the importance of following carefully the instructions for their preparation and use (Food Standards Agency, 2007). It is also important, however, not to alarm parents and to ensure that instructions for safely making up powdered infant milks are communicated consistently and simply in all materials for parents, in a way that is accessible to all.

6.6 Pesticide residues in infant formula and follow-on formula

European Commission Directive 2006/141/EC on Infant Formulae and Follow-on Formulae stipulates maximum levels for pesticide residues in infant formula and follow-on formula. The Directive states that infant formula and follow-on formula shall not contain residues of individual pesticides at levels exceeding 0.01mg/kg of the product as proposed ready for consumption or as reconstituted according to the manufacturer's instructions. In addition, the Directive specifies a list of the most toxic pesticides whose use is prohibited in agricultural products intended for use in the production of infant formula and follow-on formula. In some cases pesticides are considered not to have been used if the levels of residue present do not exceed 0.003mg/kg.

Pesticide residues in the UK food supply are regularly monitored by the Pesticide Residues Committee (PRC). The PRC provides independent advice to ministers, the chief executive of the Pesticides Safety Directorate and the FSA on matters relating to the surveillance programme for pesticide residues in food. The EU proposed a number of surveys to be carried out by each member state each year. However, the UK may extend the range of products and pesticides tested in accordance with those known to be used in the UK. The most recent UK survey which tested for pesticide residues in infant formula was the 2005 Quarter 1 survey. The products analysed included only standard infant formula and follow-on formula available from retail outlets. Samples were collected from all the main brands available in the UK (SMA, Heinz, Hipp, Cow & Gate and Aptamil) and included both ready-to-feed and powdered formula. Of the 120 samples analysed, none contained pesticide residues. The report is available at:
http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PRC/2005_PRC_Annual_Report.pdf

6.7 General contaminants in foodstuffs

European Commission Regulation 466/2001 with its subsequent amendments is the principal legislation setting maximum levels for certain contaminants in foodstuffs. The contaminants covered by the legislation include:

- heavy metals (cadmium, lead and mercury)
- mycotoxins (aflatoxins, fusarium toxins, ochratoxin A, patulin)
- nitrates and nitrites in vegetables

- inorganic tin
- dioxins
- 3-monochloropropane-1,2-diol (3-MCPD)
- polycyclic aromatic hydrocarbons (PAH).

The maximum permissible levels set for each contaminant are specific to a subset of foods or food groups. Levels specific to infant formula and follow-on formula have been set for lead, mycotoxins, nitrates, inorganic tin and PAH. The most recent UK legislation which gives effect to EU legislation is the Contaminants in Foods (England) Regulations 2007, which came into effect in March 2007.

6.8 Aluminium in infant formula

There has been a long and significant history documenting the contamination of infant milks with aluminium and the consequent health effects of this, with infant milks typically having 10-40 times more aluminium in them than breast milk (Burrell and Exley, 2010). There have been warnings made to manufacturers over several decades in relation to aluminium toxicity and the vulnerability of developing infants to this, and therefore it could be assumed that levels in current infant milks would be low. However, recent analyses in ready-to-feed formula milks were found to vary from 176 to 700µg/litre, and in powdered milks from 2.4 to 4.3µ/litre, and there has been no change in content despite calls for a reduction. Soy protein based formula and pre-term infant formula had the highest amounts and some would result in ingestion of up to 600µg/day (Burrell and Exley, 2010). These products are likely to be contaminated with aluminium from processing equipment and packaging, and a lack of progress in reducing this contaminant suggests that manufacturers do not consider it to be a health issue, despite evidence of both immediate and delayed toxicity in infants, especially pre-term infants.

Another study of milks in the UK in 2001 (Ikem et al, 2002) also reported that in some cases the amounts of aluminium, barium and thallium in infant milks exceeded stipulated water contamination levels, and again that soy protein based formula had higher aluminium contents than other formula, as did some milks made with partially hydrolysed protein.

6.9 UK food surveys

The FSA regularly undertakes surveys of a wide range of contaminants in foods. The main results and an interpretation of the results are published as food summary information sheets (FSIS) on the FSA website. Surveys where specific permitted levels of contaminants have been defined for infant formula, or where infant formula have been included as a category in the analysis, are listed in Table 18. The reports listed in Table 18 are the most recent reports for the type of contaminant.

Reports from surveys published during or after 2000 are available at:
http://www.food.gov.uk/science/surveillance/fsis2000/

Archived reports from the Ministry of Agriculture, Fisheries and Food going back to 1993 are available at the archive site:
http://archive.food.gov.uk/maff/archive/food/infsheet/index.htm

TABLE 18

Surveys of contaminants in foods undertaken in the UK

Report title	FSIS/MAFF No.	Year of publication
Survey of Metals in Weaning Foods and Formula for Infants	FSIS 17/06	2006
Polycyclic Aromatic Hydrocarbons in Baby Foods and Infant Formula	FSIS 09/06	2006
Dioxins and Dioxin-like PCBs in Infant Formula	FSIS 49/04	2004
Survey of Bisphenols in Canned Foods	FSIS 13/01	2001
Phthalates in Infant Formula – Follow-up Survey	MAFF 168	1998

6.10 How is the nutritional composition of infant milk monitored?

As part of this review we were interested to find out how the nutritional composition of infant milks was monitored in the UK, and potentially elsewhere. The majority of infant milks are not manufactured in the UK, with many milks manufactured in Ireland, France, Germany and Italy, for example. The milk and other ingredients used for these infant milks potentially come from a variety of sources, and from a number of countries of origin. New Zealand, Australia, South America, Eastern Europe and Asia are exporters of whole milk powders that may be used in infant formula manufacture. We asked the manufacturers of all the products available in the UK to provide us with information about where the milks are made, and how the nutritional composition is tested. No company chose to provide all the information we requested and many gave us no information at all despite our making several requests.

A survey of the nutrient levels in infant milks by a number of global manufacturers was published in 2009 to provide information on whether infant milks were meeting or exceeding proposed Codex Alimentarius recommendations for minimum values or guidance upper levels (GUL) for nutrients. A large quantity of milk was analysed, and formula met the minimum levels for all nutrients, but levels in some milks were found to exceed the proposed GUL for vitamins A and K, thiamin, riboflavin, niacin, vitamin B_6, folic acid, vitamin B_{12}, vitamin C, iron, copper, manganese, potassium and iodine (MacLean et al, 2009). Data for nutrients showed considerable variability and this reflects the difficulty of manufacturing a product which has to contain suitable amounts of nutrients from time of manufacture to end of shelf-life.

There have been few academic publications which look at the nutritional composition of infant formula relevant to the UK market. A study of mineral elements in infant milks in the UK (Ikem et al, 2002) concluded that the nutritional content of some formula brands were lower than recommended in zinc, magnesium and iron. Ljung et al (2011) analysed formula milks in Poland and reported that concentrations of manganese varied from 10 to several hundred times the amount a breastfed infant would receive, and that this could potentially have adverse health consequences. Very high iron and molybdenum intakes from infant formula were also highlighted as a concern in this study. In contrast, analysis of the selenium content of formula milks available in Europe showed that values are generally lower than found in breast milk and that soy protein based formula had the lowest content (Van Dael and Barclay, 2006).

Analysis of formula milks in Spain (Chávez-Servín et al, 2008) showed that milks had lower amounts of iron (65% of the amount reported on the label) and selenium (73%-80% of the amount on the label) than declared, but higher amounts of vitamins A, E and C (included to allow for losses of these vitamins on storage). Given the complex nature of degradation of some nutrients on storage, the interaction between components, and the availability of a significant number of brands and types of milk, it is surprising that there has been so little consideration of whether the nutritional composition of milks at point of sale is adequate. Levels of the fat soluble vitamins A and D, for example, are likely to be vulnerable to degradation, with limits on how much can be added in milks at point of manufacture, and had funds allowed we would have been interested in analysing formula milks for these vitamins in particular.

Food law enforcement in the UK is the responsibility of local authorities and it is the responsibility of manufacturers and importers to ensure that products comply with necessary legislation. The Home Authority Principle means that a local authority acting as a home authority or originating authority for a food (eg. because a company head office is in that authority) will place special emphasis on the legality of goods originating within its area. Whilst this reduces the duplication and cost of investigating food safety or composition, it is burdensome on those home authorities that are responsible for complex foods such as infant milk and it may be impossible for them to fund the checks that might reasonably be needed. For a food such as infant milk which is the sole source of nutrition for infants, it would appear reasonable that there was central responsibility for checking safety and composition. There does not, however, appear to be any independent system for monitoring the nutritional composition of infant formula in the UK. Those manufacturers who responded to us assured us that they made regular analytical checks of their products, but these data do not appear to be made available outside the manufacturing organisations and were not made available to us.

In theory, trading standards officers can take samples of any food product available for sale in the UK and send it for independent analysis, often with a public analyst. However, we could not find any evidence that analysis of any infant formula had been done by trading standards officers in the UK at any time before we started working on this review. Public analysts and trading standards officers whom we spoke to said that it would be too expensive and too complex to analyse infant formula and they were more likely to investigate other forms of contamination. After discussions about this with a public analyst in England, however, some analysis of macronutrient composition (carbohydrate and fats) in infant milks currently available was undertaken in May 2009 and made available to the Caroline Walker Trust (CWT). Whilst most of the analysed values for fat and sugar were similar to the declared values, there were some differences observed between declared and analysed values of linoleic acid (omega-6 fats), linolenic acid (omega-3 fats) and arachidonic acid (and LCP) as shown in Table 19. This is just one random set of analysis of a small number of products, so it cannot be taken as indicative of overall content difficulties, but it does illustrate variations in declared and analysed contents. A number of milks analysed in this survey had only 50-60% of the declared content of fatty acids present.

LCPs are highly susceptible to oxidation, and composition of infant formula must be carefully controlled to reduce degradation. One study has shown that there are significant deficits in linoleic acid content after storage of infant formula (Chávez-Servín et al, 2008).

TABLE 19

Fatty acid composition of infant milks: analysed and declared content

Milk	Linoleic acid (n-6) *mg*			Linolenic acid (n-3) *mg*			Arachidonic acid *mg*		
	Analysed	Declared	% of declared	Analysed	Declared	% of declared	Analysed	Declared	% of declared
Aptamil first milk	470	490	**96**	80	91	**88**	12	12	**100**
Aptamil 3 Follow-on Milk	350	441	**79**	45	82	**55**	0	0	-
Aptamil Growing Up Milk	270	426	**63**	43	78	**55**	0	0	-
Cow & Gate 1	490	490	**100**	82	91	**90**	8	7	**114**
Cow & Gate 2 *Now renamed Cow & Gate Infant Milk for Hungrier Babies 2*	380	450	**84**	50	83	**60**	0	0	-
Cow & Gate 3 Follow-on Milk	250	441	**57**	41	82	**50**	0	0	-
Cow & Gate Infasoy	400	521	**77**	70	95	**74**	0	0	-
Hipp Organic First Infant Milk	570	600	**95**	70	90	**78**	0	0	-
Hipp Organic Follow-on Milk	500	600	**83**	61	80	**76**	0	0	-
Hipp Organic Growing Up Milk	600	600	**100**	64	100	**64**	0	0	-
Nurture Newborn *Discontinued*	440	500	**88**	46	57	**81**	16	15	**107**
Nurture 2 *Was renamed Nurture Hungry Baby, now discontinued*	430	500	**86**	51	55	**93**	6	15	**40**
SMA White *Now renamed SMA Extra Hungry*	600	586	**102**	44	54	**82**	14	12	**117**
SMA Progress *Now renamed SMA Toddler Milk*	360	532	**68**	26	50	**52**	0	0	-
SMA Wysoy	670	608	**110**	51	44	**116**	0	0	-

Note This information was provided to us by a public analyst in 2009.

Trading standards officers are also able to review claims made on packaging and whether labels meet current food labelling regulations. The public analyst who provided us with data on the composition of milk also found a Polish milk for sale which failed to give any information in English on the package, and which would contravene the 1996 Food Labelling Regulations.

We recommend that the relevant health departments or the Food Standards Agency should commission annual random analytical checks on all infant milks available on the UK market to ensure that they do in fact contain the level of nutrients that are claimed on the label. Alternatively each company should be asked to provide the FSA with quarterly data on composition of their products at manufacture and at maximum shelf-life, including details of analytical techniques and numbers of samples analysed. These data should be open to random review and checking.

6.11 Recommendations for assessing infant milks nutritionally

In 1996, the Department of Health produced *Guidelines on the Nutritional Assessment of Infant Formulas* (Department of Health, 1996). This report made a series of recommendations and described the principles that should be followed when nutritionally assessing infant formulas. The recommendations are outlined below.

- All modifications to infant formulas should be assessed nutritionally.
- Studies should be based on a systematic review of relevant existing information. All such reviews should be made publicly available.
- At the commencement of a nutritional study there should be a clear hypothesis of functional or clinical benefit with defined selection criteria and outcome measures.
- Infant formulas modified for reasons other than to provide a functional or clinical benefit should at the minimum be subjected to studies of acceptability.
- All studies should be interpreted on the basis of outcomes of healthy infants exclusively breastfed for 4-6 months rather than the composition of human milk. In the absence of adequate data, consideration should be given to including a breastfed reference group in studies.
- Reference datasets for common outcome measures for breastfed infants should be developed.

In addition, the report made recommendations on guidelines for study design, conduct of studies and the handling of data and presentation of findings. These recommendations are of interest in light of the evidence currently being provided by manufacturers to support compositional changes in infant milk and to make claims about their benefits to infants. Few of these recommendations have been put into place by those producing infant milks or those providing evidence to support claims made about ingredients used in infant milks.

6.12 Making claims about infant milks

The composition of most infant formulas has been increasingly altered to create a product which attempts to be as similar to breast milk as possible (although it is important to reiterate that many factors in breast milk cannot be recreated). Many infant milks use comments on their packaging such as "*inspired by breast milk*" or "*as close as possible to breast milk*" and suggest that there is 'science' behind their products which makes them very close to breast milk in composition. It has also been suggested that the promise of economic benefit from innovations, exploitation of protected intellectual property and potential marketing advantages over competitors may be more powerful drivers for new infant milk product formulations than medical or scientific considerations (Koletzko and Shamir, 2006).

We reviewed evidence being used on websites and in marketing literature, by those selling infant milks in the UK, to assess the level of evidence being used to support claims. However, this is an area of work where there is considerable change in documentation and, rather than attempt to provide a comprehensive review here, we will give some examples of some of the areas where claims are made and the literature used to support them, which highlight some of the issues that need to be addressed (see section 6.12.2).

6.12.1 What guidelines should be followed when reviewing evidence on infant milks?

One of the difficulties in reviewing the evidence from scientific studies conducted on infant formula is that the majority of studies are funded by manufacturers, or use products supplied by specific manufacturers. Published guidelines (Aggett et al, 2001; Department of Health, 1996) recommend that appropriate clinical studies of nutritional and safety assessment should be performed particularly for components or combinations of components that have not been included previously in infant formulas and where there are technological as well as compositional modifications to formulas. Any modification to a formula should be based on a systematic review of relevant, existing information. This should be used to develop a clear hypothesis of the expected functional and clinical benefits for the proposed modification. Studies should be designed to test the hypothesis and the results made publicly available. Where products based on existing products are introduced, they should at least be subjected to studies of acceptability and nutritional equivalence to the existing product.

There has been considerable debate about whether collaborative research with infant formula companies should be encouraged, and opinions remain divided. It can be argued that, as there will always be a need for infant formula, it is important that research is undertaken to ensure that the optimum composition of infant milks can be developed, and that formula companies are in a position to offer funding and expertise in this area. However, others argue that, where there is a vested commercial interest in the outcome of research, it can never be viewed as entirely independent and that public health research should only be done with public funding. When research is sponsored, there is typically concern that negative or neutral findings are less likely to be published, and when reviewing research that is connected to a product that ultimately creates profit, academics are understandably more cautious. What is also surprising is the paucity of evidence that exists when considering the scale of the infant formula milk market and it has been suggested that insufficient funds are provided to research scientists within infant milk companies to test compositional changes, particularly when the amount of research funding available is compared with the scale of funds used in marketing, for example. Equally, it could also be argued that insufficient public funds have been made available for high-quality research in this area. It is evident from our review that there needs to be considerable investment by scientific research funders to ensure good-quality, unbiased studies are conducted which test the safety and efficacy of infant milk ingredients.

The process of developing, testing and marketing infant formulas requires a lot of time and money, but it is crucial that evidence provided is correct. Recommendations for the nutritional and safety assessment of infant milk formulas do not appear to have been fully adopted by all manufacturers, particularly in respect of sample size, duration and blinding and where new formulas are based on formulas already on the market. For example, each novel ingredient in the Heinz Nurture range of infant formulas (which have now been discontinued) was previously subjected to clinical trials by other manufacturers, used in a different combination and in different proportions. According to Department of Health and ESPGHAN recommendations, new milk products should be subjected to, at the very least, trials of acceptability and nutritional equivalence and the results made publicly available. We could not find any publicly available evidence of such trials.

Infants who are fed milks that have not been subjected to clinical trials or where clinical trials have been of poor quality, are in effect participating in their own trials, the results of which are not independently or objectively assessed, as any feeding problems are likely to be directed to midwives, health visitors, GPs or even consumer care lines established by manufacturers.

Member States of the EC have requested a centralised authorisation procedure for any new ingredient in infant milk, with EFSA providing advice with regard to the safety and suitability of the ingredient. It has been suggested that this could be considered as part of future legislation on dietetic foods (SCOFCAH, 2010).

6.12.2 Examples of claims made for infant milks and evidence used to support them

Below are some examples of evidence used to support claims for infant milks.

- Heinz Nurture Newborn infant milk (now discontinued) incorporated α-lactalbumin in the whey protein of the milk. The suggested benefits of α-lactalbumin in Nurture Newborn made on the Heinz website (no longer active) included a reduction in the risk of metabolic stress, kidney overload and in babies becoming overweight. Clinical trials on this infant formula did not appear to have been carried out, but the α-lactalbumin content of their formula milk (0.25g/100ml) was similar to that of SMA First Infant Milk (0.22g/100ml) and data may have been extrapolated from other studies despite the different overall combination of ingredients in the new product. This use of data from other milks, with different ingredients, is often observed but is not appropriate.
- Most of the companies that add LCPs to their formula milks appear to have supported randomised clinical trials comparing the effects on pre-term and/or term infants of formula with added LCPs against formula without added LCPs. However, not all clinical trials compare formula-fed infants to infants fed with breast milk, as recommended in the guidelines, and studies often compare two infant formula products to show efficacy.
- In a large clinical trial (Pickering et al, 1998), a group fed with formula supplemented with nucleotides had significantly higher antibody concentrations in response to both Hib and diphtheria immunisation compared with an unsupplemented group, but no difference between formula groups was observed for oral polio virus and tetanus immunisation, whereas breastfed infants had significantly higher antibody response to oral polio virus than either of the formula groups at 6 months of age. The trial was long-term (12 months), but the participating infants will have also received solid foods as well as formula and it is commonly understood that dietary factors play a role in an infant's response to immunisation, making it difficult to quantify the effects of the milk. Studies often do not allow for complementary feeding alongside formula or breast feeding when considering impacts of formula supplementation on infant outcomes.
- Evidence from a study was also used to back up claims for a protective effect of formula with nucleotides on diarrhoeal disease, using data from a study of infants in urban Chile. Whilst this study showed that infants fed a nucleotide-supplemented formula experienced significantly fewer first episodes of diarrhoea than infants fed standard formula, there were no differences between groups in the clinical characteristics of the episodes or in the pattern of enteropathogens isolated (Brunser et al, 1994). Use of data from other geographical areas may not always be generalisable.
- Evidence for the use of Betapol to create softer stools and reduce constipation was taken from a paper by Bongers et al (2007). This small study reported finding no significant differences in defecation frequency or constipation among infants fed Betapol-supplemented formula, but found a small difference in stool softness. There was however no breastfed reference group, the drop-out rates from the study were high (which is frequently observed in infant feeding studies), and the subjects were all recruited with constipation rather than as normal, healthy infants. Using studies from small numbers of infants, recruited from a selective rather than general population and which experience considerable drop-out, are common features of research in this area.

- Evidence for the use of Betapol to improve bone development and bone density was also taken from Kennedy et al (1999). This large study did show increased bone mineral density among infants on formula with Betapol when compared to those given other formula and was similar to that of breastfed babies. A considerable number of mothers, however, reported concern about runny stools among those given the feed with Betapol and this was not reported. Longer-term outcomes and other unsuccessful outcomes are not always reported when data are used to back up a positive health claim.
- A Cow & Gate product leaflet states that Cow & Gate 1 formula includes LCPs and GLA (gamma-linolenic acid) for brain and eye development and quotes the following studies: Birch et al, 1998; Birch et al, 2000; Jorgensen et al, 1996. However, Cow & Gate supplement their standard infant formula with AA and DHA at concentrations which are different to those used in the clinical trials by Birch et al (1998) and Birch et al (2000) (DHA 0.2% in Cow & Gate 1 and 0.35% in trial formula; AA 0.2% in Cow & Gate 1 and 0.72% in trial formula). This extrapolation of data from formula with different concentrations of ingredients is also commonly observed.

This small number of examples highlights the need for debate in the UK about the use of any health claims on infant formula. The European Food Safety Authority (EFSA) is currently reviewing evidence submitted by manufacturers who would like to make health claims about their products, and the majority of claims are being rejected due to poor and inappropriate evidence provision.

7 Conclusion

European Commission regulations governing the basic composition of infant milks are sufficiently flexible to allow manufacturers to develop and produce infant milks which can be marketed for specific purposes. Maximum and minimum ranges are set for macronutrients and micronutrients, whilst other components are optional – for example, prebiotics and LCPs. The regulations also allow manufacturers to add new components, based on components isolated from breast milk. Manufacturers may then suggest that the addition of these components makes infant milks increasingly similar in composition to breast milk. An increasing range of infant formula milks available on the market has increased parental choice, and is credited with increasing the sales of infant milk in the UK (Mintel, 2007). The large, expanding global market is encouraging new product development, and manufacturers are keen to extend their market with new products that extend the time an infant is given manufactured milk products.

Manufacturers have also responded to increasing nervousness among parents and carers about infant feeding problems. Minor feeding and digestive conditions in infants, such as wind and regurgitation, are not abnormal, but many parents appear unsure about what is 'normal' for an infant. This has been demonstrated by a study commissioned by the Caroline Walker Trust (CWT) which looked at parental talk board discussions (eg. internet chat lines) (Mitchell, 2009) where levels of anxiety among some parents and carers appear high, with many seeking a milk that provided a 'solution' to perceived feeding problems. This medicalising of the infant feeding process, alongside the marketing of milks which claim to be ever closer to breast milk, may have a number of implications:

- The impression that infant milks can be manufactured to be ever closer to breast milk undermines breastfeeding.
- The increase in choices of infant formula milks with special ingredients suggests that infants require a range of complicated and technical ingredients for good health. This may lead to parents who formula feed choosing costlier formula that may offer no nutritional advantage, potentially to the detriment of spending on their own diet or that of other family members.
- Faced with a range of products, it appears that parents believe that different (and more expensive) infant milks may offer them a solution that will return their babies' feeding and digestive performance to 'normal', thus medicalising the infant feeding process and potentially increasing anxiety among new parents.
- As many products suggested by the manufacturers to manage minor digestive disorders are freely available without prescription, parents may be tempted to switch formulas before consulting their GP or health visitor. Parents may be unaware of some of the issues surrounding use of certain products – for example, the increased risk of dental caries from products where lactose is replaced by more cariogenic sugars such as glucose polymers or maltodextrins (Grenby and Mistry, 2000).

- Milks designed for toddlers may give the impression that milk remains the most important source of nutrients for children even as toddlers. This may lead to an over-reliance on milk and low intakes of iron and zinc from foods, leaving the child vulnerable to iron deficiency and low zinc status when they move to cows' milk as their main drink.

The data in this report are intended as a starting point summary for work by those agencies who have a specific role in reporting on the composition and safety of infant formula. The recommendations made at the beginning of this report (see page 10) reflect some of the issues that we believe require further attention.

8 Useful addresses

Useful organisations

The organisations listed below provide a range of information and resources on infant feeding.

Association of Breastfeeding Mothers
T: 08444 122 948
E: info@abm.me.uk
www.abm.me.uk

The Baby Café
www.thebabycafe.org

The Baby Feeding Law Group
www.babyfeedinglawgroup.org.uk

Baby Milk Action
T: 01223 464420
E: info@babymilkaction.org
www.babymilkaction.org

Best Beginnings
T: 020 7443 7895
www.bestbeginnings.org.uk

BLISS (The Premature Baby Charity)
T: 020 7378 1122
E: information@bliss.org.uk
www.bliss.org.uk

The Breastfeeding Manifesto
T: 0208 752 2419
E: info@breastfeedingmanifesto.org.uk
www.breastfeedingmanifesto.org.uk

The Breastfeeding Network
T: 0844 412 0995
www.breastfeedingnetwork.org.uk

British Dietetic Association (Paediatric Group)
T: 0121 200 8080
E: info@bda.uk.com
www.bda.uk.com

British Specialist Nutrition Association
(formerly the Infant and Dietetic Foods Association)
T: 0207 836 2460
E: info@bsna.co.uk
www.bsna.co.uk

Community Practitioners' and Health Visitors' Association (CPHVA)
E: infocphva@unitetheunion.com
www.unitetheunion.com/CPHVA

Food Standards Agency (UK headquarters)
T: 020 7276 8829
E: helpline@foodstandards.gsi.gov.uk
www.food.gov.uk

Infant and Toddler Forum
T: 020 8971 0022
www.infantandtoddlerforum.org

The International Baby Food Action Network
www.ibfan.org

La Leche League
T: 0845 456 1855 (General enquiries)
0845 120 2918 (24-hour helpline)
www.laleche.org.uk

Lactation Consultants of Great Britain (LCGB)
E: info@lcgb.org
www.lcgb.org

Midwives Information and Resource Service
T: 0800 581 009
www.midirs.org

The Multiple Births Foundation
T: 0203 313 3519
E: mbf@imperial.nhs.uk
www.multiplebirths.org.uk

National Childbirth Trust
T: 0300 33 00 770
www.nct.org.uk

National Institute for Health and Clinical Excellence (NICE)
T: 0845 003 7780
www.nice.org.uk

NHS Choices
www.nhs.uk

NHS Health Scotland
T: 0131 536 5500
www.healthscotland.com

Public Health Agency (Northern Ireland)
T: 028 9031 1611
www.publichealth.hsci.net

Royal College of Midwives
T: 020 7312 3535
www.rcm.org.uk

Royal College of Nursing
T: 020 7409 3333
www.rcn.org.uk

Royal College of Paediatrics and Child Health
T: 020 7092 6000
www.rcpch.ac.uk

Scientific Advisory Committee on Nutrition (SACN)
www.sacn.gov.uk

UNICEF
www.unicef.org/nutrition/index_breastfeeding.html

UNICEF UK Baby Friendly Initiative
T: 0844 801 2414
E: bfi@unicef.org.uk
www.babyfriendly.org.uk

United Kingdom Association for Milk Banking (UKAMB)
T: 0208 383 3559
E: info@ukamb.org
www.ukamb.org

World Health Organization
www.who.int/health_topics/breastfeeding

Infant formula companies

Abbott Nutrition

Infant milks produced:
- *Abbott Isomil (discontinued)*
- *Similac High Energy*

Abbott Nutrition
Abbott House
Vanwall Business Park
Vanwall Road
Maidenhead
Berkshire SL6 4XE
T: 01628 773 355
www.abbottnutritionuk.com

Aptamil

Infant milks produced:
- *Aptamil 1*
- *Aptamil 3 Follow-on Milk*
- *Aptamil Comfort*
- *Aptamil Growing Up Milk*
- *Aptamil Hungry Milk*
- *Aptamil Pepti*
- *Aptamil Preterm*

Aptamil
Newmarket House
Newmarket Avenue
White Horse Business Park
Trowbridge
Wiltshire BA14 0XQ
T: 08457 623 628
www.aptamil.co.uk
www.milupaaptamil4hcps.co.uk

Babynat

Infant milks produced:

- *Babynat Infant Formula (discontinued)*
- *Babynat Follow-on Milk*

Babynat
Vitagermine SAS
Parc d'Activités du Courneau
Rue du Pré Meunier
Canéjan
CS 60003
33612 CESTAS Cedex
France
T: +33 5 57 96 56 82
E: info@vitagermine.com
www.babynat.co.uk

Cow & Gate

Infant milks produced:

- *Cow & Gate 1*
- *Cow & Gate Infant Milk for Hungrier Babies 2*
- *Cow & Gate 3 Follow-on Milk*
- *Cow & Gate Comfort*
- *Cow & Gate Comfort Follow-on Milk (discontinued)*
- *Cow & Gate Good Night Milk (discontinued)*
- *Cow & Gate Growing Up Milk*
- *Cow & Gate Infasoy*
- *Cow & Gate Pepti-junior*
- *Nutriprem 1*
- *Nutriprem 2*

Cow & Gate
Newmarket House
Newmarket Avenue
White Horse Business Park
Trowbridge
Wiltshire BA14 0XQ
T: 08457 623 623
www.cowandgate.co.uk
www.in-practice.co.uk

Heinz

Infant milks produced:
Note: These products have all been discontinued.

- *Nurture Gentle Infant Milk*
- *Nurture Gentle Follow-on Milk*
- *Nurture Growing Baby Follow-on Milk*
- *Nurture Hungry Baby*
- *Nurture Newborn*
- *Nurture Soya*
- *Nurture Toddler Milk*

Consumer Contact Department
H J Heinz
South Building
Hayes Park
Hayes
Middlesex UB4 8AL
T: 0208 573 7755
0800 212 991
www.heinzbaby.co.uk
www.heinzbaby4hcp.co.uk

Hipp Organic

Infant milks produced:

- *Hipp Oganic Hungry Infant Milk*
- *Hipp Organic First Infant Milk*
- *Hipp Organic Follow-on Milk*
- *Hipp Organic Good Night Milk*
- *Hipp Organic Growing Up Milk*

Hipp Organic
165 Main Street
New Greenham Park
Thatcham
Berkshire RG19 6HN
T: 0845 050 1351
E: inforequest@hipp.co.uk
www.hipp.co.uk

Holle

Infant milks produced:

- *Holle Organic Infant Formula 1*
- *Holle Organic Infant Formula 2*
- *Holle Organic Infant Formula 3*

Holle Babyfood GmbH
Baselstrasse 11
4125 Riehen
Switzerland
T: +41 61 645 96 00
E: babyfood@holle.ch
www.holle.ch/english

Mead Johnson Nutrition

Infant milks produced:

- *Enfamil AR*
- *Enfamil O-Lac*
- *Neocate LCP*
- *Nutramigen 1*
- *Nutramigen AA*
- *Pregestimil*

Mead Johnson Nutrition
BMS House
Uxbridge Business Park
Sanderson Road
Uxbridge UB8 1DH
T: 00800 8834 2568
www.enfamil.co.uk

Nutricia

Infant milks produced:

- *Caprilon*
- *Galactomin 17*
- *Galactomin 19*
- *Infatrini*
- *Kindergen*
- *Monogen*
- *Pepdite*
- *Pepdite MCT*

Nutricia
White Horse Business Park
Newmarket Avenue
Trowbridge
Wiltshire BA14 0XQ
T: 01225 711677
E: resourcecentre@nutricia.co.uk
www.nutricia.com

SMA Nutrition

Infant milks produced:

- *SMA 3 Toddler Milk*
- *SMA Extra Hungry*
- *SMA First Infant Milk*
- *SMA Follow-on Milk*
- *SMA Gold Prem 1*
- *SMA Gold Prem 2*
- *SMA High Energy*
- *SMA LF*
- *SMA Staydown*
- *SMA Wysoy*

SMA Nutrition
Pfizer Ltd
Vanwall Road
Maidenhead SLS 4UB
T: 01628 692 010
www.smanutrition.co.uk

Appendices

Appendix 1

Macro and micronutrient requirements of the Infant Formula and Follow-on Formula (England) Regulations 2007

Table 20 gives a summary of the compositional requirements of the Infant Formula and Follow-on Formula (England) Regulations 2007.

TABLE 20

Macro and micronutrient requirements for infant formula and follow-on formula

	Infant formula		Follow-on formula	
Macronutrients	Min/100ml	Max/100ml	Min/100ml	Max/100ml
Energy *kJ*	250	295	250	295
Energy *kcal*	60	70	60	70
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Protein *g*	1.8	3.0	1.8	3.5
Carbohydrate *g*	9.0	14.0	9.0	14.0
lactose *g*	4.5	ns	4.5	ns
Fat *g*	4.4	6.0	4.0	6.0
Linoleic acid *mg*	300	1200	300	1200
Linolenic acid *mg*	50	ns	50	ns
Prebiotic fibre *g*	ns	0.8[1]	ns	0.8[1]
Vitamins				
Vitamin A *µg-RE*	60	180	60	180
Vitamin C *mg*	10	30	10	30
Vitamin E *mg*	0.5[2]	5.0	0.5[2]	5.0
Vitamin D *µg*	1.0	2.5	1.0	3.0
Vitamin K *µg*	4	25	4	25
Thiamin (B_1) *µg*	60	300	60	300
Riboflavin (B_2) *µg*	80	400	80	400
Niacin *µg*	300	1500	300	1500
Vitamin B_6 *µg*	35	175	35	175
Vitamin B_{12} *µg*	0.1	0.5	0.1	0.5
Folic acid *µg*	10	50	10	50
Biotin *µg*	1.5	7.5	1.5	7.5
Pantothenic acid *µg*	400	2000	400	2000

TABLE 20 (continued)

	Infant formula		Follow-on formula	
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Minerals				
Calcium *mg*	50	140	50	140
Chloride *mg*	50	160	50	160
Copper *µg*	35	100	35	100
Fluoride *µg*	ns	100	ns	100
Iodine *µg*	10	50	10	50
Iron[3] *mg*	0.3	1.3	0.6	2.0
Magnesium *mg*	5.0	15	5.0	15
Manganese *µg*	1.0	100	1.0	100
Phosphorus[3] *mg*	25	90	25	90
Potassium *mg*	60	160	60	160
Selenium *µg*	1.0	9.0	1.0	9.0
Sodium *mg*	20	60	20	60
Zinc *mg*	0.5	1.5	0.5	1.5
Other				
Choline *mg*	7	50	ns	ns
Taurine *mg*	ns	12	ns	12
Nucleotides *mg*	ns	5.0	ns	5.0
Inositol *mg*	4.0	40	ns	ns
L-carnitine *mg*	1.2[4]	ns	ns	ns

ns = not significant

1 Fructo-oligosaccharides and galacto-oligosaccharides (prebiotic fibre) may be added to infant formula. In that case their content shall not exceed: 0.8g/100ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose.

2 Vitamin E - 0.5mg/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.5mg per 100kcal, maximum 5.0mg/100kcal.

3 For products manufactured from soya protein isolates or in a mixture with cows' milk, minimum and maximum values for iron for infant formula are 0.45mg and 2.0mg respectively and for follow-on formula 0.9mg and 2.5mg respectively. For phosphorus minimum and maximum values for both infant and follow-on formula are 30mg and 100mg respectively.

4 The L-carnitine concentration is only specified for formula containing protein hydrolysates or soya protein isolates.

Source: Infant Formula and Follow-on Formula (England) Regulations 2007

Appendix 2
Specialist infant milks

Table 20 below gives a list of specialist infant milks available in the UK. Information about the composition of specialist formula is available from the British Dietetic Association Paediatric Group (see www.bda.uk.com).

TABLE 21

Specialist infant milks available in the UK

Category	Names of infant milks included in this category
Extensively hydrolysed infant formula	Aptamil Pepti Cow & Gate Pepti-junior Nutramigen 1 Pepdite Pepdite MCT Pregestimil
Elemental formula	Neocate LCP Nutramigen AA
High-energy formula	Infatrini SMA High Energy Similac High Energy
Pre-term formula available for hospital use	Aptamil Preterm Nutriprem 1 SMA Gold Prem 1
Post-discharge formula	Nutriprem 2 SMA Gold Prem 2
Modified fat	Caprilon Monogen
Modified carbohydrate	Galactomin 17 Galactomin 19
Formula for renal disease	Kindergen

Glossary

Allergy – Adverse reaction to foods caused by the production of antibodies.

Amino acid – The base units from which proteins are made.

Atopic – Pertaining to clinical manifestations of type 1 (IgE-mediated) hypersensitivity, including allergic rhinitis (hay fever), eczema, asthma and various food allergies.

Atopy – Allergic hypersensitivity affecting parts of the body not in direct contact with the allergen, eg. eczema, asthmas and allergic rhinitis.

α-lactalbumin – Predominant whey protein of human milk.

Bifidogenic – Promoting the growth of (beneficial) bifidobacteria in the intestinal tract.

β-lactoglobulin – Predominant whey protein of bovine milk.

Casein – Globular protein that can be precipitated from milk, commonly during the cheese-making process. It consists of a group of 12-15 different proteins which make up about 75% of the proteins of milk.

Complementary feeding – The process of expanding the infant diet to include foods other than breast milk or infant formula. (Sometimes also known as weaning.)

Dextrins – A mixture of soluble compounds formed by the partial breakdown of starch by heat, acid or amylases.

Elemental infant formula – Infant formula based on synthetic free amino acids.

Fluorosis – Damage to teeth (white to brown mottling of the enamel) and bones caused by an excessive intake of fluoride.

Follow-on formula – The term often used to describe milks suitable for infants over the age of 6 months who are also receiving some solid food.

Fortification – The deliberate addition of specific nutrients to foods as a means of providing the population with an increased level of intake.

Fructo-oligosaccharides – Oligosaccharides consisting of fructose.

Fructose – Also known as a fruit sugar, a six carbon monosaccharide sugar.

Galacto-oligosaccharides – Oligosaccharides consisting of galactose.

Galactose – A six carbon monosaccharide, differing from glucose only in the position of the hydroxyl group on carbon-4.

Gastroenteritis – Inflammation of the mucosal lining of the stomach and/or small or large intestine, normally resulting from infection.

Glucose – A six carbon monosaccharide sugar occurring free in plant and animal tissues and formed by the hydrolysis of starch and glycogen. It may also be known as dextrose, grape sugar and blood sugar.

Glucose polymers – Oligosaccharides of glucose linked with alpha 1, 4 and alpha 1, 6 glycosidic links.

Glucose syrup – A kind of glucose polymer.

Glycerol – A trihydric alcohol also known as glycerine. Simple or neutral fats are esters of glycerol with three molecules of fatty acids (triglycerides sometimes known as triacylglycerols).

Hydrolysed – When a compound (complex) is split into its constituent parts by the action of water or an enzyme or catalysed by the addition of acid or alkali.

Hypernatraemia – The presence of an abnormal concentration of sodium in the blood. Hypernatraemia is generally not caused by an excess of sodium, but rather by a relative deficit of free water in the body. For this reason, hypernatraemia is often synonymous with the less precise term, dehydration. Hypernatraemia most often occurs in people such as infants, those with impaired mental status, or elderly people, who may have an intact thirst mechanism but are unable to ask for or obtain water.

Hypersensitivity – Heightened responsiveness induced by allergic sensitisation. There are several types of response including that associated with allergy.

Hypoallergenic – A term first used by advertisers to describe items that cause or are claimed to cause fewer allergic reactions.

Immunoglobulins (Ig) – The five distinct antibodies present in the serum and external secretions of the body: IgA, IgD, IgE, IgG and IgM.

Lactase – The enzyme that breaks down lactose. Sometimes called milk sugar, a disaccharide of glucose and galactose.

Lactose intolerance – The inability to metabolise lactose due to the absence of the enzyme lactase in the intestinal system or due to a low availability of lactase.

Low birthweight – Weight at birth below 2500g.

Luminal – Pertaining to the lumen, the interior of a hollow structure.

Maltodextrin – A polysaccharide produced from the partial hydrolysis of starch.

Maltose – Malt sugar or maltobiose, a disaccharide consisting of two glucose units.

Mature breast milk – Milk produced from about 14 days post partum.

Methionine – An essential sulphur-containing amino acid. It can be used by the body to make the non-essential, sulphur-containing amino acid cysteine.

Neonate – A human infant less than 28 days old. The term includes premature infants, postmature infants and full-term newborns.

Nucleotide – Compounds of purine or pyrimidine base with a sugar phosphate.

Palmitic acid – A saturated fatty acid (C16:0).

Pathogen – Disease-causing bacteria, as distinct from those that are harmless.

Peptide – Compound formed when amino acids are linked together through the peptide (-CO-NH-) linkage. Two amino acids linked in this way form a dipeptide, three a tripeptide, etc.

Phyto-oestrogens – Compounds in plant foods, especially soya bean, that have both oestrogenic and anti-oestrogenic action.

Prebiotics – Non-digestible oligosaccharides that support the growth of colonies of potentially beneficial bacteria in the colon.

Pre-term – A term used to describe infants born at less than 37 weeks' gestation.

Single cell oils – Oils produced from biomass of bacteria, algae and yeast, of potential use as animal or human food.

Small for gestational age (SGA) babies – Babies whose birthweight lies below the 10th percentile for that gestational age. They have usually been the subject of intrauterine growth restriction (IUGR), formerly known as intrauterine growth retardation. Low birthweight (LBW), is sometimes used synonymously with SGA.

Structured triglycerides – Triglycerides that have been chemically, enzymatically or genetically modified to change their nutritional and/or functional properties. They are also referred to as structured lipids.

Sucrose – Cane or beet sugar. A disaccharide composed of glucose and fructose.

Tryptophan – An essential amino acid, the precursor of serotonin (a neurotransmitter) and of niacin.

Visual acuity – The acuteness or clearness of vision, especially form vision, which is dependent on the sharpness of retinal focus and the sensitivity of the interpretative faculty of the brain. It is the most common measurement of visual function.

Whey – The liquid component of milk, which remains after the insoluble curds have been coagulated and removed.

Whey protein – The name for a collection of globular proteins that can be isolated from whey.

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