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Original Research Article

Comparative nutritional analysis of four commercial infant formulas: compliance with food and drug administration regulations and developmental appropriateness across 0-6 and 6-12-month stages

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ABSTRACT

Background: Infant formula serves as the primary nutritional source for non- breastfed infants, requiring strict adherence to regulatory standards while meeting developmental needs across different age stages. Objectives were to comparatively evaluate four commercially available infant formulas (Nestlé NAN PRO, Similac Advance, Aptamil Gold, and Nestlé Lactogen PRO) against Food and Drug administration (FDA) nutrient specifications and analyze their compositional appropriateness for stage 1 (0-6 months) and stage 2 (6-12 months).
Methods: Label-based comparative analysis of macronutrients, micronutrients, functional lipids Docosahexaenoic acid/ arachidonic acid (DHA/ARA), bioactive components [(probiotics, prebiotics, human milk oligosaccharides (HMOs), and added sugars. All values were normalized per 100 kcal and compared against food and drug administration (FDA) minimum and maximum requirements.
Results: All four formulas met FDA macronutrient specifications. Stage 2 formulations showed 14-48% protein increases and 40-300% sugar increases compared to stage 1. Aptamil Gold demonstrated the most comprehensive functional profile with five HMOs, GOS/FOS prebiotics, and DHA/ARA across both stages. NAN PRO maintained DHA/ARA consistency but discontinued probiotics in stage 2. Similac Advance exhibited the highest added sugar content in stage 2 (30 g/100 g) while retaining milk fat. Lactogen PRO emphasized digestibility through probiotics but lacked long-chain polyunsaturated fatty acids (LC-PUFAs). Iron content across all brands (6.5-9 mg/100 g stage 2) exceeded FDA minimum requirements, appropriately addressing post-6-month Anemia risk.
Conclusions: While all formulas comply with FDA nutrient specifications, significant compositional heterogeneity exists in functional ingredients and added sugars, potentially impacting gut microbiome development, neurocognitive outcomes, and metabolic programming. These findings underscore the importance of evidence-based formula selection aligned with individual infant nutritional needs.

Keywords: Infant formula, FDA regulations, DHA, Probiotics, HMOs, Nutritional composition, developmental stages

INTRODUCTION

Human milk represents the gold standard for infant nutrition, providing optimal macro- and micronutrient composition, bioactive compounds, and immunological factors crucial for growth, neurodevelopment, and immune system maturation.[1] However, when exclusive breastfeeding is not feasible due to medical, physiological, or socioeconomic reasons, infant formula serves as a critical nutritional alternative.[2]

The global infant formula market, valued at approximately $38.17 billion USD in 2021, continues to expand at a compound annual growth rate exceeding

10%, driven by increasing premature births, rising maternal employment, and growing awareness of infant nutrition.[3] This growth necessitates rigorous regulatory oversight and evidence-based formulation standards.

Regulatory framework

In the United States, infant formula composition is strictly regulated under the Federal Food, Drug, and Cosmetic Act, with specific nutrient requirements codified in 21 CFR Part 107 of the US-FDA. The FDA establishes minimum and maximum levels for 29 nutrients per 100 kilocalories, ensuring formulas provide adequate nutrition while preventing excessive intake that could burden immature metabolic systems.[4]

The key regulatory principles governing infant formula composition include requirements for protein quality and quantity, with a minimum of 1.8 g/100 kcal and biological value at least 70% of casein. Fat content must fall between 3.3 and 6.0 g/100 kcal, representing 30-54% of total calories. Essential fatty acid requirements mandate linoleic acid at a minimum of 300 mg/100 kcal, constituting at least 2.7% of calories. Micronutrient specifications define acceptable ranges for vitamins A, D, E, K, B-complex, and minerals including iron, calcium, and zinc. Additionally, the calcium to phosphorus ratio must be maintained between 1.1:1 and 2.0:1.

Developmental stage-specific requirements

Infant nutritional needs evolve rapidly during the first year of life, necessitating stage-specific formulations. Stage 1 formulas, designed for infants from birth to six months, emphasize whey-dominant protein that mimics early human milk's 70:30 whey to casein ratio. These formulas feature lower mineral content to reduce renal solute load, prioritize digestibility and immunological support, and maintain an energy density of approximately 67-70 kcal/100 mL.

Stage 2 formulas, intended for infants six to twelve months of age, reflect the changing nutritional priorities of this developmental period. These formulations contain increased protein content with higher casein ratios to support linear growth. Enhanced mineral fortification, particularly of iron, calcium, and zinc, helps prevent deficiencies during this period of rapid development. Higher energy density complements the introduction of solid foods, while bioactive compounds are maintained or enhanced to support ongoing developmental needs.

Bioactive components and functional ingredients

Modern infant formulas increasingly incorporate functional ingredients aimed at replicating human milk's bioactive properties. Long-chain polyunsaturated fatty acids represent a critical category of these functional ingredients. DHA is essential for retinal and brain development, comprising approximately 40% of brain fatty acids. ARA plays a vital role in immune function and growth signalling.[5]

Prebiotics, including Galactooligosaccharides (GOS) and Fructooligosaccharides (FOS), promote beneficial gut microbiota, particularly *Bifidobacterium* species.[6] HMOs, present at 5-20 g/L in human milk, serve multiple functions as prebiotics, pathogen decoys, and immune modulators. Commercial formulas now include synthetic HMOs such as 2'-fucosyllactose and lacto-N-neotetraose.[7] Probiotics, particularly *Lactobacillus reuteri* and *Bifidobacterium lactis* strains, support gut microbiome establishment and may reduce colic and respiratory infections.[8]

Study rationale

Despite regulatory compliance, commercial infant formulas exhibit substantial compositional variability in optional functional ingredients, added sugars, and fat sources. These differences may significantly impact infant health outcomes including gut microbiome composition, neurocognitive development, metabolic programming, and immunological function. This study provides a systematic comparative analysis of four leading infant formula brands in India across two developmental stages, evaluating both mandatory regulatory compliance and optional compositional choices that may influence infant health trajectories.

METHODS

Study design

This is a comparative descriptive analysis of nutritional composition based on manufacturer-declared label information from four commercially available infant formula brands, evaluated across two developmental stages.

Formula selection

Four globally marketed infant formula brands were selected based on market availability and representation of different formulation philosophies: Nestlé NAN PRO (Stages 1 and 2), Similac advance (Stages 1 and 2), Aptamil Gold (Stages 1 and 2) and Nestlé Lactogen PRO (Stages 1 and 2).

Data collection

Nutritional information was extracted from product labels as per 21 CFR part 107 labelling requirements. Data collected encompassed macronutrients per 100 g powder (protein, fat, carbohydrate, and energy), functional lipids (DHA and ARA), bioactive components (probiotic strains, prebiotic types including GOS/FOS, human milk oligosaccharides, and nucleotides), added sugars, and micronutrients (iron, calcium, phosphorus, zinc, vitamin D, and vitamin A).

Regulatory comparison

All nutrient values were compared against FDA specifications (21 CFR part 107) which define minimum and maximum levels per 100 kilocalories. Values were normalized where necessary to enable direct comparison with regulatory standards.

Analysis framework

Formulas were evaluated across five dimensions: regulatory compliance with FDA minimum and maximum nutrient specifications, stage-appropriate progression examining nutritional changes from stage 1 to 2, functional ingredient profile assessing presence and quantity of bioactive components, added sugar content compared against recommended limits, and fat source quality examining the types of lipids used including milk fat versus vegetable oils.

RESULTS

Stage 1 (0-6 months) formulas-comparative analysis

Table 1 presents the compositional profile of four infant formulas designed for the 0-6 month age group.

The presence of added sugars (likely maltodextrin or corn syrup solids) raises concerns about early metabolic programming and potential taste preference conditioning toward sweeter foods.

All stage 1 formulas demonstrated FDA-compliant protein levels. Protein content ranged from 10.5 g (Lactogen) to 11.5 g (Similac) per 100 g powder, translating to approximately 2.0-2.3 g/100 kcal-well above the FDA minimum of 1.8 g/100 kcal. Fat content across all formulas (21.8-24.3 g/100 g) met FDA specifications of 3.3-6.0 g/100 kcal, providing 30-54% of total calories. Notably, Similac Advance utilizes milk fat rather than vegetable oil blends, potentially providing a distinct fatty acid profile including short-chain fatty acids. Carbohydrate content showed minimal variation (56-59 g/100 g), with lactose serving as the primary carbohydrate source in all formulations.

Only two brands (NAN PRO and Aptamil Gold) included both DHA and ARA in stage 1. Aptamil Gold provided the highest levels at 95 mg each of DHA and ARA, while NAN PRO contained 40 mg each. Similac and Lactogen did not include LC-PUFAs. The absence of DHA/ARA in these latter formulas is noteworthy, given that LC-PUFA supplementation has been associated with improved visual acuity and cognitive development in multiple clinical trials.[9]

Regarding probiotics, NAN PRO and Lactogen included *Lactobacillus reuteri*, a strain clinically shown to reduce infant colic and regurgitation for prebiotics, Aptamil Gold and Lactogen contained GOS/FOS blends, though specific quantities were not disclosed on labels.[10] Aptamil Gold uniquely featured five different HMO types, representing the most advanced attempt to mimic human milk's prebiotic oligosaccharide profile.[11] Only Similac specifically declared nucleotide supplementation, which supports immune development and intestinal maturation.[12]

A critical differentiator emerged in added sugar content. NAN PRO contained 0 g added sugars, while Similac contained 10 g/100 g, and both Aptamil Gold and Lactogen contained 8 g/100 g. The presence of added sugars (likely maltodextrin or corn syrup solids) raises concerns about early metabolic programming and potential taste preference conditioning toward sweeter foods.[13]

Stage 2 (6-12 months) formulas-comparative analysis

Table 2 presents compositional data for follow-on formulas intended for infants 6-12 months.

All brands increased protein content in stage 2, reflecting increased requirements for linear growth and muscle development. NAN PRO showed a 27% increase from 11 to 14 g, Similac demonstrated a 28% increase from 11.5 to 14.7g, Aptamil displayed the largest increase at 41% from 11 to 15.5 g, and Lactogen showed the most modest increase at 14% from 10.5 to 12 g. Aptamil Gold demonstrated the highest stage 2 protein content (15.5 g), while Lactogen showed the most modest increase, potentially prioritizing digestibility over rapid growth acceleration.

The most striking compositional change occurred in added sugar content. Similac showed a 200% increase from 10 to 30 g, representing 30% of powder weight. Lactogen demonstrated a 75% increase from 8 to 14 g. NAN PRO and Aptamil showed minimal increases of approximately 1 g. Similac's stage 2 added sugar content (30 g/100 g) is exceptionally high and warrants scrutiny given evidence linking early sugar exposure to metabolic syndrome risk and taste preference programming.[14]

All formulas appropriately increased mineral fortification in stage 2. Iron content ranged from 6.5 to 9 mg/100 g, all exceeding FDA minimum requirements of 0.15 mg/100 kcal, which is critical for preventing iron-deficiency anemia that peaks at 6-18 months.[15] Calcium and phosphorus ratios were maintained within the FDA-required 1.1:2.0 range, with Aptamil providing the highest calcium content at 540 mg for optimal bone mineralization.[16] Vitamin D levels ranged from 380 to 450 IU/100 g across all formulas, adequate for calcium absorption and bone health.[17]

Regarding LC-PUFAs, NAN PRO maintained DHA/ARA at 40 mg demonstrating continuity, while Aptamil modestly increased levels to 48 mg each. Similac and Lactogen continued to omit LC-PUFAs despite ongoing brain development needs in 2nd 6 months. For probiotics, only Lactogen retained *L. reuteri* in stage 2, while NAN PRO discontinued probiotics after stage 1. Aptamil uniquely maintained 5 HMO types across both stages.

Within-brand progression analysis

Within-brand progression analysis was shown in the table number 3 below.

Table 1: Nutritional composition of stage 1 infant formulas (per 100 g powder).

Parameters	NAN PRO 1	Similac 1	Aptamil 1	Lactogen 1	FDA Min/100 kcal	FDA Max/100 kcal
Protein (g)	11	11.5	11	10.5	1.8	4.5
Fat (g)	23	21.8	24.3	22	3.3	6.0
Carbohydrate (g)	57	58	56	59	-	-
DHA (mg)	40	-	95	-	-	-
ARA (mg)	40	-	95	-	-	-
Probiotics	*L. reuteri*	-	-	*L. reuteri*	-	-
Prebiotics	-	-	GOS/FOS	GOS/FOS	-	-
HMOs	-	-	5 types	-	-	-
Nucleotides	-	+	-	-	-	-
Added sugars (g)	0	10	8	8	-	-
Fat source	Vegetable oils	Milk fat	Mixed	Vegetable oils	-	-

Table 2: Nutritional composition of stage 2 infant formulas (per 100 g powder).

Parameters	NAN PRO 2	Similac 2	Aptamil 2	Lactogen 2
Protein (g)	14	14.7	15.5	12
Fat (g)	19.5	19.5	24	19.5
Carbohydrate (g)	60	62	55	61
DHA (mg)	40	-	48	-
ARA (mg)	40	-	48	-
Probiotics	-	-	-	*L. reuteri*
Prebiotics	-	-	GOS/FOS	GOS/FOS
HMOs	-	-	5 types	-
Nucleotides	-	✓	-	-
Added sugars (g)	9	30	9	14
Iron (mg)	7.5	8	9	6.5
Calcium (mg)	450	510	540	410
Phosphorus (mg)	300	310	340	270
Zinc (mg)	3.8	3.6	4.1	3.5
Vitamin D (IU)	400	420	450	380
Vitamin A (µg)	450	430	480	410

Table 3: Stage progression summary (stage 1 → stage 2).

Parameters	NAN PRO	Similac	Aptamil	Lactogen
Protein change	+27% (11→14 g)	+28% (11.5→14.7 g)	+41% (11→15.5 g)	+14% (10.5→12 g)
DHA/ARA continuity	Maintained	Absent both stages	Maintained and increased	Absent both stages
Bioactive shift	Dropped probiotic	Maintained nucleotides	Full continuity	Maintained probiotics
Sugar change	0→9 g	+200% (10→30 g)	Minimal (+1 g)	+75% (8→14 g)
Strategic focus	Balanced macros, LC-PUFA focus	High sugar concern	Comprehensive functional profile	Digestibility emphasis

DISCUSSION

Regulatory compliance and compositional philosophy

All four evaluated infant formulas meet FDA mandatory nutrient specifications outlined in 21 CFR part 107 of the US-FDA, confirming basic safety and adequacy. However, significant compositional heterogeneity exists in optional functional ingredients, revealing divergent formulation philosophies that may meaningfully impact infant health outcomes.

Long-chain polyunsaturated fatty acids: the neurodevelopmental divide

The inclusion or omission of DHA and ARA represents a fundamental formulation decision with far-reaching implications. DHA accumulates rapidly in the brain during the first two years of life, reaching adult levels by age two. Endogenous synthesis from α-linolenic acid (ALA) is insufficient, particularly in preterm and term infants with immature desaturase enzyme systems.[18]

Aptamil Gold and NAN PRO provide DHA/ARA across both stages, aligning with recommendations from European Food Safety Authority (EFSA) and expert panels. Clinical evidence supports LC-PUFA supplementation benefits including improved visual acuity at 2 and 4 months, enhanced cognitive outcomes on Bayley Scales at 18 months, and reduced respiratory illness incidence.[19-21]

Similac and Lactogen's omission of LC-PUFAs, while not violating FDA minimums (which only mandate linoleic acid at ≥300 mg/100 kcal), represents significant nutritional gap. FDA currently does not mandate DHA/ARA, though this regulatory stance contrasts with mounting scientific evidence and international recommendations.

Human milk oligosaccharides: the prebiotic frontier

Human milk contains 5-20 g/L of oligosaccharides-3rd most abundant component after lactose and fat. These complex carbohydrates resist digestion, reaching colon intact where they selectively promote *Bifidobacterium* and *Lactobacillus* growth, inhibit pathogen adhesion to epithelial cells, and modulate immune development.[22]

Aptamil Gold's inclusion of 5 HMO types (likely including 2'-fucosyllactose and lacto-N-neotetraose) represents the most sophisticated attempt among evaluated formulas to replicate human milk's prebiotic complexity. Clinical trials demonstrate that HMO-supplemented formula produces stool microbiota more like breastfed infants, reduces infections requiring antibiotics by 30%, and lowers respiratory illness incidence.[11,23,24]

The GOS/FOS blends in Aptamil and Lactogen provide prebiotic effects, though they are structurally distinct from native HMOs. The absence of any prebiotic supplementation in NAN PRO stage 2 and Similac across both stages may result in gut microbiome profiles divergent from breastfed infants, with potential long-term metabolic and immunological implications.[25]

Probiotics: strain-specific benefits and discontinuity concerns

Lactobacillus reuteri, included in NAN PRO stage 1 and Lactogen (both stages), has the strongest clinical evidence for reducing infant colic, with a 2017 meta-analysis demonstrating 50% reduction in crying time.[8] However, NAN PRO's discontinuation of probiotics in stage 2 raises questions about gut microbiome continuity during the critical window of solid food introduction.

The gut microbiome undergoes substantial restructuring between 6-12 months as complementary foods introduce new substrate diversity. Maintaining probiotic supplementation during this transition may support beneficial colonization patterns, as demonstrated by Lactogen's consistent probiotic inclusion.[26]

Added sugars: metabolic programming implications

The dramatic added sugar escalation, particularly in Similac stage 2 (30 g/100 g powder), presents significant concerns. While the FDA does not currently set maximum added sugar limits for infant formula, the American Academy of Paediatrics recommends avoiding added sugars in children under 2 years.[27]

Several mechanisms of concern exist. First, metabolic programming effects suggest early sugar exposure may alter hypothalamic appetite regulation, predisposing to obesity and metabolic syndrome.[28] Second, taste preference conditioning means infants exposed to sweeter formulas show stronger preferences for sweet tastes at 6 and 12 months.[29] Third, high simple sugar intake promotes microbiome dysbiosis through pathogenic bacterial overgrowth and reduces beneficial *Bifidobacterium* populations.[30] Fourth, while pre-tooth eruption exposure is less concerning for dental health, conditioning for sweet preferences affects post-eruption dietary choices. The contrast between Similac (30 g added sugars in stage 2) and NAN PRO/Aptamil (9 g) represents a threefold difference with potentially divergent metabolic outcomes.

Iron fortification: addressing developmental anemia

All stage 2 formulas appropriately increased iron content (6.5-9 mg/100 g), far exceeding FDA minimums. This fortification strategy addresses the well-documented iron deficiency vulnerability window at 6-18 months when birth iron stores become depleted, rapid growth increases demand, and complementary foods often provide insufficient bioavailable iron.[15] Iron-fortified formula (≥1 mg/100 kcal) is labelled "infant formula with iron" per 21 CFR part 107, while lower-iron formulas must carry the warning "Additional Iron May Be Necessary." All evaluated formulas meet the higher fortification standard, appropriately prioritizing Anemia prevention.

Calcium, phosphorus, and vitamin D: skeletal development

Bone mineralization accelerates dramatically during infancy, with 80% of adult bone mineral content accumulated by age 18. First year is particularly critical for laying down trabecular bone architecture.[31] Aptamil Gold provided the highest calcium (540 mg/100 g stage 2) coupled with highest vitamin D (450 IU/100 g), optimizing conditions for calcium absorption and bone mineralization. All formulas-maintained calcium to phosphorus ratios within FDA-mandated 1.1-2.0 range, preventing hypocalcemia and rickets while supporting bone quality.

Stage progression appropriateness

Transition from stage 1 to 2 formulas reflects evolving nutritional priorities. Appropriate progressions observed include increased protein (27-41%) supporting linear growth velocity, enhanced mineral fortification preventing deficiency during rapid development, and maintained/increased LC-PUFA levels supporting ongoing neuromaturation. Concerning progressions include dramatic added sugar escalation (Similac showing 200% increase and lactogen showing 75% increase), probiotic discontinuation in NAN PRO during gut microbiome critical window, and persistent LC-PUFA absence in Similac and Lactogen despite continued brain development.

Comparative analysis with FDA standards and scientific literature

The comprehensive review by Bakshi et al emphasizes that infant formula processing and compositional choices have lasting effects on gut microbiota establishment, which closely parallels host immune development and growth.[32] Our findings corroborate their observations in several respects.

While all formulas meet FDA minimum protein requirements, protein quality matters significantly. Whey to casein ratio and biological value significantly affect digestibility and amino acid absorption.[33] Presence of bioactive peptides, including α-lactalbumin and β-lactoglobulin, along with their resistance to heat processing, influences mineral bioavailability and immunomodulatory effects.[34] Processing impacts are also relevant, as thermal treatments during formula manufacturing can cause Maillard reactions, reducing lysine bioavailability and forming advanced glycation end products (AGEs) that may have pro-inflammatory effects.[35] Fat globule structure differs between human, bovine, and formula sources, affecting lipid digestibility and bioactive delivery through milk fat globule membrane (MFGM).[36]

Limitations

This analysis has several limitations. First, it relies on label-based data from manufacturer declarations; independent laboratory verification was not performed. Label values do not reflect actual nutrient bioavailability, which varies by ingredient source and processing methods.[37] Also, prebiotic amounts are often undisclosed on labels, precluding dose-response evaluation. Compositional analysis cannot directly predict clinical health outcomes; clinical trial data would be needed for such determinations. Formula composition may vary by country or region; this analysis reflects specific product versions. The effects of heat treatment on nutrient stability, protein denaturation, and bioactive compound preservation were not evaluated.[38]

CONCLUSION

This comprehensive comparative analysis of four leading infant formula brands across two developmental stages demonstrates that while regulatory compliance ensures basic safety and adequacy, substantial compositional variability in functional ingredients creates a hierarchy of nutritional quality with potential long-term health implications.

A particularly concerning finding is the wide variation in added sugar content among formulas, with some products containing up to 30 gm of added sugars per 100 gm of powder in stage 2 formulations. This represents a threefold difference compared to lower-sugar alternatives and raises significant public health concerns. Early exposure to high sugar content has been linked to altered metabolic programming, increased obesity risk, taste preference conditioning toward sweeter foods, and disruption of beneficial gut microbiota. The absence of FDA-mandated maximum limits for added sugars in infant formula represents a critical regulatory gap that warrants immediate attention.

Similarly, the optional nature of neurodevelopmentally critical components such as DHA and ARA creates an uneven nutritional landscape. While some formulas provide adequate long-chain polyunsaturated fatty acids essential for brain and retinal development, others omit these entirely despite mounting scientific evidence supporting their inclusion. The FDA only requires linoleic acid right now, so it is up to the manufacturer to decide whether to add DHA and ARA. Given established importance of these fatty acids during the first year of life, regulatory bodies should consider establishing minimum requirements for LC-PUFA content.

The inconsistent inclusion of prebiotics, probiotics, and human milk oligosaccharides further illustrates the importance of evidence-based regulatory guidance. These bioactive components play crucial roles in establishing healthy gut microbiota, supporting immune development, and reducing infection risk. As scientific understanding of these functional ingredients advances, regulations should evolve to reflect current evidence regarding their benefits for infant health.

Future directions

As the infant formula market continues expanding globally, regulatory frameworks must keep pace with scientific evidence to ensure that all commercially available formulas support optimal neurocognitive, metabolic, and immunological development. The goal should be to narrow the compositional gap between infant formulas and human milk while preventing formulation choices driven primarily by cost reduction or palatability enhancement at the expense of infant health. Future research should concentrate on determining evidence-based thresholds for functional ingredients and added sugars to guide the formulation of revised regulatory standards that emphasize long-term health outcomes during this crucial developmental period.

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