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Food Research Collaboration

How secure is our infants' food supply?

Why the government's food security assessment and emergency planning must include breastfeeding and the infant formula supply chain

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Food Research Collaboration Policy Insight
March 2023

FRC Policy Insights

The FRC Policy Insights are short reports highlighting gaps and opportunities for improvement in emerging food policy in the UK. The aim is to put detailed, specialist knowledge into the public domain at a critical time for the food system.

Brexit, Covid, the climate and environmental crises, the disruption to supply chains caused by the war in Ukraine, and the UK's acute cost-of-living crisis all have consequences for food policy.

In response, there have been new laws and policy proposals, covering all aspects of the food system, from land use and agriculture to health, trade, labour, technology and innovation.

While policy is being developed, there are opportunities for improvements and course-corrections. We hope these Policy Insights will help to inform that process. If you would like to contribute, please contact the Food Research Collaboration.

Glossary

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. This definition usually also includes bottles, teats, dummies and pumps.

Commercial milk formula: An alternative term to 'breastmilk substitute', to avoid the misleading implication that such products are equivalent to breastmilk.

Donor human milk: Breastmilk that has been expressed and provided freely by a donor to a human milk bank to be fed to another mother's child.

Human milk banks: Facilities that collect, screen, store, process, and distribute donor human milk.

Infant formula: Formulas designed for healthy infants from birth to one year who are not breastfed or are partially breastfed, 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 that cover their composition and marketing.

Specialised infant milks: Commercial milk formulas specifically designed for non-breastfed / partially breastfed babies with medical conditions for whom infant formula is inappropriate (noting that breastfeeding is rarely contraindicated even in these cases). These milks can meet these infants' nutritional needs in the first six months of life, and in the second six months alongside complementary foods.

Abbreviations

DHM	Donor Human Milk
DHSC	Department of Health and Social Care
FSMP	Foods for Special Medical Purposes
FSNT	First Steps Nutrition Trust
UKRI	UK Research and Innovation
WHO	World Health Organisation

The problem: a missing ingredient in UK food security

'Food security' is understood to exist when everyone in a population has access to sufficient, safe and nutritious food for a healthy life[1]. It is has been a perennial policy priority for governments, and is now attracting renewed attention because (at a global level) environmental change is affecting both food production and food consumption, while Covid-19 and the war in Ukraine have disrupted supply chains and caused a spike in energy costs; and because (in the UK) Brexit has changed the terms on which the UK trades with the rest of the world. As a result of all these factors, food prices are spiraling. Responding to these concerns, the UK's 2020 Agriculture Act[2] required the Government to report to Parliament on the state of food security at least once every three years, and the first of these reports appeared in 2021[3]. It is a comprehensive document, more than 300 pages long, but it has a significant omission: **it fails to consider the food security of the youngest members of our society: infants (i.e. babies aged 0-12 months)**. The report uses the word 'infant' only four times, always in reference to the benefits available to certain families with young children. However, infants represent an important, uniquely vulnerable section of the population, and most of them are dependent on a single manufactured food – infant formula – for a large proportion of their food intake.

This is hardly a marginal or discountable group. The UK's public health advice[4] mirrors that of the World Health Organization (WHO)[5], making clear that **ideal feeding for babies involves exclusive breastfeeding from birth until six months of age and then continued breastfeeding alongside complementary feeding up to the age of two years**, and for as long as the mother and baby wish thereafter. But whilst research shows that many British mothers would like to breastfeed, for various reasons most do not manage to do so for as long as they had wanted, or as is ideal[6]. Consequently, the current reality is that the UK has a formula-feeding culture. A quarter of babies born in England in October 2022 did not receive breastmilk as their first feed, meaning they were likely given an infant formula[7]. And in the first quarter of 2022, over half of babies in England were already exclusively formula-fed by the age of six-eight weeks[8]. The vast majority of this infant formula is imported into the UK, supplied by just four companies, which manufacture it in other countries from ingredients that are sourced, processed and combined all over the world (Box 1).

Box 1. How infant formula ingredients travel the world

David Richmond, Trade Strategy Manager, Fonterra Co-operative Group
Written and oral evidence to International Trade Committee, UK Parliament, 23 May 2018[i].

Fonterra is the largest processor of milk in New Zealand and a 'global leader in dairy nutrition', producing more than two million tonnes annually of dairy ingredients and consumer products for over 140 markets.

"Trade in dairy is characterised by a series of highly sophisticated and complex global value chains, with products passing through multiple stages of processing and cross[ing] borders several times before they reach the final consumer...

"[For example] we have a manufacturing facility in the Netherlands that we built about five years ago. One of the by-products produced there is lactose. We send that lactose to a joint-venture partner that we have in the UK, where it is further refined into a product called galacto-oligosaccharides – GOS for short*. From there, it is sent down to a Fonterra manufacturing site in Australia and blended with New Zealand ingredients, and then sent back out to China and south-east Asia as infant formula."

[*GOS are an example of a permissible but non-mandatory ingredient with respect to the UK laws governing the composition of infant formulas[ii], which companies often add to commercial milk formulas for the purpose of making marketing claims[iii]. Such ingredients are not mandatory because they lack sufficient evidence of benefit to infant health.]

i House of Commons (2018). International Trade Committee. Oral evidence: Trade and the Commonwealth: Australia and New Zealand, HC 521i. Available at http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/international-trade-committee/trade-and-the-commonwealth-australia-and-new-zealand/oral/83414.html, accessed 3.8.22

ii (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

iii FSNT (2020). Claims made for infant formula, ingredients and formulations. Available at: https://static1.squarespace.com/static/59f75004f09ca4869407of3b/t/5eba3eac6a3b687667d9891e/1589264046551/Claims_made_for_infant_formula_and_ingredients_May2020_final.pdf

Box 2. Lessons from the 2022 US formula crisis

In 2022 a factory in the US state of Michigan producing powdered commercial milk formulas for the company Abbott had lapses in health and safety standards, meaning that many batches were contaminated with illegally high levels of the harmful bacteria Cronobacter sakazakii as well as by other pathogens: Salmonella, Clostridies difficile and Shigella[i].

Initial concerns over unsanitary conditions at the Abbott plant were raised by a former employee in October 2021. However it was not until 31 January 2022 that the US agency responsible for ensuring food safety, the Food and Drug Administration (FDA), conducted an inspection, the results of which were released on 18 March 2022. The report's findings noted the presence of Cronobacter bacteria on multiple surfaces, alongside other hygiene failings such as cracked equipment and standing water[ii].

By this point, Abbott had already ceased production (15 February) and issued a recall on their products (17 February), following reports that four infants had been infected with Cronobacter bacteria after consuming formula from the plant, of whom two died[iii]. The number of affected infants, all of whom had consumed Abbott formulas, subsequently rose, reaching nine deaths, 25 severe infections categorized as 'Life Threatening Illness/Injury' and 80 instances of 'Non-Life Threatening Illness/Injury'[iv].

The recall and plant closure led to serious national shortages of infant formula and some specialised infant milks. With just four companies supplying 90% of US infant formula, the different products recalled by Abbott and marketed under three brand names (Similac, Alimentum and Elecare) accounted for 40% of the market[v], leaving a big deficit in supply.

The crisis was exacerbated by the fact that the affected factory supplied a high proportion of infant formula to the Women, Infants and Children (WIC) social protection programme, which provides infant formula to low-income families. Consequently, some of the worst affected women and babies were in these low-income groups.

The fact that one factory being out of action affected infant formula supply and the supply of certain specialised infant milks across the country highlights the risks inherent in the US's very concentrated formula production and supply chain, which until the crisis was almost entirely based on domestically produced stock alone[vi].

The US events also highlight the danger associated with the lack of sufficiently rigorous preparation guidelines for feeds made with powdered infant formula. Powdered infant formula itself cannot be made to be sterile – a low level of contamination is inevitable and is permitted under regulations. A key factor in mitigating the inevitable health risks of its consumption is for the parent/carer to follow hygienic preparation instructions, including reconstituting the formula (i.e., turning it into a drink) in a way which kills any bacteria present. The WHO recommends using appropriate water at a temperature of at least 70ºC for reconstitution, and in the UK the NHS recommends this too[vii]. The US (and many other countries) do not make this recommendation (although many do recommend use of sterile ready-to-use infant formula for newborns and clinically vulnerable babies). Consequently, it is common practice for the infant formula to be made with warm or cold water, meaning any bacteria present can multiply and make the baby sick or, as evidenced, even kill them.

Ultimately, the recent crisis highlights the problems associated with reliance on infant formula and very low breastfeeding rates.

i IBFAN (2022). The Abbott Powdered Formula Scandal. Available at https://www.ibfan.org/the-abbott-powdered-formula-scandal/
ii IBFAN (2022). The Abbott Powdered Formula Scandal. Available at https://www.ibfan.org/the-abbott-powdered-formula-scandal/
iii Jaffe, S (2022). US infant formula crisis increases scrutiny of the FDA. The Lancet. Vol 399, issue 10342. P2177-2178. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01049-2/fulltext
iv IBFAN (2022). The Abbott Powdered Formula Scandal. Available at https://www.ibfan.org/the-abbott-powdered-formula-scandal/
v Naylor, 2022 ref from Lindy
vi FDA (2022). FDA encourages importation of safe infant formula and other flexibilities to further increase availability. Available at : https://www.fda.gov/news-events/press-announcements/fda-encourages-importation-safe-infant-formula-and-other-flexibilities-further-increase-availability
vii NHS (2019). Types of Formula. Available at: https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/bottle-feeding/types-of-formula/

A recent incident in the United States (where the majority of formula is also produced by just four companies[9]) highlighted the vulnerability of concentrated infant formula supply chains. Covid-related supply-chain issues started to affect the supply of formula in the US in late 2021[10]. In early 2022 these supply issues were dramatically exacerbated when unsanitary conditions at a commercial milk formula factory in the state of Michigan led to the bacterial contamination of a number of formula batches, an event which has been implicated in the deaths of nine babies and serious infection in another 25[11]. The temporary closure of this single factory and recall of formulas made there led to nationwide shortages of infant formula and certain specialised infant milks, leading some parents/carers to deploy harmful coping strategies such as watering down formula and making homemade versions[12]. Media also reported that shortages led to the illness and deaths of infants who were unable to access the formula they needed[13],[14]. The crisis required presidential intervention to restore both supplies and confidence[15], including by allowing imports from Europe and elsewhere (Box 2).

The situation in the UK is somewhat different, but the US crisis highlights the risk that arises when the supply of a food which is vital and non-substitutable for many infants is controlled by a handful of suppliers.

This Policy Insight shines a rare spotlight on the UK's infant formula supply chain and makes the case that the UK's food security assessment process must specifically include infant feeding – both barriers to breastfeeding and the infant formula supply chain – if the food supply of the whole population is to be secured (Box 3)**.**

How babies in the UK are fed and why

Optimal infant feeding

In the first year of life babies have unique nutritional requirements because of their small size and rapid growth and development. They are also vulnerable to infections because of their immature immune systems. Breastfeeding protects babies' health in the short and long term (reducing risks of infectious diseases, diabetes, heart disease, asthma and obesity), and also the health of their mothers (whose risk of ovarian cancer, breast cancer and heart disease is reduced by breastfeeding[16],[17],[18]). So, for the optimal health of both the baby and their mother, the public health recommendations on infant feeding from the WHO[19] and health departments across the world, including in the UK[20], are for exclusive breastfeeding for the first six months of life (i.e., breastmilk only, with no water or foods), and continued breastfeeding alongside complementary foods up to the age of two years and for as long as the mother and baby wish thereafter. When babies receive most of their nutrition from breastmilk, breastfeeding ensures that babies are food secure.

Why some parents/carers depend on commercial milk formulas to feed their babies

Whilst the public health benefits of breastfeeding are widely appreciated, it is recognised that there are exceptional circumstances in which infants cannot

Box 3. What does food security mean for infants?

The shortest food chain for infants is breastfeeding. Breastfeeding can provide infant food security – but currently this only applies to a small proportion of UK babies.

To enable women who want to breastfeed to meet their breastfeeding goals, key requirements include 'Baby-friendly'[i] maternity and other services, universal access to skilled breastfeeding support, and appropriate legislation and policies to protect breastfeeding (including maternity protections, workplace accommodations, and laws preventing the inappropriate marketing of commercial milk formula, bottles and teats).

For non-breastfed or partially breastfed babies, infant formula is necessary for infant food security. Most babies in the UK are reliant on infant formula to survive. This means that parents/carers need to be able to access appropriate (safe and suitable) infant formula, and be enabled and supported to formula feed safely and responsively. This necessitates a resilient supply chain of appropriate and affordable infant formulas.

i The UNICEF UK Baby Friendly Initiative enables public services to better support families with feeding and developing close and loving relationships so that all babies get the best possible start in life. The programme supports maternity, neonatal, health visiting and children's centre services to transform their care and works with universities to ensure that newly qualified midwives and health visitors have the strong foundation of knowledge needed to support families. The initiative protects, promotes and supports breastfeeding and supports safe and appropriate formula feeding for families that choose to use formula. For more information see https://www.unicef.org.uk/babyfriendly/

or should not be breastfed[21], and in the UK some mothers choose not to breastfeed. For babies who are not breastfed, the use of donor human milk is an alternative[22] and may be desired but may not be accessible (Box 4). Some babies therefore have no access to breastmilk, and for a much bigger proportion breastfeeding may be started but discontinued. The latter is the reality for most mothers and babies in the UK, because, whilst most mothers in the UK report that they want to breastfeed, the majority do not meet their breastfeeding goals for a variety of reasons[23].

In England the number of babies receiving either breastmilk or donor human milk at birth is 67%[24], but drop-off is high with only 49% of babies receiving any breastmilk at six-eight weeks of age[25]. The most recent national survey data indicate that only 1% of babies are exclusively breastfeeding at six months[26]. The reasons for the steep drop-off are complex but likely include a lack of support for breastfeeding (at a societal level, as well as from family, peers and healthcare professionals), and inadequate legal protections and policies (including maternity protections, workplace policies, and laws preventing misleading marketing of commercial milk formulas)[27],[28]. The result is that the majority of babies in the UK are fed a commercial milk formula from their first months of life through their first year.

For healthy infants who are not fully breastfed, or do not have access to breastmilk, infant formula is the recommended substitute for breastmilk during the first year of life[29]. Whilst no commercial milk formula can impart the immune benefits of breastmilk, during the first six months of life infant formula can provide the nutrients infants need for growth and development and, complemented by a progressively diversified diet, can support continued growth and development in the second six months of life.

At a population level and given prevailing practices, infant formula is necessary for infant food security because most babies in the UK are reliant on infant formula to survive.

Different types of commercial milk formula on the market

Breastmilk substitutes include 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[30]. 'Commercial milk formula' has been suggested as an alternative term to 'breastmilk substitute' since the latter term can potentially, and misleadingly, imply that such products are equivalent to breast milk. From the range of commercial milk formulas on the market, we argue that only infant formula and specialised infant milks need be included in the food security assessment, for reasons explained in this section.

Infant formula is a regulated product type in the UK, which must meet specific nutrition composition requirements, and is designed to support adequate

Box 4. Human milk banks

Human milk banks operate like the blood transfusion service, collecting breastmilk from screened donors and supplying it for vulnerable infants where there is a shortfall in maternal milk, according to clinical recommendation. Milk bank services support women who have additional milk to their own baby's needs to become donors; these services include health screening and blood tests, collecting, heat-treating (pasteurising) and storing donated breastmilk, and continuing to support ongoing donors[i],[ii],[iii].

Donor human milk (DHM) is used to feed infants when maternal milk is unavailable or where initial supplementation is needed. Although milk banking services used to be more widely available, no national funding or human milk banking strategy has existed in the UK for over 40 years. Consequently, DHM has become rationed for only the most extremely premature infants (generally those born weighing less than 1500 g) where the risk is higher of developing gut complications with high mortality rates if human milk is unavailable. Some element of rationing exists for all milk banks, but the WHO published recent recommendations supporting all preterm infants to have access to DHM[iv]. In Brazil, investment in a nationally equitable milk bank service from the 1990s helped to support sharp increases in breastfeeding rates, alongside a whole-system approach of legislation and community support[v].

i Recommendations for the Establishment and Operation of Human Milk Banks in Europe: A Consensus Statement From the European Milk Bank Association (EMBA) - PubMed (nih.gov)
ii The legislative framework of donor human milk and human milk banking in Europe - PubMed (nih.gov)
iii Developing global guidance on human milk banking - PubMed (nih.gov)
iv https://www.who.int/publications/i/item/9789240010765
v Brazil is a reference in Breast Milk Banks (www.gov.br)

Recent research has shown marked positive impacts where DHM is available alongside high quality lactation support in circumstances beyond the neonatal unit. Findings to date include improvements in parental psychological wellbeing, normalised maternal anxiety and depression scores, and a high proportion of mothers going on to establish breastfeeding who would otherwise have stopped[vi]. Implementation is key, with high-quality training needed for healthcare professionals supporting families, and an understanding of when DHM could potentially undermine breastfeeding.

Human milk banks also play a vital role in food security. During the recent US formula shortages, US milk banks increased capacity four-fold to meet the need of vulnerable infants in hospital or unable to be fed with alternative commercial milk formulas[vii],[viii],[ix],[x]. Currently the UK lacks human milk banking capacity to respond similarly to future formula shortages. The UK also lacks legislation to prevent commercialisation of the sector, with multiple documented ethical and safety harms[xi].(There has been a recent UK Health Security Agency product safety alert and FSA product recall from one of the first human milk commercial companies[xii].)

To meet the needs of all families cared for in hospitals or at home, significant scaling up of UK services is needed. Modelling suggests that approximately 25,000 litres/annum are needed to meet the needs of preterm infants born up to 34 weeks[xiii]. Current output from NHS-funded human milk banks is estimated at less than 10,000 litres DHM/annum[xiv]. The Hearts Milk Bank, set up by NHS professionals and academics as part of the Human Milk Foundation[xv], launched in 2018, now has a capacity of 5,000 litres DHM/annum, and is seeking to scale rapidly alongside support for NHS infrastructure. UKRI-funded research is ongoing as to the most effective way to implement human milk banking services alongside hospital- and community-based lactation support, aiming to help reverse the UK's status as having some of the lowest breastfeeding rates in the world.

vi PMID: 33404169; 26908696, 32231257; 34006969; 35641919; 34216269
vii Women | Free Full-Text | Perceptions of Human Milk Banks as a Response to the US Infant Formula Shortage: A Mixed Methods Study of US Mothers (mdpi.com)
viii https://www.nbcnews.com/news/us-news/baby-formula-shortage-strain-breast-milk-banks-rcna28583
ix https://www.nationalgeographic.com/science/article/brazil-breast-milk-banking-program-formula-crisis
x https://www.washingtonpost.com/parenting/2022/05/19/breast-milk-banks-formula-shortage/
xi The legislative framework of donor human milk and human milk banking in Europe - PubMed (nih.gov)
xii https://www.food.gov.uk/news-alerts/news/notification-of-a-recall-of-a-small-number-of-human-breast-milk-products
xiii Staff M, Shenker N, Weaver G ... A Framework for Estimating Potential Demand for Pasteurised Donor Human Milk. In review, European Journal of Operations Research.
xiv Shenker N., Hughes J., Barnett D., Weaver G. Response of UK milk banks to ensure the safety and supply of donor human milk in the COVID-19 pandemic and beyond. Infant 2020; 16(3):
xv Home - Human Milk Foundation. https://humanmilkfoundation.org/

growth 'in the first months of life'[31]. Infant formula is suitable for babies aged 0-12 months, and although no formula can replicate the immunological benefits of breastfeeding, infant formula can meet a healthy infant's nutritional needs during the first six months of life and is suitable for use alongside complementary food for the second six months. Whilst all infant formulas must meet the same compositional regulations, this can be achieved through the use of different ingredients. However, the NHS recommends that a 'first infant formula', made with cows' milk, is used from birth and throughout the first year of life if babies are not breastfed/are partially breastfed[32].

Follow-on formula is a regulated product type in the UK marketed for use from 6-12 months of age[33]. The regulations permit these products to differ from infant formulas in the amount of protein, iron and some other micronutrients they contain[34] but the NHS advises that there are no benefits to switching from infant formula to follow-on formula after six months of age and recommends that infant formula is used throughout the first year[35]. For this reason we are not recommending that their supply is considered in national food security assessments.

Specialised infant milks: A small proportion of non-breastfed / partially breast-fed infants with certain medical conditions (such as an allergy or a metabolic disease) require a specific type of specialised formula, each of which has a modified nutrient composition and different ingredients compared to infant formula in order to appropriately meet the nutrition needs of the infant given their medical condition[36]. Specialised infant milks are regulated in the UK as 'Foods for Special Medical Purposes' (FSMP)[37] (although it should be noted that not all formulas regulated as FSMP are evidence-based[38]). As specialised infant milks are essential for certain formula-fed infants, the security of their supply needs to be considered alongside infant formulas in national food security assessments.

Growing up and toddler milks: From one year of age, a commercial milk formula is not necessary despite such products being labelled, e.g., 12 months +; 2 years +. There are no specific regulations governing their composition or marketing, and the NHS advises that cows' milk is a suitable main drink from one year of age[39]. Their supply is not important to consider in national food security assessments.

Regulation of commercial milk formula in the UK

Because infant formula may be the sole source of nutrition for many infants during their first six months, the safety and suitability of the ingredients used and their overall nutritional composition are tightly regulated[40].

In the UK, the composition, labelling and some elements of marketing of certain commercial milk formulas is governed by retained EU directive (FSG) (609/2013) on Foods for Specific Groups. This directive contains delegated acts; EU delegated regulation 2016/127 relates to infant and follow-on formula and EU 2016/128 relates to commercial milk formulas marketed as foods for special medical purposes. In England and each of the devolved nations, the regulations are implemented by discrete Statutory Instruments. The fate of these retained laws under the Retained EU Law (Revocation and Reform) Bill is currently unclear[41]. This Bill in intended to enable the Government, via Parliament to amend, repeal or replace retained EU Law and includes a 'sunset' date by which all remaining retained EU Law will either be repealed, or assimilated into UK domestic law. This date is December 31st 2023, but there may be an extension for specified pieces of retained EU Law until 2026.

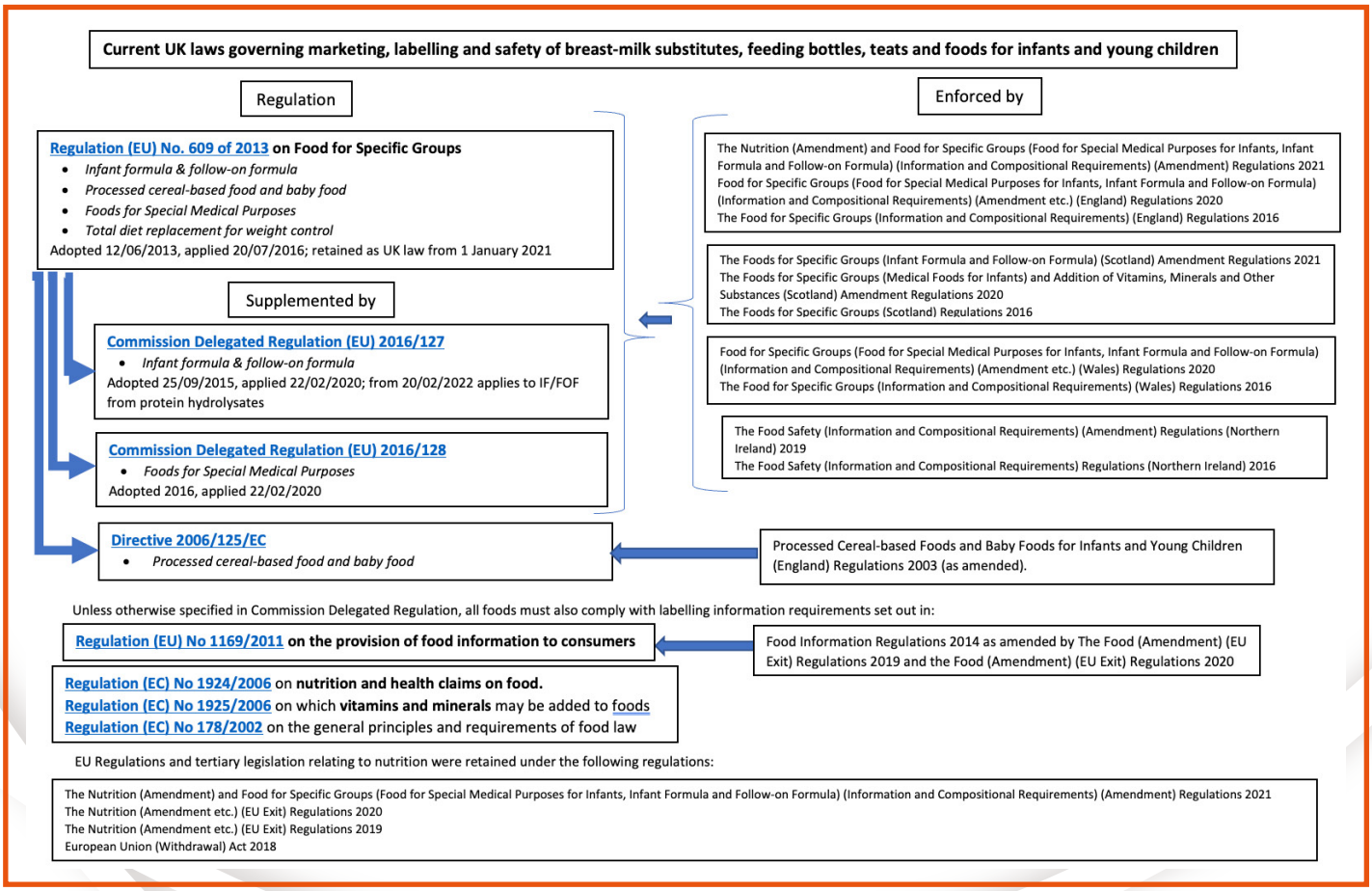
What is commercial milk formula made of and how?

All commercial milk formulas, including infant formulas, can be classified as 'ultra-processed foods', i.e., formulations of ingredients extracted from foods using industrial processes, incorporating additives[42].

They come in two forms, powder and liquid. The powder is made by industrial-level dry blending (mixing of dehydrated ingredients to uniformity) and/or a wet-mixing or spray-drying process (blending of ingredients with water in large batches, followed by homogenisation, pasteurisation, and spray-drying to produce the powdered product)[43]. The wet, 'ready-to-feed' liquid form involves the wet mixing of ingredients, with emulsifying, homogenizing and heat treatment[44].

As Box 1 illustrates, the components of commercial milk formulas are manufactured and transported globally; they are combined at plants owned by a relatively small number of companies, and the finished products are then, in turn, exported around the world.

Fig 1: Current UK laws governing commercial milk formulas



Source: The authors

The basic components of all infant formulas are proteins, fats, carbohydrates, vitamins and minerals. The majority start with a base of cows' milk or goats' milk (skimmed or full-fat, liquid or powder) or use 'demineralised whey protein concentrates' (referring to one of the two main proteins in milk, extracted, adapted to reduce mineral content and then concentrated). Some infant formulas are based on soya protein from soya beans or on 'partially hydrolysed' proteins (e.g., cows' milk proteins broken down in to smaller fragments). Most formulas then contain additions of lactose or other carbohydrates (such as maltose, maltodextrin or glucose polymers), algal oil or fish oil (to provide mandated DHA (docosahexaenoic acid)), and other oils (to provide fat and mandated ALA (alpha-linoleic acid)) and mandatory vitamins and minerals.

The major commercial milk formula producers develop their own brands with a combination of different types of each of the basic components, plus added, permissible but non-mandatory ingredients, i.e., ingredients not deemed necessary for the product to sustain adequate growth, and lacking sufficient evidence for benefit that would require their addition by law[45]. These include: oligosaccharides (including 'Human Milk Oligosaccharides' (HMOs) – synthetic analogues of a small number of the 200+ in breastmilk); arachidonic acid (ARA) (a long chain polyunsaturated fatty acid which can be synthesised from linoleic acid, a mandatory ingredient); taurine (an essential amino acid that can be synthesised by the body); and nucleotides (structural components of RNA and DNA found in breastmilk, of which five are permitted in infant formula: cytidine 5′ -monophosphate, uridine 5′ -monophosphate, adenosine 5′ -monophosphate, guanosine 5′ -monophosphate and inosine 5′ -monophosphate). Many of these ingredients are supplied to milk formula manufacturers in the form of commercial preparations or mixes (usually powders) that can easily be combined in the formula mixture.

Lastly, some additives are permissible by law, and are necessary to ensure that formulations do not separate, that acidity is regulated or ingredients resist oxidation, or if liquid formula, that they remain emulsified. These are also supplied as commercial preparations.

Table 1 shows the typical ingredient sources of infant formulas marketed in the UK.

Table 1. Typical ingredients of infant formulas marketed in the UK

Nutrients	Ingredient sources
Protein	Cows' or goats' milk whey concentrate, skimmed milk from cows' or goats' milk, fermented milk, demineralised whey, whole cow's or goats' milk, soya protein, casein glycomacropeptide
Carbohydrate	Lactose (from whey, semi-skimmed milk, whole milk), maltose, sucrose, glucose, maltodextrins, glucose / glucose syrup, oligosaccharides, pre-cooked starch, gelatinised starch
Fat Linoleic acid (LA) Alpha-Linolenic acid (ALA) Docosahexaenoic acid (DHA)	Rapeseed oil, palm oil, coconut oil, sunflower oil, anhydrous cows' milk fat, whole cows' milk fat, whole goat's milk fat Fish oil, fungal oil
Vitamins Vitamin A, C, E1, D, K , Thiamin (B1), Riboflavin (B2), Niacin, Vitamin B6, Vitamin B12, Folic acid, Folate, Biotin, Pantothenic acid	From other ingredients and from commercial preparations to top up to mandatory requirements
Minerals Calcium, Chloride, Copper, Iodine, Iron, Magnesium, Manganese, Phosphorus, Potassium, Selenium, Sodium, Zinc	From other ingredients and from commercial preparations to top up to mandatory requirements
Other Choline, Inositol, L-carnitine	Commercial preparations

Permissible additional ingredients	
Total Nucleotides	From other ingredients and from commercial preparations
Cytidine-5'-monophosphate	
Uridine – 5'-monophosphate	
Adenosine-5'-monophosphate	
Guanosine-5'-monophosphate	
Inosine-5'-monophosphate	
Taurine	From other ingredients and from commercial preparations
Oligosaccharides of which:	
- Galacto-oligosaccharides	Commercial preparations from cows' milk
- Fructo-oligosaccharides	Plant sources
- Inulin	Plant sources
- 'Human Milk Oligosaccharides'	Metabolically engineered from yeast/bacteria
Permissible (necessary) additives: Preservatives e.g. citric acid (E330), lactic acid (E270); Antioxidants e.g. L-ascorbyl palmitate (E304), sodium-L-ascorbate (E301); To prevent casein in milk coagulating when heat-treated e.g. sodium citrate (E331), potassium citrate (E332), sodium phosphate (E339), potassium phosphate (E340); Emulsifers (liquid formula only) e.g. sucrose esters of fatty acids (E473), soya lecithin (E332)	From commercial preparations

What is important is that *all* infant formula products must meet the mandated nutrition composition specifications set out in the regulations[46]. The basic nutritional profile of infant formulas is therefore very similar and all can sustain adequate growth in healthy infants.

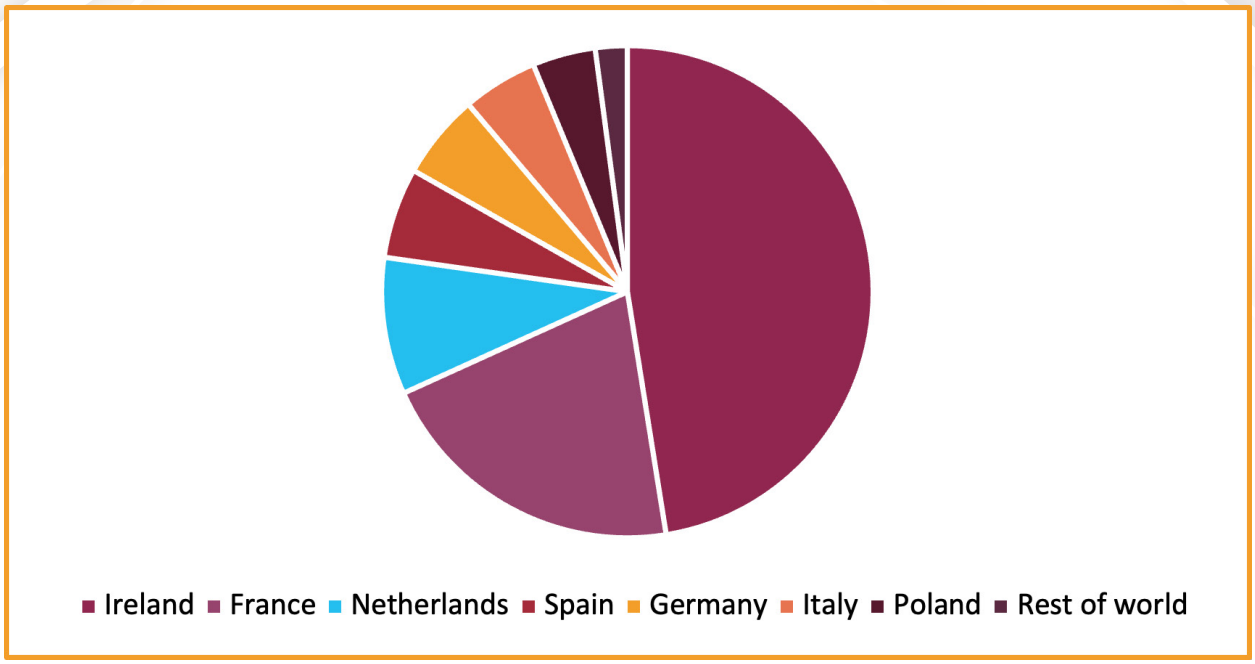
All commercial milk formulas marketed in the UK must be notified to a government competent authority (usually the Department for Health and Social Care, DHSC) before they are put on the market, which means there is assessment of compliance with the legal requirements for composition and labelling against the regulatory framework (though evidence of poor compliance with aspects of the legislation indicate that this process is not systematic or complete in practice[47,48]). If they meet regulatory requirements, the formulas are deemed safe and suitable to support adequate growth and development and are permitted to be sold.

Where does the UK's commercial milk formula come from?

The vast majority (more than 95%) of commercial milk formula on the UK market is imported, as finished products.

According to import data from the World Bank[49], in 2021 the UK imported 69.9 million kg of infant feeding products, principally from the EU. Almost half was imported from Ireland (33.2 million kg) and a further 20% from France (14.5 million kg). The Netherlands, Spain, Germany, Italy and Poland represent the other significant contributors (Table 2; Figure 2). However, this is only a partial picture as it represents the final departure point of the finished product. As highlighted

Figure 2: Proportion of UK imports of infant feeding products in 2021 supplied by country, by weight



Source: the authors

in Box 1, the ingredient supply chain is in itself complex, with composite parts sourced from around the world.

Infant formula suppliers

The market in the UK is comprised of just five brands produced by four companies: Danone Early Life Nutrition; Nestlé, HiPP UK Ltd and Kendal Nutricare (Table 2). The UK commercial milk formula market was worth £351 million in 2021/2022, of which the two Danone brands (Aptamil and Cow & Gate) alone accounted for 78% of the market (by sales). Nestlé (SMA) held 15% of the market share, HiPP UK Ltd held 6%, with Kendal Nutricare at <1% [50].

Kendal Nutricare is the only UK company, and the only company that manufactures infant formula in the UK, whereas the other three companies list manufacturing sites across Europe. Danone and Nestlé are both multinational companies, the former French the latter Swiss. HiPP is a public limited company founded in Germany but now based in Switzerland.

Table 2. Suppliers of infant formula to the UK market

Name	Brand name(s)	Manufacturing sites	Products	Additional information
Nutricia, subsidiary of Danone Early Life	Aptamil Cow & Gate	Fulda, Germany; Cuijk, Netherlands; Wexford & Macroom, Ireland	Dry & wet infant formula	"70% of Danone's European spray-drying capacity and 40% of its European finished goods packaging capacity is located in Ireland. Danone exports finished goods to over 41 countries all over the world – from UK to China."[i]
Wyeth Nutritionals Ireland Ltd, subsidiary of Nestlé	SMA	Askeaton, Ireland	Dry & wet infant formula	"Nestlé's Wyeth Nutrition infant formula plant is located in Askeaton, Co. Limerick. Nestlé Ireland is a subsidiary of Nestlé SA, the world's leading nutrition, health and wellness company. It has over 70 brands including SMA infant nutrition. Nestlé employs over 700 people in Ireland."[ii]

i Nutricia, 2020 Manufacturing & product development facility. https://www.nutricia.co.uk/hcp/discover-nutricia/manufacturing-and-product-development-facility.html

ii Nestlé, 2021. Nestlé's Wyeth Nutrition first site in Ireland and Nestlé's first food manufacturing factory in Europe to achieve platinum certification for water stewardship. https://www.nestle.co.uk/en-gb/media/pressreleases/allpressreleases/wyeth-nutrition-platinum-aws

HiPP Organics	HiPP	Pfaffenhofen Germany; Herford, Germany; Gmunden, Austria; Glina, Croatia; Hanságliget, Hungary, Mamonovo, Russia[iii]	Infant formula and food products	Herford, Germany, listed as a production site for infant formula, with cereals and other baby foods manufactured at their plants in Croatia and Austria.[iv]
Kendal Nutricare	Kendamil	Kendal, Cumbria, UK	Dried formula	The company report that they use "British raw materials", including milk sourced locally from farms in and around the Lake District, "whey from Somerset, vitamins and minerals from Kent, essential oils from Yorkshire, packaging from the Midlands."[v]

iii HiPP, 2021. Sustainability Report 2020: Pioneering our Future. https://www.hipp.com/fileadmin/redakteure/hipp_com/COM_Responsive/pdf/HiPP_Sustainability_Report_2020_English.pdf
iv HiPP, 2021. Sustainability Report 2020: Pioneering our Future. https://www.hipp.com/fileadmin/redakteure/hipp_com/COM_Responsive/pdf/HiPP_Sustainability_Report_2020_English.pdf
v Kendamil, 2022. How is Kendamil baby milk made? https://kendamil.com/blogs/blog/how-is-kendamil-baby-milk-made

Ingredient suppliers

As outlined above, infant formula is composed of many different ingredients. The primary, or base, ingredient in powdered infant formula (the format which dominates the market), is milk powder, usually cows' milk. The market for dry milk powder has experienced a significant expansion over the past 15 years, resulting in complex global production and trade dynamics as well as significant market concentration, with the market for dry milk powder dominated by a handful of multinational corporations, including New Zealand's Fonterra, and the French company Groupe Lactalis[51]. Major suppliers of the diverse variety of ingredients used in the manufacture of infant formula were identified through a combination of informal expert discussion, and desk-based searches from publicly available online sources (Table 3). However, illustrating the opacity of the supply chain, information about precisely where infant formula companies source each ingredient in their products destined for the UK market could not be ascertained. With the exception of Tirlán (formerly Glanbia Ireland), an Irish company, the companies involved were multinational organisations with multiple production sites.

Table 3. Manufacturers of ingredients for use in infant formula

Name	Location(s)	Ingredients
Glanbia Ireland – now Tirlán Ingredients	Operates 6 manufacturing plants across Ireland[i]	Cows' milk based ingredients[ii] including branded **milk protein** with a casein/whey ration of 80/20, **Whole Milk Powder** range **Skim Milk Powder** range suitable for both wet and dry blends **Lactose** for dry blending
Lactalis Ingredients	French - operates 266 factories in 51 countries	Cows' milk based ingredients[iii] including branded **milk protein**, demineralised **whey powder**, and **Lactose**, which is available with and without vitamin B2

i Tirlán Ingredients, 2020a. Our locations. https://www.tirlaningredients.com/who-we-are/our-locations
ii Tirlán Ingredients, 2020b. Infant nutrition solutions. https://www.tirlaningredients.com/solutions/infant-nutrition-solutions
iii Lactalis ingredients (no date). Infant Nutrition. https://www.lactalisingredients.com/applications/infant-nutrition/

IFF	Operates 210 manufacturing facilities globally, including major manufacturing facilities in the United States, The Netherlands, Spain, Great Britain, Germany, Indonesia, Turkey, Brazil, Mexico, Slovenia, China, India, Ireland, Finland, Denmark, Belgium and Singapore [iv]	**Human Milk Oligosaccharides (HMOs)** **Probiotics**[v]
DSM	Operates 16 production plants spanning Europe, North and South America, Canada and China[vi]. Production of different ingredients at different production sites including: Plant-based omega oils eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) made in North America[vii]	A range of products[viii] including **HMOs** **Fats**: docosahexaenoic acid (DHA) arachidonic acid (ARA) derived from algal oil **Vitamins**: A, C, D, E
Arla Foods Ingredients	Processing plants in Denmark (Danmark Protein, Arinco, Hoco), Germany (ArNoCo), Argentina, UK (MVI, North Tawton EX20, 2DA), Norway (Tine Meieri)[ix]	A range of products[x] including: **Protein** Alpha-Lactalbumin, Whey protein concentrate, Whey protein isolate, Hydrolysates, Casein, Osteopontin[xi]. **Lactose**, **Fats** Milk fat globule membrane, **Milk minerals** calcium and phosphorous
BASF	More than 230 production sites globally, but six "Verbund" sites in Germany, Belgium, China, Malaysia and the USA account for 50% of production capacity[xii]	A range of products[xiii] including: **HMO**: PREBILAC 2'-FL **Vitamins**: Vitamin K1, Riboflavin (B2), D3, B12, A, E, **Fats**: Dry n-3 omega-3 powders, Omega oils

iv IFF, 2021. 'Annual Report 2021'. Available at: https://ir.iff.com/static-files/25f3efa3-3f10-46ba-b15a-b606e902f528
v IFF, 2021
vi DSM, 2023a. Global Manufacturing Capabilities. https://www.dsm.com/pharma/en_GB/quality-and-reliability/global-manufacturing-capabilities.html
vii DSM, 2023b. Supporting maternal nutrition with plant-based omega-3s. https://www.dsm.com/human-nutrition/en/products/nutritional-lipids/nutritional-lipids-in-maternal-and-infant-health.html
viii DSM, 2022. Products with purpose: Nutritional Lipids. https://www.dsm.com/content/dam/dsm/human-nutrition/pdfs/HNH_Lipids_Product_Brochure.pdf
ix Arla Foods Ingredients, 2022a. Production sites https://www.arlafoodsingredients.com/about/contact/locations/
x Arla Foods Ingredients, 2022b. https://www.arlafoodsingredients.com/early-life-nutrition/explore-industry/ingredients--solutions/ingredients--concepts/infant-nutrition/
xi A protein that has several functions in the body mainly around immune function. It is been isolated and added to some formula but is not an ingredient found in commercial milk formulas sold in the UK.
xii BASF, 2022. BASF Verbund. https://www.basf.com/global/en/investors/calendar-and-publications/factbook/basf-group/verbund.html
xiii BASF, 2019. BASF and Glycosyn sign strategic partnership to improve gut health with human milk oligosaccharides. https://www.basf.com/global/en/media/news-releases/2019/05/p-19-210.html

Why does this matter?

Ideal feeding – and food security – for babies involves exclusive breastfeeding from birth until six months of age. However, while many British mothers would like to breastfeed, for various reasons most do not manage to do so for as long as they had wanted, or as is ideal[52]. Consequently, the current reality is that the UK has a formula-feeding culture. In the first quarter of 2022, over half of babies in England were already exclusively formula-fed by the age of six-eight weeks[53]. For these infants, their food source is 'non substitutable': apart from infant formula, there is no

safe and nutritionally adequate food source. This makes them a uniquely vulnerable group in terms of food security.

Our research has shown that the main and in many cases the only food being given to the UK's infant population depends on a supply chain that is both very concentrated – with just four supplier companies – and extremely complex, with industrially produced ingredients sourced, manufactured, processed and combined at sites around the world.

Given the widespread disruption caused by the closure and recall of the primary supplier of infant formula in the US, it seems prudent to heed the warning, especially in view of the fact that the UK supply chain is even more concentrated, with Danone accounting for over 70% of our infant formula supply, compared with 40% for Abbott in the US.

In addition, in recent years we have seen how vulnerable global food supply chains are to disruptions from a range of geopolitical and environmental causes.

Our research has also shown that the supply chain is far from transparent.

Finally, though this report has not focused on affordability, recent steep rises in the cost of infant formula will have contributed to overall food insecurity in low-income households with formula-fed babies[54].

What should be done?

A combination of the UK's formula feeding culture and highly concentrated infant formula supply chain renders many British babies highly food insecure, particularly in the event of a significant emergency. We therefore recommend the following actions to better safeguard the food security of the nation's infants:

1. Include infant formula in the UK food security assessment

Infant formula should form part of the now legally required triennial UK food security assessment. Assessment could, for example, formally record the estimated amount required, based on annual sales figures and birth statistics, the amount supplied, the number and location of suppliers, the sources of their essential ingredients, the level of stocks held by suppliers in the UK at any time, and the capacity to switch between formula suppliers or ingredient suppliers, or make alternative arrangements, in the event of a shock to supply. It could also analyze the main risks to supply in the context of current world events, and set out mitigations.

2. Include breastfeeding and formula feeding in emergency planning

Emergency planning – for events such as floods and other extreme weather events, large-scale power cuts, or supply chain disruption – should routinely make provision both for families with babies who are breastfed, and for families with babies fully or partially dependent on infant formula. In the latter case, this means ensuring access to appropriate infant formula as well as to settings for safe preparation and feeding (i.e., with appropriate supplies and water, and the capacity to heat the water to the required temperature).

One possibility to hedge the risk of a widespread serious or prolonged shortage could be for the government to have in place plans to make and supply a generic, plain-labelled infant formula, using UK-produced ingredients as far as possible, comparable to the 'National Dried Milk' available during and after the second world war[55].

3. Mandate more transparency in supply of infant formulas

As suppliers of a non-substitutable food stuff, suppliers of infant formulas should be required to make more information publicly available, to assist with emergency planning. It may be that the reliance on company information (which our research shows to be partial and inconsistently available) is itself a supply chain vulnerability, as there is no central repository of information available if emergency planning needs to be put into place.

4. Minimise the risks of bacterial contamination of powdered formulas

To avoid a crisis such as the one that engulfed the US formula supply, production facilities need to maintain sufficiently high health and safety standards through stringent rules and enforcement. But because the UK has limited control over this in a context of its reliance on imports, it is important that parents/carers are enabled to follow current NHS advice to make up powdered formulas using boiled tap water cooled to no less than 70ºC to kill any bacteria that may be present. Powdered formula labels should include warnings that the formula is not sterile and clear instructions for reconstitution which stipulate how to achieve the recommended water temperature, as advised by WHO Europe[56].

5. Secure access to specialised infant milks for those infants who need them

The security of supply chains for sufficient specialised infant milks need to be considered alongside the inclusion of infant formula in the UK food security assessment, considering for example prescription figures and looking to how medicine supply chains are assured. Emergency planning also needs to consider how to ensure access to these products for those infants dependent on them. As with infant formula, companies should be mandated to make information on specialised infant milks publicly available to assist with emergency planning.

6. Enable breastfeeding

Breastfeeding, where it is possible, offers babies food security as well as benefitting their health and that of their mother. Key priorities are increasing the numbers of mothers who want to, to initiate breastfeeding, and enabling these mothers to continue breastfeeding for longer. Actions to achieve this should include:

- Funding and supporting all neonatal, maternity and health visiting services, Children's Centres/ Family Hubs and midwifery and health visiting courses in universities to become Unicef UK Baby Friendly Initiative accredited;
- Ensuring universal access to breastfeeding support to overcome common breastfeeding challenges, delivered by peers and skilled professionals;
- Stronger legal protections for breastfeeding women returning to work;
- Upgrading and enforcing UK regulations to better prevent the inappropriate and unethical marketing of commercial milk formula, bottles and teats, which misleads both parents/ carers and health professionals. At minimum, the laws need to align with the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly Resolutions. WHO Europe provides a model law that can serve as a template[57].

7. Widen access to donor human milk

Human milk banks can play an important role in ensuring food security in the event of crisis, when donor human milk can be used to feed infants instead of commercial milk formulas where breastfeeding is not possible. In addition, the availability of donor human milk alongside high-quality breastfeeding support assists mothers to establish breastfeeding, facilitating infant food security. This means widening access to donor human milk is one important strategy to enable breastfeeding. The Government should invest in widening access to donor human milk.

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With thanks to our funders

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Please cite this Insight as:

Sibson, V., Fallon, N., and Shenker, N. (2023) *How secure is our infants' food supply? Why the government's food security assessment and emergency planning must include breastfeeding and the infant formula supply chain.* Food Research Collaboration Policy Insight.

ISBN: 978-1-903957-81-3