Baby Feeding Law Group - UK

Infant milks marketed as foods for special medical purposes (FSMP)

THE CASE FOR REGULATORY REFORM TO PROTECT INFANT HEALTH

Contents

Infant milks marketed as foods for special medical purposes (FSMP)
The case for regulatory reform to protect infant health

Written by **Susan Westland** and **Dr Vicky Sibson**.

Published in 2022 by the Baby Feeding Law Group UK.

A PDF of this resource is available on the Baby Feeding Law Group website: **www.bflg-uk.org**

Edited by **Ida Maspero**
www.idamaspero.co.uk

Design by **Katie White**
www.whitecreativecompany.co.uk

FIRST STEPS NUTRITION TRUST

FIRST STEPS NUTRITION TRUST
(secretariat of the Baby Feeding Law Group UK)
Studio 3.04
The Food Exchange
New Covent Garden Market
London SW8 5EL

www.firststepsnutrition.org
E: **vicky@firststepsnutrition.org**

REGISTERED CHARITY NUMBER: 1146408

SCAN TO FIND THIS REPORT ONLINE

Foreword

Welcome to this important new report on a topic very close to my heart. I understand all too well the marketing pressures new parents face on all aspects of baby care. When it comes to infant feeding, nothing less than the future health of the baby is at stake.

Despite most mums' desire to follow recommendations to breastfeed, we have a stubbornly low breastfeeding rate here in the UK. And while the International Code of Marketing of Breastmilk Substitutes (the Code) is designed to prevent the misleading and unethical marketing of formulas which threaten breastfeeding and babies' health, the UK's current regulation and enforcement falls woefully short of the Code.

From early on in my parliamentary career, I have campaigned on the issue of marketing and advertising of formula. In November 2016, I presented the ***Feeding Products for Babies and Children (Advertising and Promotion) Bill*** which sought to tighten up the regulation of formula marketing, and introduce independent oversight.

The bill cleared its first hurdle and its second reading was scheduled for March 2017. However, with a General Election called and Parliament dissolved soon after, sadly no further progress was made.

"For too long, the UK Government has kicked the issue into the long grass, leaving manufacturers free to continue exploiting legal loopholes"

However, I am passionate about the need to keep campaigning on this matter. For too long, the UK Government has kicked the issue into the long grass, leaving manufacturers free to continue exploiting legal loopholes – especially the use of the FSMP category – without any apparent oversight or enforcement… and all in pursuit of profit.

This is putting the health of the nation's babies and children at risk. And as the cost of living crisis escalates, it is ever more important to consider how company marketing may push parents into buying more expensive and often unnecessary formulas – further squeezing household budgets.

This thoroughly researched report builds a compelling case for stronger oversight and enforcement of existing regulation around the classification and marketing of commercial milk formulas, and a wholesale overhaul of legislation in line with the Code. This is a complex topic, but one which is too critical to ignore. I hope this report crystallises the facts sufficiently, and spurs the UK Government into action.

ALISON THEWLISS,
MP for Glasgow Central

SECTION 1

Overview

The UK remains a country where the majority of infants are wholly or partially fed with a commercial milk formula (most commonly an infant formula) from soon after birth, despite consistent calls from all public health bodies nationally and globally in support of breastfeeding.

For some non-breastfed babies, however, an infant formula may not meet their nutritional needs due to illness, prematurity or intolerance as a result of food allergy or an inherited metabolic condition. These infants may need a specialised infant milk designed for babies with medical conditions.

Such milks fall under regulations governing foods for special medical purposes (FSMP) and are known as iFSMP. The law requires all FSMP, including these milks, to be used under medical supervision. Yet, in practice, there is currently little enforcement of the regulations, or oversight of manufacturers' marketing practices.

This report examines the commercial milk formula industry's exploitation and misuse of the FSMP regulatory category, and describes how this is threatening babies' health. It demonstrates how a lack of oversight and enforcement of current legislation is allowing misleading marketing, with the industry using this category in particular to promote products in pursuit of profit.

We set out the complex landscape of problems resulting from current legislation and lack of enforcement, and call on the UK Government to improve regulation and enforcement to protect parents/carers and healthcare professionals from misleading marketing. Ultimately, these measures are essential to adequately protect infant health in the future.

AIM OF THIS REPORT

The aim of this report is to highlight these problems to policy makers and legislators in the UK Department of Health and Social Care (DHSC), the relevant enforcement agencies, politicians and healthcare professionals, and make a strong case for urgent action to better protect breastfeeding and infant health.

THE PROBLEMS

1. **Commercial milk formula manufacturers themselves decide which infant milks are marketed as iFSMP and which are not – with little oversight. The result is the marketing under FSMP regulations not just of specialised infant milks (which meet the definition of FSMP), but of so-called 'comfort milks' not scientifically shown to be effective. And conversely, the marketing of lactose-free and soya-based milks under infant milk regulations, when they should more accurately be classed as iFSMP.**

2. **A number of iFSMP (such as lactose-free and anti-reflux formulas) are freely available from retailers, meaning they are used without the medical supervision required by law. In addition, the public availability of these iFSMP also means that many parents of babies with a true clinical need for a product are being told to buy them, rather than being able to obtain them on prescription from the NHS.**

3. **The commercial milk formula industry inappropriately markets iFSMP to healthcare professionals (HCPs) on the basis of information which is not scientific or factual. This drives inappropriate use of some products and overuse of others.**

In theory, regulation around the composition and marketing of specialised infant milks should ensure their safe and appropriate use. Yet, as we outline in this report, the current approach is not fit for purpose.

SUMMARY OF RECOMMENDATIONS

To protect breastfeeding and infant health, we recommend that the UK Government takes a two-step approach to closer enforcement and improved regulation of the marketing practices of the commercial milk formula industry.

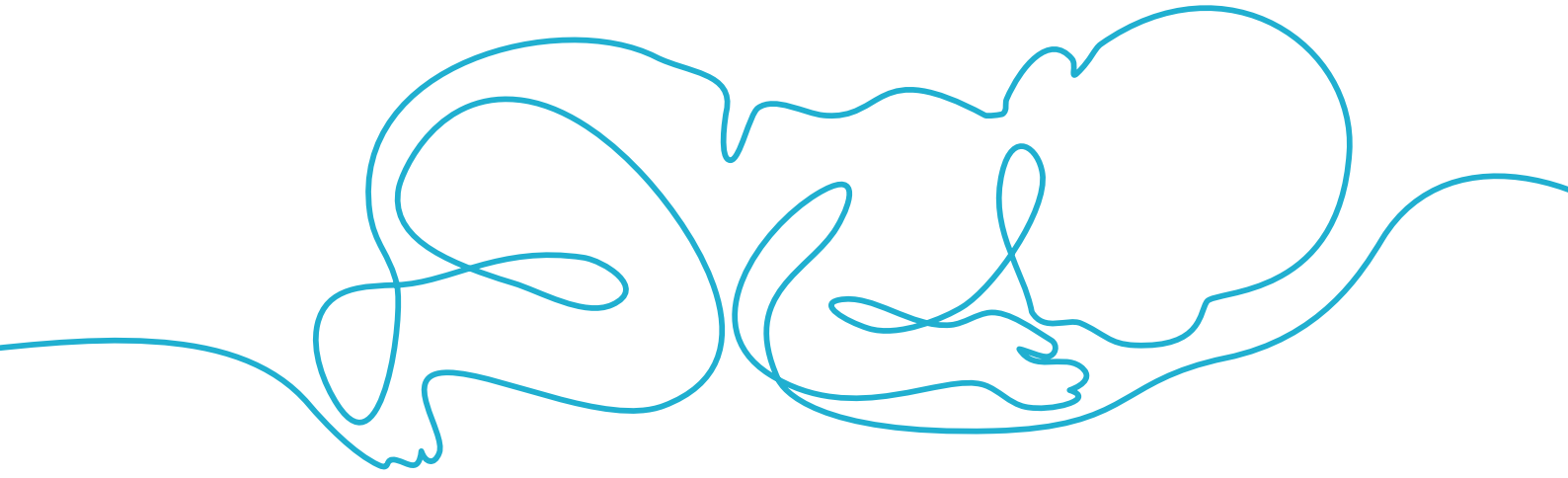
STEP 1 In the first instance – and most immediately – **the UK Government must take urgent steps to ensure greater compliance with existing laws** on the marketing of infant formulas and iFSMP, and close a loophole in the existing legislation.

This would involve robust and independent oversight of their classification (rather than leaving it to the manufacturers themselves), and greater enforcement.

STEP 2 Ultimately, **the UK Government should work towards updating its existing legislation** on the marketing of infant formula, follow-on formula and FSMP to align with the International Code of Marketing of Breastmilk Substitutes (known as the Code). This would put a stop to companies taking advantage – for marketing purposes – of the necessary distinctions between infant formula and iFSMP.

Rigorous, independent and regular monitoring and enforcement of the commercial milk formula industry's compliance with the law should be a key feature of an updated regulatory framework.

> *"Like all corporations they [commercial milk formula manufacturers] are governed by the fiduciary imperative which puts the pursuit of profits ahead of all other concerns. This mix of fiscal power, sophisticated marketing, and single-mindedness is causing great harm to public health"*
>
> (HASTINGS ET AL, 2020)



TERMINOLOGY USED IN THIS REPORT

Breastmilk substitutes	Any formulas or milks marketed or presented as a total or partial replacement for breastmilk for feeding children up to the age of three years.
Commercial milk formula	An alternative term to 'breastmilk substitute', which can potentially and misleadingly imply that such products are equivalent to breastmilk.
Infant milk	General term for different types of formulas and milks marketed for use in the first year of life.
Infant formula	Designed for healthy infants from birth to one year, meeting their nutritional needs in the first six months of life, and in the second six months alongside complementary foods. Products marketed as infant formula are subject to regulations for infant formula.
Follow-on formula	Milks marketed for feeding infants from six months to a year; however, the NHS recommends that formula-fed babies are given infant formula until 12 months of age. Products marketed as follow-on formula are subject to regulations for follow-on formula.
Foods for special medical purposes (FSMP)	A regulatory category for specialised food products marketed as suitable for individuals with specific diseases. We refer to infant milks marketed under this regulatory category as **iFSMP**. iFSMP may or may not be specialised infant milks.
Marketing	Includes product promotion, distribution, selling, advertising, product public relations, and information services (WHO, 1981).
Specialised infant milks	Commercial milk formulas specifically designed for babies with medical conditions for whom infant formula is inappropriate. These milks can meet their nutritional needs in the first six months of life, and in the second six months alongside complementary foods. We use this term to refer to infant milks shown to be effective (i.e., have an appropriate evidence base) as marketed – this is a fundamental criterion for meeting the definition of foods for special medical purposes (FSMP). These are distinct from infant milks which lack an evidence base but are being marketed as FSMP nonetheless.

ACRONYMS

ACBS	Advisory committee on borderline substances
BNFC	British national formulary for children
CCG	Clinical commissioning group
CKS	Clinical knowledge summary
COT	Committee on toxicity
CMA	Cows' milk allergy
DHSC	Department of Health and Social Care
EC	European Commission
EEC	European Economic Community
EFSA	European Food Safety Authority
ESPGHAN	European Society of Paediatric Gastroenterology, Hepatology and Nutrition
EU	European Union
FSG	Foods for specific groups
FSMP	Foods for special medical purposes
GOR	Gastro-oesophageal reflux
HCP	Healthcare professional
IBFAN	International Baby Food Action Network
ICS	Integrated care system
iFSMP	Infant milk regulated as food for special medical purposes
NICE	National Institute for Health and Care Excellence
SACN	Scientific Advisory Committee on Nutrition
Unicef	United Nations International Children's Emergency Fund
WHA	World Health Assembly
WHO	World Health Organization

SECTION 2

Milk feeds for infants: what are the options?

The normal and optimal way of feeding a baby is breastfeeding (WHO and Unicef, 2003; SACN, 2018). Breastfeeding protects infants from childhood diseases and illness later in life, and is a key factor in ensuring they reach their full potential for health and development, as well as benefiting the breastfeeding mother (SACN, 2018).

The public health recommendations of the World Health Organization (WHO and Unicef, 2003) and health departments across the world, including in the UK, are for exclusive breastfeeding for the first six months of life, and continued breastfeeding alongside complementary feeding up to the age of two years and for as long as the mother and baby wish thereafter (SACN, 2018)[1].

The **International Code of Marketing of Breastmilk Substitutes** (known as the Code) is an international voluntary code of practice designed to protect breastfeeding and inform national legislation covering the marketing of commercial milk formula and other products which may disrupt breastfeeding (WHO, 2022).

ABOUT THE CODE

For over 40 years, the global health community has recognised the harms caused by inappropriate marketing of commercial milk formulas, other milk products, foods and beverages marketed for infants and young children, as well as bottles and teats.

In 1981, the World Health Assembly (WHA), the world's highest health policy-setting body, adopted the International Code of Marketing of Breastmilk Substitutes to encourage better regulation of their marketing. This, along with its 20 subsequent WHA resolutions, is known as the Code (WHO, 2022) – the internationally agreed minimum standard needed for protecting breastfeeding, and ensuring that parents and carers using commercial milk formulas can make decisions based on full, impartial information rather than misleading, inaccurate and biased marketing claims. It provides strict rules for how products fed to or used to feed infants and young children can be marketed.

Despite unequivocal global acceptance that breastfeeding is superior to the use of commercial milk formulas, many countries fail to properly legislate against their inappropriate marketing. In the UK, the composition, labelling and some elements of marketing of infant milks are regulated as described on pages *9* and *11*, however these regulations do not incorporate all of the minimum safeguards suggested by the Code.

The 2022 Status Report on the Code from WHO, Unicef, and IBFAN assessed 194 countries' legal measures to implement the Code. The UK scored only 40%, with a notable lack of protection for young children over a year old, and limited restrictions on product promotion to healthcare workers. As a result, infants, young children and parents are not fully protected from industry practices that undermine breastfeeding (WHO, Unicef and IBFAN, 2022).

[1] It is recognised that there are exceptional circumstances in which infants cannot or should not be breastfed (WHO, 2003) and in the UK some mothers choose not to breastfeed. The WHO advises that "the choice of the best alternative – expressed breastmilk from an infant's own mother, breastmilk from a healthy wet-nurse or a human-milk bank, or a breastmilk substitute fed with a cup, which is a safer method than a feeding bottle and teat – depends on individual circumstances" (WHO, 2003). As access to donor human milk may be challenging, some babies have no or limited access to breastmilk and will require a commercial milk formula.

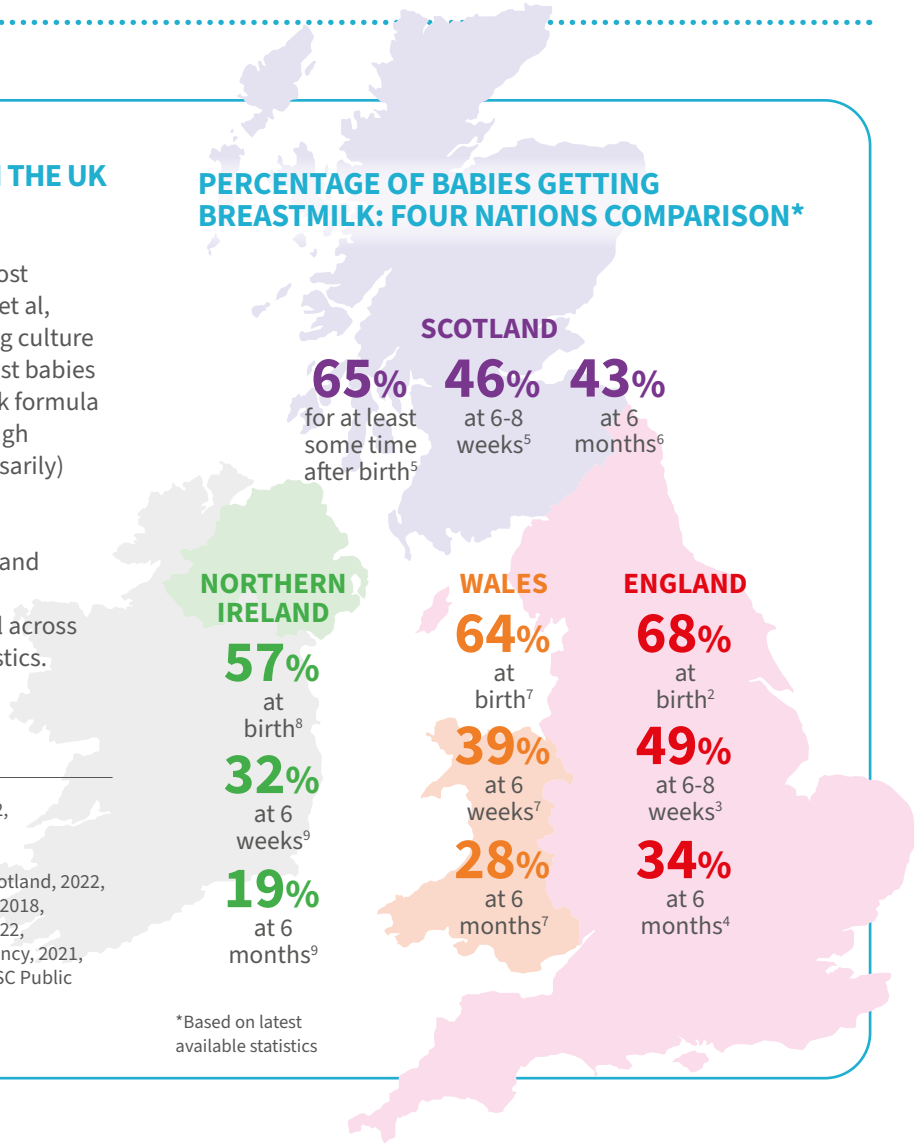
BREASTFEEDING TRENDS IN THE UK

Despite the recognised benefits of breastfeeding, and the desire of most mothers to breastfeed (McAndrew et al, 2012), the UK has a formula-feeding culture for a range of complex reasons. Most babies in the UK are fed a commercial milk formula from their first months of life through their first year, and many (unnecessarily) thereafter.

Whilst there is variation regionally and between the devolved nations, breastfeeding rates are suboptimal across the board, as shown by these statistics.

[2] In June 2022, according to NHS Digital, 2022,
[3] In 2021/2022, according to OHID, 2022,
[4] In 2010, according to McAndrew et al, 2012,
[5] In 2021/2022, according to Public Health Scotland, 2022,
[6] In 2017, according to Scottish Government, 2018,
[7] In 2021, according to Welsh government, 2022,
[8] In 2020, according to HSC Public Health Agency, 2021,
[9] Among babies born in 2018, according to HSC Public Health Agency, 2021

PERCENTAGE OF BABIES GETTING BREASTMILK: FOUR NATIONS COMPARISON*



*Based on latest available statistics

FEEDING HEALTHY, TERM BABIES WHO ARE NOT EXCLUSIVELY BREASTFED

For healthy infants who are either not breastfed or are partially breastfed (or who do not have access to donor human milk), infant and follow-on formulas can substitute for breastmilk during the first year of life. Infant formula can be used for the full first year of life. Follow-on formula, though marketed for infants from six months to one year, offers no nutritional advantages compared to infant formula and is not recommended by the NHS (NHS, 2019).

Whilst no commercial milk formula offers the immune benefits of breastmilk, it can provide the nutrients babies need to grow and develop in their first six months of life, and, complemented by a progressively diversified diet, can support continued growth and development in the second six months.

As infant formula may be the sole source of nutrition for many babies during their first six months of life, its nutritional composition and the safety and suitability of ingredients are regulated (see page ***9***). The basis of these regulations is the nutritional composition of breastmilk. However, as breastmilk is a dynamic, bioactive fluid, its benefit to infant health cannot be fully reproduced.

Despite what company marketing may suggest, the nutrient content of different brands of infant formula varies little, because by law they must all conform to the same compositional requirements. However, different ingredients can be used to achieve the mandatory nutritional composition, and the law allows some optional ingredients to be added. The regulations stipulate that infant formulas (and follow-on formulas) must be made from ingredients scientifically shown to be suitable for babies from birth. Table 1 (page ***9***) shows the key ingredients used in infant formulas in the UK.

HOW ARE INFANT AND FOLLOW-ON FORMULAS REGULATED IN THE UK?

The **composition** and certain **elements of the marketing** of infant and follow-on formula are regulated under the retained EU directive ***Foods for Specific Groups (FSG) (609/2013)***.

The directive contains delegated acts. ***EU delegated regulation 2016/127*** relates to infant formula and follow-on formula. The UK has adopted these regulations, so infant formula and follow-on formula must comply with these regulations.

The regulations cover only composition and marketing. There are no legal directives relating to the temperature at which powdered infant milks should be reconstituted for safety. Powdered infant milks are not sterile. To destroy any pathogenic bacteria they may contain, the NHS recommends that they are reconstituted with water at a temperature of 70^0C or above (NHS, 2022).

"Despite what company marketing may suggest, the nutrient content of different brands of infant formula varies little, because by law they must all conform to the same compositional requirements."

TABLE 1

TYPICAL INGREDIENTS OF INFANT FORMULAS MARKETED IN THE UK

Nutrients	Per 100ml	Ingredient sources
Energy	**66kcal**	
Protein	1.3g	Cows' or goats' milk whey concentrate, skimmed milk from cows' or goats' milk, fermented milk, demineralised whey, whole cows' or goats' milk, soya protein
Fat	3.5g	Rapeseed oil, palm oil, coconut oil, sunflower oil, anhydrous cows' milk fat, whole cows' milk fat, whole goats' milk fat
- Docosahexaenoic acid (DHA)	17g	Fish oil, fungal oil
Carbohydrate	7.4g	Lactose, maltodextrin, glucose syrup, oligosaccharides
- Lactose	7.1g	Lactose, whey, semi-skimmed milk, whole milk
Vitamins and minerals		Commercial vitamin and mineral preparations to top up to mandatory requirements
Non-nutrient ingredients		
Choline, inositol, L-carnitine		Commercial preparations
Permissible additional ingredients		
Oligosaccharides		Industrial preparations from cows' milk, or from inulin from plant sources, metabolically engineered from yeast/bacteria
Arachidonic acid		Fungal oil
Taurine		Industrial preparations

FEEDING BABIES WITH MEDICAL CONDITIONS WHO ARE NOT EXCLUSIVELY BREASTFED

Where non-breast(milk) fed or partially breast(milk) fed babies under a year old are premature or diagnosed with clinical conditions such as an allergy or a metabolic disorder, an infant formula may not be an appropriate substitute for breastmilk, and a specialised infant milk may be required[10].

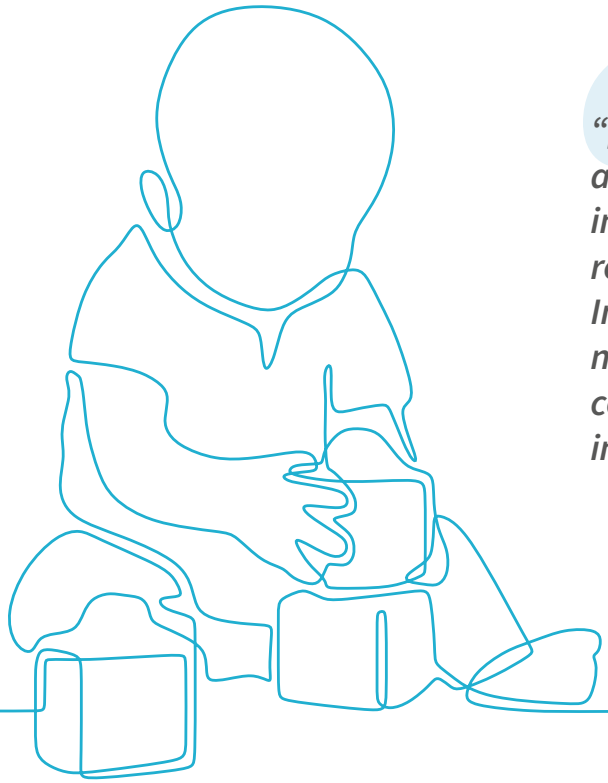
The composition and ingredients of specialised infant milks differ from infant formulas, as they are developed to meet the nutritional needs of babies with specific clinical conditions or diseases. For example, a baby who is allergic to cows' milk may become unwell if given a formula based on cows' milk protein, so a specialised infant milk based on extensively hydrolysed cows' milk protein may be prescribed.

The conditions for which specialised infant milks are indicated vary greatly in terms of severity, their impact on quality of life and their longevity. They also pose additional health risks compared with infant formula, as outlined on page ***15*** (for soya-based formula) and in ***Appendix 2*** (for lactose-free) and ***3*** (for anti-reflux formula). Therefore, their use requires ongoing medical review to ensure that they remain clinically indicated, that they are used only for as long as is necessary, and that they do not interfere with timely complementary feeding in order to avoid longer-term feeding difficulties.

Ideally, specialised infant milks should only be used when breastfeeding is contra-indicated and preferably on prescription under continuing medical supervision. In fact, they are rarely clinically necessary, and their prices are considerably higher than the same brand infant formulas (see ***Appendix 1***).

BREASTFEEDING BABIES WITH MEDICAL CONDITIONS

It is exceptionally rare for breastfeeding to be contra-indicated for sick babies. In fact for most, such as preterm babies, breastfeeding is vital to their wellbeing, short-term transition to health, and longer-term health outcomes. If a mother wishes to breastfeed, she should be supported to do so alongside the dietary management of her baby's health condition (WHO, 2009).



"[Specialised infant milks] pose additional health risks compared with infant formula... Therefore their use requires ongoing medical review... In fact, they are rarely clinically necessary, and their prices are considerably higher than same brand infant formulas."

[10] A specialised infant milk may also be indicated instead of breastmilk, but only in very rare cases, such as the presence of galactosaemia.

SECTION 3

Infant milks marketed as foods for special medical purposes (iFSMP)

Specialised infant milks for babies with a diagnosed disease, disorder or medical condition are governed by a different set of regulations than those for infant formula or follow-on formula. They fall in the regulatory category called foods for special medical purposes (FSMP), alongside other foods for patients who cannot eat normal diets.

FSMP: LEGAL DEFINITION AND REGULATION

Products considered for regulation as FSMP should be assessed against a common definition established by the Foods for Specific Groups (FSG) directive (EU) No 609/2013:

*" … 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**".*

This directive contains a delegated regulation relating specifically to FSMP, which stipulates that their formulation should be based on sound medical and nutritional principles, and their use should be proven to be safe, beneficial and effective (see box for details). The core principles of these regulations aim to avoid possible marketing abuses linked to the misclassification of products, reduce confusion for consumers on the nature of the different products being offered to them and guarantee fair competition.

However, despite the requirement that FSMP be used under medical supervision, the law does not lay down restrictions on retail practices for iFSMP beyond those relevant to infant formula and follow-on formula. So, there are no limitations on their sale to the public, and parents and carers are using these products without medical supervision.

HOW ARE IFSMP REGULATED?

The **composition** and certain **elements of marketing** of infant formula, follow-on formula and infant milks considered to be FSMP are regulated under the retained EU directive ***Foods for Specific Groups (FSG) (609/2013)***. The directive contains delegated acts and ***EU delegated regulation 2016/128*** relates specifically to FSMP. The main provisions of these regulations are as follows:

Compositional requirements:
"The formulation of FSMP shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe, beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data."

Specific requirements on food information:
- include a statement that the product must be used under medical supervision
- the statement of the disease, disorder or medical condition for which the product is intended
- where appropriate, a statement concerning adequate precautions and contra-indications.

Nutrition and health claims: must not be made and consumption of these products must not be promoted.

Labelling and presentation:
- shall not include pictures of infants, or other pictures or text which may idealise the use of the product
- must make a clear distinction between FSMP and infant and follow-on formula, particularly in respect of the text, images and colours used, to avoid confusion between them.

Advertising:
- is restricted to publications specialising in baby care, and scientific publications
- must provide only scientific, factual information.

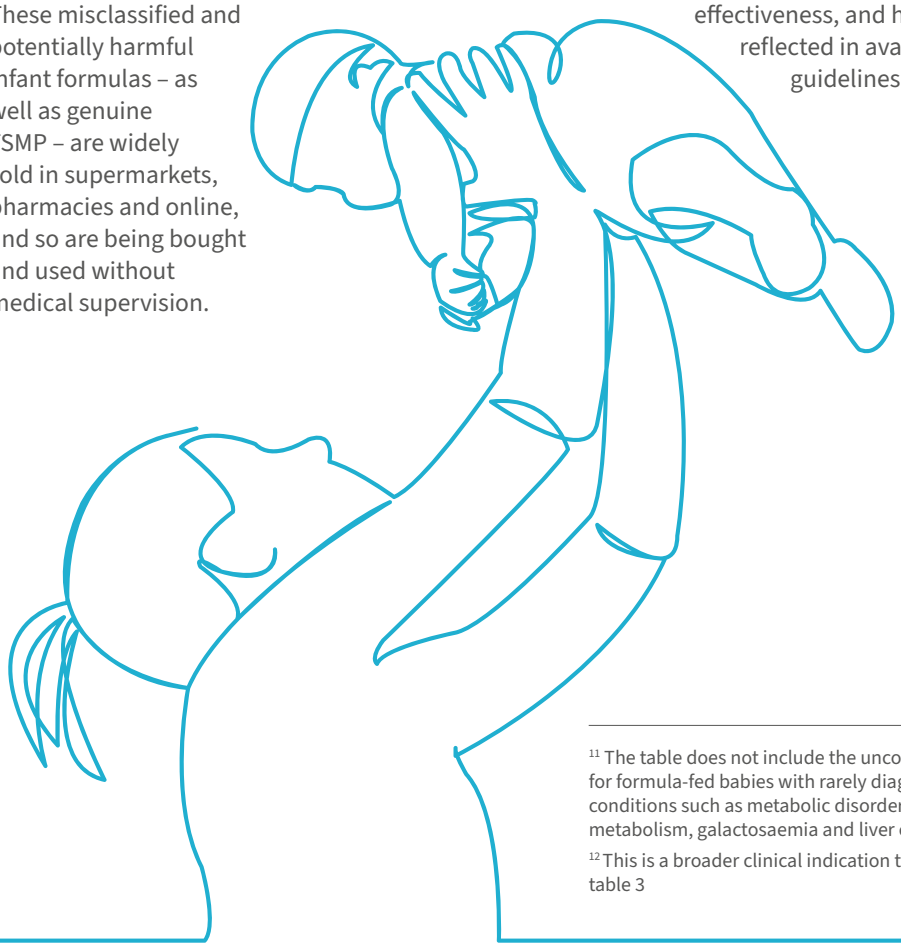
THE PROBLEM WITH PRESENT REGULATION

The legal definition of FSMP outlines their compositional requirements (fundamentally, that such products should be "effective and beneficial as evidenced by a body of scientific data"). In addition, an EC notice provides guidance on how to assess products against these requirements (EC, 2017).

However, commercial milk formula companies themselves are currently able to choose which set of regulations to market their products under, with seemingly little legal oversight. The result is the marketing under FSMP regulations not just of specialised infant milks (which meet the definition of FSMP), but of so-called 'comfort' or 'anti-colic' milks that lack robust scientific evidence of effectiveness.

On the other hand, it also means that lactose-free and soya-based formulas are being marketed under infant and follow-on formula regulations. We believe these two types of formulas would be better categorised as FSMP, and the NHS also advises that these should only be used under medical supervision (NHS, 2019).

These misclassified and potentially harmful infant formulas – as well as genuine FSMP – are widely sold in supermarkets, pharmacies and online, and so are being bought and used without medical supervision.



INFANT MILKS MARKETED AS FSMP, AND EVIDENCE (OR NOT) OF THEIR EFFECTIVENESS

Specialised infant milks for babies with rarely diagnosed medical conditions – such as metabolic disorders of protein metabolism, galactosaemia and liver or kidney failure – are recognised as essential in the nutritional management of non-breast(milk) fed or partially breast(milk) fed babies with these conditions, and their regulation as FSMP is uncontentious.

However, a number of iFSMP are more widely available and commonly used, but their clinical effectiveness (as well as agreed use) is less clear. Where there is a lack of sufficient evidence to support all (for example, so-called 'comfort' and 'anti-colic' milks) or some uses the manufacturers suggest (for example, for anti-reflux and lactose-free milks), it is difficult to support their marketing under FSMP regulations and/or their use as indicated.

Table 2 (page ***13***) outlines selected types of infant milks currently marketed as FSMP[11], the manufacturers' clinical indications for use alongside the current evidence base for their effectiveness, and how this is reflected in available national guidelines.

[11] The table does not include the uncontentious FSMP for formula-fed babies with rarely diagnosed medical conditions such as metabolic disorders of protein metabolism, galactosaemia and liver or kidney failure.

[12] This is a broader clinical indication than in the BNFC, see table 3

TABLE 2

TYPES OF INFANT MILKS CURRENTLY MARKETED AS FSMP, THEIR MANUFACTURERS' CLINICAL INDICATIONS, EVIDENCE BASE AND UK GUIDANCE FOR USE

Products which we believe are unproven and should not be marketed as iFSMP at all are highlighted in purple. iFSMP for which the manufacturers' clinical indications for use are not fully supported by evidence are highlighted pink.

iFSMP category	Clinical indication according to manufacturer	Evidence of effectiveness	UK guidance on product use
Infant milks for preterm and low-birthweight infants	Catch-up growth in pre-term infants and small for gestational age infants.	Some evidence to warrant use in babies born under 1.5kg / <32 weeks. For infants born at 32-36 weeks or 1.5-2.4kg, WHO guidelines advise use of clinical judgement to choose infant formula or preterm formula (WHO, 2022a).	No UK guidelines, but 3 international guidelines are used in UK clinical practice (Agostoni et al, 2010; Tsang et al, 2005; Koletzko et al, 2014).
Infant milks for preterm infants, post-discharge	Catch-up growth in pre-term infants and small for gestational age infants on hospital discharge.	There is scant evidence to support use for catch-up growth.	No UK guidance but ESPGHAN guidance recommends that infant milk-fed babies should receive post-discharge infant milk until 40 weeks post-conceptual age, and potentially up to 52 weeks post-conceptual age (Aggett et al, 2006).
High-energy infant milks suitable for term infants from birth	Faltering growth; disease related malnutrition; increased energy requirements in term infants.	Little high-quality published evidence to show effectiveness. What is available appears to be primarily sponsored by commercial milk formula companies (Helfer et al, 2021).	NICE Guideline NG75 (2017) on faltering growth in infants and children suggests trial of an oral liquid nutritional supplement (high energy infant milk) only where faltering growth continues despite other interventions.
Partially hydrolysed infant milks marketed as 'comfort' or 'anti-colic' milks	Colic and constipation	No robust clinical evidence of effectiveness.	NICE clinical guidance is clear there is no infant formula solution for colic (NICE CKS, 2022). The NHS recommend only practical and soothing strategies for colic (NHS, 2022a).
Thickened (anti-reflux) infant milks suitable from birth	Marketed as reducing gastro-oesophageal reflux (GOR) and vomiting or spitting up feeds in formula-fed infants[12].	Some evidence of effectiveness in the reduction of vomiting (Horvath et al, 2008; Carroll et al, 2002).	NICE guidance published in January 2015 (NICE, 2015) and NICE Quality Standard (QS112, NICE 2016) recommend carefully managed use of anti-reflux milks as part of a stepped approach to the management of GOR in formula-fed infants (NICE, 2015).
Lactose-free infant milks suitable from birth*	Marketed as suitable for management of lactose intolerance or temporary lactose intolerance[12].	It is self-evident that a lactose-free infant milk will be effective in the management of congenital or primary lactose intolerance. There is little high-quality published evidence to support use in transient (temporary) lactose intolerance as a result of gastroenteritis. Routine use in gastroenteritis is not supported by the ESPGHAN Committee on Nutrition (Aggett et al, 2001).	NHS guidance states that lactose-free formula is suitable for formula-fed babies with lactose intolerance (NHS, 2019a)
Extensively hydrolysed and amino acid based infant milks suitable from birth	Proven cows' milk allergy (CMA)	There is ample evidence of effectiveness in the management of CMA.	NICE provides guidance on how to manage suspected or diagnosed cows' milk allergy (NICE 2015b).

* Lactose-free Infant milks are currently marketed as either FSMP under EU 2016/128 or as infant formula under EU 2016/127 dependent on the manufacturer, however, the only lactose-free infant milk marketed under FSMP regulations is currently unavailable pending reformulation.

"Despite the requirement that FSMP be used under medical supervision, the law does not limit their sale to the public"

ACCESSIBILITY OF DIFFERENT INFANT MILKS MARKETED AS FSMP

As outlined above, despite the requirement that FSMP be used under medical supervision, the law does not limit their sale to the public. Consequently, some iFSMP are widely sold in supermarkets and pharmacies as well as online, whilst others may only be available on prescription.

It appears that the manufacturer determines which iFSMP are widely sold to the public, and in turn, prescribing practices[13] are influenced by each individual product type's availability to the public. Table 3 (page ***15***) lists the most commonly used iFSMP, shows which are included in the British National Formulary for Children (BNFC), and which are available for sale.

Infant milks marketed as FSMP and included in the BNFC are categorised as 'borderline substances' with Advisory Committee on Borderline Substances (ACBS) approval. The ACBS committee is responsible for determining which borderline substances are available on prescription and for which conditions they may be prescribed in NHS primary care. Their assessment includes reviewing the evidence of product effectiveness.

Notably, lactose-free and anti-reflux milks are listed on the BNFC with a more limited range of ACBS indications than those suggested by manufacturers (see ***table 2*** on page ***13***). Although they can be prescribed under specific conditions, their wide availability in shops means that most clinical commissioning groups (CCGs) in England (and equivalent bodies in the devolved nations) recommend they are purchased[14].

As a result, families of babies diagnosed with primary or congenital lactase deficiency – or who have been recommended to try an anti-reflux formula as part of a stepped approach to care (as recommended by NICE 2015, 2016) – will be expected to buy the recommended iFSMP (usually more expensive than brand-equivalent infant formula, see ***Appendix 1***) rather than having it prescribed, as happens with other disorders or rare medical conditions or diseases.

[13] Each of the different clinical commissioning groups (CCGs) in England (and their equivalent bodies in the devolved nations) may have developed their own prescribing guidelines which do not necessarily support prescribing the full BNFC list, and on occasion, may include infant feeding products not present on the BNFC list.

[14] Since July 2022, integrated care systems (ICSs) have taken over the responsibilities of CCGs, but we are not aware of any changes to the expectation that these products are purchased by the user.

TABLE 3

ACCESSIBILITY AND PRESCRIBING STATUS OF INFANT MILKS MARKETED AS FSMP

Products which we believe are unproven and should not be marketed as iFSMP at all are highlighted in purple. iFSMP for which the manufacturers' clinical indications for use are not fully supported by evidence are highlighted in pink.

iFSMP type	On BNFC	Sold in the community	Current prescribing status
Infant milks for pre-term and low birthweight infants	**X** (not used in primary care without hospital supervision.	**X**	Available on prescription by all CCGs. Started in hospital and continued by GP under hospital supervision
Infant milks for pre-term infants post discharge	**X** (not used in primary care without hospital supervision. Available through NHS supply chain)	**X**	Available on prescription by all CCGs. Started in hospital and continued by GP under hospital supervision
High energy infant milks suitable for term infants from birth	✓	**X**	Available on prescription by all CCGs. Started in hospital and continued by GP under hospital supervision
Partially hydrolysed infant milks marketed as 'comfort' or 'anti-colic' milks	**X**	✓	Not recommended, not prescribed
Thickened (anti-reflux) infant milks suitable from birth	✓ Classified as enteral feeds	✓	Carers usually advised to buy from a retailer, but occasionally prescribed
Lactose-free infant milks suitable from birth*	✓	✓	Carers usually advised to buy from a retailer, but occasionally prescribed
Extensively hydrolysed and amino acid-based infant milks suitable from birth	✓	**X**	Only available on prescription for management of CMA

CONCERNS AROUND REGULATION OF SOYA-BASED INFANT FORMULA

Only one soya-based infant milk is available in the UK, namely SMA Soya Infant Formula. It is marketed under the infant and follow-on formula regulations, despite being recommended by the manufacturer for infants with cows' milk allergy and being listed on the BNFC.

In addition, current national recommendations are that soya-based infant formula should only ever be used if recommended or prescribed by a health visitor or GP, and then only from six months (NHS, 2019, COT 2003, COT 2013). Despite this, SMA Soya is marketed as suitable from birth.

Concerns about soya protein centre around the potential impact of phyto-oestrogens on reproductive development and to a lesser extent, the potential allergenic effect in babies at high risk of atopy. The use of maltodextrin rather than lactose as a carbohydrate source in soya-based infant formula may also pose a risk to dental health.

Soya-based infant formula is freely available from pharmacies and shops, without any prior recommendation or risk assessment from a healthcare professional. It is listed on the BNFC for use in infants with proven lactose and associated sucrose intolerance in pre-school children, galactokinase deficiency, galactosaemia and proven whole cows' milk sensitivity, but is generally not recommended under CCG (or equivalent) guidelines.

Although the infant and follow-on formula regulations permit the use of soya protein in infant formula, soya infant formula also meets several qualifying concepts in the definition of FSMP. Given concerns around potential harms associated with soya-based formula, it is therefore difficult to support its regulation not as an FSMP but as an infant formula, and its general availability to the public.

* Lactose-free infant milks are currently marketed as either FSMP under EU 2016/128 or as infant formula under EU 2016/127 dependent on the manufacturer, however, the only lactose-free infant milk marketed under FSMP regulations is currently unavailable pending reformulation.

SECTION 4

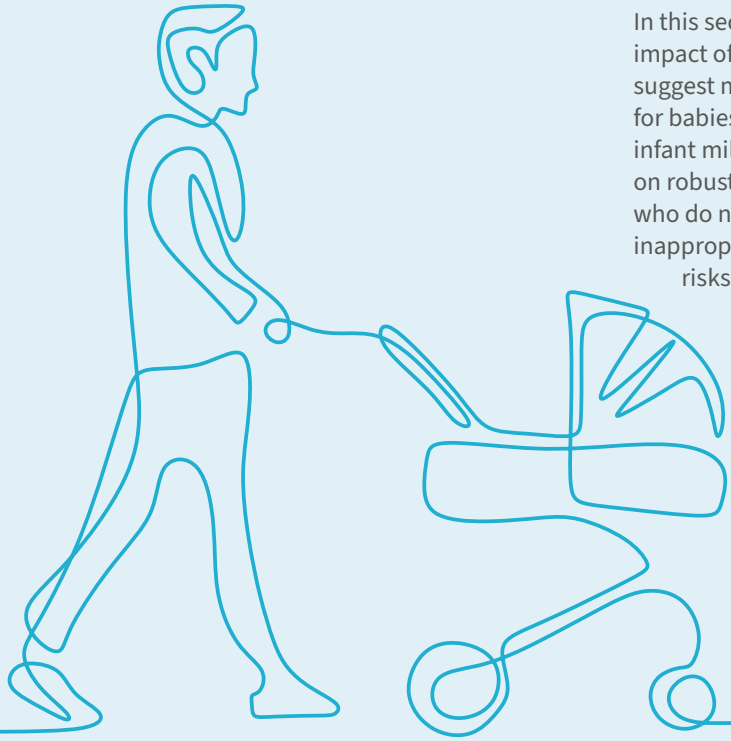
Problems with the FSMP regulations and their implementation

Current regulation around the composition and marketing of specialised infant milks is failing to contain the rapidly growing and sometimes inappropriate use of proven iFSMP (Munblit et al, 2020; Mehta et al, 2022), and also infant milks marketed as FSMP but that lack evidence of effectiveness.

Ultimately, this situation poses threats to infant health and is leading to unnecessary spending in the NHS and by families. It is the result of regulations being manipulated and regulatory limitations being exploited by commercial milk formula companies in pursuit of sales and ultimately profits.

This section identifies the three key marketing practices – routinely used by the commercial milk formula industry – which are driving the excessive and inappropriate use of iFSMP, as well as the regulatory limitations that make these practices possible. These are:

1. **The industry is permitted to determine which infant milks to market under which regulatory category, and they do not do so appropriately**
2. **The industry is allowed to sell iFSMP directly to the public in supermarkets, pharmacies and online, facilitating their use without medical supervision**
3. **The industry is allowed to mislead healthcare professionals about the nature and effectiveness of its products, on the basis of information which is not scientific and factual.**



In this section we outline the direct and indirect impact of these practices on infant health. We suggest measures to ensure that clinicians caring for babies who genuinely need specialised infant milks are able to base feeding decisions on robust scientific evidence; and that infants who do not need specialised infant milks are not inappropriately fed milks that pose additional risks to health.

1 The commercial milk formula industry can decide which infant milks are iFSMP and which are not, and do not do so appropriately

As outlined on page ***11***, the FSMP regulations aim to protect specific vulnerable groups of consumers by regulating the composition and marketing of food products specifically created for them. Their stated aim is also to increase legal clarity for business and to facilitate correct application of the legal requirements.

Crucially, however, the UK law does not require commercial milk formula companies to gain prior authorisation by any government department or delegated body to market specific products as FSMP or as infant formulas. Companies can pick and choose which products to market under which regulations.

As a result, there are infant milks being marketed in the UK under FSMP regulations that should be marketed under the infant and follow-on formula regulations. And conversely, in our opinion (and supported by NHS advice (NHS, 2019), there are infant milks marketed under the infant and follow-on formula regulations that should fall under FSMP regulations. These are:

- **Five brands of partially hydrolysed infant milks** currently marketed under FSMP regulations as suitable for the management of colic and constipation: Aptamil Comfort, Cow & Gate Comfort, Hipp Comfort, SMA Comfort and Kendamil Anti Colic. These products do not have robust evidence of effectiveness, and would therefore be more appropriately marketed under the infant and follow-on formula regulations.

- **Two brands of lactose-free infant milk** (Aptamil Lactose Free and SMA Lactose Free) and **one soya-based infant milk** (SMA Soya) currently marketed under the infant and follow-on formula regulations. However, these product types may pose added health risks over infant formula (see ***Appendix 2***, and page ***15***), meaning they would be more appropriately marketed under FSMP regulations.

The following scenario exemplifies the lack of oversight as to whether infant milks are being appropriately regulated: while the manufacturers of Aptamil Lactose Free and SMA Lactose Free have chosen to market their products under the infant and follow-on formula regulations, a third (Kendamil Lactose-free) was until recently being marketed under FSMP regulations (it is currently "unavailable pending reformulation").

We believe that commercial milk formula companies are selecting which regulations to market their products under in order to maximise their sales. As FSMP are required by law to carry statements referring to the dietary management of a disease, disorder or medical condition, this gives them indirect permission to include a 'marketing statement' such as 'for colic and crying'. This statement may act as an incentive for companies to inappropriately market infant milks as FSMP, which would be more appropriately marketed as infant formula.

Consequences of misclassification

The misclassification of infant formula as FSMP – and conversely, the misclassification of iFSMP as infant formula – may cause harms, as the protection the law should give consumers is lacking.

Manufacturers marketing unproven infant milks as FSMP – which by definition should be effective for a particular condition – may convince parents that there is a formula solution to their baby's perceived feeding problem, when in fact it may simply be normal baby behaviour (Brown et al, 2020). Allowing families to self-medicate using products which promise treatment of common infant feeding-related issues could result in a more serious health problem not being investigated promptly, with serious long-term consequences (Munblit et al, 2020).

Furthermore, implying that unproven products are effective and limiting parents' access to them by commanding a higher retail price than the brand equivalent infant formula (see ***Appendix 1***) is, in our opinion, exploitative and immoral, especially in the context of the current cost of living crisis.

Where infant milks that may pose added health risks (for example soya-based formula) are regulated as infant formula rather than as FSMP, parents are able to buy them without recommendation or advice from a healthcare professional. Their suitability and appropriateness for the baby is therefore unknown. Without medical supervision, their safe and appropriate use cannot be guaranteed.

2 The commercial milk formula industry can sell iFSMP in supermarkets, pharmacies and online, so promoting and facilitating their use without medical supervision

FSMP, by design, are intended for use under medical supervision. The majority of proven iFSMP – for example, specialised infant milks for specific metabolic disorders and diagnosed cows' milk allergy – are only available on prescription. This ensures that they are used as intended, on the advice of and under the supervision of a paediatrician or GP.

However, there is an expanding market of iFSMP branded and labelled very similarly to infant formula, and sold alongside infant formula on supermarket and pharmacy shelves. Where an infant milk lacking evidence of effectiveness is regulated as an iFSMP, and the label of the iFSMP product is not visually distinct from infant formula and follow-on formula (as the law requires, see page ***11***), parents may be encouraged to self-medicate their baby with a product they perceive to be effective.

Kendamil provides a clear example of cross-over in labelling styles – also referred to as 'cross promotion' (WHO and Unicef, 2019) – between an 'anti-colic' milk regulated as an FSMP, and infant and follow-on formula – see the case study on page ***28***, ***Appendix 4***. This blurring of boundaries between iFSMP and infant formula happens because the industry can decide which infant milks are regulated as FSMP and which are not. It is enabled by a lack of regulatory control over retail practices, and a lack of enforcement of the regulations (see page ***11***) requiring a visual distinction between iFSMP and infant formula.

Three categories of iFSMP are commonly available from supermarkets, pharmacies and online: so-called 'comfort'/'anti-colic' milks, anti-reflux milk and lactose-free infant milk (as outlined above, one of the three lactose-free products recently available was marketed as iFSMP, although it is currently unavailable pending reformulation).

'Comfort milks' are not listed on the BNFC (see page ***15***, table 3). This may either be because they have been rejected by the ACBS evaluation process to assess suitability for BNFC inclusion, or because the manufacturer has not submitted them for assessment, choosing instead to place them directly on the retail market.

Lactose-free and anti-reflux milks are listed on the BNFC and are also available from retailers (see page ***15***). Although listed on the BNFC, the ACBS indications for their use are more limited than those listed by the manufacturer (see page ***13***). By placing these products on the retail market for parents to purchase, the formula industry is creating the opportunity for these products to be used for the wider range of indications as stated on their labels and in their marketing – despite a lack of evidence of effectiveness for all indications stated.

There is also an additional risk that potential health risks are not clearly communicated to parents at the point of sale, or on the product packaging (see ***Appendix 5***). This is of concern for both iFSMP sold in supermarkets, pharmacies and online, and for the freely available infant formulas that would, in our opinion, be more appropriately marketed as FSMP (namely all lactose-free and soya formulas). A risk-benefit analysis for using an iFSMP – and communicating risks and their mitigation to the baby's parent/carer – are part of the role in supervising their use.

The combination of ready availability and the influence of manufacturers' inappropriate and pervasive marketing techniques (see page ***19***) promotes the self-medication of babies with iFSMP, and prevents the regulatory principle of use under medical supervision from being upheld.

Consequences of unsupervised use of iFSMP

The compositional modifications and/or added ingredients used in iFSMPs may pose added health risks over the use of infant formula. The potential health risks of lactose-free formula and anti-reflux formula are outlined in the case studies on pages ***26*** and ***27***, ***Appendices 2*** and ***3***. It is because of these risks that iFSMP should be used under supervision of a healthcare professional qualified to make a risk assessment on a case-by-case basis.

As stated above, allowing families to self-medicate with products implying effective treatment of common infant feeding problems may mean that a more serious health problem is not investigated quickly, with serious long-term consequences (Munblit et al, 2020).

HOW MARKETING ENCOURAGES PARENTS TO SELF-MEDICATE THEIR BABIES

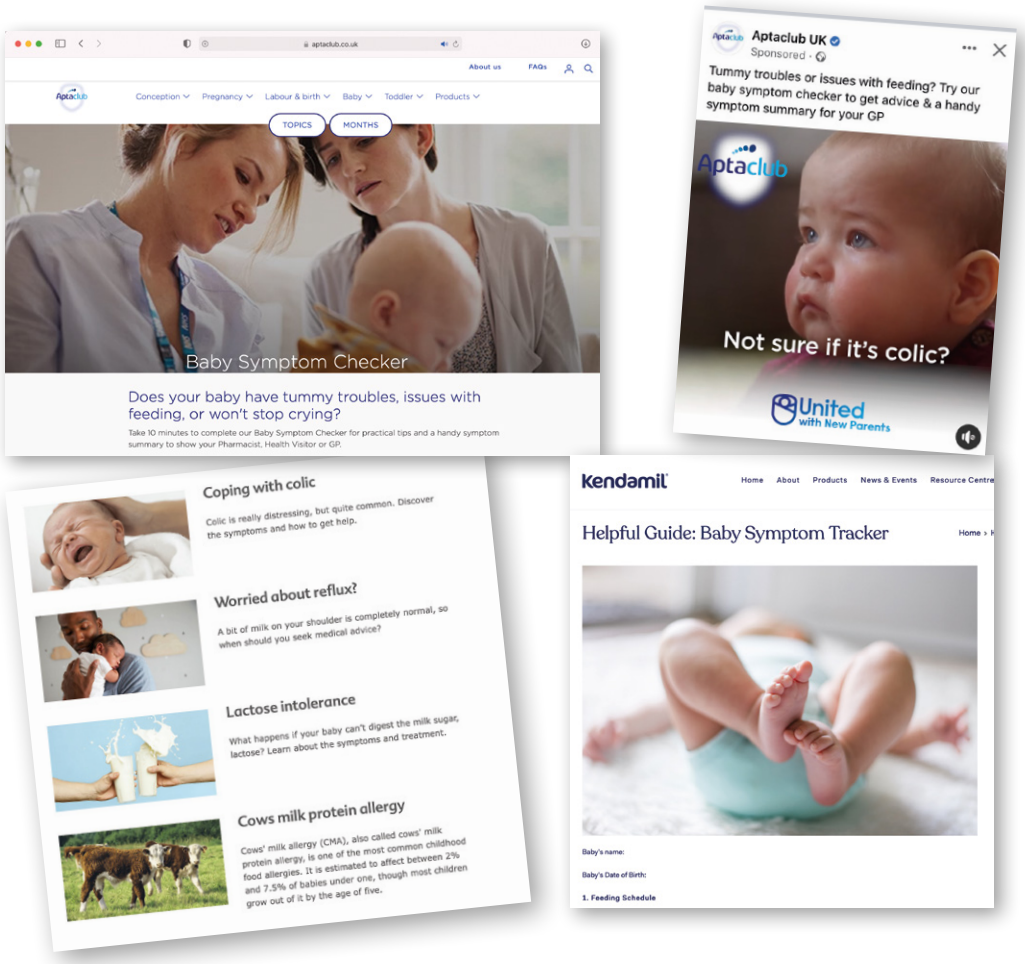
The combination of very sophisticated industry marketing practices and weak enforcement of regulations have created a market environment where parents are encouraged to self-diagnose a perceived feeding problem, and then find an infant milk 'solution', without advice from a healthcare professional.

Commercial milk formula companies initially use sophisticated marketing techniques to exploit parents' anxieties around common baby feeding behaviours such as constipation, reflux and colic. They may then subtly raise awareness of these behaviours, framing them as problems that can be solved by purchasing a product (Shewan, 2021).

The 'baby clubs' operated by most commercial milk formula companies are a convenient vehicle for this type of marketing, and most include advice on managing common feeding-related issues. These are often framed as problems or symptoms (with images of distressed, crying babies, as shown here), making both an emotional appeal to parents and medicalising normal baby behaviours.

Some websites include a symptom checker for parents to record their baby's feeding behaviour (see images). The parent is then encouraged to take this to their pharmacist or GP. Baby clubs do not explicitly recommend their iFSMP products in these symptom checkers, but may disingenuously suggest symptom management techniques, or even refer to the NHS website (which does not recommend any change of formula, except occasionally for reflux), whilst at the same time marketing iFSMP named as 'anti-colic', 'anti-reflux, 'comfort' along with a legally required statement of use, such as 'for the dietary management of reflux and regurgitation'.

In short, the ready availability of these products (which are also routinely more expensive than the same brand infant formula, see ***Appendix 1***) steers parents toward self-diagnosing 'problems' and then purchasing the formula solution presented by the manufacturer.



3 The commercial milk formula industry inappropriately markets iFSMP to healthcare professionals (HCPs) on the basis of information which is not scientific and factual.

Some babies genuinely need specialised infant milks to meet their specific nutritional needs. It is therefore essential that HCPs have access to independent, reliable and complete product information to help them find the most effective product(s) for their young patients.

The regulations make provision for this. Specifically, they permit manufacturers of commercial milk formulas to provide information and updates about their products to healthcare professionals in baby care publications as well as scientific publications, provided that the information given is "scientific and factual".

However, this presents the opportunity for commercial milk formula companies to advertise their products in magazines and journals aimed directly at HCPs. Ample evidence shows that the requirement for advertisements in journals to be both scientific and factual is routinely disregarded.

In 2022, the WHO and Unicef published a high-profile report summarising the results of a multi-country study that highlighted how commercial formula milk companies, including those operating in the UK, distort science and medicine to legitimise their claims and push their products (WHO and Unicef, 2022). The principal vehicle for this marketing is specialist infant milks (Hastings, 2020).

For example, in a 2021 study of advertisements for 'human milk substitutes' in HCP journals, the vast majority of which were for iFSMP, none complied with requirements of the International Code of Marketing of Breastmilk Substitutes (known as the Code – see page **7**), or current UK Infant and Follow-on Formula Regulations (Hickman N et al, 2021)[15].

And it is not just a problem of advertising. Industry influence permeates research, guidelines, medical education and public awareness of CMA. Many existing milk allergy guidelines have direct or indirect support from industry and they have a vested financial interest in increasing the use of iFSMPs (van Tulleken et al, 2018). The inclusion of many non-specific symptoms (constipation and colic) in the guidelines as indicative of CMA is thought to drive overdiagnosis. Research suggests that using industry-disseminated milk allergy guidelines could result in as many as 75% of infants being labelled as having milk allergy (Vincent, 2022).

REVIEWS OF ADVERTISING

First Steps Nutrition Trust has published two reviews of infant milk advertising to health professionals: Scientific and Factual? A review of breastmilk substitute advertising to healthcare professionals (FSNT, 2016) and Scientific and Factual? A further review of breastmilk substitute advertising to healthcare professionals (FSNT, 2019). These can be found at *Reviews of claims — First Steps Nutrition Trust*.

Consequences of inappropriate marketing to HCPs

Inappropriate marketing of commercial milk formulas (which do not meet the legal requirement to be scientific and factual) is problematic because it is likely to mislead HCPs by blurring the boundaries between proven iFSMP and those that lack evidence of effectiveness. This drives both inappropriate use of some products and overuse of others.

Growing evidence shows that prescriptions – and therefore consumption – of iFSMP have been on the rise in the UK and other countries at a rate not in keeping with likely increasing prevalence of the associated medical conditions. Community prescription data for England indicates that prescribed volumes of iFSMP for babies under one year of age rose 4.4-fold between 2008 and 2020, driven largely by prescriptions of extensively hydrolysed and amino acid-based formula milks for the dietary management of cows' milk allergy (CMA), which rose 4-fold and 5.4-fold respectively (R.Boyle, personal communication, Nov 16 2022).

[15] At the time of this study there were no legal restrictions on advertising of iFSMP, and so the adverts for iFSMP were assessed for compliance with the International Code of Marketing of Breastmilk Substitutes

Yet epidemiological data does not follow prescription data: the incidence of CMA in infants was not expected to rise during this period. The most commonly discussed reason for rising prescription rates is that CMA is being over-diagnosed among children with non-specific symptoms which are common in infancy, such as crying, posseting or rashes (Mehta et al, 2022).

The extent to which commercial milk formula companies drive this overdiagnosis and subsequent demand for their products is an important part of the discussion around increasing use of iFSMP for CMA. The objective of commercial milk formula companies is to increase sales revenue as, quite simply, that means greater profits. To put this into perspective in the UK, between 2008 and 2020, NHS spending on prescriptions of iFSMP for infants with CMA increased by 430%, from £10 million to £53 million each year (R. Boyle, personal communication, Nov 16 2022).

Different NHS Trusts have different dietetic and GP services, so prescribing guidelines will vary by Trust, but in many places they have been produced by individual clinical commissioning groups (CCGs), or their equivalent in the devolved nations. Research suggests that all of the 70 UK clinical guidelines relating to CMA in babies promoted overdiagnosis by listing multiple symptoms and signs that occur in healthy babies, and have little established relationship with CMA (Smith et al, 2022).

All 70 guidelines also failed to support breastfeeding, universally recommending maternal dietary restriction of dairy – something which is not considered necessary for most breastfed infants with CMA (Smith et al, 2022). A recent Delphi consensus study considering overdiagnosis concluded that a reluctance to feed, stool changes and occasional spots of blood in stools (when not occurring as a result of recent milk drinking), do not indicate CMA. When compared to current guidelines which carry conflicts of interest related to the commercial milk formula industry, the Delphi study's recommendations resulted in more restrictive criteria for detecting milk allergy, a more limited role for maternal dietary exclusions and specialised formula, and better support for breastfeeding (Allen et al, 2022).

Inappropriate prescription of effective iFSMP (i.e. specialised infant milks) and overuse of unproven iFSMP mean that many more babies than necessary are given infant milks with potentially harmful ingredients. In addition, there are indirect harms to public health due to rising NHS costs (as prescription rates increase) and avoidable additional costs for families during the current and worsening cost of living crisis.

RISE IN PRESCRIPTIONS FOR IFSMP

Extensively hydrolysed formula

4 x

increase in prescription volumes

between 2008 and 2020

Amino acid-based formula

over 5 x

increase in prescriptions

between 2008 and 2020

NHS spending on iFSMP prescriptions for CMA

430% increase

£10 million to £53 million a year

between 2008 and 2020

… yet no expected rise in incidence of cows' milk allergy

SECTION 5

Conclusions and recommendations

We believe the current approach to regulating the composition and marketing of specialised infant milks – intended to ensure their safe and appropriate use – is not fit for purpose.

There is no oversight of which infant milks are marketed under which regulations – whether as infant formula or as an FSMP. There is also no enforcement that infant milks marketed as FSMP meet the legal criteria (as exemplified by 'comfort' and 'anti-colic' milks), and provide appropriate clinical indications for use (as exemplified by the marketing of anti-reflux and lactose-free milks).

In addition, we are doubtful that all products marketed as infant formula are safe and suitable for healthy babies. Aptamil Lactose Free, SMA Lactose Free and SMA Soya formulas provide pertinent examples of this.

> ***"Urgent action is needed now to control the marketing of iFSMP, especially given the cost of living crisis and the ongoing effectiveness of social media in... driving excessive spending and overconsumption."***

It is clear that commercial milk formula companies pick and choose which regulations to adhere to in order to maximise their marketing opportunities and resulting sales, noting that prices for FSMP are routinely higher than the same brand infant formula (see page ***25***, ***Appendix 1***). This issue is made more problematic by the absence of legal restrictions on selling FSMP to the public.

The marketing of so-called 'comfort' and 'anti-colic' milks under FSMP regulations gives them legitimacy, despite a lack of evidence of effectiveness, whilst their widespread availability in supermarkets, pharmacies and online retailers no doubt boosts their sales.

The similarly widespread public availability of the FSMP lactose-free and anti-reflux formulas prevents their use under medical supervision to minimise potential harms, as the law requires. In addition, the public availability of these iFSMP also seems to affect prescribing norms: parents of babies with a true clinical need for these products are being told to buy them.

The marketing practices of commercial milk formula companies capitalise on the fact that parents often find it difficult to manage their babies' distressing, but normal, feeding behaviours. They are steered towards self-diagnosing a problem – colic and constipation, lactose intolerance, diarrhoea and wind, spitting up and regurgitation – and then offered 'solutions' in the form of expensive infant milks: comfort, lactose-free and anti-reflux formulas. Many distressing feeding behaviours are normal in healthy babies and there are often no infant milk solutions.

The wide availability of iFSMP on supermarket and pharmacy shelves and online may also discourage parents from seeking medical advice when their baby is suffering genuine ill health (for example due to primary or congenital lactose intolerance or CMA) and they could benefit from specialised infant milks and/or other medical intervention.

Lastly, in the absence of any routine monitoring and meaningful enforcement, commercial milk formula companies are regularly flouting the law that infant formula and FSMP advertising to healthcare professionals should be scientific and factual. This makes it difficult for healthcare professionals to distinguish between proven effective iFSMP, and those that are unproven but presented with implied effectiveness.

Other, currently legal, marketing tactics used by the commercial milk formula industry to target healthcare professionals exacerbate this problem. Given the potential of iFSMP for delivering health benefits or harms, the apparent absence of enforcement of the legislation that does exist in this area seems indefensible.

The health of babies is being put at risk, and families and healthcare professionals are being exploited. Urgent action is needed now to control the marketing of iFSMP, especially given the cost of living crisis and the ongoing effectiveness of social media in boosting exposure to formula marketing, thereby driving excessive spending and overconsumption.

RECOMMENDATIONS

To protect breastfeeding and infant health, we recommend that the UK Government takes a two-step approach to closer enforcement and improved regulation of the marketing practices of the commercial milk formula industry.

In the first instance – and most immediately – the UK Government must take urgent steps to ensure greater compliance with existing laws on the marketing of infant formulas and iFSMP, and close a loophole in the existing legislation.

However, ultimately, it should be working towards comprehensively updating existing legislation to align with the Code.

STEP 1

To ensure the commercial milk formula industry's compliance with current legislation and close a loophole, the UK Government must:

1.1 Put in place independent and expert oversight of the most appropriate regulatory category for each infant milk on the market, rather than leaving it for manufacturers to decide.

This is required to ensure compliance with the current legal definitions of FSMP and infant formula. We recommend that assessment includes independent evaluation of the effectiveness of each purported iFSMP in relation to its clinical indications as marketed.

This would mean that each type of infant milk would only be sold under one regulatory category (in the case of lactose-free, preferably FSMP) and that products would only be marketed for clinical indications for which they are known to be effective.

1.2 Put in place independent and expert oversight of the safety and suitability of each infant formula on the market.

This would mean reassessment of the risks associated with the use of lactose-free and soya formulas, and the appropriateness of their legal marketing under infant formula regulations, thereby closing a marketing loophole. We recommend that these types of infant milk should be regulated as iFSMP in order to manage the added risks they pose to infant health.

1.3 Enforce provisions designed to stop cross-promotion of infant formula and follow-on formula with iFSMP.

The current laws clearly articulate that infant formula, follow-on formula and iFSMP labelling should be distinct from each other. We recommend that the notification process by which commercial milk formula companies inform the DHSC of products placed on the market includes a review of the legal compliance of product labels, and that changes in labelling should also require notification. Commercial milk formula companies' compliance with the law around labelling (alongside all other provisions) should be routinely and independently assessed and enforced. Complaints to the relevant authorities regarding cross-promotion should be duly acted upon.

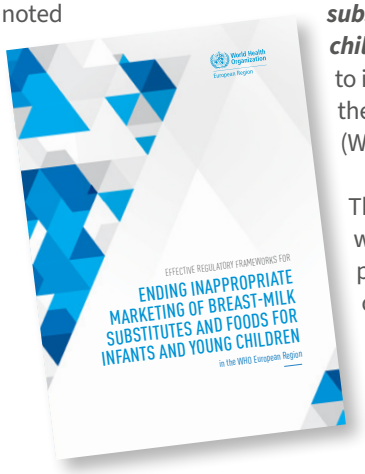
1.4 Enforce the legal requirement that adverts of commercial milk formulas, including iFSMP, to health professionals are scientific and factual.

The UK law permits advertising of commercial milk formulas to healthcare professionals on the proviso that they are scientific and factual. However, as outlined in the report, this legal requirement is both widely flouted and not enforced.

We recommend that the UK Government creates an appropriate mechanism for enforcing this provision, which once again requires independent and expert opinion.

1.5 Take action to ensure that iFSMP are only used under ongoing medical supervision, and can be prescribed when recommended by a healthcare professional.

This would mean removing iFSMP from sale in shops, supermarkets, pharmacies and online. These actions are needed to ensure the appropriate use of iFSMP, including risk management. It should be noted that actions under recommendation 1.1 would facilitate the removal of iFSMP from sale to the public, and so necessitate more appropriate NHS prescribing practices.



STEP 2

The UK Government should update its existing legislation on the marketing of infant formula, follow-on formula and FSMP to align with the Code, which would put a stop to companies taking advantage, for marketing purposes, of the necessary distinctions between infant formula and iFSMP.

Rigorous, independent and regular monitoring and enforcement of the commercial milk formula industry's compliance with the law should be a key feature of an updated regulatory framework.

The Code (see page **7**) does not distinguish between infant and follow-on formulas and those for special medical purposes; all are subject to similar marketing restrictions because all can undermine breastfeeding. One set of marketing rules would remove the current marketing advantages that exist between different infant milk types in UK law, and that have given rise to them.

We recommend that the WHO policy briefing entitled ***Effective regulatory frameworks for ending inappropriate marketing of breastmilk substitutes and foods for infants and young children in the WHO European Region*** be used to inform updates to the UK law in line with the Code and subsequent WHA resolutions (WHO, 2022b).

This briefing provides a 'model law' which would enable the consolidation of all legal provisions related to the Code in one piece of legislation. Doing so would better protect breastfeeding, prevent the continued commercialisation of infant feeding and safeguard infant health.

"One set of marketing rules would remove the current marketing advantages that exist between different infant milk types in UK law, and that have given rise to them."

APPENDICES

APPENDIX 1

COST AND COST DIFFERENCES BETWEEN INFANT FORMULAS AND SAME BRAND IFSMPS

Brand/product	Cost per 800g can*	Cost per 100ml made up formula	Cost per day at 2-3 months of age (900ml)
Aptamil First infant milk	£13.50	22p	£2.02
Aptamil Comfort	£16.00	27p	£2.48
Cost difference (%)	**+19**	**+23**	**+23**
Aptamil First infant milk	£13.50	22p	£2.02
Aptamil Anti-reflux	£16.00	27p	£2.48
Cost difference (%)	**+19**	**+23**	**+23**
Cow & Gate First infant milk	£10.00	16p	£1.47
Cow & Gate Anti-reflux	£13.00	21p	£1.93
Cost difference (%)	**+23**	**+31**	**+31**
Cow & Gate First infant milk	£10.00	16p	£1.47
Cow & Gate Comfort	£13.00	22p	£2.02
Cost difference (%)	**+23**	**+25**	**+37**
Hipp Organic Combiotic Infant milk	£12.00	19p	£1.75
Hipp Anti-reflux	£14.00	22p	£2.02
Cost difference (%)	**+17**	**+16**	**+15**
Hipp Organic Combiotic Infant milk	£12.00	19p	£1.75
Hipp Comfort	£14.00	22p	£2.02
Cost difference (%)	**+17**	**+16**	**+15**
Kendamil Classic Infant milk	£11.00**	15p	£1.38
Kendami Anti-colic (Comfort milk)	£14.49	23p	£2.12
Cost difference %	**+32****	**+53**	**+54**
SMA Pro Infant milk	£12.19	19p	£1.75
SMA Anti-reflux	£14.29	22p	£2.02
Cost difference %	**+17**	**+16**	**+15**
SMA Pro Infant milk	£12.19	19p	£1.75
SMA Comfort	£14.29	22p	£2.02
Cost difference %	**+17**	**+16**	**+15**

* *Cost data were collected on 18/10/2022 from Boots the Chemist website or the manufacturer's website*

** *As Kendamil Classic is supplied in a 900g can, differences between costs per can are not comparable with other brands*

APPENDIX 2

FSMP CASE STUDY: LACTOSE-FREE INFANT MILK

Industry indication	"For the management of lactose intolerance in infants" (Kendamil Medi +)
How this product differs from infant formula:	Replacement of lactose with glucose polymers and/or maltodextrin Higher protein content
Evidence for effectiveness	It is self-evident that a lactose-free infant milk will be beneficial for the management of congenital or primary lactose intolerance. However, there is no evidence that a lactose-free milk is beneficial in transient lactose intolerance.
Potential harms of lactose replacements	• Greater potential to cause dental caries due to the replacement of lactose with glucose and maltodextrins. • Potential disadvantages for the composition of the infants' colonic microflora and colonic physiological function, and might compromise calcium absorption (Ziegler and Fomon, 1983). • Some evidence to suggest that babies fed a lactose-free formula will have higher blood glucose and higher levels of some circulating amino acids after 120 minutes than infants fed standard infant formula, so a potentially negative impact on the baby's metabolism (Slupsky et al, 2017). • The long-term relevance of early introduction to sweet tasting, high GI foods in infancy may be considerable given that food preferences may be established very early in childhood (Augustin et al, 2015)
Potential harms of higher protein content	• 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 length or height is affected (Koletzko et al, 2009). • A Cochrane review found that higher protein intake accelerates weight gain (Fenton et al, 2014).
Potential harms of using lactose-free milks	Indirect harms from the added cost of buying a more expensive and potentially unnecessary product – it may mean less money to feed the rest of the family adequately. Reports suggest the high costs of infant milks may lead some families to unsafe feeding practices, such as diluting formula feeds (APPG, 2018).
Independent scientific opinion	ESPGHAN guidelines for the management of acute gastroenteritis in children in Europe suggest that there is weak evidence for the use of lactose-free milk for the treatment of acute diarrhoea in hospital settings, but that the routine use of lactose-free milks in community settings is not recommended (Guarino et al, 2014). Lactose-free milks are of no benefit in treating colic.

APPENDIX 3

FSMP CASE STUDY: ANTI-REFLUX INFANT MILKS

Industry indications	"For the management of frequent reflux and regurgitation" (Aptamil and Cow & Gate). "For the management of reflux and regurgitation" (Hipp and SMA)
How do these products differ from standard infant formula:	Contain starch or carob bean gum thickeners. May contain partially hydrolysed whey protein.
Evidence for effectiveness	Some low-grade evidence of effectiveness in regurgitation. Very little evidence to suggest these milks reduce acid exposure of the oesophageal mucosa or bronchopulmonary complications of gastro-oesophageal reflux. Mixed results from clinical trials that have examined the impact of thickened milks on reflux. Systematic reviews of studies using non-pharmacological and non-surgical therapies for gastro-oesophageal reflux in infants have concluded that thickened infant formulas do not appear to reduce measurable reflux, although they may reduce regurgitation (vomiting) (Horvath et al, 2008; Carroll et al, 2002).
Potential harms of using anti-reflux milks	Indirect harms from the added cost of buying a more expensive and potentially unnecessary product – it may mean less money to feed the rest of the family adequately. Reports suggest the high costs of infant milks may lead some families to unsafe feeding practices, such as diluting formula feeds (APPG, 2018).
Potential harms of lower recommended reconstitution temperature	Powdered infant formula (PIF) is not sterile. Making up PIF at temperatures lower than the 70^{0}C recommended by the UK government for infant formula increases the risk of serious illness or death from bacterial contamination. The product labels instruct use of lower water temperatures to reduce the milk clumping and failing to flow through the teat. However, we have tested all anti-reflux products on the market in the UK and found no evidence of clumping when following current UK guidelines for the reconstitution of infant formula.
Independent scientific opinion?	The use of anti-reflux milk in infants with simple reflux is not supported by the ESPGHAN Committee on Nutrition because there is no conclusive information 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). NICE guidance and quality standards in the UK (NICE, 2015, NICE 2016) outline how gastro-oesophageal reflux should be diagnosed and managed in babies. The guidance reiterates that regurgitation is a common and normal occurrence not usually needing 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 smaller feeds where appropriate, or an increase in frequency of feeds, have been attempted.

APPENDIX 4

IFSMP CASE STUDY: LABELLING OF KENDAMIL ANTI-COLIC MILK

These pack shots of Kendamil products from their website show a confusing cross-over in labelling styles (similar layout of the label, similar font types, size and colour and similar images or logos).

Where an iFSMP label is not visually distinct from the labels of infant formula and follow-on formula (as the law requires), parents may not realise that this product may pose added health risks over infant formula and should be used under medical supervision (see image A).

Where an infant milk lacking evidence of effectiveness is regulated as an iFSMP and the label of the iFSMP product is visually distinct from the labels of infant formula and follow-on formula (as the law requires), parents may be encouraged to self-medicate with a product that they perceive to be effective (see image B).

Image A: *Kendamil infant formula and follow-on formula milks are on the left and right and the most recent pack design of Kendamil Anti-colic, marketed as an iFSMP, is in the middle.*

Image B: *Kendamil infant formula and follow-on formula milks are on the left and right and the previous pack design of Kendamil Anti-colic, marketed as an iFSMP, is in the middle.*

APPENDIX 5

LIMITATIONS OF ON-PACK WARNINGS ON IFSMP SOLD OVER THE COUNTER, AND ON INFANT FORMULA THAT WOULD BE MORE APPROPRIATELY REGULATED AS FSMP

Product name and regulatory category	On-pack messaging/ instructions for use	Limitation
Aptamil anti-reflux and Cow & Gate anti-reflux (FSMP)	Because powdered milks are not sterile, failure to follow instructions may make your baby ill. Making up instructions are to boil 1 litre of freshly run water. Leave kettle to cool for 45 minutes and no longer.	These statements do not clarify that the resulting temperature of the formula when following the on-pack reconstitution instructions is likely to be significantly lower than the 70^{0}C recommended by NHS to kill bacteria which can cause serious illness and even death.
Hipp anti-reflux (FSMP)	Please follow preparation and feeding instructions carefully failure to do so may make you baby ill. Boil 500 ml of freshly run water and leave to cool for 45 minutes.	
SMA LF (infant formula)	When bottle feeding, do not allow prolonged or frequent contact of milk feeds with teeth as this increases the risk of tooth decay. Ask your healthcare professional or dentist for advice.	This statement does not clearly communicate that the added glucose syrup in this infant milk means a higher risk of tooth decay than standard lactose-containing infant formula. No direct advice to pay careful attention to baby's dental hygiene and tooth brushing is given.
SMA Soya (infant formula)	When bottle feeding, do not allow prolonged or frequent contact of milk feeds with teeth as this increases the risk of tooth decay. Ask your healthcare professional or dentist for advice.	
SMA Soya (infant formula)	Suitable from birth	No indication is given on the can that current UK guidance is that soya infant formula should only be used from six months of age (COT, 2003, 2013). The rationale for this recommendation is outlined on page ***15***.

REFERENCES

Aggett P, Agostoni C, Axelsson I, et al (2006). Feeding preterm infants after hospital discharge. A commentary by the ESPGHAN Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, 42 596-603.

Aggett P, Agostoni C, Goulet O, et al (2002). Antireflux or antiregurgitation milk products for infants and young children: a commentary by the ESPGHAN Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, 34 496-498.

Aggett PJ, Agostini C, Goulet O, et al. European Society of Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee on Nutrition (2001). The nutritional and safety assessment of breast milk substitutes and other dietary products for infants: a commentary by the ESPGHAN Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition,* 32 (3) 256-258.

Agostoni C, Buonocore G, Carnielli VP, et al (2010). Enteral nutrient supply for preterm infants: Commentary from the European Society of Pediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, 50 (1) 85-91.

Allen HI, Pendower U, Santer M, et al (2022). Detection and management of milk allergy: Delphi consensus study. *Clinical & Experimental Allergy.* 52 848- 858.

APPG (2018). *Inquiry into the cost of infant formula in the United Kingdom*. London: The All Party Parliamentary Group on Infant Feeding and Inequalities.

Augustin L, Kendall C, Jenkins D, et al (2015). Glycemic index, glycemic load and glycemic response: An International Scientific Consensus Summit from the International Carbohydrate Quality Consortium (ICQC). *Nutrition, Metabolism and Cardiovascular Diseases.* 25 (9) 795-815.

Brown, A, Jones S, and Evans E. (2020). *Marketing of infant milk in the UK: what do parents see and believe?* A report for First Steps Nutrition Trust: London. Available at: ***bit.ly/FSNmarketing***

Carroll A, Garrison M, and Christakis D. (2002). A systematic review of non-pharmacological and nonsurgical therapies for gastroesophageal reflux in infants. *Archives of Pediatrics and Adolescent Medicine.* 156 109-113.

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) (2003). *Phytoestrogens and Health*. Available at: ***bit.ly/COTphytoestro***

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) (2013). *Statement on the potential risks from high levels of soya phytoestrogens in the infant diet*. Available at: ***bit.ly/soyaphyto***

Department of Health and Social Care (DHSC) (2022). *Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013): guidance.* Available at: ***bit.ly/EU127guidance***

European Commission (EC) (2017). *European Commission Notice on the classification of Food for Special Medical Purposes (2017/C 401/01)* Available at: ***bit.ly/EC-FSMP***

(EU) No 609/2013. Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. Available at: ***bit.ly/EU609-2013***

(EU) 2016/127 Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. Available at: ***bit.ly/EU2016-127***

(EU) 2016/128 Commission Delegated Regulation (EU) 2016/128 supplementing regulation (EU) No. 609/2013 of the European Parliament and of the council as regards the specific compositional and information requirements for food for special medical purposes. Available at: ***bit.ly/EU2016-128***

Fenton RT, Premji SS, Al-Wassia H, and Sauve RS. (2014). *Higher versus lower protein intake in formula fed low birth weight infants.* Cochrane Database of Systematic Reviews.

FSNT (2019) *"Scientific and factual"? A further review of breastmilk substitute advertising to healthcare professionals*. First Steps Nutrition Trust. Available at: ***bit.ly/FSNhcp***

FSNT (2016). *"Scientific and factual"? A review of breastmilk substitute advertising to healthcare professionals.* First Steps Nutrition Trust. Available at: ***bit.ly/FSNhcp1***

Guarino A, Ashkenazi S, Gendrel D, et al (2014). ESPGHAN and Nutrition/European Society for Pediatric Infectious Diseases: Evidence based guidelines for the management of acute gastroenteritis in children in Europe*:* Update 2014. *Journal of Pediatric Gastroenterology and Nutrition.* **59** (1) 132- 152.

Hastings G, Angus K, Eadie D, and Hunt K. (2020). Selling second best: how infant formula marketing works. *Global Health.* 16 (1) 77.

Helfer B, Leonardi-Bee J, Mundell, A, et al (2021). Conduct and reporting of formula milk trials: systematic review. *British Medical Journal.* **375** n2202.

Hickman N, Morgan S, Crawley H, and Kerac M. (2021). Advertising of Human Milk Substitutes in United Kingdom Healthcare Professional Publications: An Observational Study. *J Hum Lact*. **37** (4) 674-682.

Horvath A, Dziechciarz P and Szajewska H. (2008). The Effect of Thickened-Feed Interventions on Gastroesophageal Reflux in Infants: Systematic Review and Meta-analysis of Randomized, Controlled Trials. *Pediatrics* **122** 6.

HSC Public Health Agency (2021). *Health Intelligence briefing: Breastfeeding in Northern Ireland, November 2021.* Available at: ***bit.ly/breastfeedingNI***

Koletzko B, von Kries R, Closa R et al for the European Childhood Obesity Trial Study Group (2009). Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial. *The American Journal of Clinical Nutrition.* **89 (6)** 1836–1845.

Koletzko B, Poindexter B, and Uauy R. (2014). *Nutritional Care of Preterm Infants: Scientific Basis and Practical Guidelines.* Basel: Karger.

Koletzko B, Godfrey KM, Poston L, et al. (2019). Nutrition During Pregnancy, Lactation and Early Childhood and its Implications for Maternal and Long-Term Child Health: The Early Nutrition Project Recommendations. *Annals of Nutrition & Metabolism*. **74** (2) 93-106.

McAndrew F, Thompson J, Fellows L, et al (2012). *Infant Feeding Survey 2010*. Health and Social Care Information Centre. Available at: ***bit.ly/infantfeedingsurvey2010***

Mehta S, Allen H, Campbell D, et al. (2022). Trends in use of specialised formula for managing cow's milk allergy in young children. *Clinical & Experimental Allergy.* **52**:839-847.

Munblit D, Crawley H, Hyde R, and Boyle R. (2020). Health and nutrition claims for infant formula are poorly substantiated and potentially harmful. *British Medical Journal*. **369** m875.

NHS (2022). Guide to bottle feeding: How to prepare infant formula and sterilise bottles. Available at: ***bit.ly/bottlefeedingguide***

NHS (2022a). *Colic.* Available at: ***bit.ly/NHScolic***

NHS Digital (2022). *NHS Maternity Services Monthly Statistics, England, June 2022 – Babies*. Available at: ***bit.ly/NHSbabystats***

NHS (2019). *Types of formula*. Available at: ***bit.ly/NHSformula***

NHS (2019a). *Lactose intolerance*. Available at: ***bit.ly/NHSlactose***

National Institute for Health and Care Excellence (2022). *NICE Clinical Knowledge Summaries: Infant colic*. Available at: ***bit.ly/NICEcolic***

National Institute for Health and Care Excellence (2017). *Faltering growth: recognition and management of faltering growth in children. NICE Guideline NG27*. Available at: ***bit.ly/NICEgrowth***

National Institute for Health and Care Excellence (2016). *Gastro-oesophageal Reflux Disease in Children and Young People. NICE Quality Standard 112*. Available at: ***bit.ly/NICEreflux***

National Institute for Health and Care Excellence (2015). *Gastro-oesophageal Reflux Disease: Recognition, Diagnosis and Management in Children and Young People. NICE Guideline*. Available at: ***bit.ly/NICEreflux2015***

National Institute for Health and Care Excellence (2015b). *Cows' milk protein allergy in children. NICE Clinical Knowledge Summaries*. Available at: ***bit.ly/NICEcowsmilk***

Office for Health Improvement and Disparities: *Breastfeeding at 6 to 8 weeks after birth: annual data 2021 to 2022* Available at: ***bit.ly/breastfeedingdata***

Public Health Scotland (2022). *Infant Feeding Statistics, financial year 2021-2022.* Available at: ***bit.ly/Scotfeedingstats***

Scientific Advisory Committee on Nutrition (SACN) (2018). *Feeding in the first year of life*. Available at: ***bit.ly/SACNfeeding***

Scottish Government (2018). *Scottish Maternal and Infant Nutrition Survey 2017*. Available at: ***bit.ly/Scotnutritionsurvey***

Shewan D (2021). *Pain Points: A guide to finding and solving your customers' problems*. WordStream. Accessed 15 November 2022. ***bit.ly/Wordstream-painpoints***

Slupsky CM, He X, Hernell O, Andersson Y, et al (2017). Postprandial metabolic response of breastfed infants and infants fed lactose-free vs regular infant formula: A randomized control trial. *Scientific Reports*, **7** 3640.

Smith TDH, Townsend R, Hussain HS, Santer M, and Boyle RJ. (2022). Milk allergy guidelines for infants in England promote over-diagnosis: A cross-sectional survey. *Clinical & Experimental Allergy*, **52** 188-191.

Tsang RC, Lucas A, Uauy R, and Zlotkin S. (2005). *Nutritional Needs of the Preterm Infant: Scientific Basis and Practical Guidelines.* Baltimore: Williams & Wilkins.

van Tulleken C (2018). Overdiagnosis and industry influence: how cow's milk protein allergy is extending the reach of infant formula manufacturers. *British Medical Journal* **363**, k5056.

Vincent R, MacNeill SJ, Marrs T, et al. (2022). Frequency of guideline-defined cow's milk allergy symptoms in infants: Secondary analysis of EAT trial data. *Clinical & Experimental Allergy*. **52**, 82– 93.

Welsh Government (2022). *Breastfeeding Data 2021*. Available at: ***bit.ly/Walesbreastfeeding***

World Health Organization (WHO) (2022). *The International Code of Marketing of Breast-milk Substitutes and subsequent resolutions*: Geneva: WHO. Available at: ***bit.ly/international-code***

World Health Organization (WHO) (2022a). *WHO recommendations for care of the pre-term of low birth weight infant*. Geneva: WHO. Available at: ***bit.ly/WHOpreterm***

World Health Organization (WHO) (2022b). *Effective regulatory frameworks for ending inappropriate marketing of breast-milk substitutes and foods for infants and young children in the WHO European Region.* Copenhagen: WHO Regional Office for Europe. Available at: ***bit.ly/WHOframeworks***

World Health Organization (WHO) (2009). *Acceptable Medical Reasons for Use of Breast-milk Substitutes.* Geneva: WHO. Available at: ***bit.ly/WHOreasons***

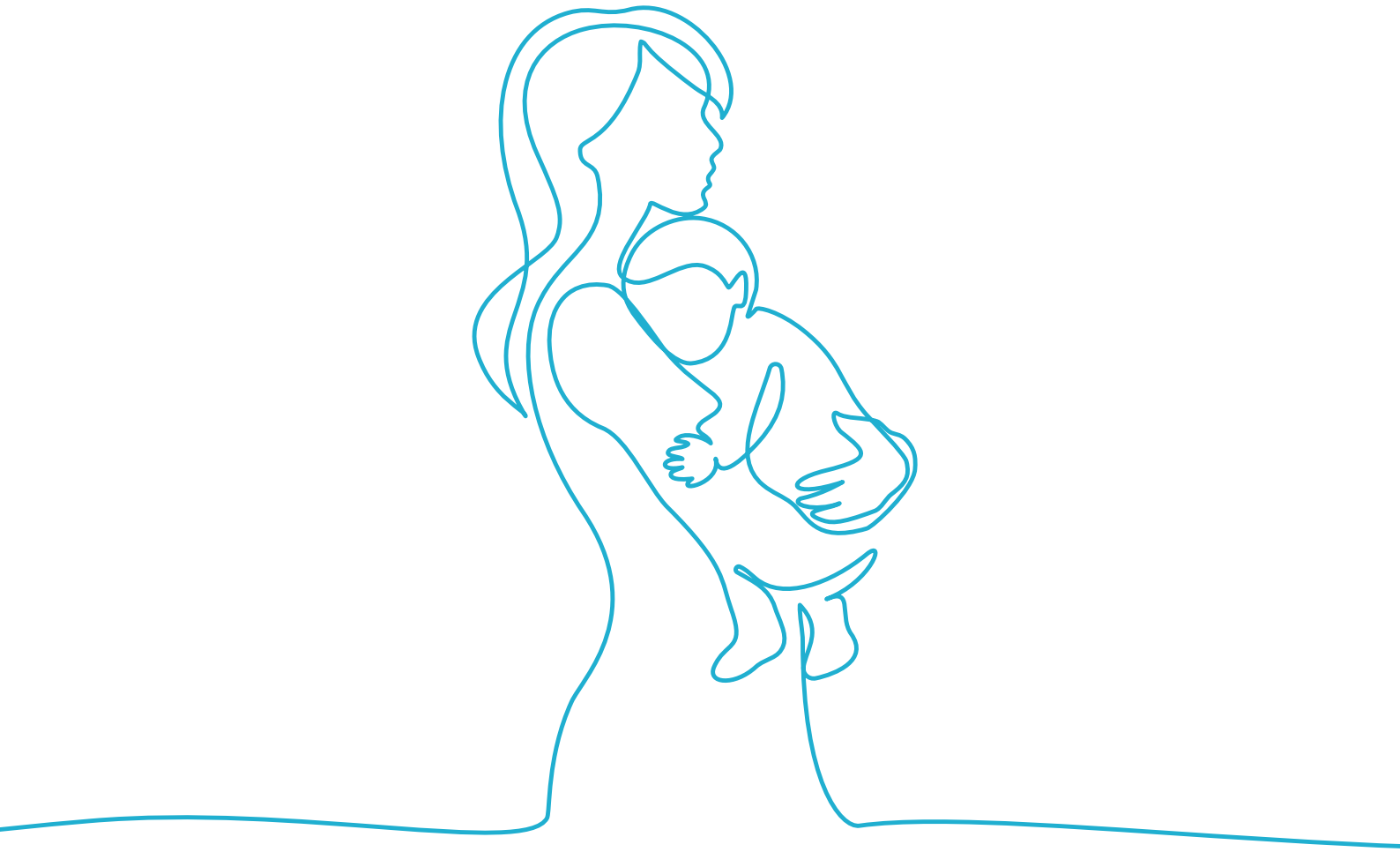
World Health Organisation (WHO) and United Nations International Children's Emergency Fund (Unicef) (2022). *How the marketing of formula milk influences our decisions on infant feeding:* Geneva: WHO and Unicef. Available at: ***bit.ly/WHOformulamarketing***

World Health Organization (WHO) and United Nations Children's Emergency Fund (Unicef) and International Baby Foods Action Network (IBFAN) (2022). *Marketing of breast-milk substitutes: national implementation of the international code, status report 2022*. Available at: ***bit.ly/WHOcode-implementation***

World Health Organisation (WHO) and United Nations International Children's Emergency Fund (Unicef) (2019). WHO/Unicef Information Note: *Cross-promotion of infant formula and toddler milks*. Available at: ***bit.ly/WHOcrosspromo***

World Health Organization (WHO) and United Nations International Children's Emergency Fund (Unicef) (2003). *Global Strategy for Infant and Child Feeding*. Geneva: WHO. Available at: ***bit.ly/WHOglobalstrategy***

Ziegler EE, and Fomon SJ. (1983) Lactose enhances mineral absorption in infancy. *Pediatric Gastroenterology and Nutrition* **2** (2) 288–294. Available at: ***bit.ly/lactose-mineral***



Baby Feeding Law Group - UK

Individual members
Dr Robert Boyle
Natasha Day

Organisations
Association of Breastfeeding Mothers
Association for Improvements in the Maternity Services
Baby Milk Action
Best Beginnings
The Breastfeeding Network
Code Monitoring Northern Ireland
Community Practitioners and Health Visitors Association
Doula UK
The Fatherhood Institute
First Steps Nutrition Trust
GP Infant Feeding Network
Henry
Hospital Infant Feeding Network
The Human Milk Foundation
Institute of Health Visiting
Lactation Consultants of Great Britain
Local Infant Feeding Information Board
La Leche League Great Britain
Leicester Mammas
Midwives Information and Resource Service
National Breastfeeding Helpline
The National Childbirth Trust
Royal College of Midwives
Save the Children
Swansea University LIFT Centre
UK Association of Milk Banking
Unicef UK Baby Friendly Initiative
Unison
Women's Environmental Network
World Breastfeeding Trends Initiative UK

Baby Feeding Law Group - UK

www.babyfeedinglawgroup.org.uk

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.

SCAN TO FIND THIS REPORT ONLINE