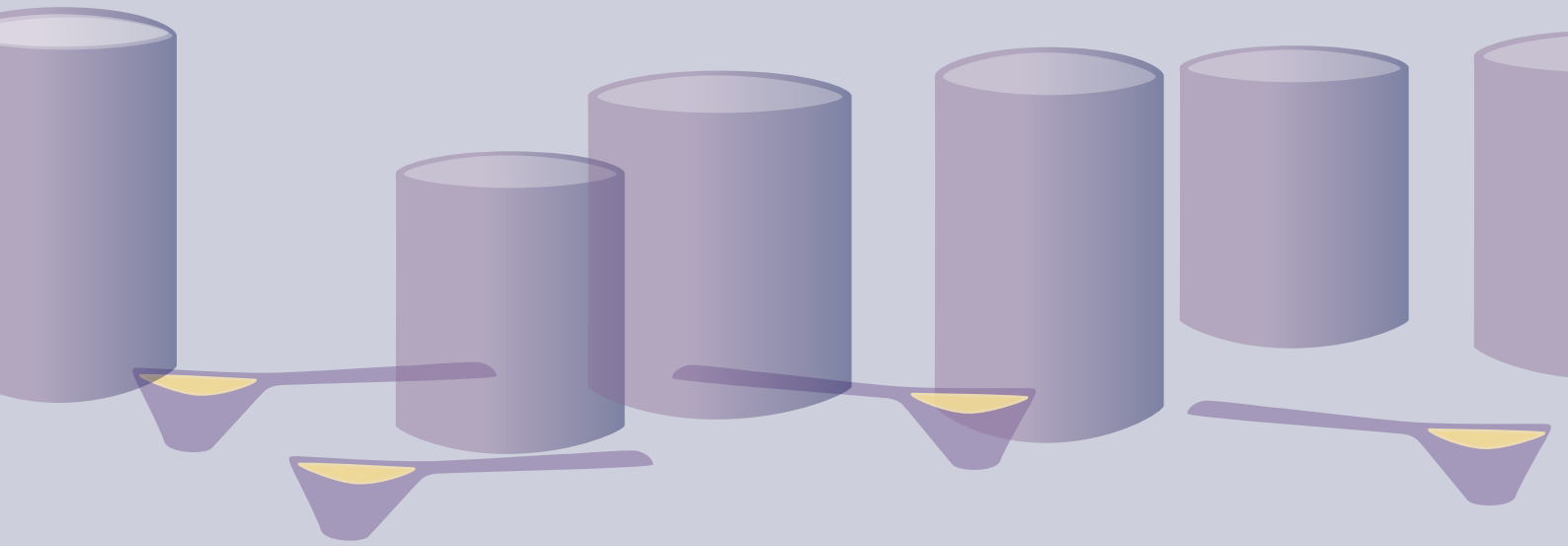
Comfort milks, lactose-free infant milks and anti-reflux infant milks

Why these products should be removed from shop, supermarket and pharmacy shelves



Baby Feeding Law Group UK

Comfort milks, lactose-free infant milks and anti-reflux infant milks – why these products should be removed from shelves in shops, supermarkets and pharmacies

Infant milks marketed under the regulations for 'foods for special medical purposes' (FSMP) include comfort milks, lactose-free infant milks and anti-reflux infant milks. We believe there are eight key reasons why these three types of infant milk should be removed from the shelves of shops, supermarkets and pharmacies.

1 Use under medical supervision

Infant milks marketed as FSMP must, by law, specify that they are for use under medical supervision. The EU has recently clarified that the use of these products under medical supervision is a defining characteristic of the products. Having them available on shop, supermarket and pharmacy shelves means that they can be used without medical supervision.

2 Health claims

Infant milks marketed as FSMP have statements on the product label outlining the medical condition the milk is designed for. These look like health claims and can suggest health benefits for a product even if public health experts do not agree that there is evidence for these.

3 Protein content

Many infant milks marketed as FSMP have a higher protein content than first infant formula and therefore may be a potential risk for later weight gain in children.

4 Added ingredients

Some infant milks marketed as FSMP have ingredients that are not normally associated with a milk diet in the first six months of life, such as glucose syrup. Some of the sugars in these products can damage developing teeth and potentially impact on metabolic responses.

5 Instructions for making up milks

Anti-reflux infant milks state on the label that they should be made up with water at a temperature *below* 70°C. Powdered infant milks are not sterile and this therefore creates a risk for an infant, as water at a temperature of less than 70°C will not kill any bacteria present in the powder. Using the product under the medical supervision expected for this product allows a risk assessment to be made.

6 Cost

Infant milks marketed as FSMP are more expensive than infant formula and this price difference could have a negative impact on family food budgets.

7 Promotion of products to health workers

Infant milks marketed as FSMP are heavily advertised in the healthcare professional literature, where there are no restrictions around the claims that can be made for product benefits. This means that health workers can be misled about the usefulness of specialised infant milks. When the products being advertised are available on the shelves of shops, supermarkets and pharmacies, it is more likely that families may be encouraged and supported to try them.

8 Marketing

In the UK, there are certain restrictions on the marketing and sale of infant formula – for example, in terms of use of idealising images, price reductions and advertising. However, those restrictions do not currently apply to infant milks marketed as FSMP.

In this briefing paper, we provide evidence to support our opinion that infant milks marketed as FSMP should only be used under medical supervision, and therefore should not be available on shop, supermarket and pharmacy shelves.

Infant milks classified as Foods for Special Medical Purposes (FSMP)

Infant formula manufacturers are able to market certain types of infant formula under a set of regulations that were designed to allow the manufacture of specialist food products for individuals with specific diseases.

Specialised infant formula are currently regulated by the *Commission Directive 1999/21/EC of 25 March 1999 on Dietary Foods for Special Medical Purposes*, which requires products to be labelled as for use 'under medical supervision'. These products fall outside the infant formula and follow-on formula regulations and therefore have historically not needed to take into account the importance of restricting marketing of breastmilk substitutes in line with the WHO *International Code of Marketing of Breastmilk Substitutes* (World Health Organization, 1981). New regulations on foods for specific groups (FSG) (EU 609/2013) were adopted by the European Parliament, the European Council and the European Commission in June 2013 (EU Commission Health and Consumers Directorate General, 2013) and came into force in the UK in July 2016. These new regulations outline some principles on composition, labelling and marketing of infant milks. The detail of the new regulations is given in the specific delegated act on foods for special medical purposes, but this does not come into law until February 2020.

Despite the fact that FSMPs, by design, are to be used under medical supervision, there has been an increasing number of infant milks marketed as FSMP on shop, supermarket and pharmacy shelves, allowing consumers to buy them directly without the need for advice or a risk assessment. The three categories of specialist milk that are commonly available over the counter are: **comfort milk, lactose-free infant milk** and **anti-reflux infant milk**.

The efficacy and usefulness of these products do not have to be agreed by an expert body, simply by the manufacturer. This means that products such as comfort milks can make claims that they help manage colic and constipation, even when there is no agreement that this is true among UK health bodies and expert committees. The loophole by which manufacturers have exploited the marketing of these products has meant that many families self-medicate with products that may be of no benefit, and which may be a less good choice than first infant formula. We believe that parents are being misled about the usefulness of specialist products.

Comfort milk

In the UK, four comfort milks are available over the counter: **Aptamil Comfort, Cow & Gate Comfort, Hipp Combiotic Comfort Milk and SMA Comfort.**

Most infant milks containing partially hydrolysed proteins are marketed as comfort milks which are 'easier to digest' and which the manufacturers claim are designed for the management of colic and constipation. They are all modified cows' milk formula based on 100% whey protein. All four products contain lactose at lower levels than those found in standard infant formula milks and all contain structured vegetable oils. Aptamil Comfort, Cow & Gate Comfort and Hipp Combiotic Comfort Milk also contain non-digestible oligosaccharides and added starch for a thicker feed.

No convincing evidence is presented by manufacturers to support the efficacy of comfort milks in managing colic, wind or gastrointestinal

discomfort. A recent Cochrane review concluded that there was no evidence for the effectiveness of changing formula type on infantile colic (Gordon et al, 2018). NICE Clinical Knowledge is clear that there is no infant formula solution for colic (National Institute for Health and Care Excellence, 2017) and NICE advises against a change in formula type. NHS Start4life only suggests practical and soothing strategies for colic (NHS Start4life, 2018). It suggests that constipation in formula-fed infants can be treated with additional drinks of water and gentle activity, but there is no advice to change formula (NHS Start4life, 2018). A 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).

For a full review of comfort milks, see the First Steps Nutrition Trust report *Infant Milks in the UK* (2018).

Lactose-free infant milk

In the UK, two lactose-free infant milks are available over the counter: **Aptamil Lactose Free and SMA LF.**

The main difference between lactose-free and standard cows' milk based infant formula is that in lactose-free milk 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).

In the very rare cases of congenital lactase deficiency leading to lactose intolerance, lactose-free formula are necessary, but these infants should be managed by a clinician.

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 that it is suitable for infants who are experiencing symptoms such as diarrhoea, tummy ache or wind. Similarly, Aptamil Lactose Free is suggested for use for infants with lactose intolerance or those suffering from diarrhoea, bloating or wind caused by temporary lactose intolerance.

In developed countries, the use of lactose-free milks as a treatment for acute gastroenteritis has been shown to have no clinical advantage over standard lactose-containing formula (Kukuruzovic and Brewster, 2002). The most recent ESPGHAN guidelines for the management of acute gastroenteritis in children in Europe suggest that the routine use of lactose-free milks in community settings is not recommended (Guarino et al, 2014).

There are also potential risks associated with the use of lactose-free formula. Diets without lactose might have disadvantages for the composition of the infants' colonic microflora and colonic physiological function, and they might compromise calcium absorption (Ziegler and Fomon, 1983). Moreover, feeding lactose-free diets from birth will cause false negative results in most neonatal screening tests for galactosaemia (Høst et al, 1999). Some newer evidence also suggests that infants fed a lactose-free formula will have higher blood glucose and higher levels of some circulating amino acids than infants fed standard infant formula, suggesting that lactose-free formula may have a negative impact on the infant metabolism (Slupsky et al, 2017).

Lactose-free milk has a greater potential to cause dental caries than infant formula. 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 milk 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.

Anti-reflux infant milk

In the UK, four anti-reflux infant milks are available over the counter: **Aptamil Anti-Reflux, Cow & Gate Anti-Reflux, Hipp Organic Combiotic Anti-Reflux and SMA Pro Anti-Reflux.**

Thickened milks (or 'anti-reflux milks') are marketed as reducing 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.

There is some evidence that anti-reflux milk can reduce regurgitation in some infants, but 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, 2002). 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, 2002).

This is supported by NICE guidance and quality standards in the UK (National Institute for Health and Care Excellence 2015; 2016), which outline how gastro-oesophageal reflux should be diagnosed and managed in infants. The guidance reiterates that regurgitation is a common and normal occurrence in infants and does not usually need any investigation or treatment. Where (rarely) there are significant symptoms of frequent regurgitation with marked distress, thickener added to milk or a thickened infant milk is recommended for trial, only after a review of feeding history, and a reduction in feed volumes where appropriate or an increase in frequency of feeds, has been attempted.

Currently, manufacturers suggest that these anti-reflux milks are made up with cold or hand-hot water, rather than with water boiled and cooled to 70°C. This is because, they say, anti-reflux milk made up with water at 70°C is likely to become lumpy. However, if the milk is made up with cold or hand-hot water, this will not kill any bacteria present in the powdered milk. We do not recommend that any infant milks are made up using water at a temperature of less than 70°C unless the risks have been assessed by a medical practitioner.

1 Use under medical supervision

Infant milks marketed as FSMP must, by law, specify that they are for use under medical supervision. The EU has recently clarified that the use of these products under medical supervision is a defining characteristic of the products. Having them available on shop, supermarket and pharmacy shelves means that they can be used without medical supervision.

Infant milks marketed as foods for special medical purposes (FSMP) are currently regulated under the *Commission Directive 1999/21/EC of 25 March 1999 on Dietary Foods for Special Medical Purposes*. This will change in February 2020 when a new delegated act comes into force under the Commission Directive EU 609/2013. EU law does not require food business operators (FBOs) to seek an authorisation to place FSMP on the market, and FBOs can market a specific product as FSMP on the basis of *their own assessment* that the product falls within the scope of the FSMP legislation.

Foods for special medical purposes are defined in Regulation (EU) No 609/2013 on foods for special groups as:

" ... food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone".

In November 2017 the European Commission published information for Member States, clarifying how FSMP should be classified. This was in response to Member States' concerns that the FSMP classification for products was potentially being misused to market products not justifying this classification (European Commission, 2017).

Two important points made by the Commission are highlighted below:

" ... given that the use of the product under medical supervision is a characterising element of FSMP, ***a product that can be used without medical supervision, in the context of the dietary management of a patient, should not be considered as FSMP.***"

"The reference in the FSMP definition to the product's use under medical supervision is very important to understand that ***health care professionals play a key role in recommending and supervising the use of FSMP, taking into account the specific situation of the patients, on a case-by-case basis****. ... For this reason, the recommendation of a health care professional cannot be the decisive element in classifying a product as FSMP; only an analysis of all the elements of the definition of FSMP, on a product-specific basis, can indicate whether a product is to be classified as FSMP or not."*

Selling these specialist products over the counter to families does not allow the products to be used under medical supervision, nor for each individual to be assessed.

2 Health claims

Infant milks marketed as FSMP have statements on the product label outlining the medical condition the milk is designed for. These look like health claims and can suggest health benefits for a product even if public health experts do not agree that there is evidence for these.

The legislative framework for FSMP allows operators to lawfully use statements referring to the dietary management of a disease, disorder or medical condition (required on a mandatory basis for FSMP). Regulation (EC) No 1924/2006 (on nutrition and health claims made on foods) prohibits the use of nutrition and health claims unless specifically authorised, so the loophole in FSMP legislation acts as an incentive for some food business operators to incorrectly place products on the market as FSMP.

Current regulations for FSMP under *Commission Directive 1999/21/EC of 25 March 1999 on Dietary Foods for Special Medical Purposes* are in place until February 2020 when a new delegated act comes into force. The statement of use shown below will remain the same in the new regulations.

Within current regulations it is stated, in Article 4, point 4, that:

"The labelling shall also include:

(a) statement "For the dietary management of ... " where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended..."

This allows manufacturers to state what they intend the product to be used for, even if there is no convincing evidence that the claims they make in these statements are true. This loophole has allowed products to be on the shelves of shops, supermarkets and pharmacies, which appear to make claims such as:

"For the dietary management of colic and constipation"

"Easy to digest infant milk"

"For the dietary management of reflux and regurgitation".

Because these statements are allowed on FSMP and do not have to be agreed as 'health claims', pharmacists and others repeat these statements as facts. For example, Boots the Chemist when challenged as to why they repeated the statement that "*Comfort milks could help manage colic and constipation*" in on-shelf promotions, said they simply repeat what the product says it is designed for. By allowing these products to be on the shelves, families are being misled.

For lactose-free milks the statement says:

"For the dietary management of lactose intolerance".

If an infant genuinely requires a lactose-free diet, this should be managed by a health professional to ensure that the correct treatment is given.

Allowing families to self-medicate can mean that a more serious health problem may not get investigated quickly, which could have serious long-term consequences.

3 Protein content

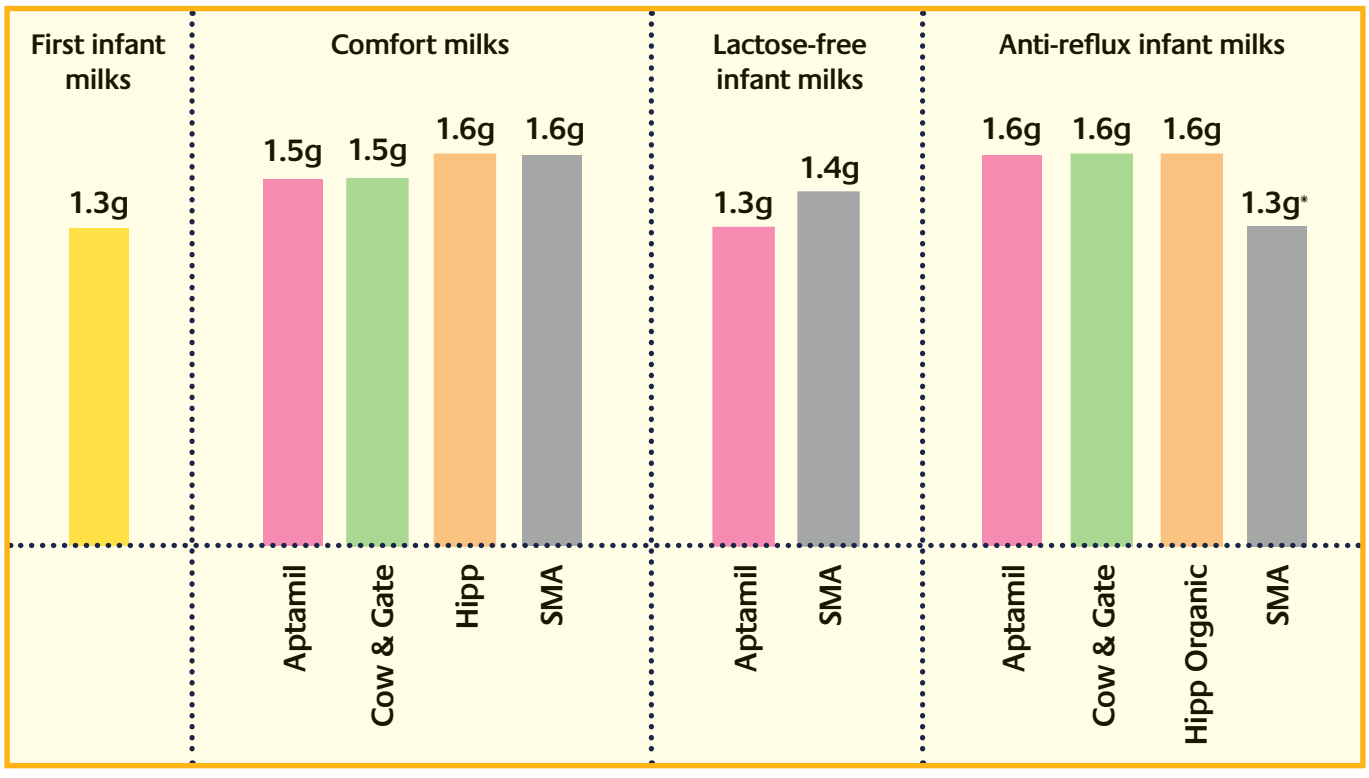
Many infant milks marketed as FSMP have a higher protein content than first infant formula and therefore may be a potential risk for later weight gain in children.

It has been reported 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, with infant formula typically providing a protein content of 1.3g/100ml.

The suggested link between body weight and protein content is thought to be due to 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 three factors are being linked to suggest that lower-protein milks may reduce weight gain in formula-fed infants, but whether protein plays a role in increased growth rate and higher BMI in childhood is still a matter of debate and requires more research (European Food Safety Authority, 2014).

Comparisons between the protein content of infant formula and that of infant milks marketed as FSMP by the four main UK brands are shown below.

Protein content (g per 100ml) of infant formula and infant milks marketed as FSMP by the four main UK brands



*SMA Pro Anti-Reflux.

4 Added ingredients

Some infant milks marketed as FSMP have ingredients that are not normally associated with a milk diet in the first six months of life, such as glucose syrup. Some of the sugars in these products can damage developing teeth and potentially impact on metabolic responses.

Some of the ingredients found in FSMP but not found in the same manufacturer's infant formula are shown below.

Ingredients found in infant milk marketed as FSMP but not typically found in infant formula

Name of FSMP product	Ingredients found in infant milk marketed as FSMP but not found in infant formula
Comfort milks	
Aptamil Comfort	Glucose syrup, potato starch, corn starch
Cow & Gate Comfort	Glucose syrup, potato starch, corn starch
Hipp Combiotic Comfort Milk	Maltodextrin
SMA Comfort	Corn syrup solids, maltodextrin
Lactose-free infant milks	
Aptamil Lactose Free	Glucose syrup
SMA LF	Glucose syrup
Anti-reflux infant milks	
Aptamil Anti-Reflux	Maltodextrin, carob bean gum
Cow & Gate Anti-Reflux	Maltodextrin, carob bean gum
Hipp Organic Combiotic Anti-Reflux	Maltodextrin, carob bean gum
SMA Pro Anti-Reflux	Potato starch

Glucose is generally not considered suitable for routine use in infant formula. However, some infant milks marketed for children with lactose intolerance 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 used 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.

It has been reported that changes to infant formula composition can impact on infant metabolism. A randomised trial of infants fed either a lactose-free infant formula or a standard formula, or who were breastfed, looked at plasma metabolites and insulin at five time points up to two hours after feeding. It showed that infants fed lactose-free formula had higher insulin levels but the lowest levels of circulating glucose at 120 minutes post consumption, higher lactate at 15 and 30 minutes, lower non-esterified fatty acids at all time points, and a slower decrease in circulating amino acids (Slupsky et al, 2017). It is hypothesised that lactose-free infant milk may have a negative impact on infant development since high circulating non-esterified fatty acids are known to stimulate ketogenesis, and this may be important in protecting the infant brain. **There is currently insufficient data that consider the long-term impact of adapted infant formula on infant health and wellbeing, and a precautionary approach should be used whenever a specialised product is not clinically indicated.**

5 Instructions for making up milks

Anti-reflux infant milks state on the label that they should be made up with water at a temperature *below* 70°C. Powdered infant milks are not sterile and this therefore creates a risk for an infant, as water at a temperature of less than 70°C will not kill any bacteria present in the powder. Using the product under the medical supervision expected for this product allows a risk assessment to be made.

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. *Salmonella* and *Cronobacter sakazakii* (previously known as *Enterobacter sakazakii*) are the organisms of greatest concern in infant formula (European Food Safety Authority, 2004), but a range of *Cronobacter* species can be present in powdered infant milks. Powdered infant formula milks contaminated with *Cronobacter sakazakii* or *Salmonella* have been the cause of infection in infants.

Younger infants are more susceptible to infection than older infants, and those 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 *Cronobacter 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).

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 (World Health Organization, 2007). In 2005, the Food Standards Agency issued guidelines on the safe preparation and storage of powdered infant formula milks and follow-on formula, and these were updated and re-issued in 2011 (Food Standards Agency, 2005; NHS, 2011). In 2013, following concern over some manufacturers suggesting that infant formula be reconstituted at temperatures below 70°C, the Department of Health reiterated its position on the safe preparation of powdered infant formula milks and follow-on formula:

"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)

Although specialised infant milks were not included in this statement, bacterial contamination is a known risk in any powdered infant milk, and where products are designed for use under medical supervision, a risk assessment can take place.

Allowing these products to be freely available on shop, supermarket and pharmacy shelves does not allow a health professional to discuss safety issues with the family.

In the small number of cases where infants have regurgitation with marked distress, as described in the NICE Clinical Guidance on *Gastro-oesophageal Reflux Disease in Children and Young People* (National Institute for Health and Care Excellence, 2015), we suggest that practitioners consider using a thickener separately to the formula of choice, and that families are encouraged to continue giving a first infant formula throughout the first year, as this is the product agreed to be the appropriate alternative if breastmilk is not being provided.

6 Cost

Infant milks marketed as FSMP are more expensive than infant formula and this price difference could have a negative impact on family food budgets.

Below we look at the differences in the costs of branded infant formula and some FSMP products in the same brand, and compare these to the cost of the currently cheapest available first infant formula.

Comparison of the costs of branded infant formula, some specialised products in the same brand, and the cheapest available first infant formula

Brand and name of infant milk	Type and package size	Spend per week for a 2-3 month old baby consuming 920ml milk/day	Difference in spend per week for a 2-3 month old baby consuming 920ml milk/day between same brand infant formula and FSMP product	Difference in spend per week for a 2-3 month old baby consuming 920ml milk/day between FSMP product and current cheapest infant formula on UK market
Cheapest first infant formula on UK market *		£6.44		
Aptamil				
Aptamil 1 First Milk	Powder, 800g	£11.59		
Aptamil Comfort	Powder, 800g	£14.17	+ £2.58	+ £7.73
Aptamil Lactose Free	Powder, 400g	£14.17	+ £2.58	+ £7.73
Aptamil Anti-Reflux	Powder, 800g	£13.52	+ £1.93	+ £7.08
Cow & Gate				
Cow & Gate 1 First Infant Milk	Powder, 800g	£8.37		
Cow & Gate Comfort	Powder, 800g	£10.95	+ £2.58	+ £4.51
Cow & Gate Anti-Reflux	Powder, 800g	£10.95	+ £2.58	+ £4.51
Hipp/Hipp Organic				
Hipp Organic Combiotic First Infant Milk	Powder, 800g	£9.66		
Hipp Combiotic Comfort Milk	Powder, 800g	£11.59	+ £1.93	+ £5.15
Hipp Organic Combiotic Anti-Reflux	Powder, 800g	£11.59	+ £1.93	+ £5.15
SMA				
SMA Pro First Infant Milk	Powder, 800g	£10.30		
SMA Comfort	Powder, 800g	£12.24	+ £1.94	+ £5.80
SMA LF (lactose-free)	Powder, 400g	£13.51	+ £3.21	+ £7.07
SMA Pro Anti-Reflux	Powder, 800g	£12.24	+ £1.94	+ £5.80

* Based on the weekly cost of Sainsbury's Little Ones First Infant Milk or Aldi Mamia First Infant Milk, 920ml formula/week costing £6.44/week.
Source: Unless otherwise stated, costs are for 2019, and are taken from *Costs of Infant Milks Marketed in the UK* (First Steps Nutrition Trust, 2019a).

A family choosing a specialist infant milk (FSMP) over a first infant formula could spend an additional £50 to £83 in the first six months if they choose a specialist formula in the same brand as the first infant formula they might choose. If they choose a specialist formula instead of using one of the current cheapest first infant milks on the UK market (Sainsbury's Little Ones or Aldi Mamia First Infant Milk), this can increase to an additional £117 to £200 in six months. When family budgets are squeezed, these additional amounts are significant. Data on household spending on food and non-alcoholic beverages in 2016-17 (ONS Family Spending to March 2017) reported that the average spend on food overall was £58 per week (Office for National Statistics, 2018). Buying infant formula may already be a significant proportion of a family food budget, and buying a type of formula that is not necessary adds to these costs.

7 Promotion of products to health workers

Infant milks marketed as FSMP are heavily advertised in the healthcare professional literature, where there are no restrictions around the claims that can be made for product benefits. This means that health workers can be misled about the usefulness of specialised infant milks. When the products being advertised are available on the shelves of shops, supermarkets and pharmacies, it is more likely that families may be encouraged and supported to try them.

As has been reported in the two reports *Scientific and Factual? A review of breastmilk substitute advertising to healthcare professionals* and *Scientific and Factual? A further review of breastmilk substitute advertising to healthcare professionals* (First Steps Nutrition Trust, 2016; 2019b), regulations allow manufacturers of breastmilk substitutes to advertise their products to healthcare professionals. The regulations say that this must be 'scientific and factual' information but there is no mechanism by which this advertising can be challenged if the content and presentation are misleading or not in line with current UK health policy. The reports highlighted above outline, for a number of adverts, why the information presented is based on weak evidence that is likely to mislead health professionals. Being able to advertise products directly through advertisements in magazines and journals that aim to professionally inform and update gives the manufacturers the opportunity both to promote their brand and to make a series of claims that appear evidence-based. When products being advertised are then available on the shelves of shops, supermarkets and pharmacies, it is more likely that families may be encouraged and supported to try them.

8 Marketing

In the UK, there are certain restrictions on the marketing and sale of infant formula – for example, in terms of use of idealising images, price reductions and advertising. However, those restrictions do not apply to infant milks marketed as FSMP.

Infant milks marketed as foods for special medical purposes (FSMP) are currently regulated under Commission Directive 1999/21/EC. Compared with regulations for the marketing of infant formula, there are fewer restrictions on how foods for special medical purposes are marketed and sold, and this is because these products were always designed to be used under medical supervision only. Guidance on how infant formula can be marketed – for example, in terms of use of idealising images, price reductions and advertising – does not apply.

Customers can obtain loyalty points from retailers if they buy infant milks marketed as FSMP, but not if they buy infant formula. Furthermore, there are no restrictions on how infant milks marketed as FSMP are put on the shelves in terms of product placement.

Conclusion

For the eight reasons listed above, we believe that infant milks marketed as FSMP should only be used under medical supervision, and therefore should not be available on shop, supermarket and pharmacy shelves.

We call on the Departments of Health and Health and Social Care in the UK, and the regulators within these departments, to protect families and ensure that all infant milks marketed as FSMP are only used when a risk assessment and individual advice can be given.

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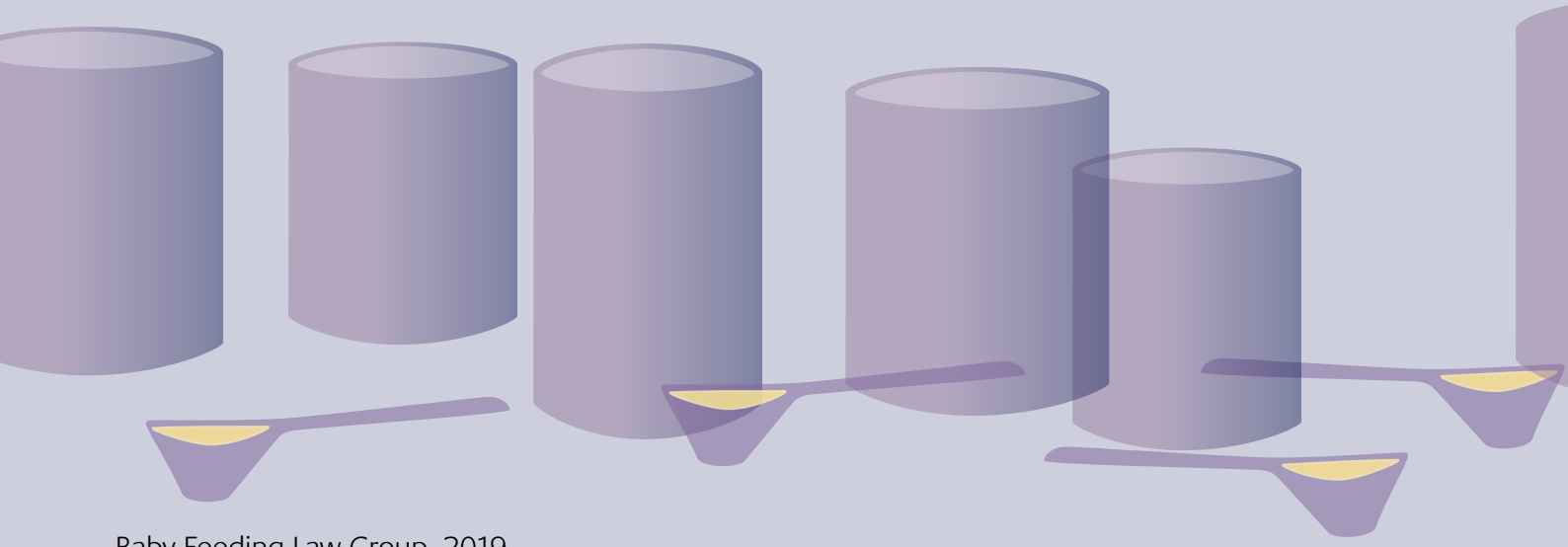
The Baby Feeding Law Group is working to strengthen UK baby feeding laws in line with UN recommendations. We aim to protect babies' health by ending marketing practices which commercialise infant feeding and threaten breastfeeding.

Baby Feeding Law Group UK Members:
Association of Breastfeeding Mothers (ABM), Association for Improvements in the Maternity Services (AIMS), Baby Milk Action, Best Beginnings, Breastfeeding Network (BfN), Community Practitioners and Health Visitors Association (CPHVA), First Steps Nutrition Trust, GP Infant Feeding Network (GPIFN), Hospital Infant Feeding Network (HIFN), Human Milk Foundation, Institute of Health Visiting, Lactation Consultants GB (LCGB), La Leche League GB (LLLGB), Leicester Mammas, Local Infant Feeding Information Board (LIFIB), Midwives Information and Resource Service (MIDIRS), National Breastfeeding Helpline, NCT, UK Association of Milk Banking (UKAMB), Unicef UK Baby Friendly Initiative, Unison, World Breastfeeding Trends Initiative UK (WBTi).



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