

Choosing a formula – what is the evidence for different milks and added ingredients?

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Infant formula is the only suitable alternative to breastmilk as the sole source of nutrition for babies in the first six months of life. The majority of formula milks are based on cow's milk with an altered mineral balance, with vegetable fats, vitamins and other substances added.

This overview describes the composition of formula milks for healthy, full-term babies and reviews the available evidence about the effectiveness of some of the optional added ingredients. It sets out current government rules and recommendations for formula milk. Much of the information is highly technical, indicating the complexity of producing an acceptable alternative to breastmilk. In order to set the scene, the background section describes how formula milks have changed over time,

and indicates the extent to which formula milk is used for feeding babies in the UK.

Specialised milks, which are sometimes prescribed for babies with special nutritional needs, such as those who are born prematurely or are ill, are not discussed.

Introduction

Formula milk can be given to babies throughout their first year, if they are not breastfed. Follow-on milks (FoMs) are also available but none of the health bodies recommend their use above infant formula. From 12 months of age, babies can be given unmodified cow's milk to drink; cow's milk can be mixed with foods for babies from the age of six months.¹ Goat's or sheep's milk, and soya, oat, rice or nut 'milks' are not recommended as a

drink for babies under a year old, because they do not contain the right quantity of nutrients. Up to the age of two, full-fat milk is recommended, as babies need the energy and vitamins provided by the fat. Skimmed milk isn't generally suitable until a child is five years old.

There is currently some confusion about which milks are appropriate for babies at different ages, which is not helped by inconsistent and, in some cases, misleading labelling. For example:

- most FoMs are labelled '3', but SMA and Holle FoMs are labelled '2'. (see table 1).
- using the term 'extra hungry' implies the product provides more energy, which it does not.

Background

Breastmilk is a live substance containing active antibodies and enzymes, which has evolved over millennia to meet babies' needs. There is no other time of life when we are entirely dependent on one food. At the same time, babies are growing very rapidly and still developing their brain, immune and gut systems. Breastmilk changes in response to the baby's needs, over the months and from feed to feed during the day, adapting to each individual baby. It is difficult to copy.

Since its introduction, commercially produced formula has constantly been altered, partly in response to research identifying more information about the components of mothers' milk, and partly due to competition between different brands. Government regulation and the cost of ingredients also have an important influence.

Much research has been carried out observing and comparing babies fed on formula and breastfed babies. Laboratory research has also been important in identifying the different components of breastmilk and how breastmilk changes. Modifications to formula include

Table 1 Infant milks commonly available in the UK

Category of infant milk	Names
First milks suitable from birth, based on cows' milk, with higher proportion of whey protein	Aptamil 1 Babynat Infant Formula SMA First Infant Milk Cow & Gate 1 Hipp Organic First Infant Milk Holle Organic Infant Formula 1
Infant milks marketed for 'hungrier babies', labelled as suitable from birth, based on cows' milk	Aptamil Extra Hungry Cow & Gate 2 Hipp Organic Hungry Infant Milk SMA Extra Hungry (V, H)
Soya milks – not recommended for use without speaking to a health professional	Cow & Gate' Infasoy SMA Wysoy (V, H) Abbott Isomil
Follow-on formula labelled as suitable from six months of age, based on cows' milk	Aptamil 3 Babynat Follow-on Milk Cow & Gate 3 Hipp Organic Follow-on Milk Holle Organic Infant Formula 2 SMA Follow-on Milk
Goodnight milks	Cow & Gate Good Night Milk* Hipp Organic Good Night Milk

V - Labelled as suitable for babies on a vegetarian diet

H - Labelled as suitable for babies on a Halal diet

* to be withdrawn from August 2010.

alteration of the protein balance, and addition of L-carnitine, and choline. Taurine was added in the 1980s, β -carotene (precursor of vitamin A and an antioxidant), inositol, nucleotides and long chain polyunsaturated fatty acids (LCPUFA) in the 1990s and oligosaccharides in this century.²

Although all these modifications have been made, an increasing body of research shows that formula-fed babies are more likely to contract respiratory, urinary, gut and ear infections and to develop conditions such as diabetes, asthma and leukaemia.³ Adults who were formula-fed as babies have increased risk factors for developing cardiovascular disease.⁴

Use of formula and follow on milk

Formula milk is very widely used in the UK. Responding to the 2005 Infant Feeding Survey, just under a quarter of mothers (24%) said that they used infant formula milk as the sole source of nutrition for their baby from birth, with an additional 11% putting their baby to the breast but also giving formula on the first day. By one week over half of all mothers (54%) had given their baby formula, while three quarters (76%) had done so by six weeks and 92% by the time the baby was six months old.⁵

The same national survey showed that a small proportion of mothers (4%) had given their baby follow-on milk by eight weeks of age, while one in ten (10%) said they had done so by four months and one third of mothers (34%) by six months. However, it should be noted that only 70% of these mothers said they knew the difference between infant formula and follow-on milk, so these figures may be unreliable.⁵

Ingredients in formula milks

Standard formula is manufactured from skimmed milk powder with a reduced protein and electrolyte content, added carbohydrates, vegetable fats – usually a mixture from palm, rapeseed, corn, coconut, sunflower oils – vitamins, minerals and other trace ingredients.⁶

Compositional standards

The composition of infant formula and follow on formula are set out in detail in



the European Directive (2006).⁷ For each essential ingredient, there are minimum and maximum values. In addition there are a limited number of optional ingredients which will be examined in more detail in following sections. The Directive also allows manufacturers to add new ingredients that have been evaluated for safety, if they notify the appropriate authority by forwarding a copy of the label.

The nutrient composition of a formula laid down in the Directive does not aim to match the composition of the nutrients in breastmilk, as absorption of nutrients from breastmilk is different. In addition, some of the vitamins in formula degrade over time so that higher quantities are added initially to allow a longer shelf life. Instead, the growth of formula-fed babies, their plasma levels and other outcomes associated with diet are compared with babies who have been breastfed. Studies which compare new ingredients or an altered balance of nutrients in formula milk should therefore always include an exclusively breastfed control group.^{8,2} For example, because the essential amino acids are not in the same balance in cow's and human milk, the concentration of protein must be higher in formula to meet all the baby's amino acid requirements.

Almost all of the research into formula milk ingredients has been funded by or carried out by formula manufacturers, who therefore influence the ingredients and topics researched. It is well recognised in pharmaceutical research, for instance, that studies with negative

findings are less likely to be published and those funded by the manufacturers of the products under question are only likely to be published if they have positive results for the product.⁹ This drawback should be borne in mind when considering the following sections.

Infant formula ingredients

There are two main proteins in cow's milk: casein and whey. When cow's milk curdles, the casein separates out as a solid and the whey protein remains in the liquid. In 'first' formula milks, often labelled 'stage 1', the whey:casein ratio has been adjusted by the addition of whey protein concentrate, to align more with the balance of proteins in human milk. The proteins in breastmilk actually vary with the stage of lactation, with a whey/casein ratio of about 10:90 in the first days of lactation and about 60:40 in 'mature' milk produced from about day three after birth, and 50:50 in late lactation, from about six months onwards.¹⁰

There are still considerable differences in the protein composition of 'first' formula and human milk, partly due to differences in concentration of α -lactalbumin and β -lactoglobulin,^{11,12} and α -caseins and β -caseins.⁶

Manufacturers also produce what they call 'second' or 'hungry baby' milks. These are similar to 'first' infant formula in most respects, but the protein is 20% whey and 80% casein, the same as that in cow's milk. Although they are labelled and marketed for hungry babies, there is no clear evidence for the claims that babies are more satisfied on these milks or that they can help delay weaning on to solid foods.

The labels of these milks state that they can be used from birth, but health professional bodies point out there is no need for babies to change from a whey-dominant to a casein-dominant formula and recommend a whey-based formula throughout the first year for babies who are not breastfed or are changing from breastfeeding.^{1,13} Casein-dominant milks tend to form a firmer curd in the stomach and there is anecdotal evidence that some babies may become constipated when switched from whey-based to casein-based infant milk.¹³

Soya formula milk

Soya-based formula milk is not usually recommended as a sole source of nutrition for babies, and should only be used on the advice of a health professional.¹⁴ This is because they have high levels of phytoestrogens which can mimic female hormones and pose a theoretical risk to children's long-term reproductive health.¹⁵

A Cochrane systematic review found that soya formula cannot be recommended for prevention of allergy or food intolerance in infants at high risk of these conditions.¹⁶ Around one in 10 babies who are allergic to cow's milk protein are also allergic to soya so extensively hydrolysed milks are now prescribed for these babies if they are not breastfed.

Soya formula does not contain lactose; rather the carbohydrates are dried glucose syrups and maltodextrins, so there is a greater risk of tooth decay than with a cows' milk formula. At present there is no soya formula suitable for vegans available in the UK. If parents do choose soya formula they should be aware of the potential risks associated with its use.

Goats' milk based formula

There are no compositional regulations for goats' milk based infant formula as it is not considered appropriate for infants. There should not be any goats' milk formula available in the UK and parents should be advised to avoid them in the first year of life.

Follow-on milks

These are breastmilk substitutes developed with less modification of the cows' milk for children over 6 months of age. They are casein-based and contain more protein, iron, and vitamin D than infant formula which is labelled as suitable from birth. Under the latest compositional standards there are few other differences between formula milk and follow on milk.⁷

Follow-on milks should not be used for babies under six months as they are not modified sufficiently for digestion in this age group. Manufacturers promote the additional iron content in follow-on milks, but iron is absorbed more effectively from foods other than milk and follow-on milk is not an important source of iron for babies on a varied diet (see below).

Newer products

Follow on formulae marketed as 'good night milks' have been introduced relatively recently in the UK. They now comply with the European Directive in terms of composition but have added starches that thicken the formula. They are named and promoted to be given in the evening, implying that they help babies to settle at night, though no evidence is put forward to support this contention.

The Scientific Advisory Committee on Nutrition (SACN) has published a statement expressing concerns about the use of these milks, pointing out that there is no evidence that they offer an advantage over formula or follow-on milks in relation to settling babies at night.¹⁷ The promotion may encourage parents to think that it is desirable for babies to sleep longer at night, at an age when there is considerable variation in sleep patterns can be expected. In addition, parents may be tempted to use these products more than once a day, and for babies younger than six months. (NB, Cow & Gate have recently announced that they will be withdrawing their GNM from August 2010.)

Babies' iron requirements

After six months of age dietary requirements for iron are increased to meet the increasing demands for growth and blood volume.¹⁸ Iron is present in a range of solid foods such as red meat, liver, kidney, pulses and green leafy vegetables. It is added in increased concentration to follow-on milk. The potential benefits and risks of continuous, routine supplementation in the form of follow on milk have been considered.¹⁹ One review found that while routine iron supplements may benefit babies with low haemoglobin, it may present risks for those with normal haemoglobin.²⁰ Specifically, iron replete babies grew more slowly in length and experienced twice as much diarrhoea when given supplements of 1mg/kg/day from four-to-nine months compared to babies not given supplements.

One study demonstrated that follow-on milk prevented iron-deficiency anaemia in a poor inner city population in comparison with cows' milk, but there is insufficient evidence comparing follow

on milk with formula milk.²¹ Other studies found that iron added to follow-on milk was not an important source of dietary iron in their populations.²⁰ SACN advises that there is no need to use follow-on milks.¹⁷

Optional ingredients

Nucleotides are now added to almost all non-organic formula milk. They form the basis of DNA and RNA, the genetic material in each cell, and therefore play a role in most biological processes. It has been suggested that nucleotides are particularly important in immune function, lipid metabolism and the growth of the gut during infancy. Nucleotides can be made in the body and thus are not generally considered an essential nutrient.

Overall, the studies used to support the use of nucleotides in standard formula show conflicting results. Most of the studies on nucleotides have been funded by formula manufacturers. Some studies indicate that nucleotides added to formula can have beneficial effects in babies, suggesting that they may become essential nutrients if the baby is not making enough.²² Other studies suggest a lower incidence of diarrhoea and an increased plasma antibody response to immunisations.²³ In a small randomised controlled trial (RCT), Singhal found nucleotides at levels currently in formula milk altered the balance of gut microbes in formula-fed infants, but there was no reduction in rates of diarrhoea.²⁴

In terms of choice, parents buying a formula can opt for a standard formula which will probably contain nucleotides, which may or may not affect their babies' health, or opt for an organic formula.

Essential fatty acids

Most manufacturers are now adding long-chain polyunsaturated fatty acids (LCPUFA) to formula milks and marketing them as providing an advantage for babies' development, in spite of the Regulations that say this claim is not permitted.

The rationale for adding LCPUFAs is that newborn babies' brains are still growing rapidly and the cell membrane phospholipids are rich in two LCPUFAs, docosahexaenoic acid (DHA) and arachidonic acid (AA). Babies fed formula

without added DHA and AA have lower plasma, red blood cell and brain levels of these fatty acids in the first months compared to breastfed babies.²⁵ However, they can be synthesised in the body, even by preterm babies born at 33 weeks.²⁶ Controversy exists over whether small amounts of LCPUFA are also essential nutrients for babies. Researchers suggest that, in early infancy, synthesis of DHA and AA could be limited by a shortage of the precursor fatty acids and/or by insufficient enzyme capacity.²⁷ There is reason to think this might be true for premature babies, but the evidence that they are beneficial for term babies is still equivocal.

Individual randomised studies have claimed that LCPUFAs have an influence on brain and eye development, generally measured by the Bayley Scales of Infant Development and visual acuity tests. Other studies have not supported this finding and one trial found lower language scores in babies who received DHA supplementation.²⁸

In 2008, an international panel of experts, including some whose research was funded by the formula industry, concluded that, as a precaution, formulas for term babies should contain DHA at levels between 0.2 and 0.5 % of total fat, and an equivalent amount of AA.²⁷ In the same year, an independent Cochrane systematic review was carried out including all high quality RCTs of formula milk with DHA plus AA or DHA alone compared to standard milk formula. The quality assessment included allocation concealment, adequate randomisation, blinding of parents and assessors to intervention, intention to treat analysis and completeness of follow up. Some 14 RCTs met the quality criteria and were included. Results showed there was no clear and consistent benefit of supplementing formula with LCPUFA on visual acuity, developmental outcomes or physical growth in term babies. The findings were the same irrespective of the type, concentration or duration of LCPUFA supplementation.³⁰

There are still more questions than clear unequivocal answers. Two more recent studies, not included in the systematic review, found conflicting results. One group has suggested that some of the differences between these study findings may have been the result

of genetic differences. Another recent study found that at four years of age children fed DHA-fortified formula as babies had IQ scores higher than children fed unfortified formula. However, babies' total intake of DHA in milk in their first six months was not associated with subsequent IQ or scores on any other test.³¹

In terms of choice, parents buying formula milk can opt for a milk with or without LCPUFAs. Although there is a theoretical argument for adding LCPUFAs as they are found in breastmilk, on balance it is unlikely that there is a long-term significant clinical benefit of using a formula with them included. If they do make a difference, it may be for a short time period, or in a sub-group of babies with a specific genetic makeup.

Oligosaccharides

Oligosaccharides (OS) are added to some formula milks and, until January this year, many were labelled as containing prebiotics, i.e. having health-enhancing properties. It is questionable whether the OS in formula milk should be classified as prebiotics as their purported effect on health is unproven.

Approximately 200 different oligosaccharides (OS) have been identified in human milk, although they are not necessarily all present at one time.³³ These are complex sugars which are not broken down by enzymes in the small intestine. Breastfed babies have a healthy pattern of microbes in their gut, with more bifidobacteria and lactobacilli, whereas formula-fed babies have more potentially harmful bacteria in bowel. The OS in breastmilk are one of the components which influence the nature of these bacteria. The OS added to formula are not naturally present in human milk and are structurally different. Most of the effects attributed to OS in human milk appear to be highly dependent on their structure. Therefore, infant formula OS may have different effects. Despite this, the message implied in advertising is that they are the same as OS found in breastmilk.

In a recent systematic review evaluating the efficacy and safety of 'prebiotic' supplementation, only 11 of 24 identified trials comparing formula milk with or without added OS were eligible for inclusion on the basis of

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methodological quality. Six trials reported significant increases – and a further two reported a trend towards increases – in bifidobacteria counts in the babies' bowels after supplementation. Overall, babies who received the OS had softer and more frequent stools. These are both seen as positive moves towards the normal gut function of breastfed babies. All but one trial reported that supplementation was well tolerated. Zeigler et al, found diarrhoea (18% vs 4%; $p=0.008$), irritability (16% vs 4%; $p=0.03$), and eczema (18% vs 7%; $p=0.046$) were reported more frequently by parents of babies who received supplements.³⁴ Parents using the 'prebiotic' blend formula in this study were also more likely to withdraw from the study than parents allocated to use the control formula.

A Cochrane systematic review of prebiotics found only two eligible studies reporting allergic disease and food hypersensitivity as an outcome for 432 infants. The quality of the studies was considered 'reasonable', although both reported at least 20% post-randomisation losses.³⁵ In one study, only babies with a parental history of allergy of atopic eczema, allergic rhinitis or asthma, who were therefore at higher risk of atopy, were eligible. An extensively hydrolysed cows' milk whey protein formula was given, after a short period of breastfeeding in some cases, with an added mixture of short-chain galacto-oligosaccharide (GOS) and long-chain fructo-oligosaccharide (FOS) versus the same formula with added maltodextrin. The authors reported a significant reduction in eczema in infants up to six months of age. These results cannot be extrapolated to non-atopic babies given normal, non hydrolysed formula.

The second study, based on general sample of babies (i.e. not at high risk for

allergy), used two different doses (4g and 8g) of a polydextrose, GOS and lactulose blend or a control formula. It reported no significant difference in eczema up to four months of age.

Meta-analysis of the two studies found no significant difference in eczema. The review concluded that there is insufficient evidence to determine the role of 'prebiotic' supplementation of infant formula for prevention of allergic disease and food hypersensitivity.³⁵

The European Food Safety Authority recently considered prebiotic claims for Immunofortis which is an oligosaccharide mix added to some Danone formula. They found insufficient evidence for a claim to 'naturally strengthen the baby's immune system'. They said the evidence, comprising 30 trials contained limited, inconsistent and irrelevant data.³⁶

Parents buying formula milk can choose one with oligosaccharides added or one without. The GOS/FOS mixture most often used normally leads to softer and more frequent stools. Some studies indicate a rise in the proportion of bifidobacteria, and sometimes lactobacilli, in the bowel in preference to pathogenic bacteria.³⁷ However, studies are inconsistent as to their effect on faecal flora and any benefits to health remain to be proved. There is insufficient evidence to indicate whether OS have an impact on the risk of developing allergies either in babies with or without a family history.

Summary and conclusions

Formula milks are used by a majority of parents of babies in the UK at some stage during their baby's first year. Formula is constantly being altered in response to new research on how formula-fed babies compare with breastfed babies. Laboratory research that measures the constituents of breastmilk, the evolutionary gold standard, is also influential. Other important factors affecting the make-up of formula are government regulation, commercial competition and the desire to increase market share, and the price of different components. For example, the combination of vegetable fats included may vary in response to price.

Unfortunately, much of the research on formula is carried out by companies with a commercial interest so it is not independent. More high quality, independent studies are needed to ensure

that research is not biased. Babies fed different formula milks should be compared with each other and also with exclusively breastfed babies. Independent systematic reviews of evidence are important as they assess the methodological rigour of each individual study and combine the results of those that are of high quality. By combining data, this kind of meta-analysis can provide additional statistical power, enabling more reliable calculations of effectiveness (health benefits and risks) to be made.

Mothers feeding their babies in different ways often change how they feed hoping

Key points

- Generally, all infant formula milks are very similar, with minor differences in optional ingredients. Anywhere in Europe, use of the term 'infant formula' is regulated and all products are required by law to satisfy key compositional criteria. If any ingredient is found to be essential, it should be added to the list in the European regulations.
- There is no nutritional need to change from an infant formula to a follow-on milk when babies reach six months. There is no evidence that they are more effective than ordinary infant formula in helping to prevent iron deficiency anaemia.
- There is little evidence for the claims that manufacturers have made for nucleotides, LCPUFAs, or oligosaccharides improving the health or development of term babies. Claims that any of these three types of additives are beneficial when added to formula milk are now against the law.
- There is no evidence that 'hungry baby' milks delay weaning or are more satisfying.
- As many of the research studies on formula milk are funded by companies with a commercial interest, independent systematic reviews are vital for identifying the methodological strengths and weaknesses of individual studies and reaching reliable conclusions about health benefits and risks.

that their baby may cry less, have less 'colic', or sleep for longer.³⁸ Those who are formula feeding often change brands hoping that this might make a difference. There is no evidence to suggest that changing brands does any good or any harm.¹ There are no independently funded head-to-head trials which fairly compare the claimed benefits of one brand of formula with another.

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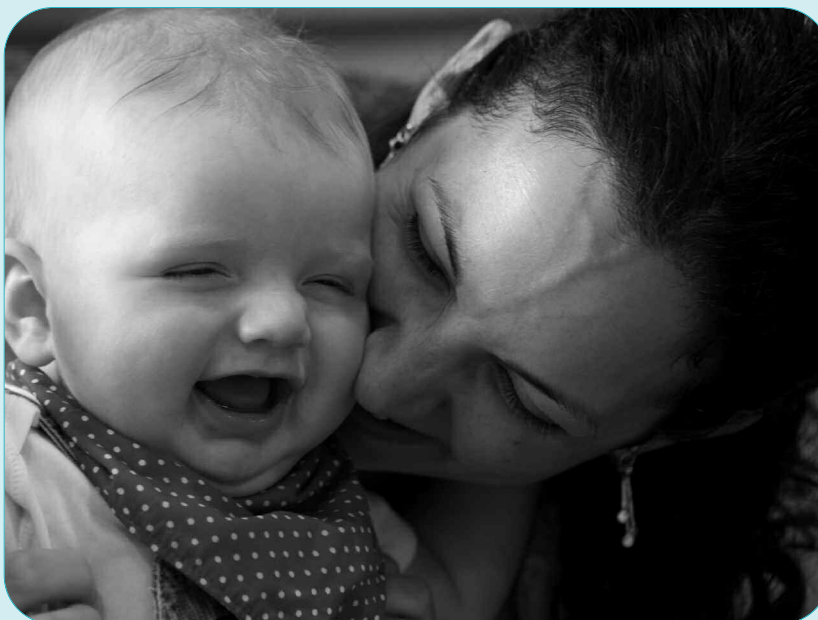
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Professional Resources



We provide products for birth environments, labour and birth, breastfeeding and expressing.



We offer a hire service for valley cushions and breast pumps as well as a bra fitting service. For more information on how you can offer these services to the parents you work with, please call NCT Enquiries on 0300 330 0770 or visit www.nct.org.uk.