Infant milks in the UK

A practical guide for health professionals

June 2013
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 regularly 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. We would like to thank the A Team Foundation (registered charity number 1077094) for funding the publication of the original report and the Welsh Assembly for a contribution to the continual updating of this resource. 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

The World Health Organization (WHO, 2003) and health departments across the developed and developing world recommend that the best way to feed an infant is exclusive breastfeeding for the first six months of life, and breastfeeding alongside complementary foods after 6 months and for as long as the mother wishes to do so. 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 and there are inherent differences between breastmilk and infant formula (Renfrew et al, 2012)

- 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.
- Infant formula does not promote neurological development as breastmilk does.
- Infant formula has no positive impact on maternal health.
- 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.
- Infant formula requires manufacturing, storage and delivery systems with inherent quality control problems.

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, First Steps Nutrition Trust 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. We strongly support 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.
**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 103.

### 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.

This report provides information on infant milks that can be purchased by families in the UK. Specialised formula available on prescription and fortified milks marketed for children over 1 year of age available worldwide are considered in separate reports and both are available on the First Steps Nutrition Trust website (www.firststepsnutrition.org).
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.

2.1 Frequently asked questions

Below are some frequently asked questions about infant milk that may be useful when answering questions from parents and carers.

Q. Where can mothers get advice to help them continue breastfeeding if they are having difficulties or are thinking about introducing formula milk?

A. Section 6 of this report provides information about helplines and organisations that can offer support to women who are breastfeeding. Many women regret giving up breastfeeding and really value the opportunity to get support to continue, and most health professionals agree that, once formula milk is introduced, breastfeeding continuation is compromised.

Q. Is there a formula milk that is closest to breastmilk?

A. No. It is impossible to recreate breastmilk and all formula milks have to be of a similar composition to comply with EU compositional requirements.

Q. Is there any evidence that a hungry baby formula will help babies to sleep better?

A. No. There is no evidence that milks marketed for hungry babies offer any advantage and it is recommended that first milks are used throughout the first year of life if babies are not breastfed.

Q. If a baby is bringing up small amounts of milk after feeds, do they need a special formula to prevent reflux?

A. Many babies will bring up small amounts of milk after feeds or if they burp. Thickened (anti-reflux) milks or partially hydrolysed milks should be used under medical supervision and many parents often require reassurance and support about what is normal behaviour among infants rather than a more expensive milk product. Anti-reflux formula should not be made up at lower temperatures as currently recommended by manufacturers unless the risks have been assessed by a medical practitioner. If there are serious concerns about reflux, parents or carers should see their GP. We believe these formula should only be used if medically prescribed and should not be available over the counter.
Q. Is soya-based formula a good option if there are allergies in the family?

A. Soy-based formula are not recommended for use in infants under 6 months of age unless recommended by a medical practitioner, due to concerns about allergy to soya, the presence of phyto-oestrogens and the use of glucose as the carbohydrate source. If infants are allergic to cow’s milk, they will be prescribed a suitable formula and it is not recommended that parents and carers use soya formula without taking professional medical advice.

Q. Do babies need follow-on formula after 6 months of age?

A. No. The Department of Health does not recommend that babies move on to follow-on formula and for that reason it is not possible to buy these milks with Healthy Start vouchers. Current advice suggests that parents and carers who use formula milk continue on a first milk throughout the first year as this is closer in composition to breastmilk than follow-on formula.

Q. What temperature should the water be to make up powdered infant formula safely?

A. There is clear guidance in the UK that all powdered infant milks should be made up with water that has been boiled and then cooled to 70°C. A number of manufacturers are suggesting anti-reflux milks are made up at lower temperatures because they ‘clump’ if made up with hotter water. We do not recommend that parents or carers follow these instructions, and milks made up at less that 70°C are not considered suitable for use for infants in the UK unless this is under medical supervision.

Q. When can I use cows’ milk as the main drink?

A. After 1 year of age children should be consuming a good mixed diet and about 400ml of whole animal milk a day. If there are concerns about the quantity and quality of food consumed, health professionals may recommend continued use of formula milk into the second year, but it is important that food is seen as the main source of nutrients for toddlers.

Q. How do toddler milks and growing-up milks differ from whole animal milk?

Toddler milks and growing-up milks contain more of some nutrients such as iron and vitamin D than whole animal milk, but they also contain more sugar and are often flavoured. Children who are eating well do not need additional nutrients from fortified milks in their second year and beyond and there is some evidence that giving lots of extra nutrients to children who don’t need them in fortified drinks may be bad for health in the longer term. For more information about fortified milks for older children see the report Fortified milks for children: A worldwide review of fortified milks marketed for children over 1 year of age. (www.firststepsnutrition.org).
### TABLE 1
A simple guide to choosing milks for infants and toddlers up to 2 years of age

<table>
<thead>
<tr>
<th>Milks suitable for use</th>
<th>Infants 0-6 months</th>
<th>Infants 6 months - 1 year</th>
<th>Babies 1 year - 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast milk</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Whole cows’ milk</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td><strong>FORMULA MILKS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant formula suitable from birth (cows’ milk based) made up at 70°C</td>
<td>✓</td>
<td>✓</td>
<td>✓ (✓)</td>
</tr>
<tr>
<td>Infant formula suitable from birth (cows’ milk based) with added probiotics made up according to manufacturer’s instructions at less than 70°C</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Infant formula marketed for hungrier babies, suitable from birth (cows’ milk based)</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
</tr>
<tr>
<td>Thickened (anti-reflux) infant formula suitable from birth, made up at 70°C</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
</tr>
<tr>
<td>Thickened (anti-reflux) infant formula suitable from birth made up according to manufacturer’s instructions at less than 70°C without medical advice.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Soy protein based infant formula suitable from birth</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
</tr>
<tr>
<td>Lactose-free infant formula suitable from birth</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
</tr>
<tr>
<td>Partially hydrolysed infant formula suitable from birth</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
<td>✓ (✓)</td>
</tr>
<tr>
<td>Follow-on formula suitable from 6 months of age</td>
<td>x</td>
<td>✓ (✓)</td>
<td>✓</td>
</tr>
<tr>
<td>Follow on formula with added probiotics made up at less than 70°C</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

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

**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.
**TABLE 1 (continued)**

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.
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If infants and babies have special medical needs, seek advice from a health professional.

<table>
<thead>
<tr>
<th>Milks suitable for use</th>
<th>Infants 0-6 months</th>
<th>Infants 6 months - 1 year</th>
<th>Babies 1 year - 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTHER MILKS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goodnight milks</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Growing-up milks and toddler milks suitable from around 1 year of age (cows’ milk based)</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Growing-up milks and toddler milks suitable from around 1 year of age (soya protein based)</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Growing-up milks and toddler milks suitable from around 2 years of age</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Goats’ milk formula</td>
<td>x(^1)</td>
<td>x(^1)</td>
<td>✓</td>
</tr>
<tr>
<td>Whole goats’ milk</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Whole sheep’s milk</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Unsweetened calcium-fortified soya milk</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Rice milk</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Oat milk</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Nut milks</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

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

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\(^1\) The current European Commission Directive on Infant Formula and Follow-on Formula and the Infant Formula and Follow-on Formula (England) Regulations (2007) are currently being changed to allow goats’ milk based infant milks and these are likely to be allowed some time later in 2013.

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3 The composition of infant milks

3.1 What ingredients are used to make infant milks?

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 and any subsequent changes to the directive. 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. About 80% of the base powder for infant formula in Europe is made in Ireland and this base powder uses milk protein, demineralised whey and lactose with added vitamins and minerals and other ingredients from other sources. Within these base powders 60% of the ingredients come from Irish milk and 40% of the ingredients are sourced from all over the world. Other milks may be based on soy protein from soya beans, with added vegetable and other oils and maltose, maltodextrin 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 with water in large batches. The wet product is then homogenised, pumped to a heat exchanger for pasteurisation, and then spray-dried to produce a powdered product. This process has the advantage of ensuring a uniform distribution of nutrients throughout the batch, but some nutrients are destroyed. 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. 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. 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.

3.2.1 What are the main differences between breastmilk and infant milks?

Breast milk is unique and it is impossible for any manufacturer to recreate it. Breastmilk is a complex, living fluid that contains all the nutrients needed by an infant, in a form that is easily absorbed, and contains a range of protective substances tailored to each infant and the environment it lives in. Breastmilk contains substances such as lactoferrin, a protein component that helps babies absorb nutrients and which binds iron in the gut so that pathogenic bacteria are inhibited; immunoglobulins and macrophages which protect the infant from infections; specific fatty acids which promote development; growth factors, anti-viral factors, anti-bacterial substances and living white blood cells. It is estimated that there are more than 100 substances present in breastmilk that are not present in artificial infant milks. In addition the milk feed of each mother changes over time, both within the feed and between feeds, to provide the fluid and nutrients the baby needs. The protective effect of breastfeeding for infants and human populations is fully accepted by all scientific agencies and health departments worldwide.

In this report we consider ingredients which are added to infant milks by manufacturers rather than the composition of breastmilk. A recent overview of the nutritional composition and the bioactive factors in human breastmilk can be found in the review by Ballard and Morrow (2013).
### 3.3 The nutritional components of infant milks

#### 3.3.1 Protein

<table>
<thead>
<tr>
<th>Key points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proteins are composed of amino acids, some of which are essential (cannot be synthesised by the human body). The protein requirements of infants have been calculated based on the concentration of amino acids found in mature human milk.</td>
</tr>
</tbody>
</table>

The majority of infant milks available in the UK are based on cows’ (bovine) milk protein but milks can be made using soy protein, and from 2013, the EU Directive on formula and follow on formula milk regulations will be amended to allow goat’s milk protein. Cows’ milk contains more protein than human milk and the proteins present in cows’ 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.

Soy protein can be used in infant formula but a higher minimum protein level is recommended as the biological value is slightly lower than for animal milk.

There has been considerable discussion in the last few years about the role of lower protein formula in managing weight gain in formula-fed infants, and protein contents of most infant formula are now at the lower end of the EU regulations to reflect this.

**α-lactalbumin**

Some infant formulas are enriched with the whey protein α-lactalbumin which is present in higher amounts in human milk compared to cows’ milk.

Insufficient evidence is yet available to support suggestions that lower protein infant formula with higher amounts of α-lactalbumin and some changes to amino-acid content offers the same protection against weight gain or other morbidities as breast feeding.

**Nucleotides**

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 cows’ milk is considerably lower than in human milk. All non-organic standard infant milks for healthy-term infants in the UK are supplemented with nucleotides.

It is suggested 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 and differences in the formula used in trials and between groups in trials make it difficult to interpret evidence related to claimed benefits.
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 these 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 cows’ milk and mature human milk. The total protein content of cows’ 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. Whey and casein are the two major proteins of human milk. Whey, the predominant protein source, 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 cows’ 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 cows’ milk are α-lactalbumin and β-lactoglobulin respectively and α-lactalbumin accounts for 28% of the total protein in human milk and only 3% of the total protein in cows’ milk. Infant formula based on cows’ milk therefore generally have a lower concentration of α-lactalbumin than human milk.

The concentration of some essential amino acids in cows’ milk are lower than in human milk, and the concentrations of tryptophan and cysteine in cows’ milk are approximately half of those in mature human milk (Heine et al, 1991). Therefore, in order for formula milk based on cows’ milk to meet the amino acid requirements of infants, the total protein content of most infant milks has historically been higher than that of breast milk. A higher minimum protein level is recommended for infant formula using soy protein as this will have a lower biological value and may have lower digestibility (Koletzko et al, 2005).

**Lower protein content and weight gain in infants**

It has been established that a higher protein content in infant formula is associated with higher weight in the first two years of life, although there is no evidence that growth is affected in terms of length or height (Koletzko et al, 2009). The protein content of most formula is now at the lower end of EU regulations, typically providing 1.2-1.3g of protein per 100ml compared to older formula which may have had protein contents closer to 2g/100ml. The suggested link between body weight and protein content is thought to be higher post-prandial and fasting circulations of branched chain amino-acids in formula-fed infants compared to breastfed infants. Concentrations of these amino-acids are linked to insulin release, which in turn is linked to metabolic alterations which might be mechanisms for weight gain (Trabulsi et al, 2011). Rapid weight gain, upward crossing of growth percentiles and a greater weight-for-length at 6 months have been identified as risk factors for overweight and obesity later in life (Taveras et al, 2009). These two factors are being linked to suggest that lower protein milks may therefore reduce weight gain in formula-fed infants.
The primary limiting factor in reducing the total protein concentration in infant formula is the ability to provide sufficient quantities of essential amino acids. Enriching whey protein fractions in formula with substantially higher concentrations of α-lactalbumin which contains the limiting amino acids tryptophan and cysteine in higher amounts has been one way in which formula manufacturers have achieved lower protein intakes in formula, and these have not shown any impact on normal growth and development (Lien et al, 2004, Trabulsi et al, 2011). The food company Arla foods which makes formula milk and formula milk ingredients for Denmark, Sweden, Argentina and Germany recently launched a report *How infant formula with Lacprodan® Alpha proteins could provide the key to the tackling the obesity crisis* (Kvistgaard, 2012), and it is likely that similar claims for ‘a new generation of low protein infant formulas’ that can tackle the obesity crisis will become more common in all markets.

In 2012, EFSA revised their conclusion on the suitability of goats’ milk as a protein source for infant and follow-on formula milks. Their revision was based on both a re-evaluation of the original clinical trial and the evidence from a new randomised control trial in 200 Australian infants. The new trial included a breastfed reference group and results from biochemical analysis of blood samples. Their overall conclusion was that protein from goats’ milk can be suitable as a protein for use in infant and follow-on formula milks (EFSA, 2012). The current European Commission Directive on Infant Formula and Follow-on Formula and the Infant Formula and Follow-on Formula (England) Regulations (2007) are currently being changed to allow goats’ milk based infant milks and these are likely to be allowed some time later in 2013.

**α-lactalbumin**

SMA Nutrition First Infant Milk claims it is closer to breast milk as it has an increased proportion of the protein α-lactalbumin compared to other first formula (although all formula have similar low protein contents and all must contain sufficient of all the amino-acids to meet regulations). It is also 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). Research sponsored by the manufacturers of SMA also reported that experimental formula with α-lactalbumin-enriched formula closer to human milk was better tolerated by the infant than standard infant formula, although human milk was tolerated better than both formula (Davis et al, 2008). Feeding-related gastrointestinal events such as constipation and regurgitation were reported to be significantly higher in infants fed on a standard formula compared to infants fed human milk in this study, and were slightly lower in those given an α-lactalbumin-enriched formula, but this was not a significant difference (Davis et al, 2008).

It is likely that all first formula will become α-lactalbumin enriched and there are manufacturers selling bovine α-lactalbumin whey products making considerable claims about their efficacy that are yet to be substantiated and agreed by scientific commitees. These may well become part of marketing approaches around infant milks in the near future but currently insufficient evidence exists to link these formula to equivalent growth in breastfed infants.
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 different 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 found in the vegetable oils commonly used as a fat source in formula milks. Some formula milk manufacturers use vegetable oils with an altered structure that more closely reflects that found in human milk, 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.

The quantity of fat in cows’ milk and human milk is similar, but the component fatty acids are very different. Cows’ milk has higher quantities of the saturated fatty acids lauric acid and myristic acid which may impact on serum cholesterol levels and lipoprotein concentrations and the amount of these fatty acids in formula is restricted. Trans fatty acids are naturally present in cows’ milk and may have negative health implications in high amounts, so there are recommendations that trans fatty acids should not exceed 3% of total fat content in formula (Koletzko et al, 2005).

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, which is used in some brands of infant milks.

Most formula milks use a blend of vegetable oils, but it is not always known which vegetable oils are being 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. Erucic acid has no known nutritional benefit and observations in animals have indicated potential myocardial alterations (Koletzko et al, 2005) and erucic acid levels in formula should not exceed 1% of fat content. 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).

**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). These findings have been given further support by the results of a more recent meta-analysis examining the effect of LCPUFA supplementation on infant cognition which reported no significant effects (Qawasmi at al, 2012).

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”. The validity of this claim is still debated, however, as it is argued that visual acuity develops slowly during the early years of life and early observations of visual measurements in infants are not predictive of later visual functions. Studies would have to follow children for seven years or longer to see if small clinical changes observed in early life had any real impact (Chambers et al, 2013). In addition it is argued that, while DHA-supplemented formula may be slightly better than unsupplemented formula, both are likely to be far less beneficial on visual development than optimal breastfeeding and therefore any claims are misleading (Kent, 2012).

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. The fatty acid palmitate accounts for about 25% of the fatty acids in human milk and about 70% of this palmitate is attached in the middle (sn-2) position of the triacylglycerol molecule. The advantage of this position is that when the enzyme pancreatic lipase cleaves the fatty acid molecules at the sn-1 and sn-3 positions, the palmitate is still attached to the glycerol backbone and, along with the freed fatty acids, can be easily absorbed through the intestine. In vegetable oils, which are the main source of fats in standard formula milks, the palmitate is predominately in the sn-1 and sn-3 positions so that, when hydrolysed by lipase, it becomes free palmitate in the intestine. Free palmitate can form complexes with calcium and these complexes are poorly absorbed (Kennedy et al, 1999). Their formation 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 vegetable oil manufactured by Loders Croklaan 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 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 and, more recently, SMA have supported clinical trials examining the nutritional efficacy of products containing Betapol, they do not market their products as containing Betapol, and SMA tell us that this may not always be the source of the structured vegetable oils included. The use of structured vegetable oils in UK formula milks is limited to the Aptamil, Cow & Gate and SMA Comfort milks and SMA First Infant milk. The structured vegetable oils are variously referred to in marketing literature as a 'special vegetable fat blend', a 'new fat blend' or 'SN-2 enriched fat blend'. There is, however, greater consistency in the ingredients lists, and all products list structured vegetable oils in their ingredients lists.

### 3.3.3 Carbohydrate

<table>
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<th>Key points</th>
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<tr>
<td>Lactose is the main source of carbohydrate in all milk and is present in infant milks either from the milk base used or because it has been added back to a milk made up from its constituent parts.</td>
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Most infant milks for sale in the UK have lactose as the main source of carbohydrate, but soy protein based formula have glucose syrups added and some milks contain maltodextrin.

Some milks marketed for older infants and children have a higher carbohydrate content than whole animal milk and these sweetened milks should be avoided for normal healthy children over 1 year of age.

Lactose is the major carbohydrate of human milk and cows' milk and provides about 40% of the energy. It is also the main source of carbohydrate in the majority of infant milks. In order to achieve the desired level of carbohydrate in infant milks, lactose is usually added back to the skimmed milk powder base. Lactose is considered to provide beneficial effects to gut physiology including prebiotic effects, softening of stools and effective absorption of water, calcium and sodium (Koletzko et al, 2005).

Sucrose and fructose cannot be added to infant formula in the EU as they could cause serious illness and death in young infants with hereditary fructose intolerance. Whilst hereditary fructose intolerance is rare, it could affect up to 1 in every 20,000 infants and as it can be fatal it is not allowed in formula for infants under 6 months of age (Koletzko et al, 2005).

Glucose is generally not considered suitable for routine use in infant formula. However, some infant milks marketed for children with lactose intolerance, and soy protein based milks, may have added glucose or glucose syrups, to achieve the desired energy intake with an acceptable level of sweetness. Infant milk with glucose as the main carbohydrate is likely to contribute to higher levels of dental decay in infants (Grenby and Mistry, 2000).

Maltodextrin is frequently used in infant milks as a carbohydrate source and is mainly derived from maize (corn) or potatoes. Maltodextrin is produced from starch by breaking up the carbon chains to change its structure. Maltodextrin is easily digestible, being absorbed
as rapidly as glucose in the body, and can be either moderately sweet or almost flavourless. It is commonly used as an ingredient in a wide variety of processed foods, particularly where bulk without sweetness is needed at low cost.

Manufacturers sometimes give unusual reasons for the use of carbohydrates in their product. For example, Babynat organic infant milk, which contains maltodextrin, reports on its website that the product:

*has a multi-carbohydrate source: lactose provides simple sugar for rapid assimilation and maltodextrins provide semi-complex sugars for a progressive assimilation.*

More complex carbohydrate fractions are often added in small quantities in infant milk as a source of prebiotics and are usually labelled as oligosaccharides or fructo-oligosaccharides.

A discussion of sugars in growing up milks can be found in section 4.12.1.

### 3.3.4 Vitamins and minerals

<table>
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<th>Key points</th>
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<tr>
<td>Vitamins and minerals are micronutrients, the majority of which cannot by synthesised by the body and must be provided in the diet regularly. Some vitamins and minerals are more easily absorbed from human milk than from formula milk and are added to formula milks in higher amounts to compensate for this.</td>
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<tr>
<td>European regulations set minimum and maximum levels of vitamins and minerals that must be present in infant formula and follow-on formula.</td>
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<tr>
<td>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.</td>
</tr>
<tr>
<td>There is some concern that high iron intakes in infants may impact on growth and immune function, as high iron intakes can impact on zinc and copper absorption.</td>
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<tr>
<td>Claims are made that milks for older infants and toddlers are important for providing enough iron and vitamin D in the diet, but there are no recommendations in the UK for the use of either follow-on formula or growing-up milks in healthy children.</td>
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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. Vitamins and minerals in breast milk are generally considered to be absorbed more efficiently than those in infant milks, and therefore more has typically been added to infant milks than would be found in breast milk, to allow for reduced absorption levels. The bioavailability of calcium and zinc are known to be significantly less in infant milk compared to breastmilk and some other micronutrients may also have lower bioavailability in formula milk, but data showing lower bioavailability for some elements such as copper is now disputed (Koletzko et al, 2005). Low iron
bioavailability from infant milks has long been assumed, but more recent studies show that iron absorption from both breast milk and infant formula is about 15-20% (Koletzko et al, 2005). There is now some concern about the higher amounts of iron in infant milks, since many infants are likely to be absorbing significantly more iron than breastfed babies. This is discussed below.

As some vitamins and minerals 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 and minerals that must be present in infant and follow-on formula milks (see Table 2). Some minerals and trace elements are added to infant milks, but some micronutrients and other elements will be present within the raw ingredients used in the milks themselves. 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.

Iron

During the first 6 months of life, infants can obtain sufficient iron from breastmilk or from an appropriate infant formula. There has been considerable discussion about the optimum level of addition of iron to formula and follow-on formula milks since newer evidence has shown that the bioavailability of iron from breastmilk and modern formula is similar at 15-20%. The current minimum and maximum standards for iron in formula milk are 0.3mg/100kcal and 1.3mg/100kcal and average first milks in the UK contain about 0.6mg/100ml which is almost 10 times higher than the amount found in mature breastmilk. There is now much greater consideration of the potential risks associated with too much iron and there is some evidence of lower copper status and copper absorption in infants fed formula with a higher level of iron (Lönnerdal and Hernell, 1994). There is also some
evidence that excessive iron intakes may result in both a reduced uptake of trace metals including copper and oxidation of lipids, due to the pro-oxidant effects of excess iron (Aggett et al, 2002b). There is evidence of an impact of high iron intakes in children aged 4-9 months who have adequate iron status on growth and on incidence of diarrhoea (Dewey et al, 2002). The regulation of iron absorption is immature in infants and does not reach adult status until after 9 months of age (Dömellof et al, 2002) which means that, whatever amounts of iron are given, they will be absorbed and accumulated which raises the risk of iron overload. The adverse affects on growth observed when high iron is given to infants may be due to interactions with zinc, and this could also impact on the immune system and be related to infection risk (Koletzko et al, 2005).

Follow-on formula are allowed to have iron contents of between 0.6mg/100kcal and 2.0mg/100kcal, with most brands having a content of about 1mg/100ml. A study in Chile among a sample of infants aged 6-12 months who received little additional iron from complementary foods given fortified formula with either 0.2mg iron per 100ml or 1.3mg iron per 100ml reported no significant difference in iron deficiency anaemia between the groups (Walter et al, 1998). This suggests that formula with a relatively small amount of iron appear to prevent iron deficiency anaemia. By 6 months of age in the UK, infants will also be receiving other foods, and many of these complementary foods will also be iron-fortified, so there is considerable potential for very high iron intakes. It is recommended in the UK that infants remain on first formula throughout the first year of life if they are not breastfed. Between 6-12 months, infants have a higher iron requirement of 7.8mg/day, but some of this will be provided by food and some from formula. Formula milk intakes of about 600ml per day will provide almost half the iron needed and the rest can be provided from a diverse diet. New recommendations for follow-on formula composition from ESPGHAN suggest a lower iron content than in the current EU regulations, with suggestions of a range between 0.9mg/100ml and 1.7mg/100ml (Koletzko et al, 2012).

Follow-on formula have been vigorously marketed as a good source of iron for older infants, but it is generally agreed that follow-on formula offers no advantage over standard infant formula after the age of 6 months (Moy, 2000). 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 six 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.
Infant formula based on soy protein will contain phytic acid and this may inhibit iron absorption (Hurrell et al, 1992). The minimum and maximum levels of iron in soya protein based formula must therefore be about 1.5 times higher than in those based on cows’ milk protein.

**Vitamin D**

Vitamin D is essential for bone health in infancy, and breastfed babies under 6 months of age should receive sufficient vitamin D if their mother had a good status in pregnancy. Government advice is that all pregnant women in the UK take vitamin D supplements in pregnancy and when breastfeeding and, if there is any concern about the vitamin status of a breastfed infant, = baby vitamin drops can be recommended from 1 month of age (Department of Health, 2012). Vitamin D is added to infant milks in the form of vitamin D3 (cholecalciferol) and infant formula provides enough vitamin D for the first year of life.

Manufacturers of fortified milks for children over 1 year of age suggest in marketing material that these milks can protect children at risk of low vitamin D intakes, and correctly point out that vitamin D is likely to be available in limited quantities in many toddler diets. It is, however, recommended that all children aged 1-4 years in the UK have daily vitamin drops containing vitamins A, C and D and these are available through the Healthy Start scheme in many areas (www.healthystart.nhs.uk). In addition it is recommended that babies and children spend some time safely outside in the summer sun (following guidance on sun safety) as they will make some vitamin D through the action of summer sunlight on the skin. The use of fortified milks for children over 1 year of age is not recommended in the UK as these milks are high in sugar.

In recent recommendations for the composition of follow-on formula, Koletzko and colleagues at the Early Years Nutrition Academy acknowledge that in many areas there are concerns over the vitamin D status of older children and that a higher maximum vitamin D content for follow-on formula may be useful in some areas (Koletzko et al, 2012). However, they make the point that, where there are vitamin D supplementation programmes in place, the vitamin D content of follow-on formula should be below maximum values.

### 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.

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, 2009).

**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. 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 cows’ 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 cows' 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 Bifidobacterium 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 that was used by Milupa in their Aptamil infant and follow-on formula, but which is no longer named on their products. The specific blend of oligosaccharides used was 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.) Aptamil products now say they contain a patented blend of GOS (90%) and FOS (10%) but older materials prepared for health professionals and available on their professional website, still say that the prebiotic blend used is Immunofortis©.

A large number of pieces of research were compiled by companies promoting formula with added prebiotics to show health benefits. Research used to support the previous use of Immunofortis came from a number of studies, including 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 two 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 and also call it a blend of GOS and FOS.

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 study carried out by Wyeth, USA, in which 154 healthy term infants were randomised to receive formula enriched with either α-lactalbumin or α-lactalbumin and fructo-oligosaccharide. After eight weeks 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.

### 3.3.8 Probiotics

<table>
<thead>
<tr>
<th>Key points</th>
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</thead>
<tbody>
<tr>
<td>Probiotics are live micro-organisms that, when consumed, may have beneficial health effects on the host. Human breastmilk contains probiotics as well as hundreds of different types of prebiotic oligosaccharides. Infant formula based on cows’ milk contains virtually no probiotics.</td>
</tr>
</tbody>
</table>

The rationale for the use of probiotics in infant milks is that they are capable of modifying the balance of intestinal microflora in favour of commensal (beneficial) bacteria over pathogenic bacteria, and this may have a protective effect against some common childhood infections including gastrointestinal infections (GIT) and respiratory tract infections (RTI).

The ESPGHAN Committee on Nutrition have found that there is too much uncertainty to draw any reliable conclusions on the efficacy of probiotics in infant milk and do not recommend their routine use in formula milks for infants.
If parents and carers do choose to use milks with added probiotics, they should be aware that manufacturers’ instructions for reconstitution are at variance with UK recommendations to reconstitute powdered milk with boiled water that has been allowed to cool to 70°C.

Probiotics are live micro-organisms that, when administered in adequate amounts confer a health benefit on the host (FAO/WHO, 2001). The composition of the intestinal microflora is recognised as a major determinant of the well-being of the host (Vandenplas et al, 2011). Human breastmilk contains probiotics as well as hundreds of different types of prebiotic oligosaccharides. Cow’s milk contains virtually none (Teitelbaum and Walker, 2002). In their efforts to provide formula milks which mimic the bifidogenic activity of breastmilk, many formula milk manufacturers have supplemented their infant milk products with prebiotics and/or probiotics. The rationale for their use in infant milks is that they may be capable of modifying the balance of intestinal microflora in favour of commensal (beneficial) bacteria over pathogenic bacteria, which it is suggested may offer a protective effect against some common childhood infections. Studies available to support the use of probiotics alone, or in combination with prebiotics (synbiotic) in formula milks vary greatly in respect of quality, the bacterial strains used, dose and outcomes measured.

There has generally been considered to be 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). The most recent research used to support the use of synbiotics in follow on formula milks comes from a randomised control trial in healthy term infants aged 6 months to 1 year. This study reported that infants who consumed follow-on formula milk supplemented with prebiotic oligosaccharides and the probiotic bacteria *Lactobacillus fermentum* (CECT5716) had fewer incidences of gastrointestinal and upper respiratory tract infections and an overall reduction in incidences of infectious diseases compared to infants who consumed a formula milk containing only prebiotic oligosaccharides (Maldonado et al, 2012). A further study sponsored and co-written by Hipp Organic, designed to examine the safety and tolerance of this formula in infants from 1 to 6 months of age, found a reduction in incidence of gastrointestinal infections only (Gil-Campos et al, 2012).

In a systematic review of randomised control trials (RCTs) that compared the use of infant or follow-on formula milks supplemented with probiotics and/or prebiotics, the ESPGHAN Committee on Nutrition noted that, whilst there was some evidence available to suggest an association between the use of specific probiotics in formula milk and a reduction in the incidence of gastrointestinal infections and antibiotic use, there was too much uncertainty to draw reliable conclusions. Where formula milks were supplemented with synbiotics, the committee found that the quantity of data from RCTs was too sparse and again concluded that there was too much uncertainty to draw reliable conclusions. The routine use of probiotic supplements in formula milk for infants was not recommended. Whilst the committee found no evidence for adverse effects of probiotic use in products for infants, they did raise some specific concerns:

“First, timing, that is, the administration often begins in early infancy, sometimes at birth when the gut microbiota is not fully established, and factors that influence microbiota may
permanently affect the development of the ecosystem. Second, duration, that is, the daily administration of such products is often prolonged (several weeks or months). Last but not least, delivery is in the form of a specific matrix (infant formula) that could be the only source of feeding of an infant." (Braegger et al, 2011).

Babynat follow-on formula and growing up milks are supplemented with *Bifidobacterium lactis*. There is some evidence from clinical trials to suggest that supplementation of infant formula with *B lactis* in combination with *Streptococcus thermophilus* is associated with a reduction in the risk of antibiotic associated diarrhea (Correa et al, 2005), colic and irritability and reduced use of antibiotics (Saavedra et al, 2004). However, in trials where *B lactis* was used alone, significant positive effects were found only for the number of episodes and duration of diarrhoea (Weizman et al, 2005).

In the UK, the only formula milks currently supplemented with probiotics are Babynat 2 Optima follow-on milk and Babynat Babybio 3 growing up milk. Hipp Organic was the only one of the market-leading formula milk companies to add probiotic bacterial strains to their infant milks. However, in spring 2013 the Department of Health informed Hipp that they did not approve of the continued addition of probiotic bacteria to their powdered formula milks. The Department of Health requested additional information on the suitability of the bacterial strain for nutritional use in infant foods and reiterated that the manufacturer’s instruction for reconstitution at 40-50ºC was at variance with Department of Health recommendations that all standard infant formula milk powders should be reconstituted at 70ºC. Reconstituting formula milks containing probiotics at 70ºC would be expected to inactivate any probiotic organisms, presumably eliminating any functional attributes (see section 3.5).

Whilst Hipp Organic conformed to existing EU and UK regulations surrounding the placement of products on the market, the Department of Health did not support their recommendation for a reconstitution temperature of 40-50ºC, and in 2013 re-iterated its recommendation that all standard infant milk powders are re-constituted at 70ºC.

Hipp Organic are now manufacturing their formula milks for use in the UK without probiotics, but existing stocks of milks with probiotics have not been withdrawn and will continue to be available until retailers run out of stock. Unfortunately, whilst healthcare workers have been informed of these changes, the Hipp website has only been partially updated, giving mixed messages to consumers and healthcare professionals. We would recommend a more consistent approach to conveying information about product changes to enable parents and carers to make more effective choices about feeding their infants.

The placing on the market and subsequent removal of milks supplemented with probiotics highlight the need for more stringent regulatory frameworks around the addition of optional ingredients to infant milks. We strongly recommend that pre-approval of products is sought prior to placing them on the market.

### 3.3.9 Additives

Most infant milks contain additives which are needed to ensure that formulations do not separate, acidity is regulated or ingredients resist oxidation, or if liquid formula, that they remain emulsified. 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. The additives that can be used in infant milks are regulated within the EU (Scientific Committee on Food, 1997) with some permitted in all infant formula and follow-on formula, and some permitted in foods for special medical purposes only. Some of the permitted additives and their uses are outlined in Table 2.

Table 2. Examples of additives permitted in infant formula, follow-on formula and foods for special medical purposes for infants and young children

<table>
<thead>
<tr>
<th>Additive</th>
<th>Why is the additive used?</th>
<th>Permitted in infant formula and follow-on formula?</th>
<th>Permitted in foods for special medical purposes?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acacia gum E414</td>
<td>Thickening agent</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Citric acid E330</td>
<td>Preservative</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sucrose esters of fatty acids E473</td>
<td>Emulsifier</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Guar gum E412</td>
<td>Thickening agent</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Lactic acid E270</td>
<td>Preservative</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-ascorbyl palmitate E304</td>
<td>Anti-oxidant</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Locust bean gum E410</td>
<td>Thicken agent</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>Mono- and di- glycerides of fatty acids E471</td>
<td>Emulsifier</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>Pectin E440</td>
<td>Thicken agent</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>Potassium citrate E332</td>
<td>To prevent casein in milk coagulating when heat treated</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Potassium phosphate E340</td>
<td>To prevent casein in milk coagulating when heat treated</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sodium carboxymethyl cellulose E466</td>
<td>Thickening and gelling agent</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>Sodium citrate E331</td>
<td>To prevent casein in milk coagulating when heat treated</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sodium phosphate E339</td>
<td>To prevent casein in milk coagulating when heat treated</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sodium-L-ascorbat E301</td>
<td>Anti-oxidant</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Soya lecithin E322</td>
<td>Emulsifier</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Xanthan gum E415</td>
<td>Thicken agent</td>
<td>×</td>
<td>✓</td>
</tr>
</tbody>
</table>
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 5.6). *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).
The availability of formula milks containing probiotics in the UK has highlighted the lack of consensus surrounding the 70°C reconstitution recommendation. Probiotics are live bacteria (see section 3.3.8), which along with pathogenic bacteria, would not survive reconstitution with water at 70°C. Babynat's preparation guidelines for formula milks containing probiotics suggest a water temperature of 40°C for reconstitution; consequently, both the live bacteria, and any pathogenic bacteria present, would survive the process. It is therefore vital that those choosing to use probiotic milks are aware of the implications of the lower reconstitution temperatures required.

Information on how to make up milks safely can be found in section 5.6.

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 anaemia, bone disease and impaired neurological development (Fewtrell et al, 2011). Infant milks typically have 10 to 40 times more aluminium in them than breast milk (Burrell and Exley, 2010). Warnings have been 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 B₆, folic acid, vitamin B₁₂, 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 and any amendments to the directive. 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 Department of Health.)

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

Table 4 provides a summary of the composition of first milks available in the UK compared with the composition of mature breast milk and the current regulations for composition calculated per 100ml of milk.
TABLE 3
Macro and micronutrient requirements for infant formula and follow-on formula

<table>
<thead>
<tr>
<th></th>
<th>Infant formula</th>
<th>Follow-on formula</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Min/100ml</td>
<td>Max/100ml</td>
</tr>
<tr>
<td>Energy kJ</td>
<td>250</td>
<td>295</td>
</tr>
<tr>
<td>kcal</td>
<td>60</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>Min/100kcal</td>
<td>Max/100kcal</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.8</td>
<td>3.0</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>9.0</td>
<td>14.0</td>
</tr>
<tr>
<td>of which lactose g</td>
<td>4.5</td>
<td>N/S</td>
</tr>
<tr>
<td>Fat g</td>
<td>4.4</td>
<td>6.0</td>
</tr>
<tr>
<td>Linoleic acid mg</td>
<td>300</td>
<td>1200</td>
</tr>
<tr>
<td>Linolenic acid mg</td>
<td>50</td>
<td>N/S</td>
</tr>
<tr>
<td>Prebiotic fibre g</td>
<td>N/S</td>
<td>0.8</td>
</tr>
<tr>
<td>VITAMINS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A µg-RE</td>
<td>60</td>
<td>180</td>
</tr>
<tr>
<td>Vitamin C mg</td>
<td>10</td>
<td>30</td>
</tr>
<tr>
<td>Vitamin E mg</td>
<td>0.5 ±</td>
<td>5.0</td>
</tr>
<tr>
<td>Vitamin D µg</td>
<td>1.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Vitamin K µg</td>
<td>4</td>
<td>25</td>
</tr>
<tr>
<td>Thiamin (B1) µg</td>
<td>60</td>
<td>300</td>
</tr>
<tr>
<td>Riboflavin (B2) µg</td>
<td>80</td>
<td>400</td>
</tr>
<tr>
<td>Niacin µg</td>
<td>300</td>
<td>1500</td>
</tr>
<tr>
<td>Vitamin B6 µg</td>
<td>35</td>
<td>175</td>
</tr>
<tr>
<td>Vitamin B12 µg</td>
<td>0.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Folic acid µg</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Biotin µg</td>
<td>1.5</td>
<td>7.5</td>
</tr>
<tr>
<td>Pantothenic acid µg</td>
<td>400</td>
<td>2000</td>
</tr>
<tr>
<td>MINERALS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium mg</td>
<td>50</td>
<td>140</td>
</tr>
<tr>
<td>Chloride mg</td>
<td>50</td>
<td>160</td>
</tr>
<tr>
<td>Copper µg</td>
<td>35</td>
<td>100</td>
</tr>
<tr>
<td>Fluoride µg</td>
<td>N/S</td>
<td>100</td>
</tr>
<tr>
<td>Iodine µg</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Iron² mg</td>
<td>0.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Magnesium mg</td>
<td>5.0</td>
<td>15</td>
</tr>
<tr>
<td>Manganese µg</td>
<td>1.0</td>
<td>100</td>
</tr>
<tr>
<td>Phosphorus³ mg</td>
<td>25</td>
<td>90</td>
</tr>
<tr>
<td>Potassium mg</td>
<td>60</td>
<td>160</td>
</tr>
<tr>
<td>Selenium µg</td>
<td>1.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Sodium mg</td>
<td>20</td>
<td>60</td>
</tr>
<tr>
<td>Zinc mg</td>
<td>0.5</td>
<td>1.5</td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Choline mg</td>
<td>7</td>
<td>50</td>
</tr>
<tr>
<td>Taurine mg</td>
<td>N/S</td>
<td>12</td>
</tr>
<tr>
<td>Nucleotides mg</td>
<td>N/S</td>
<td>5.0</td>
</tr>
<tr>
<td>Inositol mg</td>
<td>4.0</td>
<td>40</td>
</tr>
<tr>
<td>L-carnitine mg</td>
<td>1.2 ±</td>
<td>N/S</td>
</tr>
</tbody>
</table>

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 4
Macro and micronutrient composition of the three main first infant milks and mature breast milk compared to regulations for infant formula

<table>
<thead>
<tr>
<th>MACRONUTRIENTS</th>
<th>Average for first infant milks</th>
<th>Mature breast milk</th>
<th>Regulations for infant formula (re-calculated by volume)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Per 100ml</td>
<td>Per 100ml</td>
<td>Min/100ml</td>
</tr>
<tr>
<td>Energy kJ</td>
<td>250</td>
<td>295</td>
<td>60</td>
</tr>
<tr>
<td>kcal</td>
<td>66.3</td>
<td>69</td>
<td>60</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.3</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>7.4</td>
<td>7.2</td>
<td>6.0</td>
</tr>
<tr>
<td>of which lactose g</td>
<td>7.1</td>
<td>6-7</td>
<td>3.0</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.5</td>
<td>3.9</td>
<td>2.9</td>
</tr>
<tr>
<td>Linoleic acid mg</td>
<td>490.7</td>
<td>560</td>
<td>200</td>
</tr>
<tr>
<td>Linolenic acid mg</td>
<td>72.3</td>
<td>72</td>
<td>33.5</td>
</tr>
</tbody>
</table>

| VITAMINS | | | | |
| Vitamin A µg-RE | 58 | 62 | 40 | 121 |
| Vitamin C mg | 9.1 | 4.0 | 6.7 | 20.1 |
| Vitamin E mg | 1.0 | 0.34 | 0.34* | 3.35 |
| Vitamin D µg | 1.2 | 0.2-3.1 | 0.67 | 1.68 |
| Vitamin K µg | 5.2 | 0.2-0.9 | 2.68 | 16.75 |
| Thiamin (B1) µg | 66.7 | 20 | 40.2 | 201 |
| Riboflavin (B2) µg | 114.0 | 30 | 53.6 | 268 |
| Niacin µg | 453.3 | 200 | 201 | 1005 |
| Vitamin B6 µg | 46.7 | 10 | 23.45 | 117.25 |
| Vitamin B12 µg | 0.2 | 0.02-0.1 | 0.07 | 0.34 |
| Folic acid µg | 12.3 | 5 | 6.7 | 33.5 |
| Biotin µg | 1.7 | 0.7 | 1.01 | 5.03 |
| Pantothenic acid µg | 336.7 | 250 | 268 | 1340 |

| MINERALS | | | | |
| Calcium mg | 45.3 | 34 | 34 | 94 |
| Chloride mg | 42.3 | 42 | 33.5 | 107.2 |
| Copper µg | 37.7 | 40 | 23.45 | 67 |
| Fluoride µg | 3.1 | 7 | N/S | 67 |
| Iodine µg | 11.3 | 7 | 6.7 | 33.5 |
| Iron** mg | 0.6 | 0.07 | 0.2 | 0.87 |
| Magnesium mg | 4.9 | 3 | 3.35 | 10 |
| Manganese µg | 6.7 | 2.7 | 0.67 | 67 |
| Phosphorus**mg | 25.3 | 15 | 16.8 | 60.3 |
| Potassium mg | 65.0 | 58 | 40.2 | 107.2 |
| Selenium µg | 1.5 | 1 | 0.67 | 6.0 |
| Sodium mg | 16.7 | 15 | 13.4 | 40.2 |
| Zinc mg | 0.5 | 0.3 | 0.34 | 1.0 |

| OTHER | | | | |
| Choline mg | 10 | 16 | 4.7 | 33.5 |
| Taurine mg | 5.1 | 3.8 | N/S | 8.0 |
| Nucleotides mg | 3.0 | 3-7 | N/S | 3.35 |
| Inositol mg | 3.8 | 2.6 | 2.68 | 26.8 |
| L-carnitine mg | 1.1 | 0.7 | 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.
### 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 5.

#### TABLE 5 Infant milks commonly available in the UK

<table>
<thead>
<tr>
<th>Category of infant milk</th>
<th>Names of infant milks included in this category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant formula suitable from birth (cows’ milk based)</td>
<td>Aptamil 1 Babynat 1 Cow &amp; Gate 1 Hipp Organic Combiotic First Infant Milk Holle Organic Infant Formula 1 SMA First Infant Milk</td>
</tr>
<tr>
<td>Infant formula marketed for hungrier babies, suitable from birth (cows’ milk based)</td>
<td>Aptamil Hungry Milk Cow &amp; Gate Infant Milk for Hungrier Babies 2 Hipp Organic Combiotic Hungry Infant Milk SMA Extra Hungry</td>
</tr>
<tr>
<td>Thickened (anti-reflux) infant formula suitable from birth</td>
<td>Aptamil Anti-Reflux(^1) Cow &amp; Gate Anti-Reflux(^1) Enfamil AR(^2) SMA Staydown(^2)</td>
</tr>
<tr>
<td>Soy protein based infant formula suitable from birth</td>
<td>Cow &amp; Gate Infasoy(^2) SMA Wysoy(^2)</td>
</tr>
<tr>
<td>Lactose-free infant formula suitable from birth</td>
<td>Enfamil O-Lac(^2) SMA LF(^2)</td>
</tr>
<tr>
<td>Partially hydrolysed infant formula suitable from birth</td>
<td>Aptamil Comfort Cow &amp; Gate Comfort SMA Comfort</td>
</tr>
<tr>
<td>Follow-on formula suitable from 6 months of age</td>
<td>Aptamil 3 Follow-on Milk Babynat 2 Optima Cow &amp; Gate 3 Follow-on Milk Hipp Organic Combiotic Follow-on Milk Holle Organic Infant Follow-on Formula 2 SMA Follow-on Milk</td>
</tr>
<tr>
<td>Goodnight milks</td>
<td>Hipp Organic Good Night Milk</td>
</tr>
<tr>
<td>Growing-up milks and toddler milks suitable from around 1 year of age (cows’ milk based)</td>
<td>Aptamil Growing Up Milk 1+ Year Babynat Babybio 3 Cow &amp; Gate Growing Up Milk 1-2 Years Hipp Organic Combiotic Growing Up Milk Holle Organic Growing-up Milk 3 SMA Toddler Milk</td>
</tr>
<tr>
<td>Soy protein based growing-up milks and toddler milks suitable from 1 year of age</td>
<td>Alpro Soya Junior+</td>
</tr>
<tr>
<td>Growing-up milks and toddler milks suitable from 2 years of age</td>
<td>Aptamil Growing Up Milk 2+ Year Cow &amp; Gate Growing Up Milk 2-3 Years</td>
</tr>
</tbody>
</table>

1. This milk is currently only available from Boots chemists.
2. These milks are available on prescription but may also be available for purchase in consultation with a pharmacist or at supermarkets.
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 or follow-on formula milks currently on the market suitable for vegans as the vitamin D used is sourced from sheep’s wool. Alpro Soya Junior 1+ is a soya protein based milk for children from 1 year of age. It contains a plant based source of vitamin D and is suitable for vegans.

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. We have been informed by manufacturers that it is the factory that is often given halal approval status rather than the product itself, so that milks of the same brand but of different types may not both be Halal. Cow and Gate powdered milks are all halal for example, but none of the ready-to-feed milks in the same ranges are.
TABLE 6 Infant milks suitable for vegetarians, vegans and for those wanting halal products

Note: Always check the label as formulations can change.

<table>
<thead>
<tr>
<th>Category of infant milk</th>
<th>Suitable for vegetarians</th>
<th>Suitable for vegans</th>
<th>Halal approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant formula suitable from birth (cows’ milk based)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aptamil 1</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Babynat 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cow &amp; Gate 1</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Hipp Organic Combiotic First Infant Milk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holle Organic Infant Formula 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMA First Infant Milk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant formula marketed for hungrier babies, suitable from birth (cows’ milk based)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aptamil Hungry Milk</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Cow &amp; Gate Infant Milk for Hungrier Babies 2</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Hipp Organic Combiotic Hungry Infant Milk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMA Extra Hungry</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Thickened (anti-reflux) infant formula suitable from birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aptamil Anti-Reflux</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Cow &amp; Gate Anti-Reflux</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Enfamil AR</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMA Staydown</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soy protein based infant formula suitable from birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cow &amp; Gate Infasoy</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMA Wysoy</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose-free infant formula suitable from birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enfamil O-Lac</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMA LF</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partially hydrolysed infant formula suitable from birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aptamil Comfort</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Cow &amp; Gate Comfort</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>SMA Comfort</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-on formula suitable from 6 months of age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aptamil 3 Follow-on Milk</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Babynat 2 Optima</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cow &amp; Gate 3 Follow-on Milk</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Hipp Organic Combiotic Follow-on Milk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holle Organic Infant Follow-on Formula 2</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>SMA Follow-on Milk</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goodnight milks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hipp Organic Good Night Milk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growing-up milks and toddler milks suitable from around 1 year of age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aptamil Growing Up Milk 1+ Year</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Babynat Babybio 3</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Cow &amp; Gate Growing Up Milk 1-2 Years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hipp Organic Combiotic Growing Up Milk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holle Organic Growing-up Milk 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMA Toddler Milk</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soy protein based growing-up milks and toddler milks from 1 year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alpro Junior 1+</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growing-up milks and toddler milks suitable from around 2 years of age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aptamil Growing Up Milk 2+ Year</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cow &amp; Gate Growing Up Milk 2-3 Years</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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 primarily 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 some nutrients have to be added in higher quantities than are found in breast milk as they are less well 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)

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Aptamil 1</th>
<th>Babynat 1</th>
<th>Cow &amp; Gate 1</th>
<th>Hipp Organic Combiotic First Infant Milk</th>
<th>Holle Organic Infant Formula 1</th>
<th>SMA First Infant Milk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>66</td>
<td>67</td>
<td>66</td>
<td>66</td>
<td>68</td>
<td>67</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.3</td>
<td>1.35</td>
<td>1.3</td>
<td>1.4</td>
<td>1.4</td>
<td>1.3</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>60:40</td>
<td>60:40</td>
<td>60:40</td>
<td>60:40</td>
<td>60:40</td>
<td>65:35</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>7.4</td>
<td>8.1</td>
<td>7.4</td>
<td>7.0</td>
<td>7.4</td>
<td>7.3</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>7.0</td>
<td>5.0</td>
<td>7.0</td>
<td>6.8</td>
<td>5.9</td>
<td>7.3</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Lactose, oligosaccharides</td>
<td>Maltodextrin</td>
<td>Lactose, oligosaccharides</td>
<td>Oligosaccharides, lactose</td>
<td>Maltodextrin</td>
<td>Lactose</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.4</td>
<td>3.2</td>
<td>3.4</td>
<td>3.5</td>
<td>3.6</td>
<td>3.6</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>DHA</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>In approved ratio</td>
<td>✓</td>
<td>N/A</td>
<td>✓</td>
<td>✓</td>
<td>N/A</td>
<td>✓</td>
</tr>
<tr>
<td>LCP source</td>
<td>Vegetable and fish oils</td>
<td>N/A</td>
<td>Vegetable and fish oils</td>
<td>Vegetable and fish oils</td>
<td>N/A</td>
<td>Fungal and algal oils (vegetable source)</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils (Beta-palmitate)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Prebiotics</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Probiotics</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Inositol</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-carnitine</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Suitable for vegetarians¹</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Halal approved</td>
<td>✓</td>
<td>x</td>
<td>✓²</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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

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

2 Powder formulation only.
4.5 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 is 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)

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Aptamil Hungry Milk</th>
<th>Cow &amp; Gate Infant Milk for Hungrier Babies 2</th>
<th>Hipp Organic Combiotic Hungry Infant Milk</th>
<th>SMA Extra Hungry</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>66</td>
<td>66</td>
<td>67</td>
<td>67</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.6</td>
<td>1.6</td>
<td>1.6</td>
<td>1.6</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>20:80</td>
<td>20:80</td>
<td>20:80</td>
<td>20:80</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>7.8</td>
<td>7.8</td>
<td>7.3</td>
<td>7.0</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>7.4</td>
<td>7.4</td>
<td>7.1</td>
<td>7.0</td>
</tr>
<tr>
<td><strong>Source of added carbohydrates</strong></td>
<td>Lactose, oligosaccharides</td>
<td>Lactose, oligosaccharides</td>
<td>Lactose, oligosaccharides</td>
<td>Lactose</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.1</td>
<td>3.1</td>
<td>3.5</td>
<td>3.6</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>DHA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>In approved ratio</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>LCP source</td>
<td>Vegetable and fish oils</td>
<td>Vegetable and fish oils</td>
<td>Vegetable and fish oils</td>
<td>Fungal and algal oils (vegetable source)</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Prebiotics</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Probiotics</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Inositol</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Choline</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-carnitine</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Suitable for vegetarians (^1)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>✓ (^2)</td>
</tr>
<tr>
<td>Halal approved</td>
<td>✓</td>
<td>✓(^2)</td>
<td>x</td>
<td>✓</td>
</tr>
</tbody>
</table>

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.

3  Powder formulation only.
4.6 Thickened (anti-reflux) infant formula suitable from birth

**Key points**

Thickened (anti-reflux) infant formula with added rice, corn starch or carob bean gum are suggested to help improve gastro-oesophageal reflux. These products can be medically prescribed in the UK but are also available over the counter.

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.

Manufacturer guidance on how to make up thickened formula are not in line with current recommendations for making up infant formula safely, since they suggest using cold or hand-hot water rather than water boiled and left to cool to $70^\circ$C. Where these milks are prescribed advice should be taken on how to make them appropriately.

These are milks for special medical purposes and should only be used under medical supervision (as must be stated on the label by law), so we do not advise families to self-medicate their infants with these formula.

Thickened infant formulas have been formulated to help improve gastro-oesophageal reflux (bringing up milk into the oesophagus) and vomiting or spitting up feeds in formula-fed infants. Whilst reflux does not generally result in health 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 four thickened infant formulas available: Aptamil Anti-Reflux (Danone); Cow & Gate Anti-Reflux (Danone); Enfamil AR (Mead Johnson) and SMA Staydown (SMA Nutrition). All of these formulas are available on prescription, can be purchased over the counter at pharmacies without a prescription, and can all be used from birth. Aptamil Anti-Reflux and Cow & Gate Anti-Reflux are the most recent thickened milks to become available on the UK market, and the on-pack nutritional information suggests that the products have an identical composition. The whey:casein ratio of these milks is 20:80 and this is suggested as slowing gastric emptying.

The thickening agent used in Enfamil AR is rice starch and in SMA Staydown it is corn starch. SMA Nutrition suggests that rice starch is associated with constipation, based on evidence from a study by Ramirez-Mayans et al (2003) where 3 out of 24 infants being fed milk containing 5% (5g/100ml) rice starch suffered constipation. Enfamil suggest that rice starch is the natural choice for thickening milks as it is typically used as a first weaning food, and uses evidence from a study by Vanderhoof et al (2003) which concluded that Enfamil AR did not cause constipation. SMA suggests 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. The thickening agent used in Danone products is carob bean gum.
and it is suggested that this is not split by salivary amalyse and therefore maintains the viscosity of the feed into the stomach (Wenzl et al, 2003).

SMA supports the use of its formula for managing anti-reflux by reference to clinical trials (Ramirez-Mayans et al, 2003; Xiniás 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.

Danone support the use of their anti-reflux product by reference to clinical trials using their products. A prospective, double-blind trial in 20 infants reported that there was no change in the regurgitation frequency between groups receiving the thickened formula and the placebo group, but there was a significant decrease in the length of time of oesophageal acid exposure (Vandenplas et al, 1994). In a further placebo-controlled crossover study in 14 healthy infants, the frequency and amount of regurgitation were reduced after consuming an infant formula thickened with carob bean gum, compared to when the infants were fed the same formula without thickener. However, there was no significant reduction in the occurrence or duration of acid gastro-oesophageal reflux. The decrease in regurgitation was thought to have resulted from the decrease in the number of non-acid GER episodes when thickened formula milk was consumed (Wenzl et al, 2003).

A more recent clinical trial including 60 infants and their carers was designed to evaluate the efficacy of parental reassurance in combination with different types of formula milk. This trial reported that regurgitation frequency was reduced in all of the three groups, and there was no significant difference in regurgitation frequency between groups receiving standard formula milk, formula milk thickened with rice cereal, or formula thickened with bean gum. All participating parents were reassured in the same way. The only significant difference between groups was that infants receiving formula milk thickened with bean gum experienced a greater increase in weight during the trial. The authors suggest that this effect may be due to the greater (although not statistically significant) decrease in regurgitation frequency in this group (Hegar et al, 2008).

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).
Thickened anti-reflux formula are considered to be foods for special medical purposes (FSMP) rather than standard formula and they should therefore be labelled with the statement: ‘For use under medical supervision’.

The Department of Health has not asked manufacturers to change the instructions for making up the formula in line with recommendations for standard formula because they are FSMP, and currently manufacturers suggest they are made up with cold or hand-hot water rather than with water boiled and cooled to 70°C. We do not recommend that infant formula is given to infants if it has not been made up using standard instructions, unless the risks have been assessed under medical supervision. Anti-reflux formula made up with water at 70°C is likely to become lumpy and this may be a barrier to their use if they are purchased over the counter.

The nutritional composition and ingredients used in thickened (anti-reflux) infant formula suitable from birth are given in Table 9.
TABLE 9
The nutritional composition of thickened (anti-reflux) infant formula suitable from birth

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Aptamil Anti-Reflux</th>
<th>Cow &amp; Gate Anti-Reflux</th>
<th>Enfamil AR</th>
<th>SMA Staydown</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>66</td>
<td>66</td>
<td>69</td>
<td>67</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>1.6</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>20:80</td>
<td>20:80</td>
<td>20:80</td>
<td>20:80</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>6.8</td>
<td>6.8</td>
<td>7.6</td>
<td>7.0</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>6.1</td>
<td>6.1</td>
<td>4.3</td>
<td>5.2</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Lactose, maltodextrin, carob bean gum</td>
<td>Lactose, maltodextrin, carob bean gum</td>
<td>Lactose, rice starch, glucose polymers</td>
<td>Lactose, gelatinised maize starch</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.5</td>
<td>3.5</td>
<td>3.5</td>
<td>3.6</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>DHA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>In approved ratio</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>LCP source</td>
<td>Vegetable and fish oils</td>
<td>Vegetable and fish oils</td>
<td>Single cell oils (vegetable source)</td>
<td>Fungal and algal oils (vegetable source)</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Prebiotics</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Inositol</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-carnitine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>✓</td>
<td>✓</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>Suitable for vegetarians</td>
<td>×</td>
<td>×</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Halal approved</td>
<td>ANS</td>
<td>ANS</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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

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

**Key points**

Soy protein based infant formula has protein from soya beans, and the carbohydrate source is glucose syrup. They contain no cows’ milk protein or lactose.

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 and carers should always seek advice before feeding their infant soy protein based infant formula.

Soy protein based milks combine protein from soya beans with water, vegetable oils, glucose syrup and vitamins and minerals.

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.

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).

The required composition of soy protein based infant formula is different to that of cows’ milk based formula for a number of micronutrients including iron and phosphorus due to differences in bioavailability.

Soy protein based formula are suitable for vegetarians but not for vegans.

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

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Cow &amp; Gate Infasoy</th>
<th>SMA Wysoy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>66</td>
<td>67</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.6</td>
<td>1.8</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>7.0</td>
<td>6.9</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Glucose syrup</td>
<td>Glucose syrup</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.5</td>
<td>3.6</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>DHA</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Prebiotics</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Inositol</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-carnitine</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Suitable for vegetarians</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Halal approved</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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 infant formula suitable from birth

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Enfamil O-Lac</th>
<th>SMA LF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>68</td>
<td>67</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.42</td>
<td>1.5</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>N/K</td>
<td>60:40</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>7.2</td>
<td>7.2</td>
</tr>
<tr>
<td>– of which lactose mg</td>
<td>less than 7</td>
<td>less than 6.7</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Glucose polymers, citrate</td>
<td>Dried glucose syrup</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.7</td>
<td>3.6</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>DHA</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>In approved ratio</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>LCP source</td>
<td>Single cell oils (vegetable source)</td>
<td>Fungal and algal oils (vegetable source)</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓¹</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils</td>
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<td>✗</td>
</tr>
<tr>
<td>Prebiotics</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Inositol</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-carnitine</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Suitable for vegetarians²</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Halal approved</td>
<td>✗</td>
<td>✓</td>
</tr>
</tbody>
</table>

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’ and are based on modified cows’ milk with 100% whey protein.

No convincing evidence is presented by manufacturers to support the efficacy of these milks in preventing colic, wind, gastrointestinal discomfort or regurgitation.

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 three partially hydrolysed infant formulas available: Aptamil Comfort, Cow & Gate Comfort and SMA Comfort. They are all modified cows’ milk formula based on 100% whey protein. All three products contain lactose at lower levels than those found in standard infant formula milks and all contain structured vegetable oils. Aptamil Comfort and Cow & Gate Comfort milks also contain non-digestible oligosaccharides and added starch for a thicker feed. Aptamil Comfort and Cow & Gate Comfort milks are suggested by the manufacturer as suitable for infants experiencing colic and constipation and these products have an identical nutrient profile. SMA Comfort milk is formulated to ease mild digestive discomfort in terms of minimising fussing and wind and helping to resolve stooling difficulties such as constipation.

Manufacturers support the use of their products by reference to clinical trials, but trial data presented is not convincing. In a clinical trial including 932 infants with minor feeding problems, a reduction in the number of episodes and frequency of colic and regurgitation and an increase in the number and frequency of stools were observed in infants fed a ‘comfort milk’. However, no control group was included in the study so it was not possible to establish whether the amelioration of symptoms was due to the comfort formula used (Savino et al, 2003).

In a further prospective, randomised controlled trial, 267 infants with symptoms of colic were fed comfort milk for a period of two weeks. Parental reports of episodes of colic and crying were lower in the group fed comfort milk than in the group fed standard infant formula. As infants in the control group also received simethicone, an anti-foaming agent taken orally to reduce bloating, discomfort and pain caused by excess gas in the stomach or intestinal tract, it was difficult to establish links between formula type and amelioration of symptoms (Savino, 2006).

Danone products are also supported by reference to a randomised, double-blind clinical trial designed to evaluate the nutritional adequacy and bifidogenicity of a comfort infant formula in which 154 healthy infants were fed either a standard infant formula or a Numico brand comfort formula containing non-digestible oligosaccharides over a 12-week period. Satisfactory growth was supported for both formula milks and higher counts of bifidobacteria were observed in the faeces of the group fed comfort formula. It is interesting
that this trial also reported that there were no significant differences in formula tolerance between the groups and that the number and reasons for study drop-out were not significantly different between the groups. The main reasons for drop-out were feeding problems including flatulence, stool quality or vomiting/pussetting (Schmelzle et al, 2003). This suggests that the incidence of feeding problems was unrelated to the feeding regime. Similarly, in a clinical trial reported in an oral presentation at a conference, and used in support of SMA Comfort milk, gastrointestinal tolerance between healthy infants fed either a standard formula milk or SMA Comfort milk were not statistically significant although there were slightly less formed or hard stools in the group receiving comfort milk (Beller et al, 2011).

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

The National Institute 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).

Comfort milks are the most expensive infant milks commonly available, with Aptamil and Cow & Gate Comfort milks currently 16-17% more expensive than their standard first infant formula and SMA Comfort 37% more expensive than SMA First Infant Milk.

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

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Aptamil Comfort</th>
<th>Cow &amp; Gate Comfort</th>
<th>SMA Comfort</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>66</td>
<td>66</td>
<td>67</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.5</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>100:0</td>
<td>100:0</td>
<td>100:0</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>7.2</td>
<td>7.2</td>
<td>7.1</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>2.7</td>
<td>2.7</td>
<td>3.9</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Glucose syrup, potato and corn starch, oligosaccharides, lactose</td>
<td>Glucose syrup, potato and corn starch, oligosaccharides, lactose</td>
<td>Lactose, corn syrup solids, maltodextrin</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.4</td>
<td>3.4</td>
<td>3.6</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>DHA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Prebiotics</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Inositol</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-carnitine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Suitable for vegetarians</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Halal approved</td>
<td>ANS</td>
<td>ANS</td>
<td>✓</td>
</tr>
</tbody>
</table>

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 marketed 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 marketed 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 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 (Lozzof 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. A further discussion of the role of iron in infant and child health can be found in section 3.3.4.

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*

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Energy kcal</th>
<th>Protein g</th>
<th>Carbohydrate g</th>
<th>Fat g</th>
<th>Vitamin D µg</th>
<th>Calcium mg</th>
<th>Iron mg</th>
<th>Zinc mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aptamil 1</strong></td>
<td>66</td>
<td>1.3</td>
<td>7.4</td>
<td>3.4</td>
<td>1.2</td>
<td>47</td>
<td>0.53</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Aptamil 3 Follow-on Milk</strong></td>
<td>68</td>
<td>1.4</td>
<td>8.6</td>
<td>3.0</td>
<td>1.4</td>
<td>61</td>
<td>1.0</td>
<td>0.51</td>
</tr>
<tr>
<td><strong>Cow &amp; Gate 1</strong></td>
<td>66</td>
<td>1.3</td>
<td>7.4</td>
<td>3.4</td>
<td>1.2</td>
<td>47</td>
<td>0.53</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Cow &amp; Gate 3 Follow-on Milk</strong></td>
<td>68</td>
<td>1.4</td>
<td>8.6</td>
<td>3.0</td>
<td>1.5</td>
<td>68</td>
<td>1.0</td>
<td>0.57</td>
</tr>
<tr>
<td><strong>Hipp Organic Infant Formula 1</strong></td>
<td>66</td>
<td>1.4</td>
<td>7.0</td>
<td>3.5</td>
<td>1.2</td>
<td>60</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Hipp Organic Combiotic Follow-On Milk</strong></td>
<td>70</td>
<td>1.5</td>
<td>7.9</td>
<td>3.5</td>
<td>1.2</td>
<td>73</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>SMA First Infant Milk</strong></td>
<td>67</td>
<td>1.3</td>
<td>7.3</td>
<td>3.6</td>
<td>1.2</td>
<td>42</td>
<td>0.64</td>
<td>0.6</td>
</tr>
<tr>
<td><strong>SMA Follow-on Milk</strong></td>
<td>67</td>
<td>1.5</td>
<td>7.2</td>
<td>3.6</td>
<td>1.5</td>
<td>50</td>
<td>1.2</td>
<td>0.8</td>
</tr>
</tbody>
</table>
### TABLE 14
The nutritional composition of follow-on formula suitable from 6 months of age

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Aptamil 3 Follow-on Milk</th>
<th>Babynat 2 Optima</th>
<th>Cow &amp; Gate 3 Follow-on Milk</th>
<th>Hipp Organic Combiotic Follow-on Milk</th>
<th>Holle Organic Infant Formula 2</th>
<th>SMA Follow-on Milk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>68</td>
<td>66</td>
<td>68</td>
<td>70</td>
<td>69</td>
<td>67</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.4</td>
<td>1.44</td>
<td>1.4</td>
<td>1.5</td>
<td>1.6</td>
<td>1.5</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>50:50</td>
<td>20:80</td>
<td>20:80</td>
<td>N/K</td>
<td>N/K</td>
<td>60:40</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>8.6</td>
<td>8.24</td>
<td>8.6</td>
<td>7.9</td>
<td>8.2</td>
<td>7.2</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>6.1</td>
<td>3.38</td>
<td>8.3</td>
<td>7.6</td>
<td>4.9</td>
<td>7.2</td>
</tr>
<tr>
<td>Carbohydrate source</td>
<td>Malto-dextrin, lactose, oligosaccharides</td>
<td>Corn malto-dextrin, lactose</td>
<td>Lactose, oligosaccharides</td>
<td>Lactose, oligosaccharides</td>
<td>Malto-dextrin, corn starch</td>
<td>Lactose</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.0</td>
<td>3.07</td>
<td>3.0</td>
<td>3.5</td>
<td>3.3</td>
<td>3.6</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>DHA</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>In approved ratio</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>✗</td>
</tr>
<tr>
<td>LCP source</td>
<td>Fish oils</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Fungal and algal oils (vegetable source)</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x¹</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Prebiotics¹</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Probiotics²</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>x</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Inositol</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>x</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>x</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>x</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>x</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Suitable for vegetarians³</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Halal approved</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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 Only powder formulations contain probiotics as the temperatures used in preparing RTF destroy live cultures.
3 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 Powder formulation only.
4.11 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

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Hipp Organic Good Night Milk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>70</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.6</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>N/K</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>8.0</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>5.0</td>
</tr>
<tr>
<td>Carbohydrate source</td>
<td>Organic corn starch, lactose, rice flakes and buckwheat flakes</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.5</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td></td>
</tr>
<tr>
<td>DHA</td>
<td>x</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
</tr>
<tr>
<td>Vitamins meeting regulations</td>
<td>✓</td>
</tr>
<tr>
<td>Minerals meeting regulations</td>
<td>✓</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
</tr>
<tr>
<td>Structured vegetable oils</td>
<td>x</td>
</tr>
<tr>
<td>Prebiotics</td>
<td>x</td>
</tr>
<tr>
<td>Nucleotides</td>
<td>x</td>
</tr>
<tr>
<td>Inositol</td>
<td>x</td>
</tr>
<tr>
<td>Taurine</td>
<td>x</td>
</tr>
<tr>
<td>Choline</td>
<td>x</td>
</tr>
<tr>
<td>Added antioxidants</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>x</td>
</tr>
<tr>
<td>Suitable for vegetarians</td>
<td>x</td>
</tr>
<tr>
<td>Halal approved</td>
<td>x</td>
</tr>
</tbody>
</table>

AA = arachidonic acid      DHA = docosahexaenoic acid      LCP = long chain polyunsaturated fatty acid
N/K = not known
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 healthy 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 and 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 at least three 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
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).

**Sugars in growing-up milks and toddler milks**

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. 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). Growing-up milks and toddler milks contain almost twice as much sugar per 100ml as cows’ milk, and Aptamil, Cow & Gate and SMA growing-up milks all contain vanilla flavouring. 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.

The naturally occurring sugar in milk is lactose, but this does not give milk an overly sweet taste. Adding sugars to fortified milks serves a number of purposes for manufacturers:

- The sweet taste it gives the product is attractive to children.
- The addition of extra carbohydrate allows the protein and fat content to be moderated.
- Sugars are cheap ingredients, particularly components such as maltodextrin.

Manufacturers rarely provide clear data on the added sugar content of their fortified milks in a form which allows the consumer to clearly see how much additional sugar they provide compared with whole animal milk.

**What are the health consequences of additional sugar in the diets of children?**

Plain animal milk has a composition which may be protective against the development of insulin resistance and chronic disease (Pereira et al, 2002) and therefore if alternatives to this increase risk of chronic disease, this is of concern to public health. The consumption of easily absorbed sugars can stimulate excessive postprandial hypoglycaemia and insulinaemia, which may be linked to risks of obesity, type 2 diabetes and coronary heart disease (Brand-Miller et al, 2013).

Fortified milk with glucose sugars is likely to contribute to higher levels of dental decay in infants and children (Grenby and Mistry, 2000) and the added sugars in many milks may present risk of oral ill-health to older children. The health risks associated with regular consumption of fortified sweetened milk products by young children could therefore be significant.

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, 2012). 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). 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 16-18.
**TABLE 16**
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

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Full-fat cows’ milk</th>
<th>Aptamil Growing Up Milk 1+ Year</th>
<th>Cow &amp; Gate Growing Up Milk 1-2 Years</th>
<th>Hipp Organic Combiotic Growing Up Milk</th>
<th>SMA Toddler Milk</th>
</tr>
</thead>
<tbody>
<tr>
<td>For use from age</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
</tr>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>67</td>
<td>67</td>
<td>67</td>
<td>66</td>
<td>66</td>
</tr>
<tr>
<td>Protein g</td>
<td>3.3</td>
<td>1.5</td>
<td>1.5</td>
<td>2.0</td>
<td>1.8</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>4.8</td>
<td>8.5</td>
<td>8.5</td>
<td>7.9</td>
<td>7.4</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>3.84</td>
<td>6.0</td>
<td>5.9</td>
<td>7.7</td>
<td>7.4</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Lactose, other monosaccharides and oligosaccharides</td>
<td>Maltodextrin, oligosaccharides, lactose</td>
<td>Lactose, oligosaccharides, maltodextrin</td>
<td>Lactose, oligosaccharides</td>
<td>Lactose</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.8</td>
<td>2.8</td>
<td>2.8</td>
<td>2.8</td>
<td>3.3</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>DHA</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A µg</td>
<td>52</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>70</td>
</tr>
<tr>
<td>Vitamin C mg</td>
<td>1.0</td>
<td>14</td>
<td>14</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Vitamin D µg</td>
<td>0.03</td>
<td>1.7</td>
<td>1.7</td>
<td>2.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Calcium mg</td>
<td>115</td>
<td>84</td>
<td>84</td>
<td>70</td>
<td>78</td>
</tr>
<tr>
<td>Zinc mg</td>
<td>0.4</td>
<td>0.9</td>
<td>0.9</td>
<td>0.7</td>
<td>0.93</td>
</tr>
<tr>
<td>Iron mg</td>
<td>0.05</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prebiotics</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Probiotics</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Taurine</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Suitable for vegetarians</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Halal approved</td>
<td>✓</td>
<td>x²</td>
<td>x³</td>
<td>x</td>
<td>✓</td>
</tr>
</tbody>
</table>

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.
2 Powder formulation only is vegetarian.
3 Powder formulation only is halal approved.
### TABLE 17
The nutritional composition of growing-up milks and toddler milks suitable from around 1 year of age (those available only as powder formulation)

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Babynat Babybio 3</th>
<th>Holle Organic Growing-up Milk 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For use from age</strong></td>
<td>10 months</td>
<td>10 months</td>
</tr>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>66</td>
<td>68</td>
</tr>
<tr>
<td>Protein g</td>
<td>1.62</td>
<td>1.9</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>20:80</td>
<td>N/K</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>8.07</td>
<td>8.2</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>3.48</td>
<td>5.7</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Maltodextrin, lactose</td>
<td>Starch, maltodextrin</td>
</tr>
<tr>
<td>Fat g</td>
<td>3.07</td>
<td>3.0</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>DHA</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A µg</td>
<td>81</td>
<td>64</td>
</tr>
<tr>
<td>Vitamin C mg</td>
<td>10.1</td>
<td>13</td>
</tr>
<tr>
<td>Vitamin D µg</td>
<td>1.27</td>
<td>1.2</td>
</tr>
<tr>
<td>Calcium mg</td>
<td>70</td>
<td>67</td>
</tr>
<tr>
<td>Zinc mg</td>
<td>0.59</td>
<td>0.6</td>
</tr>
<tr>
<td>Iron mg</td>
<td>1.24</td>
<td>0.9</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prebiotics</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Probiotics</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Taurine</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Choline</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Contains soya</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Suitable for vegetarians¹</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Halal approved</td>
<td>×</td>
<td>×</td>
</tr>
</tbody>
</table>

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 18
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

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Semi-skimmed cows’ milk</th>
<th>Aptamil Growing Up Milk 2+ Year</th>
<th>Cow &amp; Gate Growing Up Milk 2-3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For use from age</strong></td>
<td>12 months</td>
<td>2 years</td>
<td>2 years</td>
</tr>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>46</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Protein g</td>
<td>3.5</td>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>Whey:casein ratio</td>
<td>20:80</td>
<td>50:50</td>
<td>50:50</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>4.7</td>
<td>6.6</td>
<td>6.6</td>
</tr>
<tr>
<td>– of which lactose</td>
<td>4.85</td>
<td>5.5</td>
<td>5.5</td>
</tr>
<tr>
<td>Source of added carbohydrate</td>
<td>Lactose, other monosaccharides and oligosaccharides</td>
<td>Lactose, oligosaccharides, maltodextrin</td>
<td>Lactose, oligosaccharides, maltodextrin</td>
</tr>
<tr>
<td>Fat g</td>
<td>1.7</td>
<td>1.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>DHA</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A µg</td>
<td>20</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Vitamin C mg</td>
<td>2</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Vitamin D µg</td>
<td>0.01</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Calcium mg</td>
<td>120</td>
<td>110</td>
<td>110</td>
</tr>
<tr>
<td>Zinc mg</td>
<td>0.4</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Iron mg</td>
<td>0.02</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prebiotics</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Taurine</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Choline</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains soya</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Suitable for vegetarians(^1)</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Halal approved</td>
<td>✓</td>
<td>x(^2)</td>
<td>x(^2)</td>
</tr>
</tbody>
</table>

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 is halal approved
4.12.2 Soy protein based growing-up milks and toddler milks

Key points
Soya based milks for children from about 1 year of age are offered by the manufacturer as an alternative to standard soya milk.

Alpro Soya Junior 1+ provides more energy than standard unsweetened soya milk as it contains greater quantities of fats and carbohydrates, but it contains less protein than standard unsweetened soya milk. Whilst all soya milks are generally fortified with calcium and vitamins B₁₂, niacin, riboflavin, vitamin D and vitamin E, Alpro Soya Junior 1+ is also fortified with iron and vitamin C and is sweetened with fructose-glucose syrup.

From the age of 1 year, children should be obtaining the majority of their nutrients from a balanced diet rather than relying on fortified milk products. Whilst the majority of soya protein based milks are fortified products, standard, unsweetened, soya milk is a suitable alternative milk drink for children.

The typical ingredients used to make standard soya milks are water, hulled soya beans, sugars and vegetable oils. Alpro Soya Junior 1+ is a liquid soya based milk and the first soya milk to be marketed in the UK specifically for children from 1 year of age. It provides more energy than standard soya milk due to the higher proportion of fats and carbohydrates it contains. The protein content of Alpro Soya Junior 1+ is slightly lower than is typical of standard soya milks. Whilst standard soya milks are generally fortified with calcium and vitamins B₁₂, niacin, riboflavin, vitamin D and vitamin E, Alpro Soya Junior 1+ is also fortified with iron and vitamin C.

Standard soya milks are generally sweetened with sugar, however there are unsweetened versions available. Alpro Soya Junior 1+ is sweetened with fructose-glucose syrup and contains flavouring. The flavourings used are nature identical, which means that they are natural flavours which have been changed by enzymes or other chemical process to mimic the flavour required. 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 (see section 4.12.1).

From 1 year of age, children 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 products to supply them. However, for children who require soya milk rather than cows’ milk, there is no unfortified milk alternative available and it is recommended that the most suitable alternative for toddlers who require a soy protein based milk drink is standard unsweetened, calcium-fortified soya milk.

The nutritional composition and ingredients used in Alpro Soya Junior 1+ and a typical supermarket own brand, unsweetened soya milk are given in Table 19.
**TABLE 19**
The nutritional composition of soy protein based growing-up milks suitable from around 1 year of age, compared with standard unsweetened soya milk

<table>
<thead>
<tr>
<th>Nutrients per 100ml</th>
<th>Unsweetened calcium fortified soya milk</th>
<th>Alpro Soya Junior 1+</th>
</tr>
</thead>
<tbody>
<tr>
<td>For use from age</td>
<td>12 months</td>
<td>12 months</td>
</tr>
<tr>
<td><strong>MACRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy kcal</td>
<td>33</td>
<td>62</td>
</tr>
<tr>
<td>Protein g</td>
<td>3.4</td>
<td>2.6</td>
</tr>
<tr>
<td>Carbohydrate g</td>
<td>0.2</td>
<td>7.7</td>
</tr>
<tr>
<td>– of which lactose g</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Carbohydrate source</td>
<td>Maltodextrin</td>
<td>Maltodextrin, fructose-glucose syrup</td>
</tr>
<tr>
<td>Fat g</td>
<td>1.9</td>
<td>2.3</td>
</tr>
<tr>
<td>Added LCPs AA</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>DHA</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td><strong>MICRONUTRIENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A µg</td>
<td>Tr¹</td>
<td>0.0</td>
</tr>
<tr>
<td>Vitamin C mg</td>
<td>0.0¹</td>
<td>7.8</td>
</tr>
<tr>
<td>Vitamin D µg</td>
<td>0.8</td>
<td>0.75</td>
</tr>
<tr>
<td>Calcium mg</td>
<td>120</td>
<td>100</td>
</tr>
<tr>
<td>Zinc mg</td>
<td>0.3¹</td>
<td>N/K</td>
</tr>
<tr>
<td>Iron mg</td>
<td>0.43¹</td>
<td>1.1</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prebiotics</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Probiotics</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Taurine</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Choline</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Contains soya</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contains fish oil</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Suitable for vegetarians</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Halal approved</td>
<td>NK</td>
<td>NK</td>
</tr>
</tbody>
</table>

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

1 Data source: Food Standards Agency (2002)
4.12.3 Goats’ milk and goats’ milk based infant milks

**Key points**

Following advice from EFSA in 2012 that goats’ milk protein is suitable for use in infant formula and follow-on formula, the current European Commission Directive on Infant Formulae and Follow-on Formulae and the UK regulations will be amended in 2013 to allow goats’ milk protein based formula.

EFSA accepted that goats’ milk protein was a suitable protein source for infants but did not change their conclusion that there is insufficient data to support goats’ milk based infant formula as having lower allergenicity than cows’ milk based 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 were excluded from the current European Commission Directive on Infant Formulae and Follow-on Formulae on the basis of original recommendations made by the European Food Safety Authority (EFSA, 2006). Advice from EFSA in 2012 now recommends that goats’ milk protein is suitable for use in infant and follow-on formula (EFSA, 2012). The original recommendation was based on evidence 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 at that time to establish the suitability of goats’ milk protein as a protein source in infant formula.

In 2012, EFSA revised their conclusion on the suitability of goats’ milk as a protein source for infant and follow-on formula milks. Their revision was based on both a re-evaluation of the original clinical trial and the evidence from a new randomised control trial in 200 Australian infants. The new trial included a breastfed reference group and results from biochemical analysis of blood samples. Their overall conclusion was that protein from goats’ milk can be suitable as a protein for use in infant and follow-on formula milks (EFSA, 2012). The current European Commission Directive on Infant Formulae and Follow-on Formulae and the Infant Formula and Follow-on Formula (England) Regulations (2007) are currently being revised to allow goats’ milk formula and follow-on formula and this should be in place later in 2013.
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 and this has not changed. 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

4.12.4 Other milks unsuitable for infants and toddlers
Cows’ milk or milk from any other animal (e.g. 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). 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; 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

<table>
<thead>
<tr>
<th>Age category</th>
<th>Royal College Nursing feeding guidance</th>
<th>Suggested intake per day</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Up to 2 weeks</strong></td>
<td>7–8 feeds per day 60-70ml per feed</td>
<td>420-560 ml/day</td>
</tr>
<tr>
<td></td>
<td>ml/kg/day</td>
<td>150</td>
</tr>
<tr>
<td><strong>2 weeks - 2 months</strong></td>
<td>6-7 feeds per day 75-105ml per feed</td>
<td>450-735 ml/day</td>
</tr>
<tr>
<td></td>
<td>ml/kg/day</td>
<td>150</td>
</tr>
<tr>
<td><strong>2-3 months</strong></td>
<td>5-6 feeds per day 105-180ml/day</td>
<td>525-1080ml/day</td>
</tr>
<tr>
<td></td>
<td>ml/kg/day</td>
<td>150</td>
</tr>
<tr>
<td><strong>3-5 months</strong></td>
<td>5 feeds per day 180-210ml per feed</td>
<td>900-1050ml/day</td>
</tr>
<tr>
<td></td>
<td>ml/kg/day 3-4 months</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>ml/kg/day 4-5 months</td>
<td>120</td>
</tr>
<tr>
<td><strong>About 6 months</strong></td>
<td>4 feeds per day 210-240ml/day</td>
<td>840-960 ml/day</td>
</tr>
<tr>
<td></td>
<td>ml/kg/day</td>
<td>120</td>
</tr>
</tbody>
</table>

**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 6,625ml and 7,520ml of milk, suggesting some varieties in the energy density of milks per scoop if the final products meet similar compositional standards.

5.5 Water used to make up powdered milk

It is recommended that powdered formula milks are made up using fresh water from the cold tap 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).

5.6 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). In 2013, following concern over some manufacturers suggesting that their products be reconstituted at temperatures below 70°C,
the Department of Health reiterated its position on the safe preparation of powdered infant formula milks:

"We would like to reiterate that the position of the Department of Health and the Food Standards Agency is that it is best practice to make up infant feeds by reconstituting formula powder using water at a temperature of 70°C or above.... we want to be clear that all standard, non-specialised infant formula and follow on formulas, including those containing probiotics, should be prepared in-line with current best practice, regardless of the presence of any other contrary instruction on the product, in order to minimise the risk of infection." (Department of Health, 2013)

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.

**We do not recommend that any milks are made up using water at a temperature of less than 70°C unless the risks have been assessed by a medical practitioner.**
### TABLE 21
Guidelines on the safe preparation and storage of powdered infant formula milks

#### General recommendations

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Make up feeds one at a time as the baby needs them.</td>
<td>To reduce the holding time between reconstituting and using feeds in order to minimise the amount of time during which bacterial multiplication can occur.</td>
</tr>
<tr>
<td>Sterilise all bottles and equipment to be used.</td>
<td>The infant’s immune system is not as well developed as an adult’s. This recommendation minimises the risk of illness and infection.</td>
</tr>
<tr>
<td>Use water from the cold tap to make up feeds. Do not use bottled or artificially softened water.</td>
<td>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 SO₄) level is no higher than 250mg/l.</td>
</tr>
</tbody>
</table>

#### Recommendations for making up a feed using formula milk powder

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boil at least 1 litre of fresh water from the cold tap in a kettle. Do not use previously boiled water. Leave the water to cool for no more than 30 minutes.*</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>To avoid contamination of bottles with bacteria from tap water or unclean work surfaces.</td>
</tr>
<tr>
<td>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.</td>
<td>Scoop sizes differ between manufacturers and between different milk powders from the same manufacturer. Too much powder may result in constipation or dehydration.</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

• 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. Do not follow that advice.

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 and 2010 found that many parents and carers did not follow guidelines for the reconstitution of formula milk (Bolling et al, 2007, Health and Social Care Information Service, 2012). In 2005 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 2010 Infant Feeding Survey (Health and Social Care Information Service, 2012) reported that almost half (49%) of all mothers who had made up powdered formula in the last seven days followed all three recommendations of only making one feed at a time, making feeds within 30 minutes of the water boiling, and adding the water to the bottle before the powder. This is a substantial increase on the proportion of mothers following all three guidelines in 2005 (13%), and is likely to be primarily due to the increase in the proportion of mothers making up only one feed at a time. Mothers in Northern Ireland were the most likely to have followed all three recommendations (58%), while mothers in Scotland were the least likely to have done so (45%).

Guidelines for health professionals on safe preparation, storage and handling of powdered infant formula are available at http://www.food.gov.uk/multimedia/pdfs/formulaguidance.pdf

Guidelines for parents and carers can be found at http://www.nhs.uk/conditions/pregnancy-and-baby/pages/making-up-infant-formula.aspx#close

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
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 which 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

**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 antenatal 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

Public Health England
T: 020 7654 8000
www.gov.uk/government/organisations/public-health-england

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

Alpro
*Infant milks produced*
- Alpro Soya Junior 1
T: 0800 0 188 180
E: info@alprohelpline.co.uk
www.alpro.com/uk

Aptamil
*Infant milks produced:*
- Aptamil 1
- Aptamil 3 Follow-on Milk
- Aptamil Anti-Reflux
- Aptamil Comfort
- Aptamil Growing Up Milk 1+ Year
- Aptamil Growing Up Milk 2+ Year
- Aptamil Hungry Milk

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

Babynat
*Infant milks produced:*
- Babynat 1
- Babynat 2 Optima
- Babynat Babybio 3

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 Anti-Reflux
- 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 and Gate Infasoy

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 Combiotic First Infant Milk
- Hipp Organic Combiotic Hungry Infant Milk
- Hipp Organic Combiotic Follow-on Milk
- Hipp Organic Good Night Milk
- Hipp Organic Combiotic 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
www.hipp4hcps.co.uk

Holle
*Infant milks produced:*
- Holle Organic Infant Formula 1
- Holle Organic Infant Follow-on Formula 2
- Holle Organic Growing-up Milk 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

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

Infant milks produced:

- SMA Comfort
- SMA Extra Hungry
- SMA First Infant Milk
- SMA Follow-on Milk
- SMA LF
- SMA Staydown
- SMA Toddler Milk
- SMA Wysoy

SMA Nutrition
Nestlé UK Ltd
Clarion House
Norreys Drive
Maidenhead
SL6 4FL
T: 01828 580433

www.smahcp.co.uk
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.

A further strengthening of regulations in the EU on the marketing of follow-on formula was agreed in June 2013, with new regulation restricting claims that can be made and the use of idealising images.

**Infant feeding patterns in the UK**
The most recently available national Infant Feeding Survey of parents across the UK (Health and Social Care Information Service, 2012) show that, in 2010:

- About a fifth of mothers (19%) did not initiate breastfeeding at birth
- 31% of parents introduced infant formula on the first day of life.
- 43% of mothers who used both breast and formula feeding used formula at all or almost all feeds from birth
- By 1 week of age more than half of infants (52%) had had some infant formula, and by 6 weeks of age 73% of infants had been given infant formula.
- By 4-10 weeks, 33% of infants were entirely fed on infant formula and 26% were given formula and breastmilk
- By 4-6 months of age, 60% of infants were entirely fed on infant formula.
- By 9 months, 95% of infants had had some infant milk.

Data from elsewhere suggests that in 2011 56.8% of parents of infants aged 0-1 years in the UK used infant milks 2-3 times a day or more (Mintel, 2012).

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, 16% of parents did so before 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. Only 68% of mothers said they knew the difference between follow on formula and formula. Non-working women were more likely to use follow on formula before 6 months of age.
Mothers who did use follow-on formula by 4-6 months said they did so on the advice of a health professional (17%) or because they thought it was better for the baby (18%) and 8% because they had seen information advertised. By the time their babies were 8-10 months of age, the majority of mothers were using follow-on formula.

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 (Previously owned by Pfizer, now owned by Nestlé)
- Hipp Organic (owned by Hipp).

In 2011 the infant milk market in the UK was worth £307 million with predictions to increase to £355 million in 2012 (Mintel, 2012). The value of the infant milk market grew by 73% between 2004 and 2009 (Business Insights, 2009) and will have grown a further 35% in the past three years. 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 in 2006 and now gives parents vouchers to buy milk in supermarkets and other retailers rather than giving milk free at clinics – 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). More recent increases also reflect the increasing length of time parents choose to use fortified milk and the rapidly expanding toddler and growing up milk sector.

A summary of the main brands, their market share in 2009, and the amount that they spent on promoting their brands in 2011, is shown in Table 22.

<table>
<thead>
<tr>
<th>Parent company</th>
<th>Brands of milk</th>
<th>Market share of infant milk sales 2009</th>
<th>Amount spent on marketing in 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danone</td>
<td>Aptamil, Cow &amp; Gate</td>
<td>54%</td>
<td>£13.656 million on Aptamil follow-on and growing-up milks and Cow &amp; Gate follow-on formula and growing-up formula</td>
</tr>
<tr>
<td>Pfizer</td>
<td>SMA Nutrition</td>
<td>40%</td>
<td>£1.172 million – SMA follow-on formula</td>
</tr>
<tr>
<td>Hipp</td>
<td>Hipp Organic</td>
<td>2%</td>
<td>£360,000 – Hipp follow-on formula</td>
</tr>
</tbody>
</table>

Sources:
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.


**European legislation on 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’)

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• 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 (e.g., 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).


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 (EU Commission Health and Consumers Directorate General, 2008) and Germany in 2008/2009 ((EU Commission Health and Consumers Directorate General, 2008a), 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 ensure 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 cows’ 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.

**Probiotics** – Live micro-organisms that when consumed, may have beneficial health effects on the host.

**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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