Infant milks in the UK

A practical guide for health professionals

May 2012

FIRST STEPS NUTRITION TRUST

Infant Milks in the UK: A Practical Guide for Health Professionals – March 2012
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ISBN 978 1 908924 00 1

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. The report will be updated quarterly and the date of this publication appears as a footer on each page.

Acknowledgements

This report is based on a previous report written by the authors for The Caroline Walker Trust in 2011, which can be accessed at www.cwt.org.uk. We would like to thank the A Team Foundation (registered charity number 1077094) for funding the original publication of this report, and The Organix Foundation (registered charity number 1127780) for funding this quarterly updated version for health professionals. Thanks are also due to all those who provided information for this report.

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First Steps Nutrition Trust is a charity that is a focal point for objective, evidence-based information and resources about the importance of good nutrition from pre-conception to 5 years. For more information, see our website www.firststepsnutrition.org

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Acronyms

AA	Arachidonic acid
ACBS	Advisory Committee on Borderline Substances
ALA	α-linolenic acid
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
DHA	Docosahexaenoic acid
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
LBW	Low-birthweight
LCPs	Long chain polyunsaturated fatty acids
PAH	Polycyclic aromatic hydrocarbons
PC	Phosphatidyl choline
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
TDI	Tolerable dietary intake
TPAN	Total potentially available nucleotide
WHO	World Health Organization

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 the next page.)

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 First Steps Nutrition Trust (FSNT) 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. The FSNT 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 6.

This guide for professionals follows a previous report written by the same authors and published by The Caroline Walker Trust. The original report made a series of recommendations and suggestions for how the infant milk market in the UK can be better regulated and supported, and that report can be accessed at http://www.cwt.org.uk/pdfs/infantsmilk_web.pdf. This more practical guide aims to provide health professionals with quarterly updated information on infant milks in the UK in a more accessible format.

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 meet all an infant's nutritional needs during the first six months of life and which complies with the regulations for infant formula.

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 and which comply with the regulations for follow-on formula.

A glossary of terminology surrounding infant formula can be found on page 88.

1.1 What does this report contain?

This report provides information on infant milks currently available in the UK. The information will help health professionals and others who give information to parents to provide clear and accurate advice.

The report provides information on:

- what infant milks contain and what we know about the ingredients used and their composition
- what milks are currently available and key points about these
- how much milk is recommended and how to make up infant milk feeds safely.

Section 6 gives sources of further information. Appendix 1 gives background information about infant milks and the infant milk market, and Appendix 2 provides information about monitoring the composition and safety of infant milks.

2 A simple guide to choosing milks for infants and toddlers

Table 1 gives a summary guide to choosing milks for infants and toddlers up to 2 years of age, who do not have any special medical needs. The rationale for the information given in this table can be found in section 4 of this report.

TABLE 1
A simple guide to choosing milks for infants and toddlers up to 2 years of age

✓ = Safe to give.
(✓) = Safe to give, but seek advice from a health professional as these milks may not be recommended for use, may be for specific conditions only, or there may be little evidence that they offer any benefit.
X = Do not give this milk.

Breastfeeding gives infants the best start in life.
If parents and carers wish to bring up their infants as a vegetarian or vegan, they are strongly advised to breastfeed during the first year of life.
If infants and babies have special medical needs, seek advice from a health professional.

Milks suitable for use	Infants 0-6 months	Infants 6 months - 1 year	Babies 1 year - 2 years
Breast milk	✓	✓	✓
Whole cows' milk	x	x	✓
FORMULA MILKS			
Infant formula suitable from birth (cows' milk based)	✓	✓	(✓)
Infant formula marketed for hungrier babies, suitable from birth (cows' milk based)	(✓)	(✓)	(✓)
Thickened infant formula suitable from birth	(✓)	(✓)	(✓)
Soy protein based infant formula suitable from birth	(✓)	(✓)	(✓)
Lactose-free infant formula suitable from birth	(✓)	(✓)	(✓)
Partially hydrolysed infant formula suitable from birth	(✓)	(✓)	(✓)
Follow-on formula suitable from 6 months of age	x	(✓)	(✓)
OTHER MILKS			
Goodnight milks	x	(✓)	(✓)
Growing-up milks and toddler milks suitable from around 1 year of age	x	x	(✓)
Growing-up milks and toddler milks suitable from around 2 years of age	x	x	x
Goats' milk formula	x	x	(✓)
Whole goats' milk	x	x	✓
Whole sheep's milk	x	x	✓
Unsweetened full-fat soya milk, calcium-fortified	x	x	✓
Rice milk	x	x	x
Oat milk	x	x	x
Nut milks	x	x	x

The rationale for the information given in this table can be found in the appropriate sections of this report.

3 The composition of infant milks

3.1 What ingredients are used to make infant milks and where do they come 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.

3.2 How are infant 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 does not involve the use of water in the manufacturing process, reducing 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.

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 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.

3.3 The nutritional components of infant milks

3.3.1 Protein

Key points

Proteins are composed of amino acids, some of which are essential (cannot be synthesised by the human body). The protein requirements of infants are based on the concentration of amino acids found in mature human milk.

The majority of infant milks available in the UK are based on bovine (cows') milk protein. Bovine milk contains more protein than human milk and the proteins present in bovine milk differ from human milk in both the ratio of the proteins whey and casein and in the amino acid profile of the proteins present.

In order to bring the protein profile of formula milk closer to that of human milk, bovine milk can be modified to alter the whey:casein ratios.

Some infant formulas are enriched with the whey protein α-lactalbumin. It has been suggested that this milk may be better tolerated by infants.

Cows' 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, while 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). 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 standard infant formula, or 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).

Nucleotides

Key points

Nucleotides are important metabolic regulators and are involved in energy transfer and breaking down large molecules. At times of rapid growth or in disease, the body may not be able to synthesise nucleotides at the rate they are required and so must rely on dietary sources.

The concentration of nucleotides in bovine milk is considerably lower than in human milk. Regulations permit nucleotides to be added to formula milk.

Studies in infants suggest that dietary nucleotides 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 some immunisations.

Studies used to support the use of nucleotides in standard infant formula have shown conflicting results however, and differences in the formula used in trials and between groups in trials makes it difficult to interpret evidence related to claimed benefits.

All non-organic standard infant milks for healthy term infants in the UK are supplemented with 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 used 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 3.0mg/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 make 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.

3.3.2 Fat

Key points

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. Fat supplies 50% of energy in infants who are exclusively breastfed and fats are added to infant milks to supply 50% of dietary energy. The fat source in infant milks is mainly vegetable oils, but a variety of oils can be used and the source of oils used in manufacture may not be known.

The quantity of fat in cows' milk and human milk is similar, but human milk is higher in unsaturated fats, particularly the polyunsaturated fatty acids linoleic (LA) and α-linolenic acid (ALA). Humans can synthesise some long chain polyunsaturated fatty acids (LCPs) from simpler fatty acid precursors, but they cannot synthesise LA and ALA which must be provided in the diet. EU regulations stipulate minimum concentrations of LA and ALA in infant formula milks.

Long chain polyunsaturated fatty acids (LCPs)

Arachidonic acid (AA) and docosahexaenoic acid (DHA) are LCPs found in high concentrations in neural (brain) tissue and the retina of the eye. Mammals including humans can synthesise these AA and DHA from LA and ALA respectively. Human milk contains small amounts AA and DHA but cows' milk does not. EU regulations permit the addition of AA and DHA to formula milks.

Trials which have examined the potential beneficial effects of using formula supplemented with DHA and AA on visual function and neurodevelopment have had mixed results, but the available evidence is strongest for a beneficial effect of supplemented formula on visual development.

Most infant formula in the UK are now supplemented with LCPs.

Structured triglycerides

The position of fatty acids in triglycerides has an impact on their function. The fatty acid palmitate in human milk is more easily absorbed than the palmitate in cows' milk. The structure of the cows' milk palmitate used in formula milk is altered, as this may aid digestion and improve calcium absorption.

Betapol is a structured triglyceride used in some infant formulas. The evidence available for the efficacy of Betapol in aiding constipation and improving calcium absorption from formula milk has been inconsistent.

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.

However, evidence from a recent randomised control trial considering normal growth of infants fed formula with and without canola oil found no differences in weight or length gain between 4 weeks and 7 months of age (Rzehak et al, 2011). 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.

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"*.

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 the 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 usage 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 ready-to-feed 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.

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, 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 (Kennedy et al, 1999). 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, but 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. Both Cow & Gate and Aptamil list structured triglycerides in the ingredients lists for products designed to relieve minor digestive problems. Ingredients lists for SMA products are not available online for all products but, of those that are available, SMA First Infant Milk includes structured triglycerides in the ingredients list.

3.3.3 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).

3.3.4 Vitamins and minerals

Key points

Vitamins and minerals are micronutrients, the majority of which cannot by synthesised by the body and must be provided in the diet regularly.

European regulations set minimum and maximum levels of vitamins that must be present in infant and follow-on formulas.

Vitamins and minerals are more easily absorbed from human milk than from formula milk and must therefore be present in formula milks in higher concentrations than they are in breast milk.

Some vitamins and minerals deteriorate during storage, so the length of time milks are stored will impact on the amount of vitamins and minerals available. This highlights the need for regular monitoring of the composition of formula milks available to buy 'off the shelf' in the UK.

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 on Infant Formulae and Follow-on Formulae 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 interesting to note that there are some anomalies between levels set by the European Commission Directive on Infant Formulae and Follow-on Formulae and the 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.

3.3.5 Fluoride content of infant milks

> **Key points**
>
> Fluoride protects against dental caries, but too much fluoride during the development of teeth may result in brown mottling and pitting (fluorosis) of tooth enamel. EU specifications set only maximum levels of fluoride in infant and follow-on formula milks.
>
> Most ready-to-feed infant milks are made using demineralised tap water, allowing tighter control over the final fluoride content of the product.
>
> The fluoride content of powder formula reconstituted with tap water will vary depending on whether or not the water supply used is fluoridated. In the UK not all water supplies are fluoridated.
>
> The fluoride intake of infants consuming formula milks reconstituted with tap water fluoridated to the levels recommended by the panel of dietary reference values of COMA will fall within the levels of safe intakes for infants aged up to 6 months. Infants who are fed on formula milk in areas where water is fluoridated will receive considerably more fluoride than breastfed babies.

Most ready-to-feed (RTF) infant 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, but 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 fluoride 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 make up 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 level of 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 an 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.

3.3.6 Other ingredients

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.

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.

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 companies, 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 (Koletzko et al, 2009b).

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.

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 USA in a sample of infants to ensure that the addition of lutein does not impact on growth (Capeding et al, 2010).

3.3.7 Prebiotics

Key points

Prebiotics are non-digestible food ingredients that may stimulate the growth and/or activity of one or more of the bacteria in the colon. Colonic bacteria may produce compounds that are either harmful or beneficial to the host. Bifidogenic prebiotics stimulate the growth and activity of beneficial bacteria.

Human milk contains over 200 oligosaccharides which are thought to have a bifidogenic effect on the colonic microflora of infants, protecting them from hazards in their specific environment. Infant formula based on bovine milk contains virtually no prebiotic oligosaccharides.

A mixture of a small number of fructo-oligosaccharides (FOS) and galacto-oligosaccharides (GOS), which have been shown to have a bifidogenic effect in adults have been added to infant formula in an attempt to reproduce the bifidogenic activity of breast milk.

Some trials claim to have shown health benefits. However, the European Food Safety Authority has found that evidence linking consumption of formula milks containing added FOS and GOS with a strengthened immune system are insufficient to make a health claim.

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 among 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*, while 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 six 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". Whilst Danone products still contain added FOS and GOS, the Immunofortis patent is no longer used in the marketing of the products.

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 formula enriched with either 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.

3.4 Water used to make up powdered milk

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 sulphate (SO4) 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 if an emergency arises and mains water supplies are disrupted. Often in these circumstances bottled water is made available to households and it is important that in emergency situations clear information is given to parents and carers on whether it is safe to use this for making up infant milks. 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).

3.5 Contaminants in infant milks

3.5.1 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 5.5). *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, 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 3.2) (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 recommendation 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, thiamin, folate and vitamin C), and 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 contamination 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).

3.5.2 Aluminium

There has been a long and significant history documenting the contamination of infant milks with aluminium and the consequent health effects of this, with aluminium toxicity associated with aeaemia, bone disease and impaired neurological development (Fewtrell et al, 2011). Infant milks typically have 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, in recent analyses of ready-to-feed formula milks, aluminium levels were found to vary from 176 to 700µg/litre, and in powdered milks from 2.4 to 4.3µg/litre, and there has been no change in content despite calls for a reduction. Soy protein based infant 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. A recent study of pre-term infants fed intravenous fluids which were high in aluminium showed both impaired neurological development at 18 months and reduced bone mass at 13-15 years, and although there is likely to be much greater toxicity associated with intravenous administration of fluid, these findings suggest significantly more should be done to reduce intakes (Fewtrell et al, 2011). EFSA considered aluminium toxicity in 2008 (EFSA, 2008) and suggested that 3 month old infants were typically exposed to aluminium at around 0.6-0.9mg/kg bw/week and 0.75-1.1mg/kg bw/week for soya formula, but acknowledged that the concentration in some formula brands was four times higher and that intakes could frequently exceed the current tolerable weekly intake of 1mg/kg bw/week. Breastfed infants are exposed to less than 0.07mg/kg bw/week.

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 infant formula had higher aluminium contents than other formula, as did some milks made with partially hydrolysed protein.

3.5.3 Uranium

There has been some concern that infant formula made up with some waters could contain high levels of uranium, which is thought to have potential toxic effects on kidney function. The World Health Organization (WHO) has set a guideline maximum level of 15µg/litre for uranium in water, but there is some concern that infants given infant formula made up with water that has 15µg/litre could mean that infants under 6 months consume up to four times the tolerable dietary intake (TDI) also set by WHO (Committee on Toxicity, 2006). At the present time there are not thought to be any health concerns to infants related to uranium in infant milk, but COT (the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) acknowledges that it has little data in this area and the impact of these intakes is uncertain. Some bottled waters may have high levels of uranium and so it is important that, if a bottled water is used to make up a feed, the bottled water should specify that it is suitable for infant formula.

3.6 Results of surveys of the nutritional composition of infant milks

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 between products, 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 infant 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.

4 Infant milks available in the UK

This section describes the types of infant milk currently available in the UK and the basic composition of those milks. The compositional requirements are determined by the Infant Formula and Follow-on Formula Regulations 2007. 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.

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

Table 2 gives a summary of the compositional requirements of the Infant Formula and Follow-on Formula (England) Regulations 2007.

TABLE 2

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

	Infant formula		Follow-on formula	
	Min/100ml	Max/100ml	Min/100ml	Max/100ml
Energy kJ	250	295	250	295
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
of which lactose g	4.5	N/S	4.5	N/S
Fat g	4.4	6.0	4.0	6.0
Linoleic acid mg	300	1200	300	1200
Linolenic acid mg	50	N/S	50	N/S
Prebiotic fibre g	N/S	0.8[1]	N/S	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
MINERALS				
Calcium mg	50	140	50	140
Chloride mg	50	160	50	160
Copper µg	35	100	35	100
Fluoride µg	N/S	100	N/S	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	N/S	N/S
Taurine ***mg***	N/S	12	N/S	12
Nucleotides mg	N/S	5.0	N/S	5.0
Inositol mg	4.0	40	N/S	N/S
L-carnitine mg	1.2 [4]	N/S	N/S	N/S

N/S = 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

TABLE 3

Macro and micronutrient composition of average first milks and mature breast milk compared to regulations for infant formula

	Average for first infant milks	Mature breast milk	Regulations for infant formula (re-calculated by volume)	
	Per 100ml	Per 100ml	Min/100ml	Max/100ml
MACRONUTRIENTS				
Energy kJ			250	295
kcal	67	69	60	70
Protein g	1.3	1.1[1]	1.2	2.0
Carbohydrate g	7.3	7.2	6.0	9.4
of which lactose g	6.8	6-7[1]	3.0	N/S
Fat g	3.5	3.9	2.9	4.0
Linoleic acid mg	491	560[2]	200	800
Linolenic acid mg	72	72[2]	33.5	N/S
VITAMINS				
Vitamin A µg-RE	60	82	40	121
Vitamin C mg	10.3	4.0	6.7	20.1
Vitamin E mg	1.1	0.34	0.34*	3.35
Vitamin D µg	1.2	0.2-3.1[1]	0.67	1.68
Vitamin K µg	5.6	0.2-0.9[1]	2.68	16.75
Thiamin (B_1) µg	74	20	40.2	201
Riboflavin (B_2) µg	137.4	30	53.6	268
Niacin µg	497	200	201	1005
Vitamin B_6 µg	62.4	10	23.45	117.25
Vitamin B_{12} µg	0.2	0.02-0.1[1]	0.07	0.34
Folic acid µg	14.2	5	6.7	33.5
Biotin µg	2.2	0.7	1.01	5.03
Pantothenic acid µg	448	250	268	1340
MINERALS				
Calcium mg	50	34	34	94
Chloride mg	45	42	33.5	107.2
Copper µg	37.8	40	23.45	67
Fluoride µg	3.1	7[1]	N/S	67
Iodine µg	11.8	7	6.7	33.5
Iron** mg	0.5	0.7	0.2	0.87
Magnesium mg	5.4	3	3.35	10
Manganese µg	8.0	2.7[1]	0.67	67
Phosphorus**mg	29.4	15	16.8	60.3
Potassium mg	69.6	58	40.2	107.2
Selenium µg	1.5	1	0.67	6.0
Sodium mg	19.2	15	13.4	40.2
Zinc mg	0.6	0.3	0.34	1.0
OTHER				
Choline mg	13	16 [3]	4.7	33.5
Taurine mg	5.1	3.8 [4]	N/S	8.0
Nucleotides mg	3.0	3-7 [5]	N/S	3.35
Inositol mg	4.4	2.6 [6]	2.68	26.8
L-carnitine mg	1.4	0.7 [7]	0.8***	N/S

See the notes on the next page.

Note: Where regulations do not state a minimum amount, they are not considered a requirement. In these cases, the average stated for currently available first infant milks does not include those milks where the ingredient is not present.

N/S = not significant

* 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.

** 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.

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

Sources:
Average for first infant milks: taken from an average of the three main first infant milks sold in the UK.
Mature breast milk composition: Food Standards Agency (2002) except for: 1 Royal College of Midwives (2009); 2 Specker et al (1987); 3 Holmes-McNary et al (1996); 4 Agostoni et al (2000); 5 Carver (2003); 6 Pereira et al (1990); 7 Mitchell et al (1991).
Regulations for infant formula: Infant Formula and Follow-on Formula (England) Regulations 2007.

4.2 Types of infant milks commonly available in the UK

For the purposes of this report we have divided infant milks available into the categories shown in Table 4. Sections 4.3-4.11 give basic information and nutritional composition information about each category.

TABLE 4
Infant milks commonly available in the UK

Category of infant milk	Names of infant milks included in this category
Infant formula suitable from birth (cows' milk based)	Aptamil 1 Cow & Gate 1 Hipp Organic First Infant Milk Holle Organic Infant Formula 1 SMA First Infant Milk
Infant formula 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 SMA Extra Hungry
Thickened infant formula suitable from birth	Enfamil AR SMA Staydown
Soy protein based infant formula suitable from birth	Cow & Gate Infasoy SMA Wysoy
Lactose-free infant formula suitable from birth	Enfamil O-Lac SMA LF
Partially hydrolysed infant formula suitable from birth	Aptamil Comfort Cow & Gate Comfort
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 SMA Follow-on Milk
Goodnight milks	Hipp Organic Good Night Milk
Growing-up milks and toddler milks suitable from around 1 year of age	Aptamil Growing Up Milk 1+ Year Cow & Gate Growing Up Milk 1-2 Years Hipp Organic Growing Up Milk Holle Organic Infant Formula 3 SMA Toddler Milk
Growing-up milks and toddler milks suitable from around 2 years of age	Aptamil Growing Up Milk 2+ Year – *new product* Cow & Gate Growing Up Milk 2-3 Years

Details of the manufacturers of these infant milks, and their contact details, can be found in section 6.

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 infant milks available in the UK is given in Table 5.

TABLE 5
Specialist infant milks available in the UK

Category	Names of infant milks included in this category
Extensively hydrolysed infant formula	Aptamil Pepti 1 Aptamil Pepti 2 Cow & Gate Pepti-junior Nutramigen 1 Nutramigen 2 Pepdite Pepdite 1+ Pepdite MCT Pepdite MCT 1+ 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

4.3 Milks suitable for specific population groups

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.

Table 6 shows which infant formula and infant milks are suitable for vegetarians and vegans, and which are halal-approved.

4.3.1 Infant milks for vegetarians

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.

4.3.2 Infant milks for vegans

There are no infant milks currently on the market suitable for vegans as the vitamin D used is sourced from sheep's wool.

4.3.3 Halal and kosher milks

Many infant milks have sought approval for use by communities who require halal products. 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 the case particularly during Passover.

TABLE 6
Infant milks suitable for vegetarians, vegans and for those wanting halal products

Note: Always check the label as formulations can change.

Category of infant milk		Suitable for vegetarians	Suitable for vegans	Halal approved
Infant formula suitable from birth (cows' milk based)	Aptamil 1			✓
	Cow & Gate 1			✓
	Hipp Organic First Infant Milk			
	Holle Organic Infant Formula 1			✓
	SMA First Infant Milk			✓
Infant formula 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			
	SMA Extra Hungry	✓ *		✓
Thickened infant formula suitable from birth	Enfamil AR	✓		
	SMA Staydown	✓		✓
Soy protein based infant formula suitable from birth	Cow & Gate Infasoy	✓		✓
	SMA Wysoy	✓		✓
Lactose-free infant formula suitable from birth	Enfamil O-Lac	✓		
	SMA LF	✓		✓
Partially hydrolysed infant formula suitable from birth	Aptamil Comfort			
	Cow & Gate Comfort			
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			✓
	SMA Follow-on Milk	✓ *		✓
Goodnight milks	Hipp Organic Good Night Milk			
Growing-up milks and toddler milks suitable from around 1 year of age	Aptamil Growing Up Milk 1+ Year			✓
	Cow & Gate Growing Up Milk 1-2 Years			✓
	Hipp Organic Growing Up Milk			
	Holle Organic Infant Formula 3			
	SMA Toddler Milk			✓
Growing-up milks and toddler milks suitable from around 2 years of age	Aptamil Growing Up Milk 2+ Year – *new product*			✓
	Cow & Gate Growing Up Milk 2-3 Years			✓

* Powder formulation only.

4.4 Infant formula suitable from birth (cows' milk based)

Key points

Infant formula suitable to use from birth based on modified cows' milk is the most commonly used infant formula.

This may be used as the sole source of nutrition for infants up to 6 months of age and is also suitable throughout the first year of life.

Compositional differences between brands are due to the addition of some non-mandatory ingredients but the composition of milks is generally very similar as they are designed to meet compositional regulations.

Infant formula suitable from birth are designed to meet the nutritional requirements of healthy term infants as the sole source of nutrition in the first six months of life, but can be used alongside complementary foods throughout the first year. These milks have been modified to make them as similar in composition to breast milk as is achievable, but many of the unique ingredients in breast milk cannot be reproduced and many nutrients have to be added in far higher quantities than are found in breast milk as they are less easily absorbed.

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 section 3.3.2 for more information about these ingredients.)

The nutritional composition and ingredients used in infant formula based on cows' milk suitable from birth are given in Table 7.

TABLE 7

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

Nutrients per 100ml	Aptamil 1	Cow & Gate 1	Hipp Organic First Infant Milk	Holle Organic Infant Formula 1	SMA First Infant Milk
MACRONUTRIENTS					
Energy kcal	66	66	67	68	67
Protein g	1.3	1.3	1.4	1.4	1.3
Whey:casein ratio	60:40	60:40	60:40	60:40	65:35
Carbohydrate g	7.4	7.4	7.3	7.4	7.3
– of which lactose g	7.0	7.0	7.2	5.9	7.3
Fat g	3.4	3.5	3.5	3.6	3.6
Added LCPs AA	✓	✓	✓	×	✓
DHA	✓	✓	✓	×	✓
In approved ratio	✓	✓	✓	N/A	✓
LCP source	Vegetable and fish oils	Vegetable and fish oils	Vegetable and fish oils	N/A	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]	×	×	×	×	×
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.

4.5 Infant formula marketed for hungrier babies, suitable from birth (cows' milk based)

Key points

Formula marketed for hungrier babies has a casein:whey ratio similar to cows' milk.

It is suggested that a higher casein content can slow gastric emptying, resulting in greater satiety and a better night's sleep, but there is no evidence to support this.

The nutritional composition of casein dominant formulas is slightly different to that of whey dominant infant formulas. However, the reported nutrient composition for both types of milk are within recommended levels.

In addition to first infant formula, most manufacturers also offer an infant formula for 'hungrier babies'. These milks are predominantly casein-based and it is suggested that a whey:casein ratio of approximately 20:80 (which is similar to that in cows' milk) can 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 formula marketed for hungrier babies suitable from birth are given in Table 8.

TABLE 8

The nutritional composition of infant formula 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**	**SMA Extra Hungry**
MACRONUTRIENTS				
Energy kcal	66	66	67	67
Protein g	1.6	1.6	1.6	1.6
Whey:casein ratio	20:80	20:80	20:80	20:80
Carbohydrate g	7.8	7.8	7.7	7.0
– of which lactose g	7.4	7.4	7.2	7.0
Fat g	3.1	3.1	3.3	3.6
Added LCPs AA	✓	✓	✓	✓
DHA	✓	✓	✓	✓
In approved ratio	✓	✓	✓	✓
LCP source	Vegetable and fish oils	Vegetable and fish oils	Vegetable 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

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.

4.6 Thickened infant formula suitable from birth

Key points

Thickened infant formula with added rice or corn starch are suggested to help improve gastro-oesophageal reflux, but there is little evidence that these products offer any such benefit.

While some studies have shown that thickened infant formula can reduce regurgitation in some infants, their use in infants with simple reflux is not supported by the ESPGHAN Committee on Nutrition.

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.

Thickened infant formulas 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 infant formulas 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 infant formulas 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 infant formulas 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 infant formula 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 formula suitable from birth are given in Table 9.

TABLE 9

The nutritional composition of thickened infant formula 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.

4.7 Soy protein based infant formula suitable from birth

Key points

Soy protein based infant formula are free of any animal products, the protein is from soya beans, and the carbohydrate source is glucose, corn syrup or sucrose.

Soy protein based infant formula have sometimes been used for children who 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.

Concerns have been raised over the potential allergenic effect of soy protein based milks in infants at high risk of atopy and over the effects that the phyto-oestrogens present in soy protein based milks might have on future reproductive health.

Whilst soy protein based milks have been shown to support normal growth and development in healthy term infants, the Chief Medical Officer has recommended that soy protein based milks should not be used for infants under 6 months of age who have cows' milk protein allergy or intolerance.

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).

When the carbohydrate source is glucose rather than lactose, milks have a greater potential to cause dental caries. Parents and carers using these milks are advised 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.

Advice in the UK is that parents should always seek advice before feeding their infant soy protein based infant formula.

Soy protein based milks are free of any animal products, the protein source is soya bean, and the carbohydrate source is glucose, corn syrup or sucrose. 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 formula 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 over 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 formula 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 formulas 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 formula and of cows' milk protein based infant formula, 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 infant 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 formula.

The nutritional composition and ingredients used in soy protein based infant formula suitable from birth are given in Table 10.

TABLE 10
The nutritional composition of soy protein based infant formula suitable from birth

Nutrients per 100ml	Cow & Gate Infasoy	SMA Wysoy
MACRONUTRIENTS		
Energy kcal	66	67
Protein g	1.6	1.8
Carbohydrate g	7.0	6.9
Carbohydrate source	Glucose syrup	Dried glucose syrup
Fat g	3.5	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	✓	✓
Halal approved	✓	✓

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

4.8 Lactose-free infant formula suitable from birth

Key points

Lactose intolerance is a clinical syndrome which can cause abdominal pain, diarrhoea, flatulence and/or bloating after ingestion of food containing lactose. The degree of lactose intolerance varies among individuals.

Infants who cannot tolerate any lactose can only be treated by excluding lactose from the diet. In infants this can be achieved by using lactose-free infant formula or incubating feeds (human milk or formula) with the enzyme lactase which breaks the sugar into its component parts. In primary lactose intolerance where the degree of lactase deficiency varies, the use of lactose-free formula may help to relieve the symptoms.

In the UK, the lactose-free formulas Enfamil O-Lac and SMA LF 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.

In lactose-free formula the carbohydrate source is glucose rather than lactose, so these milks have a greater potential to cause dental caries. Parents and carers using these milks are advised 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 main difference between lactose-free and standard cows' milk based infant 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 among 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 among 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 formula 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 formula 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 formulas 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 formula 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 formula, 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 formula 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 formula 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 formula suitable from birth are given in Table 11.

TABLE 11
The nutritional composition of lactose-free formula 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 mg	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.

4.9 Partially hydrolysed infant formula suitable from birth

Key points

Infant formula containing partially hydrolysed proteins are marketed as ‘easier to digest’. They are based on modified cows’ milk with 100% whey protein. Both products available have an identical nutrient profile.

A recent paper from a large randomised trial in healthy term infants fed formula milks containing partially hydrolysed protein and reduced lactose or a standard infant formula reported that there was no difference in tolerance of intact compared to partially hydrolysed protein (Berseth et al, 2009).

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

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. They are both modified cows’ milk formula based on 100% whey protein. Both 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). Both products contain partially hydrolysed proteins, structured vegetable oils, reduced lactose, and prebiotics. Cow & Gate Comfort is formulated for ‘comfortable digestion’ and is claimed to help protect the immature, sensitive digestive system. It has an identical nutrient profile to Aptamil Comfort.

Neither 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 for Health and Clinical Excellence (NICE) considers that there is insufficient evidence to suggest that infant formulas based on partially or extensively hydrolysed cows’ milk protein can help prevent allergies (National Institute for Health and Clinical Excellence, 2008).

The nutritional composition and ingredients used in partially hydrolysed infant formula suitable from birth are given in Table 12.

TABLE 12
The nutritional composition of partially hydrolysed infant formula suitable from birth

Nutrients per 100ml	Aptamil Comfort	Cow & Gate Comfort
MACRONUTRIENTS		
Energy kcal	66	66
Protein g	1.5	1.5
Whey:casein ratio	100:0	100:0
Carbohydrate g	7.2	7.2
– of which lactose g	2.7	2.7
Carbohydrate source	Lactose, glucose syrup, potato and corn starch	Lactose, glucose syrup, potato and corn starch
Fat g	3.4	3.4
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.

4.10 Follow-on formula suitable from 6 months of age

Key points

Follow-on formula are designed for infants over the age of 6 months who are receiving complementary foods. They contain relatively more protein, micronutrients and iron than infant formula designed for use from birth. However, there is no evidence to suggest that infants receiving complementary foods containing adequate protein, carbohydrate, fat and iron need the higher levels of nutrients provided in follow-on formula.

There is some evidence to suggest that excessive iron intakes in infancy may result in a reduced uptake of other trace metals, and the oxidation of lipids, and that high iron intakes among iron-replete infants and toddlers may actually have an adverse effect on growth and development. Follow-on formula are therefore not recommended by health professionals.

Current UK infant feeding guidelines recommend that, after 6 months of age, additional iron requirements should be met by including iron-rich complementary foods, and that the introduction of cows' milk, which has a lower iron content than breast milk, should be postponed until 12 months of age. It is advised that first formula milks remain the milk of choice during the first year if babies are not breastfed.

Follow-on formula cannot be purchased using Healthy Start vouchers.

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 excessive 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). A recent large study from Chile which looked at the impact of iron-fortified formula in infants aged 6-12 months on a range of cognitive and learning outcomes at 10 years of age, showed that iron-replete infants given iron-fortified formula did significantly less well in terms of long-term development than similar infants given low-iron formula, or iron-deficient infants given high-iron formula (Lozoff et al, 2011). 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 cows' 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 effect 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 formula remain the milk of choice during the first year if babies are not breastfed.

Some of the differences between infant formulas suitable from birth and follow-on formulas are shown in Table 13.

The nutritional composition and ingredients used in follow-on formula suitable from 6 months of age are given in Table 14.

TABLE 13

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

Nutrients per 100ml	Energy kcal	Protein g	Carbo-hydrate g	Fat g	Vitamin D µg	Calcium mg	Iron mg	Zinc mg
Aptamil 1	66	1.3	7.4	3.4	1.2	47	0.53	0.5
Aptamil 3 Follow-on Milk	68	1.4	8.6	3.0	1.4	61	1.0	0.51
Cow & Gate 1	66	1.3	7.4	3.4	1.2	47	0.53	0.5
Cow & Gate 3 Follow-on Milk	68	1.4	8.6	3.0	1.5	68	1.0	0.57
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
SMA First Infant Milk	67	1.3	7.3	3.6	1.2	42	0.64	0.6
SMA Follow-on Milk	67	1.5	7.2	3.6	1.5	50	1.2	0.8

TABLE 14
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	SMA Follow-on Milk
MACRONUTRIENTS						
Energy kcal	68	66	68	69	69	67
Protein g	1.4	1.62	1.4	1.5	1.6	1.5
Whey:casein ratio	50:50	40:60	20:80	40:60	N/K	60:40
Carbohydrate g	8.6	7.87	8.6	7.7	8.2	7.2
– of which lactose g	6.1	3.89	8.3	7.4	4.9	7.2
Carbohydrate source	Lactose, malto-dextrins	Lactose, malto-dextrins	Lactose	Lactose	Lactose, malto-dextrins, corn starch	Lactose
Fat g	3.0	3.07	3.0	3.5	3.3	3.6
Added LCPs AA	✓	✗	✗	✗	✗	✓
DHA	✓	✗	✗	✗	✗	✓
In approved ratio	✓	N/A	N/A	N/A	N/A	✓
LCP source	Fish oils	N/A	N/A	N/A	N/A	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]	✗	✗	✗	✗	✗	✓[3]
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 phosphorus content of this milk is marginally higher than regulations state.
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.
3 Powder formulation only.

4.11 Goodnight milks and food drinks

4.11.1 Goodnight milks

Key points

Goodnight milks have a whey:casein ratio of 20:80 and contain cereal thickeners.

Goodnight milks are suggested to help babies settle at bedtime. However, there is no evidence to support this suggestion.

The Scientific Advisory Committee on Nutrition (SACN) has raised concerns over the use of goodnight milk products. Claims made about settling infants at night can undermine breastfeeding by convincing parents that children aged 6 months plus should sleep longer at night, and inappropriate use of these milks might result in the development of nursing bottle caries.

Goodnight milks are significantly more expensive than the same brand standard follow-on formula.

Goodnight milks are another example of product diversification in 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. Goodnight milks differ from standard infant and follow-on formula in that they have added ingredients which make the products thicker than standard formulas. Products are anecdotally suggested to help settle babies at bedtime, but there is no evidence that this is the case.

The principles behind the use of goodnight milks are that the addition of rice starch or 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 use of these starches means 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.

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 formula. 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 Hipp Organic Good Night Milk are given in Table 15.

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 15
The nutritional composition of goodnight milks

Nutrients per 100ml	Hipp Organic Good Night Milk
MACRONUTRIENTS	
Energy kcal	70
Protein g	1.6
Whey:casein ratio	N/K
Carbohydrate g	8.0
– of which lactose g	5.0
Carbohydrate source	Lactose, organic corn starch, rice flakes and buckwheat flakes
Fat g	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	✗
Halal approved	✗

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

4.11.2 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 16 summarises the features of the brands of food drinks available on the German market.

TABLE 16
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 Pediatrics and Adolescent Medicine (DGKJ) (2007)

The use of cereal in milks is discouraged in the UK and these food drinks will be associated with all the risks identified by SACN for goodnight milks (see page 56).

4.12 Milks for which there are no compositional regulations

4.12.1 Growing-up milks and toddler milks

Key points

Growing-up milks and toddler milks are offered by the infant milk manufacturers as an alternative to, or to complement, whole cows' milk for toddlers from about 1 year of age. These milks currently fall outside any compositional regulations, and for the majority of children there is no rationale for giving these milks.

Promotion and marketing of these products led to a 21.5% increase in sales between 2009-2010. Parents may mistakenly believe their toddlers need these milks to provide sufficient nutrition because promotional materials compare the nutrients in these milks with the nutrients in cows' milk alone, rather than comparing them with a combination of milk and food.

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, but are also typically lower in calcium and are sweeter than cows' milk. They are around five times more expensive than cows' milk and are generally not recommended by health professionals.

Full-fat cows' milk is a suitable choice as the main drink for most toddlers from the age of 1 year, who should be obtaining the majority of their nutrients from a balanced diet rather than relying on fortified milk products. The Department of Health recommends that, from the age of 2 years, children who are growing normally and eating a healthy balanced diet can move on to semi-skimmed cows' milk.

Growing-up milks and toddler milks are offered by the infant formula manufacturers as an alternative to, or to complement, whole 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, but are also typically lower in calcium than cows' milk. Recent additions to the market have been toddler milks aimed at older toddlers aged 2 to 3 years. These milks are offered as a semi-skimmed version of the manufacturers' original growing-up milks. These milks are lower in fat, carbohydrates and protein than growing up milks for younger toddlers, but the vitamin and mineral content remains similar. Typically, they contain less protein and calcium than semi-skimmed cows' milk.

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. 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. The Department of Health recommends that from the age of 2 years, children who are growing normally and eating a healthy balanced diet can move on to semi-skimmed cows' milk. For more information on eating well for children under the age of 5 years see www.firststepsnutrition.org

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 and toddlers' 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. Aptamil, Cow & Gate and SMA growing-up milks all contain vanilla flavouring.

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).

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. In 2010 this sector increased sales by 21.5% (Mintel, 2011). 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 (Advertising Standards Authority, 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 USA 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. In the UK, toddler milks aimed at children aged 2-3 years have recently been launched by Aptamil and Cow & Gate. 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 17 -19.

TABLE 17

The nutritional composition of growing-up milks and toddler milks suitable from around 1 year of age (RTF formulation), compared with full-fat cows' milk

Nutrients per 100ml	Full-fat cows' milk	Aptamil Growing Up Milk 1+ Year	Cow & Gate Growing Up Milk 1-2 Years	Hipp Organic Growing Up Milk	SMA Toddler Milk
For use from age	12 months	12 months	12 months	12 months	12 months
MACRONUTRIENTS					
Energy kcal	67	67	67	66	66
Protein g	3.3	1.9	1.5	1.9	1.8
Whey:casein ratio	20:80	20:80	30:70	20:80	20:80
Carbohydrate g	4.8	8.1	8.5	7.9	7.4
– of which lactose g	3.84	7.8	5.9	7.7	7.4
Carbohydrate source	Lactose, other mono-saccharides and oligosaccharides	Lactose	Lactose, maltodextrins	Lactose	Lactose
Fat g	3.8	3.0	2.8	2.8	3.3
Added LCPs AA	×	×	×	×	✓
DHA	×	×	×	×	✓
MICRONUTRIENTS					
Vitamin A µg	52	65	65	65	70
Vitamin C mg	1.0	14	14	10	12
Vitamin D µg	0.03	1.7	1.7	2.0	1.5
Calcium mg	115	91	84	70	78
Zinc mg	0.4	0.89	0.9	0.7	0.93
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/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 18

The nutritional composition of growing-up milks and toddler milks suitable from around 1 year of age (those available only as powder formulation)

Nutrients per 100ml	Holle Organic Infant Formula 3
For use from age	10 months
MACRONUTRIENTS	
Energy kcal	68
Protein g	1.9
Whey:casein ratio	N/K
Carbohydrate g	8.2
– of which lactose g	5.7
Carbohydrate source	Lactose, maltodextrin, starch
Fat g	3.0
Added LCPs AA	×
DHA	×
LCP source	N/A
MICRONUTRIENTS	
Vitamin A µg	64
Vitamin C mg	13
Vitamin D µg	1.2
Calcium mg	67
Zinc mg	0.6
Iron mg	0.9
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

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 19

The nutritional composition of growing-up milks and toddler milks suitable from around 2 years of age (powder formulation), compared with semi-skimmed cows' milk

Nutrients per 100ml	Semi-skimmed cows' milk	Aptamil Growing Up Milk 2+ Year	Cow & Gate Growing Up Milk 2-3 Years
For use from age	12 months	2 years	2 years
MACRONUTRIENTS			
Energy kcal	46	50	50
Protein g	3.5	1.1	1.1
Whey:casein ratio	20:80	50:50	50:50
Carbohydrate g	4.7	6.6	6.6
– of which lactose g	4.85	5.5	5.5
Carbohydrate source	Lactose, other monosaccharides and oligosaccharides	Lactose, maltodextrins	Lactose, maltodextrins
Fat g	1.7	1.9	1.9
Added LCPs AA	×	×	×
DHA	×	×	×
MICRONUTRIENTS			
Vitamin A μg	20	65	65
Vitamin C mg	2	14	14
Vitamin D μg	0.01	1.7	1.7
Calcium mg	120	110	110
Zinc mg	0.4	0.9	0.9
Iron mg	0.02	1.2	1.2
OTHER			
Prebiotics	×	✓	✓
Taurine	×	✓	✓
Choline	×	✓	✓
Contains soya	×	✓	✓
Contains fish oil	×	×	×
Suitable for vegetarians[1]	✓	×	×
Halal approved	✓	✓	✓

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.

4.12.2 Goats' milk and goats' milk based infant milks

> **Key points**
>
> Goats' milk based infant milks fall outside compositional regulations and therefore should not be given to infants.
>
> Goats' milk based infant milks 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). Their decision was based on concerns surrounding the suitability of goats' milk protein as a protein source in infant formula. EFSA also concluded that that there was insufficient data to support the belief that the incidence of allergic reactions is lower when feeding goats' milk based infant milks compared with cows' milk based infant formula.
>
> Goats' milk based infant milk is unsuitable for babies who are lactose-intolerant as it contains similar levels of lactose to cows' milk based infant formulas.

Goats' milk based infant milks 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 based infant milk, 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 based infant milk 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 based infant milk 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 infant milks compared with cows' milk based infant 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 infant milk 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 use in the first year of life.

4.12.3 Other milks unsuitable for infants and toddlers

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."

5 How much milk is needed and how to make it up safely

5.1 Birth to 6 months

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, and the RCN recommends that parents learn to recognise feeding cues given by their infants. 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. Parents should bottle feed in the same way that they are encouraged to breastfeed, offering one to one contact and meeting each individual infant's needs.

The RCN feeding guidelines use data from Shaw and Lawson (2001) to suggest that healthy infants between the ages of 1 week and 3 months have a milk 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.

All manufacturers of infant milks provide guidelines on their packaging which show typical volumes of formula to use according to the age and weight of the infant. These can be confusing as they vary from brand to brand and are often different from those given by the Royal College of Nursing. All feeding guidelines are however just guidance, and it is important that parents and carers do not become too concerned about their infant accepting the exact amounts of milk as stated on packaging as long as the infant is growing and developing well, as appetites vary between individuals and over time. It is important not to force infants to drink more milk than they wish.

5.2 Older infants

General guidance on feeding infants is found in the Department of Health publication *Birth to Five* (Department of Health, 2011). Guidance devised by The Caroline Walker Trust suggests that, by 7-9 months of age, infants should be getting significant amounts of nutrients from food, and the amount of formula milk consumed should be around 600ml a day (Caroline Walker Trust, 2011).

By 10-12 months of age, the amount of milk consumed should be around 400ml per day as food takes over as the main source of energy and nutrients.

For more information about milk and food in the first year of life, see www.firststepsnutrition.org

TABLE 20
Guidelines for infant feeding by age

Age category	Royal College Nursing feeding guidance	Suggested intake per day
Up to 2 weeks	7–8 feeds per day 60-70ml per feed	420-560 ml/day
	ml/kg/day	150
2 weeks - 2 months	6-7 feeds per day 75-105ml per feed	450-735 ml/day
	ml/kg/day	150
2-3 months	5-6 feeds per day 105-180ml/day	525-1080ml/day
	ml/kg/day	150
3-5 months	5 feeds per day 180-210ml per feed	900-1050ml/day
	ml/kg/day 3-4 months	150
	ml/kg/day 4-5 months	120
About 6 months	4 feeds per day 210-240ml/day	840-960 ml/day
	ml/kg/day	120
	General guidance on feeding after 6 months	
7-9 months	Milk could be offered at breakfast (150ml), lunch (150ml), tea (150ml), and before bed (150ml).	About 600ml per day
10-12 months	Milk could be offered at breakfast (100ml), tea (100ml), and before bed (200ml).	About 400ml per day
1-2 years	Milk could be offered at snack times twice each day (100ml x 2), and as a drink before bed (200ml).	About 400ml per day of whole cows' milk or other suitable milk drink

5.3 Ready-to-feed milks

The main advantage of ready-to-feed (RTF) formula is that no errors can be made when making up the milk as can occur when using powdered formula. In addition, RTF formula is sterile until opened, whilst powdered milks are not. Infants may also accept RTF milk straight from the carton without it 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 and it is not known how parents and carers manage portion sizes of milk when they buy cartons of formula.

5.4 Powdered milks

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).

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.

5.5 How to make up infant milks 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 (Food Standards Agency, 2005; NHS, 2011).

Bacteria multiply most rapidly at temperatures between 7°C and 65°C. Even at 5°C – the temperature recommended for domestic fridges – multiplication will continue but at a much reduced rate. The guidelines are designed to reduce the holding time between reconstituting and using feeds in order to minimise the amount of time during which bacterial multiplication can occur and include recommendations for cleaning and sterilising all feeding equipment and for making up formula.

The guidelines are summarised in Table 21. Following these guidelines can reduce the risk of infection from micro-organisms in powdered infant formula milks.

TABLE 21
Guidelines on the safe preparation and storage of powdered infant formula milks

General recommendations	
Recommendation	**Rationale**
Make up feeds one at a time as the baby needs them.	To reduce the holding time between reconstituting and using feeds in order to minimise the amount of time during which bacterial multiplication can occur.
Sterilise all bottles and equipment to be used.	The infant's immune system is not as well developed as an adult's. This recommendation minimises the risk of illness and infection.
Use tap water to make up feeds. Do not use bottled or artificially softened water.	Bottled water is not sterile and may contain too much sodium or sulphate. If you must use bottled water, check on the label that the sodium (Na) level is less than 200mg/l and the sulphate (SO or SO^4) level is no higher than 250mg/l.
Recommendations for making up a feed using formula milk powder	
Recommendation	**Rationale**
Boil at least 1 litre of fresh tap water in a kettle. Do not use previously boiled water. Leave the 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 that may be present in powdered formula.
Clean and disinfect all equipment and work surfaces to be used, and wash your hands. Keep teat and bottle cap on the up-turned lid of the steriliser. If using a cold water steriliser, shake off excess solution and rinse bottles in cooled boiled water from the kettle. Do not use tap water.	To avoid contamination of bottles with bacteria from tap water or unclean work surfaces.
Pour the correct amount of cooled, boiled water into bottles and double-check the volume before adding the powder. Fill the scoop loosely with milk powder according to the manufacturer's instructions. Level off the scoop using the leveller provided or the back of a clean, dry knife. Always use the scoop provided with the powder you are using. Add the powder to the water in the bottle.	Scoop sizes differ between manufacturers and between different milk powders from the same manufacturer. Too much powder may result in constipation or dehydration.
Holding the edge of the teat, put it on the bottle and then secure the retaining ring and cap. Shake the bottle until the powder is dissolved.	
Cool the formula by holding the bottom of the bottle under cold running water. Do not allow the tap water to touch the bottle cap. Test the temperature of the milk by shaking a small amount onto the back of your wrist. It should be body temperature and feel warm or cool but not hot.	
Discard any of the feed that has not been used.	

- 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.

Source: Food Standards Agency, 2005; NHS, 2011.

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 before 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

The Baby Feeding Law Group produce a DVD – *Infant Milk Explained* – showing how milk can be made up safely. See www.babyfeedinglawgroup.org.uk

6 For more information

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
For breastfeeding information, a list of local support groups, and current breastfeeding news.

The Baby Café
www.thebabycafe.org
A charity that coordinates a network of breastfeeding drop-in centres and other services to support breastfeeding mothers across the UK and other parts of the world.

The Baby Feeding Law Group
www.babyfeedinglawgroup.org.uk
Works for the implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant World Health Assembly Resolutions into legislation in the UK.

Baby Milk Action
T: 01223 464420
E: info@babymilkaction.org
www.babymilkaction.org
A non-profit organisation which aims to save lives and to end the avoidable suffering caused by inappropriate infant feeding.

Best Beginnings
T: 020 7443 7895
www.bestbeginnings.org.uk
For simple, practical visual guidance on breastfeeding, aimed at parents.

BLISS (The Premature Baby Charity)
T: 020 7378 1122
E: information@bliss.org.uk
www.bliss.org.uk
Provides support and care to premature and sick babies across the UK.

The Breastfeeding Manifesto
T: 0208 752 2419
E: info@breastfeedingmanifesto.org.uk
www.breastfeedingmanifesto.org.uk
The Breastfeeding Manifesto was produced in 2006 by over 20 UK organisations working to improve awareness of the health benefits of breastfeeding and its role in reducing health inequalities. The aim of the Breastfeeding Manifesto Coalition is to achieve widespread cross-party support for the Breastfeeding Manifesto, and to ensure that its principles are reflected in government policy and legislation in the UK.

The Breastfeeding Network
T: 0844 412 0995
www.breastfeedingnetwork.org.uk
An independent source of support and information for breastfeeding women and those involved in their care.

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
The trade association representing the manufacturers of products designed to meet the nutritional needs of individuals at different lifestages or with specific health requirements.

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

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

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
Helps mothers to breastfeed through mother-to-mother support, encouragement, information and education.

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

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

The Multiple Births Foundation
T: 0203 313 3519
E: mbf@imperial.nhs.uk
www.multiplebirths.org.uk
Offers support to multiple-birth families, and education and advice to professionals about their special needs.

National Childbirth Trust
T: 0300 33 00 770
www.nct.org.uk
For information to support parents on all aspects of antenatal and postnatal care.

National Institute for Health and Clinical Excellence (NICE)
T: 0845 003 7780
www.nice.org.uk
For public health guidance on ante and postnatal care and nutrition.

NHS Choices
www.nhs.uk
Government-sponsored information site on all aspects of health.

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
A charity that supports human milk banking in the UK.

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

Infant formula companies

Abbott Nutrition
Infant milks produced:
- *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 1+ Year*
- *Aptamil Growing Up Milk 2+ Year*
- *Aptamil Hungry Milk*
- *Aptamil Pepti 1*
- *Aptamil Pepti 2*
- *Aptamil Preterm*

Aptamil
Newmarket House
Newmarket Avenue
White Horse Business Park
Trowbridge
Wiltshire BA14 0XQ
T: 0800 996 1000
www.aptamil.co.uk
www.milupaaptamil4hcps.co.uk

Babynat
Infant milks produced:
- *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 3 Follow-on Milk*
- *Cow & Gate Infant Milk for Hungrier Babies 2*
- *Cow & Gate Growing Up Milk 1-2 years*
- *Cow & Gate Growing Up Milk 2-3 years*
- *Cow & Gate Comfort*
- *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: 0800 977 4000
www.cowandgate.co.uk
www.in-practice.co.uk

Hipp Organic
Infant milks produced:
- *Hipp Organic 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*
- *Nutramigen 1*
- *Nutramigen 2*
- *Nutramigen AA*
- *Pregestimil*

Mead Johnson Nutrition
BMS House
Uxbridge Business Park
Sanderson Road
Uxbridge UB8 1DH
T: 01895 230575
www.enfamil.co.uk

Nutricia
Infant milks produced:
- *Caprilon*
- *Galactomin 17*
- *Galactomin 19*
- *Infatrini*
- *Kindergen*
- *Monogen*
- *Neocate LCP*
- *Pepdite*
- *Pepdite 1+*
- *Pepdite MCT*
- *Pepdite MCT 1+*

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

SMA Nutrition
Infant milks produced:
- *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 Toddler Milk*
- *SMA Wysoy*

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

Appendices

Appendix 1
Background

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, but 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 advances 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).

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 that 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).

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 the International Baby Food Action 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 on the Protection, Support and Promotion of Breastfeeding, 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.

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.

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 formula 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 formula. It is not clear what proportion of parents know the difference between first milk and follow-on formula. 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.

The infant milk market in the UK

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

- Aptamil (Nutricia, owned by Danone)
- Cow & Gate (Nutricia, owned by Danone)
- SMA Nutrition (Wyeth, owned by Pfizer)
- Hipp Organic (owned by Hipp).

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 2010, is shown in Table 22.

TABLE 22
Main brands of infant milks in the UK, their market share (2009), and amounts spent on marketing (2010)

Parent company	Brands of milk	Market share of infant milk sales 2009[1]	Amount spent on marketing in 2010[2]
Danone	Aptamil Cow & Gate	54%	£5.5 million – Aptamil follow-on and growing-up milks £10 million – Cow & Gate follow-on formula and growing-up formula
Pfizer	SMA Nutrition	40%	£4.5 million – SMA follow-on formula
Hipp	Hipp Organic	2%	£203,00 – Hipp follow-on formula

Sources:
1 Business Insights (2009).
2 Mintel (2011).

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 formula 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.

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 USA 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 USA are sold through supported government welfare programmes (Kent, 2006). The Western European market is approximately the same size as the USA 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 Appendix 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).

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 the following (Food Standards Agency, 2007).

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 upper 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 section 4.1.

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).

Appendix 2
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: EC Regulation No. 2073/2005 on Microbiological Criteria for Foodstuffs* 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

European safety reviews of infant milk manufacturers

The European Commission Directorate General for Health and Consumers 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 Consumers 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 Consumers Directorate General, 2007b) and Poland in 2007 (EU Commission Health and Consumers Directorate General, 2007c), and in the UK in 2008 (EU Commission Health and Consumers 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 the next page). 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.

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 described 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 USA, 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 an irregular heartbeat). In 2003 a soy protein based formula produced specifically for the Israeli kosher market and lacking vitamin B1 entered the marketplace, with infants suffering central nervous system damage. Several infants 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 USA 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).

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 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 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.

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 USA.

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.

Glossary

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

Amino acids – 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.

Ig – See *Immunoglobulins (Ig).*

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 2,500g.

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.

SGA – See *Small for gestational age* (SGA) babies.

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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ISBN 978 1 908924 00 1

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