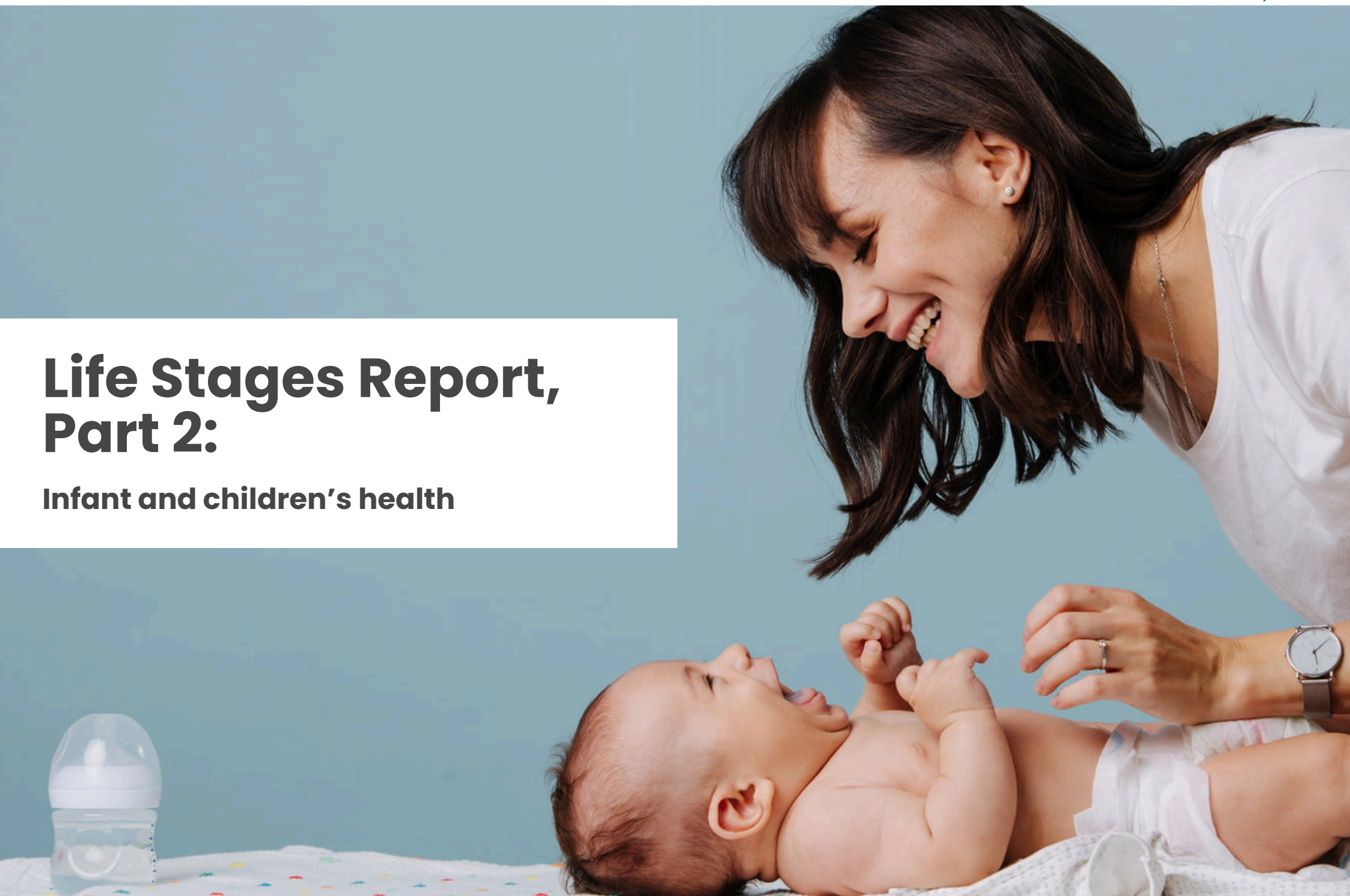


Life Stages Report, Part 2:

Infant and children's health



Introduction

Infants and children have unique developmental needs and adequate nutrition in the first years of life is the foundation for good health in later years. In this report, we explore the latest ingredient innovations that are improving infant formula, preventing allergies in childhood, and spurring product development in emerging growth areas, such as sleep health for children.

The Vitafoods Insights Life Stages report is published in three parts. This is part two.



Improving infant formula



The first 1,000 days of life are crucial to a baby's cognitive development and can impact health throughout adulthood.¹ What's more, if a baby is exclusively bottle-fed, infant formula is the only source of nutrients it will receive until weaning begins.

While breast milk is universally recognised as the best milk for babies in terms of nutrition, many women are not able to breastfeed, perhaps due to health reasons or because they must return to work. Creating a nutrient-dense formulation that replicates breast milk as closely as possible is therefore crucial.

Some recent ingredient innovations in this space include bovine milk-derived osteopontin (bmOPN), which was approved as a novel food by the European Food Safety Authority (EFSA) in 2022 at a maximum use level of 151 mg per litre in infant formula and follow-on formula.² Osteopontin is a heavily phosphorylated,

acidic glycoprotein with strong calcium-binding properties that may provide immune benefits.³



Other ingredient innovations focus on how specific nutrient blends can optimise certain biological pathways that are important for health, such as the production of myelin. During the first year of life, the volume of white matter in the human brain increases by up to 16%. A crucial element of this development is myelination.⁴ Myelin is a lipid-rich sheath that insulates and protects the nerve fibres

that are vital for cognitive and behavioural development. The nutrients found in breast milk are known to promote myelin formation.

One 2019 study compared the brain and neurocognitive development in children who were exclusively breastfed versus formula-fed for at least three months.⁵ The researchers noted “significantly improved” overall myelination in breastfed children as well as better general, verbal, and non-verbal cognitive abilities compared with children who were exclusively formula-fed.

However, the scientists also noted important findings for infant formula manufacturers: there were “significant developmental differences” among bottle-fed babies depending on the composition of the formula they received. They also found that certain nutrients were significantly associated with early myelination trajectories, particularly long-chain fatty acids, iron, choline, sphingomyelin, and folic acid.

Using the right combination of such nutrients from bioavailable sources and in the right quantities in infant formula could therefore help increase myelination levels.



Working with scientists and clinicians from Rhode Island Hospital and Pennington Biomedical Research Center in the US, Nestlé scientists have developed a blend of nutrients they say had a positive impact on brain structure development in infants as young as three and six months.⁶ Tested

in a clinical study using non-invasive brain image analysis, the product was made with whey protein concentrate enriched in alpha-lactalbumin and phospholipids with added DHA, ARA, iron (fortified through ferrous sulphate heptahydrate), folic acid, and vitamin B12 (fortified through cyanocobalamine).

Based on the research, in 2022 Nestlé launched Nutrilearn Connect, an infant formula product aimed at increasing myelination over the first months of life.

Misleading marketing practices are still rife

Despite the progress that has been made in improving the nutrient density of infant formula, much work is still to be done – not least in putting a halt to misleading marketing practices.

A 2023 study published in the British Medical Journal evaluated the health claims made on more than 750 breast milk substitute products across 15 countries,

finding that most of the claims had little or no supporting evidence of good quality.

Popular claims related to the benefits of ingredients such as long-chain polyunsaturated fatty acids, prebiotics, probiotics, and hydrolysed protein, but either failed to provide any scientific evidence to support the claim or relied on opinion pieces, reviews, or unscientific sites. When registered trials were cited, 90% of these carried a high level of bias, authored by researchers who were paid by or affiliated with the formula industry, for instance.⁷

“Although advances have been made in implementing mandatory compositional and information requirements for infant formula, transparency is still lacking about health and nutrition claims linked to infant formula,” concluded the researchers, adding that health and nutrition claims for products regarded as breast milk substitutes should not be permitted.



Spotlight on synthetic biology

A growing number of companies are using novel food technologies to produce some of the nutrients found in breast milk.

Boston-based Conagen, Singapore-based TurtleTree Labs, New York-headquartered Helaina, and Harmony Baby Nutrition are just some of the startups using precision fermentation. This involves rewriting the genetic code of a specific organism – a microbe, yeast strain, or microalgae – and instructing it to produce the molecule of interest. The gene-edited organism is then separated from the target molecule, usually by mechanical means such as filtration, meaning the final product is GM-free.

Other companies, such as US startup Biomilk and Israel's Wilk, use cell-culturing methods to produce the nutrients of interest. This approach involves taking mammary epithelial cells and mixing them with nutrient-rich cell growth media in a bioreactor that recreates the conditions in

the breast. The cells multiply, absorb the nutrients, and secrete human breast milk.⁸

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Some of the specific nutrients that foodtech startups in this space are producing include:

Lactoferrin

Human lactoferrin is an iron-binding protein that is linked to several physiological and protective functions, including anti-infective and anti-inflammatory activities. It also regulates

iron absorption in the infant gut and has a probiotic effect.

Lactoferrin exists in cow's milk but in much smaller quantities than human breast milk. Human colostrum (the first breast milk produced by the body) contains around 7 grams per litre, compared to 1.5 milligrams per litre in cow's milk.⁹ Extraction from dairy milk is therefore resource-heavy and unsustainable.

2'-FL

Human milk oligosaccharides (HMOs) are important nutritional compounds only found in breast milk. The most abundant HMO in human milk is 2'-fucosyllactose (2'-FL), which plays a role in promoting a healthy gut microbiome, strengthening the gut barrier function, and suppressing pathogens.

FBA

Phenylalanine-butyramide (FBA) works by releasing the short-chain fatty acid butyrate. Butyrate is an important

postbiotic and probiotic molecule for building gut health and immunity but has an unpleasant taste that has made it difficult to commercialise as a food ingredient. Synthetic biology startups say they can produce a version that is tasteless and odourless.

And others...

Other nutrients of interest include lactadherin, a protein also known as milk fat globule-epidermal growth factor 8 (MFG-E8); lysozyme, an antibacterial enzyme; alpha-lactalbumin, a whey

protein that is rich in essential amino acids; and secretory immunoglobulin A (sIgA), an antibody that plays a crucial role in protecting the infant's digestive and respiratory systems.

This list is far from exhaustive. Given the huge number of nutrients present in breast milk, the category could be wide open for future innovation.

"One can imagine that any bioactive [or] nutri-functional component present in breast milk will at some point [be able to]

be manufactured using precision fermentation and/or synthetic biology," said Raphaëlle O'Connor, founder and director of health consultancy iNewtrition.

Nevertheless, O'Connor said that replicating the complexity of breast milk in a lab setting is a significant challenge. "It may be difficult to completely mimic the full spectrum of bioactive components and their interactions, potentially leading to an incomplete nutritional profile compared to natural breast milk," she said.

There may also be ethical implications that need to be carefully evaluated.

"There are concerns related to the use of human-derived cells or genetic material in the production process. Ensuring that the technology is ethically and socially acceptable requires thoughtful consideration and public engagement," she added.



Could plant-based
infant formula
be the next big
opportunity?



The overwhelming majority of infant formula products on the market today are made from dairy milk. According to data from Mintel's Global New Product Database, the global share of plant-based infant formula launches stood at just 2% of total launches at the end of December 2021 and 1% of launches between January and April 2022.

However, it predicts that demand could grow in coming years. Over half (58%) of UK parents of children aged under four are concerned about the environmental impact of infant and toddler milk production, while 62% of Chinese parents who feed their infant with formula say they would be willing to pay more for plant-based versions, according to Mintel surveys.

Plant-based drinking milks have been criticised for not fully replicating the nutrient profile of dairy milk. If consumers adopt them as a like-for-like substitute for dairy milk, there is a risk of generating

nutrient deficiencies. When it comes to feeding babies, whose sole source of nutrients may be infant formula, the stakes are even higher.

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Soy is best for plant-based nutrition

According to the US Healthy Drinks, Healthy Kids guidelines, developed by experts from several non-profit associations including the Academy of Nutrition and Dietetics (AND), the American Academy of Pediatrics (AAP), and the American Heart Association (AHA), plant-based milks are

not recommended as a complete dairy milk replacement for young children due to wide variations in nutrient content.¹⁰

“With the exception of fortified soy milk, these milks are not adequate nutritional substitutes for dairy milk, which has many nutrients essential for healthy growth and development,” the guidelines read.

(Soy protein is the best-performing plant ingredient for protein digestibility corrected amino acid score, known as PDCAAS.)

The guidelines state that parents of children with soy and dairy allergies should consult a paediatrician or registered dietitian to advise on a suitable milk substitute and ensure the child's diet provides the required nutrients.

Nevertheless, the market for non-dairy infant formula – although very small – is growing.

Hamutal Yitzhak is CEO and director of

plant-based infant formula brand Else Nutrition, which has a range of dairy-free and soy-free products for babies aged six months and over, including formula and cereals. Yitzhak is aware that many plant-based brands fall short of nutritional requirements.

“Despite undoubted beneficial properties of plant raw materials, a careful inspection reveals that commercial plant-based drinks vary from cow milk infant formulas significantly from a nutritional point of view,” she said. “Their suitability for feeding infants as a sole nutrition has been reported to affect growth and nutritional status adversely, thus is dangerous and may cause significant nutrient deficiencies.”

However, Yitzhak, who used to be head of infant nutrition at dairy-based formula manufacturer Abbott, believes there is a place for carefully formulated plant-based formula. Else Nutrition aims to replicate the health outcomes of breast milk – rather

than mimic specific ingredients and components – using whole-food, dairy-free ingredients.

“There are specific guidelines and regulations defining the exact nutrients that should be in an infant formula. Else infant formula was developed based on the regulatory requirements for this age group, using almonds and buckwheat as main ingredients and micronutrients such

as vitamins, minerals, and others to provide all nutrients needed for adequate growth of infants,” she said.

Some of the ingredients the company uses in its products include vegetable oils for omega-3 fatty acids. It also adds the polyunsaturated fatty acids, docosahexaenoic acid (DHA) and arachidonic acid (ARA).



READ MORE: [US supplement brands failing to meet nutritional needs of pregnant women \(click image\)](#)

“We developed from a belief that young infants deserve a viable, clean, plant-based alternative made with minimally processed ingredients. Just as we as adults are looking for natural, clean, minimally processed food, our children deserve a similar approach to feeding. Though most infant formulas on the market are based on cow milk and the infant formula market is a daunting category to enter, we strongly believe that the alternative we are offering is needed,” Yitzhak said.

Enter hybrid blends

Rejecting an either-or approach, hybrid blends of both plant- and dairy-based ingredients may be the answer for formula brands looking to tick both nutritional and environmental boxes.

In 2022, Danone launched its Dairy & Plants Blend baby formula to meet parents’ desire for feeding options that are suitable for vegetarian, flexitarian, and plant-based diets, while still meeting their baby’s

specific nutritional requirements.¹¹

The manufacturer said it drew on 50 years of scientific breastmilk research and its knowledge of plant-based nutrition – its portfolio includes the brands Alpro and Silk – to develop the formulation.

Launched first in the Netherlands under the Nutrilon brand before being expanded

globally under the Aptamil brand, the products are made with 60% non-GM soy protein and other plant ingredients including vegetable oils, such as sunflower, coconut, and rapeseed oils; DHA from algae; and fibres from chicory roots. The 40% dairy component provides casein and whey protein from cow’s milk and other nutrients such as lactose.



Infant formula: Adapting in the face of supply chain disruptions



Since the start of the Covid-19 pandemic, the infant formula sector has experienced significant disruptions, from ingredient sourcing to rising costs and from pathogen outbreaks to recalls.

The US in particular has been a case in point highlighting the vulnerability of the supply chain. In the highly consolidated US market, where four companies produce 90% of supplies, parents found supermarket shelves empty for months on end, with out-of-stock rates reaching almost 40% in May 2022.¹² The crisis, sparked by an Abbott Nutrition factory closure and product recall due to a suspected bacterial contamination, was compounded by a lack of manufacturers to step in to fill the gap and restrictions on foreign imports, among other factors.¹³

With the situation back to normal, attention has now turned to preventing further crises. In June 2023, the US Food and Drug Administration (FDA) commissioned the National Academies of Sciences, Engineering, and Medicine to conduct a study evaluating the US formula industry, notably the challenges it faces; diversity of suppliers; and how the market differs from that of the EU. The study's findings will be sent to the FDA and the US Congress.¹⁴

Recent geopolitical events have also rocked the global infant formula market, forcing manufacturers to consider sourcing alternative ingredients.



READ MORE: [Infant formula: Overcoming challenges in nutrition, safety, and supply \(click image\)](#)

Russia's invasion of Ukraine in 2022 and the subsequent ongoing war has had a huge impact on global supplies of sunflower oil, a key ingredient in infant formula that is used to provide essential fatty acids, such as oleic and linoleic acid.

Before the war, Ukraine was the world's biggest sunflower oil producer and 91% of its production was exported globally.¹⁵ The sudden restriction in supplies led to prices of sunflower oil (and sunflower oil-derived ingredients, such as the emulsifier lecithin) skyrocketing in the immediate aftermath, forcing food and drink manufacturers to reformulate.¹⁶

Mintel analyst Rick Miller noted that safflower oil may be a functional equivalent for infant formula manufacturers looking to diversify their supplies.

"With mounting pressure on sunflower production, safflower oil might be the key consideration for infant formula brands. Safflower oil is often used interchangeably with sunflower oil due to its similar fatty acid profile and resistance to drought," he said in a Mintel report.¹⁷

Safflower oil also has the advantage of having a relatively clean image compared to palm oil.

"Safflower oil could also be part of a positive ingredient transition

from palm oil," he said. "Palm oil has a negative profile due to its role in deforestation. For instance, 33% of French parents state 'palm oil free' as a factor in their choice of infant formula and the EU recently drafted a law to place an import ban on palm oils that are linked to deforestation."

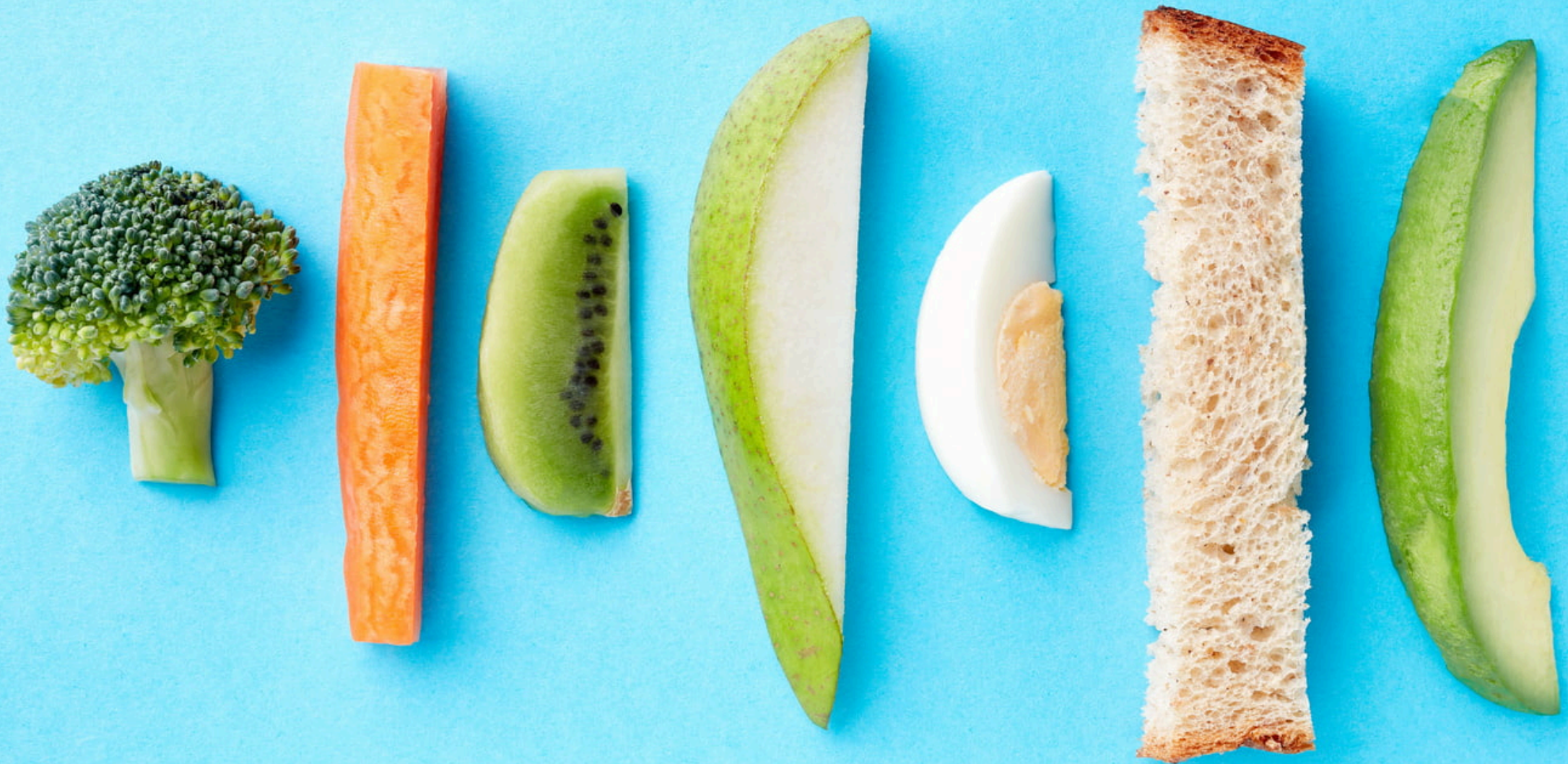
Miller also noted that the war in Ukraine has led to an increase in the price of dairy ingredients due to rising costs of agricultural inputs such as fertilisers. Given the prominence of dairy ingredients in formula, brands may start to explore using plant-based ingredients (or hybrid blends) to keep consumer-facing prices down.

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With mounting pressure on sunflower production, safflower oil might be the key consideration for infant formula brands."

Rick Miller, associate director of specialised nutrition, Mintel

However, there are no easy swaps in this category. Infant formula is the most highly regulated food in the world and changing the formulation of products requires careful consideration to ensure that alternatives are safe, nutritionally equivalent, and authorised for use in formula.



Using nutrition to prevent food allergies

Food allergies affect around 2.5% of the general population but prevalence can range from 1% to 10%, depending on the country. The prevalence of some allergies is also on the rise: it is estimated that peanut allergy among children in the UK, North America, and Australia, for instance, has doubled in 10 years to affect 1.8%, 1.4%, and 3.0%, respectively.¹⁸

Medical advice used to recommend that parents delay exposure to solid foods and avoid allergenic foods completely. However, in 2015, a pivotal piece of research – the Learning Early about Peanut (LEAP) study – showed that early introduction of peanuts significantly decreased the frequency of peanut allergy among children at high risk, and modulated immune responses to peanuts.¹⁹ This prompted a “paradigm shift” in nutritional guidance for allergy prevention, according to the World Allergy Organization.²⁰



READ MORE: Prenatal vitamin D supplementation impacts eczema risk in infants ([click image](#))

Introducing allergens to small babies, however, is not easy. It is dangerous to give nuts to infants even in powder form as this can form a thick paste in the baby's mouth, for instance, while eggs – another major allergen – must be cooked for 20 minutes at 170°C or boiled for 30 minutes at 100°C to break down one of the major allergy-causing proteins, OVA.²¹

Spotting an opportunity, some functional infant food startups have developed products that make early introduction of allergens easier.

In Europe, Dutch startup Vini Mini makes soluble peanut and cashew flours that can be given to breastfed or bottle-fed babies as well as follow-on products to be mixed with fruit and vegetable purees during the weaning period.²²

US startup Lil Mixins makes a soluble peanut powder using 100% defatted, dehydrated, and ground peanut protein; baked or boiled egg powders; and soluble

powders of other major allergens, including sesame, soy, and almond.

Using probiotics to prevent allergies – before birth

Lil Mixins' latest product is a range of probiotics that aims to tackle a major cause of food allergies – atopic eczema – before birth.

Developed on the premise that “allergy prevention starts before birth”, the product comes in a dual format, with probiotic capsules to be taken by the mother-to-be during pregnancy and after the birth while she is nursing, as well as probiotic drops for the breastfed baby.

“The ‘whitespace’ was really that no one was showing parents how to reduce the risk of eczema,” co-founder and CEO Meenal Lele said. “We talk all the time about how eczema is the biggest risk factor for food allergy. So, logically, we should also be trying to prevent eczema – and it turns out, that's very possible with



the use of *Lactobacillus rhamnosus* given perinatally. Basically about 50% of eczema is preventable, [based on] solid data with 10-year outcomes.”

Lil Mixins commissioned and financed a meta-analysis of randomised trials, which concluded that *L. rhamnosus* – taken with or without other probiotics – appears to have a positive effect in reducing the incidence of atopic eczema in children.²³

Nevertheless, findings on the benefits of prenatal supplementation are mixed and more research is needed. One systematic review looking at whether probiotics in pregnancy reduce allergies and asthma in infancy and childhood concluded that results were inconsistent – although the authors added that “probiotics may have the potential to reduce infant allergies when administered prenatally”, particularly in children at high risk of allergy development.²⁴



Sleep health for kids:
An untapped opportunity?

S

cientists are increasingly understanding the importance of sufficient sleep – both in terms of quantity and quality – on overall physical and cognitive health and wellbeing.

This is of even greater importance for children, who need more sleep than adults: up to 17 hours a day for infants under three months and 10 hours per night for 18-year-olds, according to the US Centers for Disease Control and Prevention.²⁵

Insufficient sleep in children – defined as less than nine hours a night – is associated with impaired cognitive functions such as decision-making, conflict-solving, and learning, as well as increased impulsivity, stress, depression, anxiety, aggressive behaviour, and thinking problems, according to an 8,000-strong observational study of nine- and ten-year-olds.²⁶

Triggered by the Covid-19 pandemic, which disrupted children's routines, prevented them from going outside, and caused sleeplessness, demand for products that promote sleep health for children is on the rise, according to Mintel, which called the category an emerging opportunity.

"Parents are concerned about their children's sleep health and are looking for products to help them sleep better," wrote Yunn Lim, consumer lifestyle analyst for Asia.²⁷

Mintel consumer research shows that 46% of US parents treat their children's sleep health issues by giving them vitamins, minerals, or supplements, while over one-third (34%) of UK parents are interested in non-prescription remedies with calming properties for their children.



Easy-to-consume formats are essential

Formats that are easy for children to consume, such as gummies, sprays, and dissolvable tabs, are essential for this category, while beneficial nutrients include magnesium, which has an EU- authorised health claim for the reduction of tiredness and fatigue, and botanicals such as ashwagandha, L-theanine, and schisandra.

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Parents are concerned about their children's sleep health and are looking for products to help them sleep better.”

Yunn Lim, consumer lifestyle analyst, Mintel

Other “exciting options” to watch in the sleep health category include saffron, glycine, tart cherry juice, chamomile, and holy basil, according to Adrian Lopresti, managing director of Clinical Research Australia (speaking generally and not specifically for children).²⁸

Some products on the market are using these ingredients already. UK health food and supplement retailer Holland & Barrett makes private-label “night-time gummies” for children aged three and upwards under its H&B Kids brand. One gummy provides 20 mg of

ashwagandha extract, 50 mg of green tea extract, 20 mg of chamomile extract, and 25 mg of cherry extract.

In the US, Vicks ZzzQuil makes low-dose melatonin gummies to help children sleep better, blending 0.5 mg of melatonin with lavender and chamomile extracts.

However, the Sleep Foundation warned that there is little research on the long-term effects of use of melatonin – the hormone involved in regulating the circadian rhythm – in children, and the potential risks and side effects of using it are not fully known. Children who take melatonin supplements may experience symptoms like bedwetting, drowsiness, headaches, and agitation, it noted. Parents should also be aware of the risk of accidental overdose and work closely with a paediatrician on the use of melatonin, it added.²⁹



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Key takeaways

- Novel production technologies, such as precision fermentation and cell culturing, are allowing companies to produce nature-identical nutrients found in breast milk, such as human lactoferrin and human milk oligosaccharides (HMOs).
- Global supply chain disruptions and rising costs have forced many infant formula brands around the world to seek new ingredient sources – swapping fatty acids derived from sunflower oil for safflower, for instance – although changing the formulation of breast milk substitutes can be a burdensome undertaking in this highly regulated category.
- Plant-based infant formula is niche but demand is growing. However, some independent medical associations warn that only fortified soy is an adequate nutritional substitute for dairy milk for children.
- Food allergies among children are on the rise but can be prevented through targeted dietary interventions, notably the early introduction of allergens. Some functional food and drink brands are developing products to help parents do this in a safe and controlled way.
- Sleep health is an emerging opportunity and there are many ingredients that can play a role in improving the quality of children's sleep, from magnesium to L-theanine.

- Brands should be conscious of the unique nutritional requirements and developmental needs of children, who are not simply small adults. Formulations must be created accordingly.





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