CONFIDENT VIEW AHEAD

Infant Feeding and Formula: From Nourishment to Innovation

Navigating Safety, Science, and the Imperative for Infant Formula Innovation

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EXECUTIVE SUMMARY

Breastfeeding remains the gold standard of infant nutrition — this is not in dispute. Yet today, just 48% of infants worldwide are exclusively breastfed for the recommended six months, and for millions of families, infant formula is not a lifestyle choice but a necessity. This edition of Confident View Ahead examines the complex interplay of breastfeeding advocacy, information access, product safety, and the profound unmet need to advance innovation in infant formula. It calls on governments, regulators, industry, and the scientific community to advance infant formula not as a competitor to breastfeeding, but as a critical healthcare product that deserves the same rigor, investment, and regulatory clarity as any other therapeutic product for vulnerable populations.

1. Breastfeeding: The Uncontested Foundation

There is no ambiguity in the science: breastfeeding is the optimal source of nutrition for infants during the first six months of life and beyond. The World Health Organization (WHO) and UNICEF recommend exclusive breastfeeding for the first six months, followed by continued breastfeeding alongside appropriate complementary foods for up to two years or longer. The benefits are profound and well-documented — for infants and mothers alike.

For infants, breastfeeding reduces the risk of infections, diarrhea, pneumonia, obesity, and non-communicable diseases, while supporting immune system development, neurocognitive growth, and long-term health. For mothers, breastfeeding is associated with lower risks of breast and ovarian cancer, type 2 diabetes, and cardiovascular disease. Improving breastfeeding rates could save more than 820,000 children's lives annually.[4,5]

> "Breastfeeding is a public health imperative — but the conditions that make it possible are not equally distributed across society."

Global Breastfeeding Rates: Progress and Persistent Gaps

The Global Breastfeeding Scorecard, published annually by WHO and UNICEF, reflects encouraging trends: over the past twelve years, the rate of exclusive breastfeeding among infants under six months of age has increased by more than ten percentage points globally, reaching approximately 48% in 2024. The WHO's World Health Assembly had set a target of 50% exclusive breastfeeding by 2025, and the trajectory is close.[1,3]

Twenty-three countries across Africa, Asia, Europe, and Oceania have achieved increases of more than ten percentage points since 2017. For example, Rwanda and Sri Lanka report exclusive breastfeeding rates approaching 81%.[6] By contrast, the United States sits at approximately 25.8% exclusive breastfeeding at six months.[6] In 2016–2022, only 46% of newborns worldwide were breastfeeding within one hour of birth, well below the 70% target set for 2030.[33]

These figures reflect meaningful progress — yet they also underscore that more than half of the world's infants are not exclusively breastfed for the recommended duration. For these families, the quality, safety, and accessibility of infant formula is not an abstract concern: it is a daily reality.

2. The Breastfeeding Reality: Why Barriers Matter

Breastfeeding is natural — but it is not always straightforward. A wide range of individual, structural, and systemic barriers prevent women from breastfeeding exclusively, regardless of intent or desire. Acknowledging these barriers is not an argument against breastfeeding promotion — it is an argument for honest, empathetic, and complete support systems for women and families.

Medical and Physiological Challenges

It is estimated that approximately 1-5% of women experience primary lactation insufficiency — an inability to produce enough milk to exclusively breastfeed — while a far greater proportion encounter significant difficulties in the early weeks, including problems with latch, mastitis, engorgement, nipple damage, and pain. For some infants, conditions such as cleft palate, tongue-tie, or metabolic disorders like phenylketonuria (PKU) or galactosaemia make breastfeeding clinically contraindicated. Maternal health conditions — including communicable diseases, certain medications, or the use of chemotherapy — may also preclude safe breastfeeding.

These are medical realities, and they require clinical guidance and access to evidence-based alternatives.

Structural and Socioeconomic Barriers

Many of the most powerful barriers to breastfeeding are structural. Globally, only a minority of countries provide six months of paid maternity leave, the duration recommended to exclusively breastfeed. For example, in the United States, federal policy provides no guaranteed paid parental leave, placing significant economic pressure on mothers to return to work far earlier

than breastfeeding would otherwise require. The number of countries meeting the ILO Convention 183 standard for maternity leave has barely changed over the past decade.[9]

Even for mothers who can breastfeed, the physical and logistical infrastructure is often absent. Workplace facilities for nursing or pumping, privacy, sanitary conditions, and break time are inconsistently available. In humanitarian contexts, 23% of countries had all three core elements for infant and young child feeding in emergencies in place as of 2021.[3] Without addressing these structural conditions, breastfeeding promotion cannot reach its full potential.

- Inadequate paid maternity leave forcing early return to work
- Absence of lactation facilities and workplace accommodation
- Cultural norms and social stigma around public breastfeeding
- Limited access to trained lactation support and peer counselling
- Formula use in hospital settings contributing to early cessation
- Emergency and humanitarian settings lacking infant feeding support

3. The Information Gap: When Policy Silences Rather Than Supports

The WHO International Code of Marketing of Breast-Milk Substitutes (the WHO Code), adopted in 1981, was designed to protect breastfeeding by restricting the marketing of infant formula and other breast milk substitutes. Its principles are sound: commercial promotion should never undermine breastfeeding, and manufacturers should not market formula as equivalent or superior to breast milk.[8]

However, the implementation of the WHO Code — and the broader regulatory and advocacy environment that has grown around it — has in some cases created an unintended consequence: the systematic restriction of access to accurate, objective information about infant formula for the women who need it most.

> "The goal of protecting breastfeeding must never come at the cost of leaving parents uninformed about the safe use of a product that may be their infant's only source of nutrition."

Healthcare professionals — the most trusted source of feeding advice — are in many jurisdictions restricted or discouraged from proactively discussing the composition, preparation, or brand selection of infant formula. Informational literature about formula is restricted in clinical settings. Online search and social media marketing restrictions, while well-intentioned, also limit the reach of factual, non-commercial information. The result, paradoxically, is that parents who cannot breastfeed may be less equipped to make safe, informed decisions about the alternatives.

When families lack access to accurate information about infant formula — its composition, preparation, storage, and selection — the consequences can be serious: incorrect dilution (both

over- and under-), unsafe water use, inappropriate substitutes, and delayed recognition of feeding problems. Health literacy around infant formula is itself a public health issue.

Infant formula is the only suitable substitute for breast milk when it is needed. This is WHO's own position. Families, healthcare professionals, and caregivers must be empowered – not restricted – in accessing the information they need to use it safely and effectively. The appropriate target of regulation is harmful commercial promotion, not the flow of evidence-based health information.

4. Infant Formula Safety: A Non-Negotiable Standard

Infant formula is not an ordinary food product. For a population of exclusively formula-fed infants, it is their sole source of nutrition for the first six months of life – a responsibility without parallel in the food system. When formula safety fails, the consequences are not merely serious: they are potentially fatal.

A Sector Defined by Recalls and Safety Events

The period from 2022 to 2025 has been particularly consequential for infant formula safety. In early 2022, a major US manufacturer's voluntary recall of powdered formula products — triggered by consumer complaints linking the formula to Cronobacter sakazakii and Salmonella infections at a single manufacturing facility — contributed to a severe national shortage, exposing deep vulnerabilities in the country's highly concentrated formula supply chain.[10]

The years that followed brought a succession of further recalls across multiple manufacturers. In early 2023, two separate recalls were initiated for potential Cronobacter sakazakii contamination—one involving approximately 150,000 cans of a plant-based formula and another involving multiple lot sizes of a widely distributed powdered product. In December 2023, Israeli health authorities confirmed Cronobacter contamination in batches of a specialized hypoallergenic formula exported from the United States, prompting the voluntary recall of over 675,000 cans from the US market. In late 2025, a major pan-European and international recall was triggered by the detection of cereulide — a toxin produced by Bacillus cereus — in arachidonic acid (ARA) oil sourced from a Chinese supplier and used by multiple leading infant nutrition manufacturers globally. Contamination was traced back to October 2024, with dozens of infant cases reported across multiple countries. [10,12]

Most recently, in December 2025, the US Centers for Disease Control and Prevention initially confirmed ten cases of infant botulism linked to an infant formula brand. In February 2026 the investigation closed with finding 48 cases and zero deaths. [12]

These events share a common thread: infant formula, as a category, is uniquely vulnerable to manufacturing failures, supply chain contamination risks, and gaps in regulatory oversight – and the margin for error is zero.

The Regulatory Gap

While infant formula is subject to food safety regulations in most jurisdictions, the standards are not universally aligned with the product's risk profile. In the United States, for example, the FDA Inspector General's 2024 report found inadequate policies and procedures across complaint handling, inspection timelines, and recall authority. The FDA lacked a dedicated organizational

structure for whistleblower complaints related to infant formula, resulting in delays exceeding 15 months in addressing a critical 2021 complaint regarding the facility.[11]

The US currently lacks enforceable regulatory limits for heavy metals and PFAS in infant formula – unlike the EU, Canada, and Australia, which all have maximum contaminant levels for foods for infants and young children/infant formula. As part of Operation Stork Speed regulators are actively testing and evaluating broader toxic contaminants. Operation Stork Speed, initiated in May 2025, has also resulted in: As of February 2026, the FDA publishes a list of Infant Formulas marketed in the US, which is periodically updated. And now the first comprehensive nutrient review since 1998. [14]

> "Infant formula requires not just food-grade standards but pharmaceutical-like-grade vigilance — proactive surveillance, transparent supply chains, and regulatory frameworks commensurate with its role as a life-sustaining product."

5. Market Dynamics: A Sector Treating Formula as a Cash Cow

The global infant formula market is significant and growing. Estimates for 2024 market value range from approximately USD 47–82 billion, with projections of sustained double-digit CAGR growth through 2032–2034 driven by rising workforce participation among women, urbanization, and growing demand for premium and specialty formulations, particularly across the Asia Pacific.[30]

Yet despite this commercial scale, the infant formula sector exhibits structural characteristics that are at odds with the health imperatives of its primary beneficiary – the infant.

Concentration, Barriers, and the Innovation Deficit

The market is highly concentrated. In the United States, a small number of manufacturers control the vast majority of supply, a structure that the 2022 shortage demonstrated to be a critical national vulnerability. High capital costs, expensive clinical trial requirements, complex/unclear regulatory approval processes, and contracting arrangements with hospital systems and federal programs (such as WIC in the US) create formidable barriers to new market entrants.

This concentration has a predictable consequence: reduced incentive for meaningful innovation. When a small number of players dominate a captive market with significant power, a formula can become a cash cow – reliable revenue with limited pressure to advance the science. The Operation Stork Speed expert panel noted that FDA regulatory processes for new infant formula registrations or significant compositional changes are unclear, which hinders market entry and reduces the diversity of available products.[16]

Price and Access Problem

Standard powder infant formula retails at approximately USD 20–30/kg globally in mainstream channels. Specialty and premium formulas – including those enriched with HMOs, organic

ingredients, or hydrolyzed proteins — command higher prices. For families in lower-income situations, the cost of nutritionally adequate formula represents a significant household burden. The public health consequences of formula unaffordability — dilution, early introduction of inappropriate foods, use of non-validated alternatives — are serious and largely invisible.

Governments and the industry must confront an uncomfortable tension: the regulatory environment that maintains the high safety bar for infant formula also slows innovation and reduces competition. Resolving this requires deliberate policy and regulatory design — not deregulation, but smarter, faster pathways for evidence-based innovation in the service of infant health.

6. The Nutritional Gap: What Breast Milk Knows That Formula Doesn't

Understanding what separates breast milk from infant formula is not simply an academic exercise — it is the innovation roadmap for the next generation of formula products. Human milk is a living biological fluid of extraordinary complexity, and is designed to meet the precise nutritional and developmental needs of the human infant.

Protein: Quantity, Quality, and Kind

Human milk contains lower total protein than cow's milk-based infant formula, at approximately 1.0–1.3 g/100 mL, compared with 1.5–1.8 g/100 mL in standard formula. This difference is intentional in evolutionary terms: the lower protein load of human milk aligns with lower early infant growth rates and may reduce the risk of obesity and metabolic syndrome later in life. Formula-fed infants are typically exposed to higher protein intakes, which has prompted a sustained industry effort toward reducing protein content while maintaining amino acid adequacy — the 'lower protein' formula movement — with some regulatory progress in Europe.[26]

The protein composition of human milk also differs fundamentally from cow's milk-derived formula. Human milk's whey-to-casein ratio is approximately 70:30 in early lactation and transitions over time; most formula products are based on cow's milk proteins with a typical ratio of 60:40. More significantly, the dominant whey protein in human milk is alpha-lactalbumin, which is rich in tryptophan and is a source of bioactive peptides. The dominant whey protein in cow's milk — and most formula — is beta-lactoglobulin, which is absent from human milk entirely and is a major allergen.[26] What also hasn’t been appreciated well is that alpha-lactalbumin in cow's milk is not identical to the alpha-lactalbumin in human milk.

Human milk also contains a range of uniquely functional proteins absent or present only in trace amounts in formula: lactoferrin (an iron-binding glycoprotein with antimicrobial, immunomodulatory, and prebiotic properties), secretory IgA (the primary immunoglobulin of mucosal immunity), lysozyme (a bacteriostatic enzyme), osteopontin (involved in immune regulation and gut development), and bile salt-stimulated lipase (critical for fat digestion in the neonatal gut).[26]

Fats: Structure and Function

Human milk fat is approximately 3.5–5.0 g/100 mL and provides around 50% of the infant's caloric intake. What distinguishes human milk fat is not simply its quantity but its structure: it is delivered in the form of milk fat globules surrounded by the milk fat globule membrane (MFGM), a complex of phospholipids, glycoproteins, and cholesterol with demonstrated roles in brain development, immune function, and gut maturation.

The fatty acid profile of human milk is also distinctive: it contains docosahexaenoic acid (DHA) and arachidonic acid (ARA) — long-chain polyunsaturated fatty acids (LCPUFAs) critical to brain and retinal development — as well as significant quantities of saturated and monounsaturated fats. Standard infant formula, particularly in the US, has historically failed to mandate DHA and ARA, relying instead on linoleic acid as a precursor with inefficient conversion. The EU mandated DHA inclusion in infant formula from February 2020; the US, under Operation Stork Speed, is now actively reviewing this gap.

The sn-2 position fatty acid structure of human milk — where palmitic acid is esterified at the sn-2 position of the triglyceride — also differs from standard formula fats, affecting fat absorption, calcium retention, and stool consistency. Structured lipid formulations attempting to replicate this feature are an area of active research and commercial development.

Human Milk Oligosaccharides: The Bioactive Frontier

Perhaps the most well-studied gap between human milk and infant formula is in the realm of human milk oligosaccharides (HMOs). HMOs are the third most abundant solid component of human milk after lactose and lipids, with over 150 distinct structures identified. They are profoundly bioactive: essentially indigestible by the infant, they function primarily as prebiotics — selectively feeding Bifidobacterium longum subsp. infantis and other beneficial gut bacteria to establish the bifidobacteria-rich microbiome characteristic of breastfed infants.[22,24]

Beyond their prebiotic role, HMOs act as decoy receptors that block pathogen adhesion to intestinal epithelial cells, modulate immune responses through cytokine signalling, support gut barrier integrity, and are increasingly linked to neurocognitive development — with sialylated HMOs (3'-sialyllactose and 6'-sialyllactose) in particular showing associations with cognitive and motor development outcomes.[22,24]

Until recently, infant formula contained no HMOs whatsoever. The technology now exists to synthesize several of the most abundant HMOs at commercial scale — principally 2'-fucosyllactose (2'FL) and lacto-N-neotetraose (LNnT) — using fermentation-based bioprocessing, typically from genetically modified E. coli or Corynebacterium glutamicum. These are structurally and functionally identical to their naturally occurring counterparts in human milk.[22,32]

Clinical evidence increasingly supports the benefits of HMO supplementation in formula: randomised controlled trials have demonstrated that formula containing 2'FL and LNnT produces a gut microbiome more similar to that of breastfed infants, with associated reductions in respiratory morbidity, lower inflammatory cytokine profiles, and improved immune outcomes. A five-HMO formula (including 2'FL, DFL, LNT, 3'SL, and 6'SL) has now demonstrated gut

maturation outcomes that more closely resemble those of human milk feeding than those of standard formula.[23,24,25,29]

The Living Biology of Breast Milk

Beyond macro and micronutrients and HMOs, human milk contains an extraordinary array of bioactive components that are absent from current formula: immunoglobulins, growth factors (EGF, IGF-1, TGF-β), hormones (including leptin and adiponectin, with roles in metabolic programming), cytokines, stem cells, exosomes, and a living microbiome. These components interact dynamically, change over the course of lactation, and respond to the infant's own signaling. Replicating this dynamism is not currently possible – but understanding it provides the scientific framework for iterative formula improvement.[27]

> "Human breast milk is the evolutionary blueprint. The gap between formula and breast milk represents not a failure of science but an invitation for decades of meaningful innovation."

7. Innovation Opportunities: Advancing Formula in the Interest of Infants

The science of infant nutrition has accelerated dramatically in the past two decades. The tools of precision fermentation, recombinant protein production, synthetic biology, and advanced microbiome science are creating opportunities that were inconceivable when current regulatory frameworks were established. The question is whether regulatory systems and industry investment strategies will rise to meet them.

Human Milk Oligosaccharides: From Two to Many

The first generation of HMO-supplemented formulas focused on 2'FL and LNnT – now approved and incorporated by major manufacturers globally. The next frontier involves expanding the HMO profile toward the diversity found in human milk: five-HMO blends have demonstrated promising early clinical results, and research is advancing on additional structures including sialylated HMOs and N-acetylated HMOs. The challenge is not only scientific but economic: HMO synthesis at scale remains costly, particularly for less abundant structures, and regulatory approval pathways – particularly for novel HMO variants – vary significantly by jurisdiction.

Recombinant Human Milk Proteins

The ability to produce nature-identical human milk proteins through precision fermentation represents one of the most transformative near-term opportunities in infant nutrition. The priority targets include human lactoferrin, human alpha-lactalbumin, secretory IgA, and osteopontin.

Human lactoferrin is particularly significant: bovine lactoferrin is already included in some formula products, but human lactoferrin – structurally distinct and bioactive – is not yet commercially available. Precision fermentation approaches using engineered yeast are progressing through

the development pipeline; at least one US company is conducting pre-clinical studies. Two provisional patents for precision-fermented human lactoferrin have been filed in Australia alone.

Consumer acceptance research from Australia found strong positive attitudes among primary caregivers toward precision-fermentation-derived human lactoferrin in infant formula — with common themes of reassurance about human-identical protein, trust in regulatory oversight, and empathy toward parents who have no choice but to formula-feed. Concerns centered on accessibility and equitable pricing.[28]

Milk Fat Globule Membrane (MFGM)

The MFGM is a phospholipid-rich biological membrane surrounding fat globules in human and bovine milk. Its inclusion in formula has been associated with improvements in brain development, immune function, and gut maturation in clinical trials. Bovine MFGM-enriched ingredients are now commercially available and have received approvals in Australia (FSANZ-approved Arla Foods Ingredients' Lacprodan® MFGM-10 in April 2025) and the European Union. This represents a validated, near-term innovation with meaningful nutritional significance.[19]

Functional Fats and Structured Lipids

Advances in lipid science include sn-2 palmitate (OPO; 1,3-dioleoyl-2-palmitoylglycerol) to replicate the triglyceride structure of human milk fat, thereby improving fat absorption and stool consistency; DHA/ARA standardization across global markets; and investigation into improving omega-3 and omega-6 balance, including reducing excessive linoleic acid from seed oils. The Operation Stork Speed expert panel in 2025 recommended establishing mandatory DHA and ARA requirements for US formula, as well as maximum linoleic acid concentrations, bringing US standards closer to international consensus.[15]

Microbiome-Targeted Interventions

The infant gut microbiome is now understood to be a critical mediator of immune, metabolic, and neurodevelopmental outcomes. Beyond HMOs as prebiotics, formula innovation is exploring the addition of specific probiotic strains — particularly Bifidobacterium longum subsp. infantis — that co-evolved with human milk and are markedly depleted in formula-fed infants in developed countries. Synbiotic formulations (pre- and probiotic combinations) represent an emerging category with growing clinical evidence.

Critical principle: Innovation in infant formula must be held to the highest standards of clinical evidence. The vulnerability of the target population demands rigorous, pre-market safety and efficacy demonstration. But evidence standards must not become a substitute for regulatory ambition. Pathways to approval, not merely thresholds for evidence, must be designed to enable and reward genuine innovation.

8. Policy and Regulatory Developments: A Global Stocktake

United States: Operation Stork Speed

The US infant formula regulatory environment underwent a significant recalibration following the 2022 shortage crisis. In March 2025, the Department of Health and Human Services and the

FDA jointly announced Operation Stork Speed — a multi-pronged initiative to modernize oversight of infant formula. Key elements include:

- The first comprehensive review of infant formula nutrient standards since 1998, with a Request for Information issued in May 2025 and comments received through September 2025
- Establishment of a joint Nutrition Regulatory Science Program with the NIH to investigate critical research questions in infant nutrition
- Increased testing for heavy metals, PFAS, spore-forming microbiological contaminants (including Clostridium botulinum and Bacillus cereus), and contaminants in dairy ingredients
- Encouragement of new formula developers and clarification of innovation pathways
- Enhanced supply chain transparency and resilience measures[13,14]

An expert panel convened in June 2025 for Operation Stork Speed identified key regulatory gaps, including the absence of a public registry of FDA-registered formulas, overly complex approval processes for novel ingredients, lack of mandatory reporting of all positive test results, and the absence of US enforceable limits for heavy metals and PFAS. The panel recommended legislative updates, supply chain transparency requirements, and alignment with global safety standards.[16]

The US FDA currently does not mandate DHA or ARA in infant formula — a position out of step with EU, Australian, and Codex Alimentarius standards, and one that Operation Stork Speed review is expected to address.[15,31]

Australia: FSANZ P1028 and the MFGM Milestone

Australia has undertaken one of the most comprehensive reviews of infant formula standards globally. In June 2024, Food Standards Australia New Zealand (FSANZ) announced approval of Proposal P1028, a major revision to the Australia New Zealand Food Standards Code governing infant formula products. Key changes effective from September 2024 (with a five-year transition period) include:

- Clarified product categories, including renaming specialized formula as Special Medical Purpose Products for Infants (SMPPi) with accompanying definitions
- Protein source requirements specifying that infant formula protein must be derived from cow milk, goat milk, sheep milk, soy protein isolate, or partially hydrolysed protein — with any other source requiring pre-market safety assessment
- Updated composition requirements across energy, macro- and micronutrients, minerals, and vitamins
- Prohibition on added fructose and sucrose (with limited exceptions)
- Mandatory product differentiation between infant formula and follow-on formula[17]

Notably, the policy guideline on infant formula products was amended in November 2024 to expand the definition of 'infant formula product' to include cell-based human milk products, ensuring that precision-fermentation-derived and recombinant products are regulated consistently with traditional formula. This is a significant and forward-looking regulatory step.[18]

In April 2025, FSANZ approved the use of MFGM-enriched whey protein concentrate (Lacprodan® MFGM-10) as a nutritive substance in infant formula — adding to a series of approvals for bioactive ingredients including lactoferrin and HMOs (2'FL from multiple sources, including GM E. coli).[19,32]

New Zealand opted out of the P1028 standard in 2024 — a decision that has been the subject of significant criticism, given evidence that industry lobbying influenced the NZ government's departure from the joint regulatory program. This divergence creates regulatory complexity and may disadvantage New Zealand infants.[21]

European Union: A More Advanced Regulatory Baseline

The EU's infant formula regulatory framework, governed primarily by Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013), has been progressively updated and is among the most advanced globally. From February 2020, the EU mandated the inclusion of DHA in infant formula at 20–50 mg/100 kcal — alongside requirements for LCPUFAs more broadly and updated specifications for vitamins and minerals.[20]

The European Food Safety Authority (EFSA) plays a central role in safety assessments for novel food ingredients, including HMOs. Multiple HMOs (2'FL, LNnT, 3'FL, 2'FL+LNnT blends) have received EU approval for use in infant formula, and the regulatory pathway for additional structures is established[20,23], albeit lengthy. EFSA's novel food assessment procedures maintain rigorous evidence standards; regulatory compliance costs for novel ingredients in the EU account for an estimated 15–20% of total product development expenditures — creating barriers for smaller innovators.[16]

The EU framework also includes stricter limits on contaminants and pesticide residues than the US, and more established requirements for specialized formulas. However, the pace of regulatory update for emerging innovations — particularly precision fermentation-derived proteins — remains an area for further development, with no specific approval pathway yet established for recombinant human milk proteins at the EU level.

Regulatory Gaps: Where Further Policy Work Is Needed

Despite recent progress, significant regulatory and policy gaps remain across jurisdictions:

- US: No enforceable limits for heavy metals (lead, arsenic, cadmium, mercury) or PFAS in infant formula. Urgent legislative and regulatory action is needed. Heavy metals and PFAS
- No jurisdiction has yet established a clear regulatory pathway specifically for precision fermentation-derived human milk proteins (lactoferrin, alpha-lactalbumin, sIgA) in infant formula. Australia's updated policy guideline positions it ahead of other markets for recombinant human milk proteins
- Clinical trial requirements, protein quality studies, and growth studies in the US are acknowledged by experts to require revision, and clear pathways are required without compromising rigour. Innovation approval timelines
- The absence of a publicly maintained list of registered/approved infant formulas in the US is a supply chain resilience risk that Congress and the FDA must address. Public formula registry

- While 2'FL and LNnT are approved in major markets, regulatory frameworks for sialylated and N-acetylated HMOs are not yet established globally. Codex Alimentarius work on HMO standards should be accelerated. HMO expansion
- Manufacturers in most jurisdictions are not legally required to report all positive contamination test results — even those not yet distributed to market. This is a critical gap for early warning systems. Mandatory reporting
- Significant divergence in infant formula standards between the EU, US, Australia, and Asia creates barriers for innovative companies and means that infants in some jurisdictions have access to measurably less advanced nutritional products. Global harmonization

9. The Strategic Imperative: What Business Leaders and Policymakers Must Do

Infant formula sits at the intersection of public health policy, food safety regulation, and high-stakes commerce. For executives, policymakers, and advocates, the current moment demands clarity of purpose: the infant must be the beneficiary, not a secondary consideration behind commercial or advocacy priorities.

For Industry

- Treat formula as a pharmaceutical-adjacent product with corresponding quality, safety, and transparency standards — not as a food commodity
- Invest in genuine innovation — particularly in HMO diversity, recombinant proteins, MFGM, and microbiome science — with robust clinical evidence programs
- Engage proactively with regulators to design approval pathways that are scientifically rigorous and practically navigable
- Ensure supply chain transparency, multi-source ingredient strategies, and proactive contamination surveillance to prevent recurrence of the 2022–2025 safety events

For Governments and Regulators

- Establish enforceable limits for heavy metals and PFAS in infant formula
- Develop specific regulatory pathways for precision fermentation-derived and recombinant human milk proteins
- Simplify and clarify innovation approval processes without compromising evidence standards
- Mandate transparency: a public registry of approved/registered infant formulas should be a minimum standard in all major markets
- Expand paid parental leave and workplace breastfeeding support — the most cost-effective breastfeeding interventions available
- Ensure that WHO Code implementation does not systematically restrict access to evidence-based information about formula for families who need it
- Invest in post-market surveillance and proactive ingredient testing

For Healthcare Professionals

- Feel empowered to provide objective, evidence-based information about infant formula – its composition, preparation, and selection – as part of comprehensive infant feeding support
- Advocate for the training, systems, and materials needed to counsel families on both breastfeeding and safe formula use
- Apply clinical evidence standards when evaluating new formula innovations, and communicate findings to families in accessible, non-judgmental terms

> "Families deserve complete information, high-quality products, and the support to make the best feeding decisions for their infants. That is the standard to which governments, industry, and healthcare professionals must be held."

10. Confident View Ahead: Our Perspective

Infant feeding sits at a complex intersection of biology, ethics, commerce, advocacy, and policy – and the stakes could not be higher. At Confident Strategy Group, we work with manufacturers, governments, scientific organizations, and advocacy bodies, navigating this terrain precisely. We have worked in infant feeding and infant formula globally for over 25 years. Our perspective is grounded in three convictions:

First, breastfeeding promotion and formula innovation are not in conflict – they are complementary public health imperatives. The same commitment to infant health that drives breastfeeding support must drive the relentless improvement of formula quality, safety, and nutritional adequacy.

Second, the infant formula sector has underinvested in innovation relative to its commercial scale and its public health obligation. The tools are now available. The science is mature enough. What is needed is the policy and regulatory environment and the commercial will to act.

Third, information is a public health good. Restricting access to accurate, evidence-based information about infant formula – for parents, healthcare professionals, or the public who need it – does not protect infants. It exposes them to risk. The goal is informed decision-making, not information control.

The organizations that will lead in this space are those that approach infant nutrition with the rigor, transparency, and genuine commitment to health outcomes that this uniquely vulnerable population demands. The window for positioning and scientific opportunity is open – but it requires acting with clarity and with courage.

References

1. WHO/UNICEF. Global Breastfeeding Scorecard 2024. Geneva: World Health Organization; 2024. Available from: https://knowledge.unicef.org/child-nutrition-and-development/resource/global-breastfeeding-scorecard-2024
2. WHO/UNICEF. World Breastfeeding Week 2024: Joint Statement. Geneva: World Health Organization; July 31, 2024. Available from: https://www.who.int/news/item/31-07-2024-on-world-breastfeeding-week--unicef-and-who-call-for-equal-access-to-breastfeeding-support
3. WHO/UNICEF. Global Breastfeeding Scorecard 2023: Rates of Breastfeeding Increase Around the World Through Improved Protection and Support. Geneva: World Health Organization; 2023. Available from: https://www.who.int/publications/i/item/WHO-HEP-NFS-23.17
4. Victora CG, Bahl R, Barros AJD, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet. 2016;387(10017):475–490. doi:10.1016/S0140-6736(15)01024-7
5. Rollins NC, Bhandari N, Hajeebhoy N, et al. Why invest, and what it will take to improve breastfeeding practices? Lancet. 2016;387(10017):491–504. doi:10.1016/S0140-6736(15)01044-2
6. Worldwide breastfeeding rates by country 2026. World Population Review. Available from: https://worldpopulationreview.com/country-rankings/breastfeeding-rates-by-country
7. Keenan JI, Mirjalili F, Baker M, et al. Rates and time trends in the consumption of breastmilk, formula, and animal milk by children younger than 2 years from 2000 to 2019: analysis of 113 countries. Lancet Child Adolesc Health. 2021;5(9):619–630. doi:10.1016/S2352-4642(21)00168-1
8. WHO. International Code of Marketing of Breast-Milk Substitutes. Geneva: World Health Organization; 1981.
9. ILO. Maternity Protection Convention (No. 183). Geneva: International Labour Organization; 2000.
10. US Food and Drug Administration. Status Update on FDA's Infant Formula Response Activities. Washington, DC: FDA; September 2023. Available from: https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/status-update-fdas-infant-formula-response-activities
11. US Department of Health and Human Services, Office of Inspector General. The Food and Drug Administration's Inspection and Recall Process Should Be Improved to Ensure the Safety of the Infant Formula Supply. Washington, DC: HHS OIG; 2024. Available from: https://oig.hhs.gov/reports/all/2024/the-food-and-drug-administrations-inspection-and-recall-process-should-be-improved-to-ensure-the-safety-of-the-infant-formula-supply/
12. Whitworth J. Infant formula contamination dates back to 2024. Food Safety News. February 2026. Available from: https://www.foodsafetynews.com/2026/02/infant-formula-contamination-dates-back-to-2024/
13. HHS/FDA. HHS, FDA Announce Operation Stork Speed to Expand Options for Safe, Reliable, and Nutritious Infant Formula for American Families. Press Release. March 18, 2025. Available from: https://www.fda.gov/news-events/press-announcements/hhs-fda-announce-operation-stork-speed-expand-options-safe-reliable-and-nutritious-infant-formula
14. FDA. Operation Stork Speed. Updated February 2026. Available from: https://www.fda.gov/food/infant-formula-homepage/operation-stork-speed
15. Abrams SA, et al. Food and Drug Administration Expert Panel on Infant Formula 'Operation Stork Speed' June 2025: Part 1, Nutrient Considerations. Adv Nutr. 2026. doi:10.1016/j.advnut.2025.100393
16. Henderson B. 'Operation Stork Speed' Expert Panel Highlights Infant Formula Safety Vulnerabilities. Food Safety Magazine. January 16, 2026. Available from: https://www.food-safety.com/articles/11053-operation-stork-speed-expert-panel-highlights-infant-formula-safety-vulnerabilities
17. Food Standards Australia New Zealand. Approval Report: Proposal P1028 – Infant Formula. Canberra: FSANZ; June 13, 2024. Available from: https://www.foodstandards.gov.au/sites/default/files/2024-06/Supporting%20Document%202%20-%20Decision%20Regulation%20Impact%20Statement.pdf
18. Australian Food Ministers' Meeting. Communiqué – 15 November 2024. Canberra: Australian Government; 2024. Available from: https://www.foodregulation.gov.au/activities-committees/food-ministers-meeting/communiques/food-ministers-meeting-communique-15-november-2024

19. Arla Foods Ingredients. Australia approves Arla Foods Ingredients' MFGM for use in infant formula. Press Release. April 30, 2025. Available from: https://www.arlafoodsingredients.com/about/press-releases/australia-approves-arla-foods-ingredients-mfgm-for-use-in-infant-formula/

20. European Commission. Commission Delegated Regulation (EU) 2016/127. Brussels: Official Journal of the European Union; 2016. Amended 2020.

21. Hull N, Bradley A, Boatwright M, et al. Profits Before Health? New Zealand Government Rejection of Stricter Infant Formula Marketing Standards and the Lobbying Behind It. Matern Child Nutr. 2025;21(4):e70087. doi:10.1111/mcn.70087

22. Bode L. Human milk oligosaccharides: every baby needs a sugar mama. Glycobiology. 2012;22(9):1147–1162. doi:10.1093/glycob/cws074

23. Kassai S, et al. Gastrointestinal barrier function, immunity, and neurocognition: The role of human milk oligosaccharide (hMO) supplementation in infant formula. Compr Rev Food Sci Food Saf. 2024;23(1):e13271. doi:10.1111/1541-4337.13271

24. Ayechu-Muruzabal V, et al. Functional effects of human milk oligosaccharides (HMOs). Gut Microbiome. 2023;4:e6. doi:10.1017/gmb.2023.3

25. Sela DA, et al. Infant formula with a specific blend of five human milk oligosaccharides drives the gut microbiota development and improves gut maturation markers: a randomized controlled trial. Front Nutr. 2022;9:920362. doi:10.3389/fnut.2022.920362

26. Deng W, et al. Which is the optimal choice for neonates' formula or breast milk? Nat Prod Bioprospect. 2024;14(1):27. doi:10.1007/s13659-024-00444-0

27. Dewey KG, et al. Human milk bioactive components and child growth and body composition in the first 2 years: A systematic review. Am J Clin Nutr. 2024;119(1):127–145. doi:10.1093/ajcn/nqad302

28. Rosen-Carole CB, et al. Primary carers' readiness for human lactoferrin in infant formula using precision fermentation. Future Foods. 2024;10:100447. doi:10.1016/j.fufo.2024.100447

29. Pediatric Gastroenterology. Clinical evidence and mechanistic pathways of human milk oligosaccharide supplementation in infant formula. Front Nutr. 2025;12:1599678. doi:10.3389/fnut.2025.1599678

30. GMI. Infant Formula Market Size & Share, Growth Analysis 2025–2034. Global Market Insights; 2025. Available from: https://www.gminsights.com/industry-analysis/infant-formula-market

31. FDA. Infant Formula Nutrient Requirements; Request for Information. Federal Register. May 14, 2025;90:20475–20479. Available from: https://www.federalregister.gov/documents/2025/05/14/2025-08419/infant-formula-nutrient-requirements-request-for-information

32. FSANZ. Call for comment on 2'-FL from GM Escherichia coli W in infant formula products. Supporting Document 1. Application A1308. Canberra: Food Standards Australia New Zealand; 2025. Available from: https://www.foodstandards.gov.au/sites/default/files/2025-05/A1308%20SD1%20at%20Approval_0.pdf

33. Morales E, et al. Global breastfeeding efforts: a long way to go. Clin Exp Pediatr. 2024;67(11):559–560. doi:10.3345/cep.2024.00967

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